List of Approved Drugs

April 2004 to September 2025

Review Categories of New Drugs

Review Category	Products
1	Gastrointestinal drugs, dermatologic drugs, immunosuppressive drugs, and others (not classified as other categories)
2	Cardiovascular drugs, antiparkinsonian drugs, anti-Alzheimer's drugs
3-1	Central/peripheral nervous system drugs (excluding anesthetic drugs)
3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
4	Antibacterial drugs, antiviral drugs (excluding AIDS drugs), antifungal drugs, antiprotozoal drugs, anthelmintic drugs
5	Reproductive system drugs, drugs for urogenital system, combination drugs
6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs (drugs for inflammatory diseases)
6-2	Hormone drugs, drugs for metabolic disorders (including diabetes mellitus, osteoporosis, gout, and inborn errors of metabolism)
AIDS drugs	Anti-HIV drugs
Oncology drugs	Antineoplastic drugs
Blood products	Blood products
Vaccines	Vaccines (only those to be used for prevention of infection), antitoxic serum, etc.
Radio-pharmaceuticals	Radiopharmaceuticals
In vivo diagnostics	Contrast agents, reagents for function tests (excluding in-vitro diagnostics)
Bio-CMC	Quality of biologics, biosimilars

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in May 2025

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
5	May 19, 2025	1	Slinda 28 Tablets (ASKA Pharmaceutical Co., Ltd.)	Approval	Drospirenone	A drug with a new indication, a new dosage, and other characteristics for contraception.
1	May 19, 2025	2	Fabhalta Capsules 200 mg (Novartis Pharma K.K.)	Change	Iptacopan hydrochloride hydrate	A drug with a new indication for the treatment of complement 3 glomerulopathy. [Orphan drug]
3-2	May 19, 2025	3	Vabysmo Solution for Intravitreal Injection 120 mg/mL Vabysmo Kit for Intravitreal Injection 120 mg/mL (Chugai Pharmaceutical Co., Ltd.)	Change Change	Faricimab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of choroidal neovascularization associated with angioid streaks. [Orphan drug]
Vaccines	May 19, 2025	4	mRESVIA Intramuscular Injection Syringes (Moderna Japan Co., Ltd.)	Approval	mRNA encoding the F glycoprotein from RSV subtype A stabilized in the prefusion conformation	A drug with a new active ingredient indicated for the prevention of disease caused by RS virus infection.
Oncology drugs	May 19, 2025	5	Blenrep for I. V. Infusion 100 mg (GlaxoSmithKline K.K.)	Approval	Belantamab mafodotin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	May 19, 2025	6	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Change Change	Osimertinib mesilate	Drugs with a new indication for the maintenance treatment for locally-advanced, unresectable epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer following definitive chemoradiation therapy.
Vaccines	May 19, 2025	7	Spikevax Intramuscular Injection (Moderna Japan Co., Ltd.)	Change	mRNA encoding the spike protein of SARS-CoV-2	A drug with a new additional pediatric dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19).
Oncology drugs	May 19, 2025	8	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.
Oncology drugs	May 19, 2025	9	Scemblix Tablets 20 mg Scemblix Tablets 40 mg (Novartis Pharma K.K.)	Change Change	Asciminib hydrochloride	Drugs with a new indication and a new dosage for the treatment of chronic myelogenous leukemia.
Oncology drugs	May 19, 2025	10	Rybrevant Intravenous Infusion 350 mg (Janssen Pharmaceutical K.K.)	Change	Amivantamab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable advanced or recurrent epidermal growth factor receptor (*EGFR*) mutation-positive non-small cell lung cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in June 2025

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-2	Jun. 24, 2025	1	(1) Anerem 20 mg for I.V. Injection (2) Anerem 50 mg for I.V. Injection (Mundipharma K.K.)	Approval Change	Remimazolam besilate	(1) A drug with a new indication and a new dosage in an additional dosage form for sedation during gastrointestinal endoscopy. (2) A drug with a new indication, a new dosage, and other characteristics for sedation during gastrointestinal endoscopy.
3-1	Jun. 24, 2025	2	Xeomin 50 Units for Intramuscular Injection Xeomin 100 Units for Intramuscular Injection Xeomin 200 Units for Intramuscular Injection (Teijin Pharma Limited)	Change Change Change	Incobotulinumtoxin A	Drugs with a new route of administration indicated for the treatment of chronic sialorrhea.
3-1	Jun. 24, 2025	3	HyQvia 10% S.C.Injection Set 5g/50mL HyQvia 10% S.C.Injection Set 10g/100mL HyQvia 10% S.C.Injection Set 20g/200mL (Takeda Pharmaceutical Company Limited)	Change Change Change	pH4-treated acidic normal human immunoglobulin (subcutaneous injection) and Vorhyaluronidase alfa (genetical recombination)	Drugs with a new indication and a new dosage for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy (in the cases where patients show an improvement in their acute phase treatment).
3-1	Jun. 24, 2025	4	Spydia Nasal Spray 5 mg Spydia Nasal Spray 7.5 mg Spydia Nasal Spray 10 mg (Aculys Pharma, Inc.)	Approval Approval Approval	Diazepam	Drugs with a new route of administration indicated for the treatment of status epilepticus. [Orphan drug]
1	Jun. 24, 2025	5	Velsipity Tablets 2 mg (Pfizer Japan Inc.)	Approval	Etrasimod L-arginine	A drug with a new active ingredient indicated for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jun. 24, 2025	6	(1) Lialda Tab. 600 mg (2) Lialda Tab. 1200 mg (Mochida Pharmaceutical Co., Ltd.)	Approval Change	Mesalazine	(1) A drug with a new dosage in an additional dosage form indicated for the treatment of ulcerative colitis (excluding severe cases). (2) A drug with a new dosage indicated for the treatment of ulcerative colitis (excluding severe cases).
6-2	Jun. 24, 2025	7	Pombiliti for I.V. Infusion 105 mg (Amicus Therapeutics, Inc.)	Approval	Cipaglucosidase alfa (genetical recombination)	A drug with a new active ingredient indicated for use as a combination therapy with miglustat for the treatment of late-onset Pompe disease (LOPD). [Orphan drug]
6-2	Jun. 24, 2025	8	Opfolda Capsules 65 mg (Amicus Therapeutics, Inc.)	Approval	Miglustat	A drug with a new indication and a new dosage in an additional dosage form for use as a combination therapy with cipaglucosidase alfa (genetical recombination) for the treatment of late-onset Pompe disease (LOPD). [Orphan drug]
2	Jun. 24, 2025	9	Amvuttra Subcutaneous Injection 25 mg Syringe (Alnylam Japan, K.K.)	Change	Vutrisiran sodium	A drug with a new indication for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary). [Orphan drug]
2	Jun. 24, 2025	10	Airwin for Subcutaneous Injection 45 mg Airwin for Subcutaneous Injection 60 mg (MSD K.K.)	Approval Approval	Sotatercept (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
Oncology drugs	Jun. 24, 2025	11	Welireg Tablets 40 mg (MSD K.K.)	Approval	Belzutifan	(1) A drug with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma that has progressed after cancer chemotherapy. (2) A drug with a new active ingredient indicated for the treatment of von Hippel-Lindau disease-associated tumors. [Orphan Drug (only for [2])]
Oncology drugs	Jun. 24, 2025	12	Inrebic Capsules 100 mg (Bristol-Myers Squibb K.K.)	Approval	Fedratinib hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of myelofibrosis. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 24, 2025	13	Talvey Subcutaneous Injection 3 mg Talvey Subcutaneous Injection 40 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Talquetamab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma (for use only if refractory or intolerant to standard therapies). [Orphan drug]
6-1	Jun. 24, 2025	14	Rinvoq Tablets 15 mg Rinvoq Tablets 7.5 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of giant cell arteritis in patients who have not responded sufficiently to conventional treatments.
1	Jun. 24, 2025	15	Tremfya Intravenous Infusion 200 mg Tremfya Subcutaneous Infusion 100 mg syringe Tremfya Subcutaneous Infusion 200 mg syringe Tremfya Subcutaneous Infusion 200 mg pen (Janssen Pharmaceutical K.K.)	Change Change Change Change	Guselkumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
Oncology drugs	Jun. 24, 2025	16	(1) Nesp Injection 5 μg Plastic Syringe Nesp Injection 10 μg Plastic Syringe Nesp Injection 15 μg Plastic Syringe Nesp Injection 20 μg Plastic Syringe Nesp Injection 30 μg Plastic Syringe Nesp Injection 40 μg Plastic Syringe Nesp Injection 60 μg Plastic Syringe Nesp Injection 120 μg Plastic Syringe Nesp Injection 180 μg Plastic Syringe (2) Darbepoetin Alfa Injection 5 μg Syringe [KKF] Darbepoetin Alfa Injection 10 μg Syringe [KKF] Darbepoetin Alfa Injection 15 μg Syringe [KKF] Darbepoetin Alfa Injection 20 μg Syringe [KKF] Darbepoetin Alfa Injection 30 μg Syringe [KKF] Darbepoetin Alfa Injection 40 μg Syringe [KKF] Darbepoetin Alfa Injection 60 μg Syringe [KKF] Darbepoetin Alfa Injection 120 μg Syringe [KKF] Darbepoetin Alfa Injection 180 μg Syringe [KKF] ([1] Kyowa Kirin Co., Ltd., [2] Kyowa Kirin Frontier Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Darbepoetin alfa (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of anemia resulting from the administration of belzutifan.
Oncology drugs	Jun. 24, 2025	17	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable hepatocellular carcinoma.
Oncology drugs	Jun. 24, 2025	18	Yervoy Injection 20 mg Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change Change	Ipilimumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable hepatocellular carcinoma.
Oncology drugs	Jun. 24, 2025	19	Elrexfio S.C. Injection 44 mg Elrexfio S.C. Injection 76 mg (Pfizer Japan Inc.)	Change Change	Elranatamab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma (for use only if refractory or intolerant to standard therapies). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in August 2025

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Aug. 8, 2025	1	Capvaxive for Intramuscular Injection Syringes (MSD K.K.)	Approval	Pneumococcal 21-valent conjugate vaccine (mutated diphtheria CRM197 conjugate)	A drug with a new active ingredient indicated for the prophylaxis of pneumococcal disease in the elderly or in adults who are considered to be at a high risk of pneumococcal disease.
2	Aug. 25, 2025	2	Doptelet Tablets 20 mg (Swedish Orphan Biovitrum Japan Co., Ltd.)	Change	Avatrombopag maleate	A drug with a new indication and a new dosage for the treatment of persistent and chronic immune thrombocytopenia.
3-1	Aug. 25, 2025	3	Vorzzz Tablets 2.5 mg Vorzzz Tablets 5 mg Vorzzz Tablets 10 mg (Taisho Pharmaceutical Co., Ltd.)	Approval Approval Approval	Vornorexant hydrate	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-2	Aug. 25, 2025	4	Setaneo Ophthalmic Solution 0.002% (Santen Pharmaceutical Co., Ltd.)	Approval	Sepetaprost	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
1	Aug. 25, 2025	5	(1)Magmitt Tablets 100 mg (2)Magmitt Tablets 200 mg (3)Magmitt Tablets 250 mg (4)Magmitt Tablets 330 mg (5)Magmitt Tablets 500 mg (6)Magmitt Fine Granules 83% (Magmitt Pharmaceutical Co., Ltd.)	Approval Change Change Change Change Change	Magnesium oxide	(1) A drug with a new pediatric dosage in an additional dosage form indicated for the treatment of constipation. (2) (3) (4) (5) (6) Drugs with a new pediatric dosage indicated for the treatment of constipation.
6-2	Aug. 25, 2025	6	Yorvipath Subcutaneous Injection 168 μg Pen Yorvipath Subcutaneous Injection 294 μg Pen Yorvipath Subcutaneous Injection 420 μg Pen (Teijin Pharma Limited)	Approval Approval Approval	Palopegteriparatide	Drugs with a new active ingredient indicated for the treatment of hypoparathyroidism. [Orphan drug]
Oncology drugs	Aug. 25, 2025	7	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and new dosage for the treatment of unresectable, advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer. [Orphan drug]
Oncology drugs	Aug. 25, 2025	8	Yervoy Injection 20 mg Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change Change	Ipilimumab (genetical recombination)	Drugs with a new indication and new dosage for the treatment of unresectable, advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer. [Orphan drug]
3-1	Aug. 25, 2025	9	Koselugo Capsules 10 mg Koselugo Capsules 25 mg (Alexion Pharma GK)	Change Change	Selmetinib sulfate	Drugs with a new dosage indicated for the treatment of plexiform neurofibroma in patients with neurofibromatosis type 1. [Orphan drug]
2	Aug. 25, 2025	10	Kisunla Intravenous Infusion 350 mg (Eli Lilly Japan K.K.)	Change	Donanemab (genetical recombination)	A drug with a new dosage indicated for slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease.
Oncology drugs	Aug. 25, 2025	11	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change	Trastuzumab deruxtecan (genetical recombination)	A drug with a new indication for the treatment of hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-low or -ultralow inoperable or recurrent breast cancer.
Vaccines	Aug. 25, 2025	12	Silgard 9 Aqueous Suspension for Intramuscular Injection Syringes (MSD K.K.)	Change	Recombinant adsorbed 9-valent human papillomavirus virus-like particle vaccines (yeast origin)	A drug with a new indication for the prevention of the following diseases caused by infection with human papillomavirus types 6, 11, 16, 18, 31, 33, 45, 52, and 58: ・Anal cancer (squamous cell carcinoma) and its precursor lesions (anal intraepithelial neoplasia [AIN] 1, 2, and 3)
Oncology drugs	Aug. 25, 2025	13	Calquence Tablets 100 mg (AstraZeneca K.K.)	Change	Acalabrutinib maleate hydrate	A drug with a new indication and a new dosage for the treatment of mantle cell lymphoma.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in September 2025

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Sep. 19, 2025	1	Nexletol Tablets 180 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Bempedoic acid	A drug with a new active ingredient indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Sep. 19, 2025	2	Nurtec OD Tablets 75 mg (Pfizer Japan Inc.)	Approval	Rimegepant sulfate hydrate	A drug with a new active ingredient indicated for the acute treatment and prevention of migraine attacks.
1	Sep. 19, 2025	3	Ycanth Topical Solution 0.71% (Torii Pharmaceutical Co., Ltd.)	Approval	Cantharidin	A drug with a new active ingredient indicated for the treatment of molluscum contagiosum.
1	Sep. 19, 2025	4	Bylvay Granules 200 μg Bylvay Granules 600 μg (Ipsen Co., Ltd.)	Approval Approval	Odevixibat hydrate	Drugs with a new active ingredient indicated for the treatment of pruritus in patients with progressive familial intrahepatic cholestasis. [Orphan drug]
6-2	Sep. 19, 2025	5	Fujichenon Granular Tablets 125 (Fujimoto Pharmaceutical Corporation)	Approval	Chenodeoxycholic acid	A drug with a new indication and a new dosage in an additional dosage form for the treatment of cerebrotendinous xanthomatosis. [Orphan drug]
3-1	Sep. 19, 2025	6	Imaavy Intravenous Infusion 300 mg Imaavy Intravenous Infusion 1200 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Nipocalimab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants). [Orphan drug]
3-2	Sep. 19, 2025	7	Izervay for Intravitreal Injection 20 mg/mL (Astellas Pharma Inc.)	Approval	Avacincaptad pegol sodium	A drug with a new active ingredient indicated for slowing the progression of geographic atrophy secondary to age-related macular degeneration. [Conditional approval]
3-2	Sep. 19, 2025	8	Dormicum Syrup 2 mg/mL (Maruishi Pharmaceutical Co., Ltd.)	Approval	Midazolam	A drug with a new route of administration indicated for anesthetic premedication. [Drugs for specific use]
4	Sep. 19, 2025	9	Xofluza Granules 2% (Shionogi & Co., Ltd.)	Change	Baloxavir marboxil	A drug with a new additional pediatric dosage indicated for the treatment of influenza A or B virus infection.
6-1	Sep. 19, 2025	10	Neffy Nasal Spray 1 mg Neffy Nasal Spray 2 mg (Alfresa Pharma Corporation)	Approval Approval	Adrenaline	Drugs with a new route of administration indicated for the adjunctive treatment for anaphylactic reactions caused by bee venom, foods, drugs, and others (for use only in individuals with a history of anaphylaxis or at a high risk of anaphylaxis).
Oncology drugs	Sep. 19, 2025	11	Tecentriq Intravenous Infusion 840 mg Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Atezolizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of relapsed or refractory extranodal NK/T-cell lymphoma, nasal type.
Oncology drugs	Sep. 19, 2025	12	Voranigo Tablets 10 mg Voranigo Tablets 40 mg (Nihon Servier Co., Ltd.)	Approval Approval	Vorasidenib citric acid hydrate	Drugs with a new active ingredient indicated for the treatment of *IDH1* or *IDH2* gene mutation-positive glioma. [Orphan drug]
Oncology drugs	Sep. 19, 2025	13	Hernexeos Tablets 60 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Zongertinib	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent *HER2* (*ERBB2*) mutation-positive non-small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Sep. 19, 2025	14	Ibtrozi Capsules 200 mg (Nippon Kayaku Co., Ltd.)	Approval	Taletrectinib adipate	A drug with a new active ingredient indicated for the treatment of *ROS1* fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer. [Orphan drug]
Radiopharmaceuticals	Sep. 19, 2025	15	Pluvicto Injection (Novartis Pharma K.K.)	Approval	Lutetium (^{177}Lu) vipivotide tetraxetan	A drug with a new active ingredient indicated for the treatment of PSMA-positive, metastatic castration-resistant prostate cancer.
Radiopharmaceuticals	Sep. 19, 2025	16	Locametz Kit (Novartis Pharma K.K.)	Approval	Gozetotide	A drug with a new active ingredient indicated for the support of selection of patients with prostate cancer, for whom PSMA-targeted therapy is indicated.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Radiopharmaceuticals	Sep. 19, 2025	17	GalliaPharm ^{68}Ge/^{68}Ga Generator (Eckert & Ziegler Radiopharma GmbH)	Approval	Gallium (^{68}Ga) chloride	A drug with a new active ingredient indicated for gallium (^{68}Ga) radiolabelling of radiopharmaceutical precursors approved for positron emission tomography (PET) imaging.
Bio-CMC	Sep. 19, 2025	18	Aflibercept BS Solution 40 mg/mL for IVT Injection "NIT" Aflibercept BS Kit 40 mg/mL for IVT Injection "NIT" (Fuji Pharma Co., Ltd.)	Approval Approval	Aflibercept (genetical recombination) [aflibercept biosimilar 2]	Biosimilars indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization, macular edema following retinal vein occlusion, and choroidal neovascularization in patients with pathologic myopia.
Bio-CMC	Sep. 19, 2025	19	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL "SCD" Aflibercept BS Kit for Intravitreal Injection 40 mg/mL "SCD" (SamChunDang Pharm. Co., Ltd.)	Approval Approval	Aflibercept (genetical recombination) [aflibercept biosimilar 3]	Biosimilars indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization, macular edema following retinal vein occlusion, and choroidal neovascularization in patients with pathologic myopia.
3-1	Sep. 19, 2025	20	(1) Koselugo Granules 5 mg (2) Koselugo Granules 7.5 mg (3) Koselugo Capsules 10 mg (4) Koselugo Capsules 25 mg (Alexion Pharma GK)	Approval Approval Change Change	Selmetinib sulfate	(1) (2) Drugs with a new dosage in an additional dosage form indicated for the treatment of plexiform neurofibroma in patients with neurofibromatosis type 1. (3) (4) Drugs with a new dosage indicated for the treatment of plexiform neurofibroma in patients with neurofibromatosis type 1. [Orphan drug]
3-1	Sep. 19, 2025	21	Spinraza Intrathecal Injection 28 mg Spinraza Intrathecal Injection 50 mg (Biogen Japan Ltd.)	Approval Approval	Nusinersen sodium	Drugs with a new dosage in an additional dosage form indicated for the treatment of spinal muscular atrophy. [Orphan drug]
1	Sep. 19, 2025	22	(1) Cellcept Capsules 250 (2) Cellcept Powder for Oral Suspension 31.8% (3) Mycophenolate Mofetil Capsules 250 mg [VTRS] ([1] [2] Chugai Pharmaceutical Co., Ltd., [3] Viatris Healthcare G.K.)	Change Change Change	Mycophenolate mofetil	Drugs with a new indication and a new dosage for the treatment of refractory nephrotic syndrome (for use frequent relapsing or steroid-dependent nephrotic syndrome). [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
Oncology drugs	Sep. 19, 2025	23	Libtayo I.V. Infusion 350 mg (Regeneron Japan KK)	Change	Cemiplimab (genetical recombination)	A drug with a new indication for the treatment of unresectable advanced or recurrent non-small-cell lung cancer.
Bio-CMC	Sep. 19, 2025	24	Denosumab BS 120 mg RM for S.C. Injection "F" (Fuji Pharma Co., Ltd.)	Approval	Denosumab (genetical recombination) [denosumab biosimilar 1]	A biosimilar indicated for the treatment of bone lesions due to multiple myeloma and bone metastasis of solid tumor.
Oncology drugs	Sep. 19, 2025	25	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for the preoperative and postoperative adjuvant treatment for non-small cell lung cancer and preoperative and postoperative adjuvant treatment for bladder cancer.
Bio-CMC	Sep. 19, 2025	26	(1) Tocilizumab BS for Intravenous Infusion 80 mg "CT" (2) Tocilizumab BS for Intravenous Infusion 200 mg "CT" (3) Tocilizumab BS for Intravenous Infusion 400 mg "CT" (4) Tocilizumab BS 162 mg Syringes for S.C. Injection "CT" (5) Tocilizumab BS 162 mg Auto-Iinjector for S.C. Injection "CT" (Celltrion Healthcare Japan K.K.)	Approval Approval Approval Approval Approval	Tocilizumab (genetical recombination) [tocilizumab biosimilar 1]	(1) (2) (3) Biosimilars indicated for the following diseases: ・The treatment of rheumatoid arthritis (including the prevention of structural joint damage), polyarticular-course juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis, in patients who have not sufficiently responded to conventional treatments. ・The improvement of various symptoms and laboratory findings associated with Castleman's disease for whom resection of lymph nodes is not indicated. ・The treatment of cytokine release syndrome induced by the treatment of malignant tumor. (4) (5) Biosimilars indicated for the following disease： ・The treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
Blood products	Sep. 19, 2025	27	Jivi for iv injection 500 Jivi for iv injection 1000 Jivi for iv injection 2000 Jivi for iv injection 3000 (Bayer Yakuhin, Ltd.)	Change Change Change Change	Damoctocog alfa pegol (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Sep. 19, 2025	28	Tecentriq Intravenous Infusion 840 mg Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Atezolizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of following diseases: ・Unresectable advanced or recurrent non-small cell lung cancer ・Postoperative adjuvant treatment for PD-L1 positive non-small cell lung cancer ・PD-L1 positive, hormone receptor (HR)-negative, and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer ・Extensive-stage small-cell lung cancer
Oncology drugs	Sep. 19, 2025	29	Lumakras Tablets 120 mg (Amgen K.K.)	Change	Sotorasib	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent KRAS G12C mutation-positive colorectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 19, 2025	30	Vectibix for Intravenous Infusion 100 mg Vectibix for Intravenous Infusion 400 mg (Takeda Pharmaceutical Company Limited)	Change Change	Panitumumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent KRAS G12C mutation-positive colorectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 19, 2025	31	Jaypirca Tablets 50 mg Jaypirca Tablets 100 mg (Eli Lilly Japan K.K.)	Change Change	Pirtobrutinib	Drugs with a new indication for the treatment of relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma) with resistant or intolerant to other BTK inhibitors.
Radiopharmaceuticals	Sep. 19, 2025	32	Raiatt MIBG-I 131 Injection (PDRadiopharma Inc.)	Change	3-Iodobenzylguanidine (^{131}I)	A drug with a new indication and a new dosage for the treatment of MIBG-positive neuroblastoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Bio-CMC	Sep. 19, 2025	33	Golimumab BS 50 mg Syringe for S.C. Injection “F” (Fuji Pharma Co., Ltd.)	Approval	Golimumab (genetical recombination) [golimumab biosimilar 1]	A biosimilar indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jun. 24, 2024	1	Nexium Capsules 10 mg Nexium Capsules 20 mg Nexium Granules for Suspension 10 mg Nexium Granules for Suspension 20 mg (AstraZeneca K.K.)	Change Change Change Change	Esomeprazole magnesium hydrate	Drugs with a new additional pediatric dosage indicated for the prevention of recurrent reflux esophagitis and gastric or duodenal ulcer after dosing non-steroid anti-inflammatory drugs, and prevention of recurrent gastric or duodenal ulcer after dosing low-dose aspirins.
1	Jun. 24, 2024	2	Fabhalta Capsules 200 mg (Novartis Pharma K.K.)	Approval	Iptacopan hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal haemoglobinuria.
1	Jun. 24, 2024	3	Vtama Cream 1% (Japan Tobacco Inc.)	Approval	Tapinarof	A drug with a new active ingredient indicated for the treatment of atopic dermatitis and plaque psoriasis.
1	Jun. 24, 2024	4	(1) Skyrizi Intravenous Infusion 600 mg (2) Skyrizi for Subcutaneous Injection 360 mg Auto Dosers (3) Skyrizi for Subcutaneous Injection 180 mg Auto Dosers (AbbVie GK)	Change Change Approval	Risankizumab (genetical recombination)	1) A drug with a new indication and a new dosage for the remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (2) (3) Drugs with a new indication and a new dosage in an additional dosage form for the maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Sep. 24, 2024	5	Veltassa 8.4 g Powder for Suspension (Single-dose package) (Zeria Pharmaceutical Co., Ltd.)	Approval	Patiromer sorbitex calcium	A drug with a new active ingredient indicated for the treatment of hyperkalaemia.
1	Sep. 24, 2024	6	Lupkynis Capsules 7.9 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Voclosporin	A drug with a new active ingredient indicated for the treatment of lupus nephritis.
1	Sep. 24, 2024	7	Venoglobulin IH 10% I.V. 0.5 g/5 mL Venoglobulin IH 10% I.V. 2.5 g/25 mL Venoglobulin IH 10% I.V. 5 g/50 mL Venoglobulin IH 10% I.V. 10 g/100 mL Venoglobulin IH 10% I.V. 20 g/200 mL (Japan Blood Products Organization)	Change Change Change Change Change	Polyethylene glycol treated human normal immunoglobulin	Drugs with new indications and a new dosage for the treatment of antibody-mediated rejection in the following organ transplantations; kidney transplantation, liver transplantation, heart transplantation, lung transplantation, pancreas transplantation, small intestine transplantation. [Orphan drug]
1	Sep. 24, 2024	8	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of refractory nephrotic syndrome (for use steroid-resistant nephrotic syndrome). [Orphan drug]
1	Sep. 24, 2024	9	Jakavi Tablets 5 mg Jakavi Tablets 10 mg Jakavi Oral Solution for Pediatric 0.5% (Novartis Pharma K.K.)	Change Change Approval	Ruxolitinib phosphate	Drugs with a new indication and a new additional pediatric dosage and a drug with a new indication and a new additional pediatric dosage in an additional dosage form for the treatment of graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
1	Dec. 27, 2024	10	Zeposia Capsules 0.92 mg Zeposia Capsules Starter Pack (Bristol-Myers Squibb K.K.)	Approval Approval	Ozanimod hydrochloride	Drugs with a new active ingredient indicated for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Dec. 27, 2024	11	Oldamin for Injection 1 g (Fuji Chemical Industries Co., Ltd.)	Change	Monoethanolamine oleate	A drug with a new indication and a new dosage for the use in sclerotherapy of venous malformation.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Mar. 27, 2025	12	(1) Tremfya Intravenous Infusion 200 mg (2) Tremfya Subcutaneous Injection 200 mg Syringe (3) Tremfya Subcutaneous Injection 200 mg Pen (4) Tremfya Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Approval Approval Change	Guselkumab (genetical recombination)	(1) A drug with a new route of administration indicated for the remission induction therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (2)(3) Drugs with a new indication and a new dosage in an additional dosage form for the maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (4) A drug with a new indication and a new dosage for the maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Mar. 27, 2025	13	Livmarli Oral Solution 10 mg/mL (Takeda Pharmaceutical Company Limited)	Approval	Maralixibat chloride	A drug with a new active ingredient indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome and progressive familial intrahepatic cholestasis. [Orphan drug]
1	Mar. 27, 2025	14	Bepio Wash Gel 5% (Maruho Co., Ltd.)	Approval	Benzoyl peroxide	A drug with a new dosage in an additional dosage form indicated for the treatment of acne vulgaris.
1	Mar. 27, 2025	15	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of nephrotic syndrome (frequently relapsing or steroid-dependent nephrotic syndrome).
1	Mar. 27, 2025	16	(1) Omvoh Intravenous Infusion 300 mg (2) Omvoh Subcutaneous Injection 100 mg Autoinjectors (3) Omvoh Subcutaneous Injection 100 mg Syringes (4) Omvoh Subcutaneous Injection 200 mg Autoinjectors (5) Omvoh Subcutaneous Injection 200 mg Syringes (Eli Lilly Japan K.K.)	Change Change Change Approval Approval	Mirikizumab (genetical recombination)	(1) A drug with a new indication and a new dosage for the treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (2)(3) Drugs with a new indication, a new dosage, and other characteristics for the treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (4)(5) Drugs with a new indication and a new dosage in an additional dosage form for the treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
6-2	Jun. 24, 2024	17	Awiqli Injection FlexTouch 300 Units Awiqli Injection FlexTouch 700 Units (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin icodec (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Jun. 24, 2024	18	(1) Trulicity Subcutaneous Injection 0.75 mg Ateos (2) Trulicity Subcutaneous Injection 1.5 mg Ateos (Eli Lilly Japan K.K.)	Change Approval	Dulaglutide (genetical recombination)	(1) A drug with a new dosage for the treatment of type 2 diabetes mellitus. (2) A drug with a new dosage in an additional dosage form for the treatment of type 2 diabetes mellitus.
6-2	Sep. 24, 2024	19	Tepezza for Intravenous Infusion 500 mg (Amgen K.K.)	Approval	Teprotumumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of active thyroid eye disease. [Orphan drug]
6-2	Dec. 27, 2024	20	Zepbound Subcutaneous Injection 2.5 mg Ateos Zepbound Subcutaneous Injection 5 mg Ateos Zepbound Subcutaneous Injection 7.5 mg Ateos Zepbound Subcutaneous Injection 10 mg Ateos Zepbound Subcutaneous Injection 12.5 mg Ateos Zepbound Subcutaneous Injection 15 mg Ateos (Eli Lilly Japan K.K.)	Approval Approval Approval Approval Approval Approval	Tirzepatide	Drugs with a new indication, a new dosage, and other characteristics for the treatment of obesity. For use only in patients with any of hypertension, hyperlipidemia or type 2 diabetes mellitus who have not responded sufficiently to diet therapy and exercise therapy, and meet the following conditions: • BMI of 27 kg/m^2 or greater in the presence of at least two obesity-related comorbidities or • BMI of 35 kg/m^2 or greater
2	Aug. 28, 2024	21	Azilva Tablets 10 mg Azilva Tablets 20 mg Azilva Granules 1% (Takeda Pharmaceutical Company Limited)	Change Change Change	Azilsartan	Drugs with a new additional pediatric dosage (aged 2 years to 5 years) indicated for the treatment of hypertension.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Sep. 24, 2024	22	Kisunla Intravenous Infusion 350 mg (Eli Lilly Japan K.K.)	Approval	Donanemab (genetical recombination)	A drug with a new active ingredient indicated for slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease.
2	Sep. 24, 2024	23	Yuvanci Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Macitentan/Tadalafil	A new combination drug indicated for the treatment of pulmonary arterial hypertension.
2	Sep. 24, 2024	24	Treprost Inhalation Solution 1.74 mg (Mochida Pharmaceutical Co., Ltd.)	Change	Treprostinil	A drug with a new indication and a new dosage for the treatment of pulmonary hypertension associated with interstitial lung disease. [Orphan drug]
2	Nov. 22, 2024	25	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (Novartis Pharma K.K.)	Change Change	Eltrombopag olamine	Drugs with a new additional pediatric dosage indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Nov. 22, 2024	26	Romiplate for S.C. Injection 250 μg (Kyowa Kirin Co., Ltd.)	Change	Romiplostim (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Nov. 22, 2024	27	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Dec. 27, 2024	28	(1) Uptravi Tablets 0.2 mg (2) Uptravi Tablets 0.4 mg (3) Uptravi Tablets for Pediatric 0.05 mg (Nippon Shinyaku Co., Ltd.)	Change Change Approval	Selexipag	(1), (2) Drugs with a new additional pediatric dosage and other characteristics and (3) a drug with a new additional pediatric dosage in an additional dosage form, indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Feb. 20, 2025	29	Lixiana Tablets 15 mg Lixiana Tablets 30 mg Lixiana Tablets 60 mg Lixiana OD Tablets 15 mg Lixiana OD Tablets 30 mg Lixiana OD Tablets 60 mg (Daiichi Sankyo Company, Limited)	Change Change Change Change Change Change	Edoxaban tosilate hydrate	Drugs with a new indication for the prevention of thrombus/embolus formation in patients with chronic thromboembolic pulmonary hypertension.
2	Mar. 27, 2025	30	Beyonttra Tablets 400 mg (Alexion Pharma GK)	Approval	Acoramidis hydrochloride	A drug with a new active ingredient indicated for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary).
2	Mar. 27, 2025	31	Camzyos Capsules 5 mg Camzyos Capsules 2.5 mg Camzyos Capsules 1 mg (Bristol-Myers Squibb K.K.)	Approval Approval Approval	Mavacamten	Drugs with a new active ingredient indicated for the treatment of symptomatic obstructive hypertrophic cardiomyopathy. [Orphan drug]
2	Mar. 27, 2025	32	Rivaluen LA Patch 25.92 mg Rivaluen LA Patch 51.84 mg (Towa Pharmaceutical Co., Ltd.)	Approval Approval	Rivastigmine	Drugs in a new dosage form for indicated for inhibiting progression of symptoms of dementia in patients with mild and moderate Alzheimer's disease.
5	Sep. 24, 2024	33	Alyssa Combination Tablets (Fuji Pharma Co., Ltd.)	Approval	Estetrol hydrate/Drospirenone	A new combination drug with a new active ingredient indicated for the treatment of dysmenorrhea.
5	Sep. 24, 2024	34	Kidparen Injection (Otsuka Pharmaceutical Factory, Inc.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for the supplementation of water, electrolytes, calories, amino acids, and vitamins in patients with chronic renal failure (for use only in patients with or at a risk of hyperkalemia or hyperphosphatemia) for whom receiving oral or enteral nutrition is impossible or insufficient and the total parenteral nutrition is the only choice.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
5	Sep. 24, 2024	35	Enosolid Semi Solid for Enteral Use (EN Otsuka Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding, especially for patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
5	Mar. 27, 2025	36	Carbostar 2 · L for Dialysis Carbostar 2 · P for Dialysis (Yoshindo Inc.)	Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations to be used as perfusion fluids for hemodialysis in patients with chronic renal failure (use in any of the following cases: • When the patient's blood sugar level is not controlled well with sugarless dialysate. • When dialysate with a high calcium concentration may cause hypercalcemia).
Radio-pharmaceuticals	Dec. 27, 2024	37	Tauvid Injection (PDRadiopharma Inc.)	Approval	Flortaucipir (^{18}F)	A drug with a new active ingredient indicated for the support of selection of patients with mild cognitive impairment and mild dementia due to Alzheimer's disease, for whom donanemab (genetical recombination) is indicated. [Expedited review]
In vivo diagnostics	Sep. 24, 2024	38	Alaglio Divided Granules 1.5 g Alaglio Oral 1.5 g (SBI Pharmaceuticals Co., Ltd.)	Change Change	Aminolevulinic acid hydrochloride	Drugs with a new dosage and other characteristics indicated for the visualization of tumor tissues of the non-muscle invasive bladder cancer in transurethral resection of bladder tumor. [Orphan drug]
3-1	Jun. 24, 2024	39	(1) Briviact Tablets 25 mg (2) Briviact Tablets 50 mg (3) Briviact for I.V. Injection 25 mg (UCB Japan Co., Ltd.)	Approval Approval Approval	Brivaracetam	(1) (2) Drugs with a new active ingredient indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. (3) A drug with a new active ingredient indicated for the following treatment; partial seizures (including secondary generalized seizures) in patients with epilepsy. It is used as an alternative therapy for blevaracetam oral formulation in patients who are temporarily unable to be administered orally.
3-1	Jun. 24, 2024	40	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new indication and a new additional pediatric dosage for the treatment of upper and lower limb spasticity.
3-1	Sep. 24, 2024	41	Rexulti Tablets 1 mg Rexulti Tablets 2 mg Rexulti OD Tablets 0.5 mg Rexulti OD Tablets 1 mg Rexulti OD Tablets 2 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Brexpiprazole	Drugs with new indications and a new dosage for the treatment of excessive motor activity or verbal/physical aggression attributable to rapid changes in mood and/or irritability, outburst associated with Alzheimer's dementia.
3-1	Sep. 24, 2024	42	Quviviq Tablets 25 mg Quviviq Tablets 50 mg (Nexera Pharma Co., Ltd.)	Approval Approval	Daridorexant hydrochloride	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Sep. 24, 2024	43	Firdapse Tablets 10 mg (DyDo Pharma, Inc.)	Approval	Amifampridine phosphate	A drug with a new active ingredient indicated for the improvement of muscle weakness in patients with Lambert-Eaton myasthenic syndrome. [Orphan drug]
3-1	Sep. 24, 2024	44	Rozebalamin for Injection 25 mg (Eisai Co., Ltd.)	Approval	Mecobalamin	A drug with a new indication and a new dosage in an additional dosage form for slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis (ALS). [Orphan drug]
3-1	Sep. 24, 2024	45	Evrysdi Dry Syrup 60 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Risdiplam	A drug with a new indication and a new additional pediatric dosage (under 2 months of age) for the treatment of spinal muscular atrophy. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 27, 2024	46	Vyvdura Combination Subcutaneous Injection (Argenx Japan K.K.)	Change	Efgartigimod alfa (genetical recombination) and Vorhyaluronidase alfa (genetical recombination)	A drug with a new indication and a new dosage for the treatment of chronic inflammatory demyelinating polyneuropathy. [Orphan drug]
3-1	Dec. 27, 2024	47	Qalsody Intrathecal Injection 100 mg (Biogen Japan Ltd.)	Approval	Tofersen	A drug with a new active ingredient indicated for slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis with *SOD1* mutation. [Orphan drug]
3-2	Sep. 24, 2024	48	Septocaine Combination Injection Cartridge (GC Showayakuhin Corporation)	Approval	Articaine hydrochloride/ Adrenaline bitartrate	A new combination drug with a new active ingredient indicated for infiltration anesthesia or nerve block in the fields of dentistry and oral surgery.
3-2	Dec. 27, 2024	49	Ryjusea Mini ophthalmic solution 0.025% (Santen Pharmaceutical Co., Ltd.)	Approval	Atropine sulfate hydrate	A drug with a new indication in a new dosage form for slowing the progression of myopia.
4	May 17, 2024	50	Prevymis Tablets 240 mg Prevymis Intravenous Infusion 240 mg (MSD K.K.)	Change Change	Letermovir	Drugs with a new indication for the prophylaxis of cytomegalovirus disease in organ transplantation.
4	Jun. 24, 2024	51	Avigan Tablets 200 mg (Fujifilm Toyama Chemical Co., Ltd.)	Change	Favipiravir	A drug with a new indication and a new dosage for the treatment of severe fever with thrombocytopenia syndrome virus infection. [Orphan drug]
4	Jun. 24, 2024	52	Zavicefta Combination for Intravenous Infusion (Pfizer Japan Inc.)	Approval	Avibactam sodium/Ceftazidime hydrate	A new combination drug with a new active ingredient indicated for the treatment of sepsis, pneumonia, cystitis, pyelonephritis, peritonitis, intra-abdominal abscess, cholecystitis, and liver abscess caused by Zavicefta-sensitive *Escherichia coli* , *Citrobacter* spp., *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Proteus* spp., *Morganella morganii* , *Haemophilus influenzae* , and *Pseudomonas aeruginosa* .
4	Jun. 24, 2024	53	Livtencity Tablets 200 mg (Takeda Pharmaceutical Company Limited)	Approval	Maribavir	A drug with a new active ingredient indicated for the treatment of cytomegalovirus disease in organ transplantation (including hematopoietic stem cell transplantation) that is refractory to conventional anti-cytomegalovirus therapy. [Orphan drug]
4	Dec. 27, 2024	54	Tepoxx Capsules 200 mg (Japan Biotechno Pharma Co., Ltd.)	Approval	Tecovirimat hydrate	A drug with a new active ingredient indicated for the treatment of smallpox, mpox, cowpox, as well as complications due to replication of vaccinia virus following vaccination against smallpox . [Expedited review]
4	Dec. 27, 2024	55	Kavigale Injection Solution 300 mg (AstraZeneca K.K.)	Approval	Sipavibart (genetical recombination)	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Expedited review]
4	Mar. 27, 2025	56	Prevymis Tablets 240 mg Prevymis Intravenous Infusion 240 mg Prevymis Granules 20 mg Prevymis Granules 120 mg (MSD K.K.)	Change Change Approval Approval	Letermovir	(1) Drugs with a new pediatric dosage in an additional dosage form indicated for the prophylaxis of cytomegalovirus disease in organ transplantation. (2) Drugs with a new pediatric dosage in an additional dosage form indicated for the prophylaxis of cytomegalovirus disease in allogeneic hematopoietic stem cell transplantation. [Orphan Drug (only for [2])]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Jun. 24, 2024	57	(1) Relvar 50 Ellipta 14 dose for Pediatric (2) Relvar 50 Ellipta 30 dose for Pediatric (3) Relvar 100 Ellipta 14 dose (4) Relvar 100 Ellipta 30 dose (GlaxoSmithKline K.K.)	Approval Approval Change Change	Fluticasone furoate/Vilanterol trifenatate	(1) (2) New combination drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed). (3) (4) Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Jun. 24, 2024	58	Benlysta for S.C. Injection 200 mg Autoinjector (GlaxoSmithKline K.K.)	Change	Belimumab (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 24, 2024	59	Cellcept Capsules 250 Cellcept Powder for Oral Suspension 31.8% (Chugai Pharmaceutical Co., Ltd.)	Change Change	Mycophenolate mofetil	Drugs with a new indication and a new dosage for the treatment of systemic sclerosis-associated interstitial lung disease. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Aug. 28, 2024	60	Nucala for s.c. Injection 100 mg Syringe Nucala for s.c. Injection 100 mg Pen (GlaxoSmithKline K.K.)	Change Change	Mepolizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of chronic rhinosinusitis with nasal polyps (for use only in patients who have not responded sufficiently to conventional treatments).
6-1	Sep. 24, 2024	61	Bimzelx Syringe for S.C. Injection 160 mg Bimzelx Autoinjector for S.C. Injection 160 mg (UCB Japan Co., Ltd.)	Change Change	Bimekizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of hidradenitis suppurativa.
6-1	Sep. 24, 2024	62	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg Rinvoq Tablets 30 mg (AbbVie GK)	Change Change Change	Upadacitinib hydrate	Drugs with a new additional pediatric dosage indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Dec. 27, 2024	63	(1) Fasenra Subcutaneous Injection 30 mg Syringe (2) Fasenra Subcutaneous Injection 30 mg Pen (AstraZeneca K.K.)	Change Approval	Benralizumab (genetical recombination)	(1) A drug with a new indication and a new dosage and (2) a drug with a new indication and a new dosage in an additional dosage form, indicated for the treatment of eosinophilic granulomatosis with polyangiitis in patients who have not responded sufficiently to conventional therapies.
6-1	Feb. 20, 2025	64	Andembry S.C. Injection 200 mg Pens (CSL Behring K.K.)	Approval	Garadacimab (genetical recombination)	A drug with a new active ingredient indicated for the prophylaxis of acute attacks of hereditary angioedema.
6-1	Feb. 20, 2025	65	Humira 40mg for S.C. Injection Syringe 0.4 mL Humira 40mg for S.C. Injection in pre-filled pen 0.4 mL (AbbVie GK)	Change Change	Adalimumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of non-radiographic axial spondyloarthritis in patients who have not responded sufficiently to conventional treatments. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Mar. 27, 2025	66	Dupixent 300 mg Syringe for S.C. Injection Dupixent 300 mg Pen for S.C. Injection (Sanofi K.K.)	Change Change	Dupilumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of chronic obstructive pulmonary disease (for use only in patients who have not responded sufficiently to conventional treatments).
6-1	Mar. 27, 2025	67	Otezla Tablets 10 mg Otezla Tablets 20 mg Otezla Tablets 30 mg (Amgen K.K.)	Change Change Change	Apremilast	Drugs with a new indication for the treatment of palmoplantar pustulosis in patients who have not responded sufficiently to local treatment.
6-1	Mar. 27, 2025	68	Ilaris Solution for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change	Canakinumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of adult-onset Still's disease in patients who have not responded sufficiently to conventional treatments. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
AIDS drugs	Aug. 28, 2024	69	Truvada Combination Tab. (Gilead Sciences, Inc.)	Change	Emtricitabine/ Tenofovir disoproxil fumarate	A drug with a new indication and a new dosage for the pre-exposure prophylaxis against HIV-1 infection. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	May 17, 2024	70	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer.
Oncology drugs	May 17, 2024	71	Braftovi Capsules 50 mg Braftovi Capsules 75 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Encorafenib	Drugs with new indications and a new dosage for the treatments of unresectable *BRAF* mutation-positive thyroid cancer that has progressed after cancer chemotherapy and unresectable *BRAF* mutation-positive anaplastic thyroid cancer.
Oncology drugs	May 17, 2024	72	Mektovi Tablets 15 mg (Ono Pharmaceutical Co., Ltd.)	Change	Binimetinib	A drug with new indications and a new dosage for the treatments of unresectable *BRAF* mutation-positive thyroid cancer that has progressed after cancer chemotherapy and unresectable *BRAF* mutation-positive anaplastic thyroid cancer.
Oncology drugs	May 17, 2024	73	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable biliary tract cancer.
Oncology drugs	May 17, 2024	74	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Kirin Co., Ltd.)	Change	Pegfilgrastim (genetical recombination)	A drug with a new indication for the mobilization of hematopoietic stem cells to the peripheral blood for autologous hematopoietic stem cell transplantation.
Oncology drugs	Jun. 24, 2024	75	Jaypirca Tablets 50 mg Jaypirca Tablets 100 mg (Eli Lilly Japan K.K.)	Approval Approval	Pirtobrutinib	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory mantle cell lymphoma with resistance or intolerance to other BTK inhibitors.
Oncology drugs	Jun. 24, 2024	76	Targretin Capsules 75 mg (Minophagen Pharmaceutical Co., Ltd.)	Change	Bexarotene	A drug with a new indication for the treatment of adult T-cell leukemia/lymphoma with skin lesions.
Oncology drugs	Jun. 24, 2024	77	Omjjara Tablets 100 mg Omjjara Tablets 150 mg Omjjara Tablets 200 mg (GlaxoSmithKline K.K.)	Approval Approval Approval	Momelotinib hydrochloride hydrate	Drugs with a new active ingredient indicated for the treatment of myelofibrosis.
Oncology drugs	Jun. 24, 2024	78	Haiyitan Tablets 50 mg (Haihe Biopharma K. K.)	Approval	Gumarontinib hydrate	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent *MET* exon 14 (METex14) skipping mutation-positive non-small cell lung cancer.
Oncology drugs	Jun. 24, 2024	79	Retevmo Capsules 40 mg Retevmo Capsules 80 mg (Eli Lilly Japan K.K.)	Change Change	Selpercatinib	Drugs with a new indication and a new dosage for the treatment of *RET* fusion gene-positive advanced or recurrent solid tumor. [Orphan drug]
Oncology drugs	Jun. 24, 2024	80	Ezharmia Tablets 50 mg Ezharmia Tablets 100 mg (Daiichi Sankyo Company, Limited)	Change Change	Valemetostat tosilate	Drugs with a new indication for the treatment of relapsed or refractory peripheral T-cell lymphoma. [SAKIGAKE review]
Oncology drugs	Jun. 24, 2024	81	Paraplatin Injection 50 mg Paraplatin Injection 150 mg Paraplatin Injection 450 mg (Clinigen K.K.)	Change Change Change	Carboplatin	Drugs with a new indication and a new dosage for the treatment of endometrial cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Aug. 28, 2024	82	Alecensa Capsules 150mg (Chugai Pharmaceutical Co., Ltd.)	Change	Alectinib hydrochloride	A drug with a new indication, a new dosage, and other characteristics for the postoperative adjuvant treatment for anaplastic lymphoma kinase (*ALK*) fusion gene-positive non-small cell lung cancer. [Orphan drug]
Oncology drugs	Aug. 28, 2024	83	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the preoperative and postoperative adjuvant treatment for non-small cell lung cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Aug. 28, 2024	84	Alimta Injection 100 mg Alimta Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Pemetrexed sodium hydrate	Drugs with a new indication and a new dosage for the preoperative adjuvant treatment for non-squamous non-small cell lung cancer.
Oncology drugs	Aug. 28, 2024	85	Pemetrexed for I.V. Infusion 100 mg “NK” Pemetrexed for I.V. Infusion 500 mg “NK” Pemetrexed for I.V. Infusion 800 mg “NK” Pemetrexed Solution for I.V. Infusion 100 mg “NK” Pemetrexed Solution for I.V. Infusion 500 mg “NK” Pemetrexed Solution for I.V. Infusion 800 mg “NK” (Nippon Kayaku Co., Ltd.)	Change Change Change Change Change Change	Pemetrexed sodium hemipentahydrate	Drugs with a new dosage for the preoperative adjuvant treatment for non-squamous non-small cell lung cancer.
Oncology drugs	Sep. 24, 2024	86	Fruzaqla Capsules 1 mg Fruzaqla Capsules 5 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Fruquintinib	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 24, 2024	87	Tasfygo Tablets 35 mg (Eisai Co., Ltd.)	Approval	Tasurgratinib succinate	A drug with a new active ingredient indicated for the treatment of unresectable *FGFR2* fusion gene-positive biliary tract cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Sep. 24, 2024	88	Augtyro Capsules 40 mg (Bristol-Myers Squibb K.K.)	Approval	Repotrectinib	A drug with a new active ingredient indicated for the treatment of *ROS1* fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Sep. 24, 2024	89	Rybrevant Intravenous Infusion 350 mg (Janssen Pharmaceutical K.K.)	Approval	Amivantamab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent epidermal growth factor receptor (EGFR) gene exon 20 insertion mutation-positive non-small cell lung cancer.
Oncology drugs	Sep. 24, 2024	90	Trodelvy for Injection 200 mg (Gilead Sciences, Inc.)	Approval	Sacituzumab govitecan (genetical recombination)	A drug with a new active ingredient indicated for the treatment of hormone receptor-negative and human epidermal growth factor receptor 2 (HER2)-negative unresectable or recurrent breast cancer in patients who have previously been treated with chemotherapy. [Priority review]
Oncology drugs	Sep. 24, 2024	91	Padcev for I.V. infusion 20 mg Padcev for I.V. infusion 30 mg (Astellas Pharma Inc.)	Change Change	Enfortumab vedotin (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable urothelial carcinoma. [Priority review]
Oncology drugs	Sep. 24, 2024	92	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of unresectable urothelial carcinoma. [Priority review]
Oncology drugs	Sep. 24, 2024	93	(1) Tafinlar Dispersible Tablets for Pediatric 10 mg (2) Tafinlar Capsules 50 mg (3) Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Approval Change Change	Dabrafenib mesilate	(1) A drug with a new indication and a new dosage in an additional dosage form for the treatment of *BRAF* mutation-positive low-grade glioma. (2) (3) Drugs with a new indication for the treatment of *BRAF* mutation-positive low-grade glioma. [Orphan drug]
Oncology drugs	Sep. 24, 2024	94	(1) Mekinist Dry Syrup for Pediatric 4.7 mg (2) Mekinist Tablets 0.5 mg (3) Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Approval Change Change	Trametinib dimethyl sulfoxide	(1) A drug with a new indication and a new dosage in an additional dosage form for the treatment of *BRAF* mutation-positive low-grade glioma. (2) (3) Drugs with a new indication for the treatment of *BRAF* mutation-positive low-grade glioma. [Orphan drug]
Oncology drugs	Nov. 22, 2024	95	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of locally advanced cervical cancer. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 22, 2024	96	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of advanced or recurrent endometrial cancer.
Oncology drugs	Nov. 22, 2024	97	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication and a new dosage for the maintenance therapy of advanced or recurrent endometrial cancer with proficient mismatch repair (pMMR) in patients who have received chemotherapy including treatment with durvalumab (genetical recombination).
Oncology drugs	Nov. 22, 2024	98	Randa Injection 10 mg/20 mL Randa Injection 25 mg/50 mL Randa Injection 50 mg/100 mL (Nippon Kayaku Co., Ltd.)	Change Change Change	Cisplatin	Drugs with a new dosage indicated for the treatment of cervical cancer. [Expedited review]
Oncology drugs	Dec. 27, 2024	99	Brukinsa Capsules 80 mg (BeiGene Japan GK.)	Approval	Zanubrutinib	A drug with a new active ingredient indicated for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma), Waldenström's macroglobulinemia, and lymphoplasmacytic lymphoma.
Oncology drugs	Dec. 27, 2024	100	Balversa Tablets 3 mg Balversa Tablets 4 mg Balversa Tablets 5 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	Erdafitinib	Drugs with a new active ingredient indicated for the treatment of unresectable urothelial carcinoma with *FGFR* 3 gene mutation or fusion gene that has progressed after cancer chemotherapy.
Oncology drugs	Dec. 27, 2024	101	Calquence Tablets 100 mg (AstraZeneca K.K.)	Approval	Acalabrutinib maleate hydrate	A drug with a new active ingredient indicated for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma).
Oncology drugs	Dec. 27, 2024	102	Datroway for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Approval	Datopotamab deruxtecan (genetical recombination)	A drug with a new active ingredient indicated for the treatment of hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative unresectable or recurrent breast cancer in patients who have previously been treated with chemotherapy.
Oncology drugs	Dec. 27, 2024	103	Lunsumio for Intravenous Infusion 1 mg Lunsumio for Intravenous Infusion 30 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Mosunetuzumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory follicular lymphoma.
Oncology drugs	Dec. 27, 2024	104	Imdelltra for I.V. Infusion 1 mg Imdelltra for I.V. Infusion 10 mg (Amgen K.K.)	Approval Approval	Tarlatamab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 27, 2024	105	Tecvayli Subcutaneous Injection 153 mg Tecvayli Subcutaneous Injection 30 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Teclistamab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma (for use only if refractory or intolerant to standard therapies). [Orphan drug]
Oncology drugs	Dec. 27, 2024	106	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable urothelial carcinoma.
Oncology drugs	Dec. 27, 2024	107	Randa Injection 10 mg/20 mL Randa Injection 25 mg/50 mL Randa Injection 50 mg/100 mL (Nippon Kayaku Co., Ltd.)	Change Change Change	Cisplatin	Drugs with a new indication and a new dosage for the treatment of urothelial carcinoma.
Oncology drugs	Dec. 27, 2024	108	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of advanced or recurrent endometrial cancer. [Orphan drug]
Oncology drugs	Feb. 20, 2025	109	Tecentriq Intravenous Infusion 1200 mg Tecentriq Intravenous Infusion 840 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Atezolizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable alveolar soft part sarcoma.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Feb. 20, 2025	110	Epkinly Subcutaneous Injection 4 mg Epkinly Subcutaneous Injection 48 mg (Genmab K.K.)	Change Change	Epcoritamab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory follicular lymphoma (Grade 1 to Grade 3 A).
Oncology drugs	Feb. 20, 2025	111	Sarclisa 100 mg I.V. Infusion Sarclisa 500 mg I.V. Infusion (Sanofi K.K.)	Change Change	Isatuximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of multiple myeloma.
Oncology drugs	Feb. 20, 2025	112	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Bristol-Myers Squibb K.K)	Change Change	Lenalidomide hydrate	Drugs with a new dosage indicated for the treatment of multiple myeloma.
Oncology drugs	Mar. 27, 2025	113	Tevimbra I.V. Infusion 100 mg (BeiGene Japan GK)	Approval	Tislelizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent esophageal cancer.
Oncology drugs	Mar. 27, 2025	114	Lazcluze Tablets 80 mg Lazcluze Tablets 240 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Lazertinib mesilate hydrate	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent epidermal growth factor receptor (*EGFR)* mutation-positive non-small cell lung cancer.
Oncology drugs	Mar. 27, 2025	115	Tivdak for Intravenous Infusion 40 mg (Genmab K.K.)	Approval	Tisotumab vedotin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of advanced or recurrent cervical cancer that has progressed after cancer chemotherapy.
Oncology drugs	Mar. 27, 2025	116	Tibsovo Tablets 250 mg (Nihon Servier Co., Ltd.)	Approval	Ivosidenib	A drug with a new active ingredient indicated for the treatment of *IDH1* mutation-positive acute myeloid leukemia. [Orphan drug]
Oncology drugs	Mar. 27, 2025	117	Venclexta Tablets 10 mg Venclexta Tablets 50 mg Venclexta Tablets 100 mg (AbbVie GK)	Change Change Change	Venetoclax	Drugs with a new indication and a new dosage for the treatment of relapsed or refractory mantle cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 27, 2025	118	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for maintenance treatment of limited-stage small cell lung cancer following definitive chemoradiation therapy. [Orphan drug]
Oncology drugs	Mar. 27, 2025	119	Rybrevant Intravenous Infusion 350 mg (Janssen Pharmaceutical K.K.)	Change	Amivantamab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent epidermal growth factor receptor (*EGFR)* mutation-positive non-small cell lung cancer.
Bio-CMC	Jun. 24, 2024	120	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL "GRP" (Global Regulatory Partners GK)	Approval	Aflibercept (genetical recombination) [aflibercept biosimilar 1]	A biosimilar indicated for the treatment of macular edema following retinal vein occlusion, choroidal neovascularization in patients with pathologic myopia, and diabetic macular edema.
Bio-CMC	Dec. 27, 2024	121	Ustekinumab BS 45 mg Syringe for S.C. Injection "YD" (Yoshindo Inc.)	Approval	Ustekinumab (genetical recombination) [ustekinumab biosimilar 2]	A biosimilar indicated for the treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis
Bio-CMC	Mar. 27, 2025	122	Ustekinumab BS 45 mg Syringes for S.C. Injection "CT" (Celltrion Healthcare Japan K.K.)	Approval	Ustekinumab (genetical recombination) [ustekinumab biosimilar 3]	A biosimilar indicated for the treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis.
Vaccines	Jun. 24, 2024	123	Covgoze Intramuscular Injection (Shionogi & Co., Ltd.)	Approval	Recombinant coronavirus (SARS-CoV-2) spike protein antigen	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]
Vaccines	Jun. 24, 2024	124	Typhim Vi Syringe for Injection (Sanofi K.K.)	Approval	Salmonella typhi (TY2 strain) purified Vi capsular polysaccharide	A drug with a new active ingredient indicated for the prevention of typhoid fever.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Aug. 28, 2024	125	Prevenar20 Suspension Liquid for Injection (Pfizer Japan Inc.)	Change	Pneumococcal polysaccharide conjugated to CRM197 carrier protein	A drug with a new indication and a new dosage for the prophylaxis of pneumococcal disease in the elderly and in individuals who are considered to be at a high risk of pneumococcal disease.
Vaccines	Sep. 5, 2024	126	Nuvaxovid Intramuscular Injection 1 mL (Takeda Pharmaceutical Company Limited)	Approval	SARS-CoV-2 rS (Omicron JN.1 variant)	A drug with a new indication, a new dosage, and other characteristics in an additional dosage form for the prevention of disease caused by SARS-CoV-2 infection (COVID-19).
Vaccines	Sep. 13, 2024	127	Kostaive Intramuscular Injection (Meiji Seika Pharma Co., Ltd.)	Change	mRNA encoding the spike protein of SARS-CoV-2 (Omicron JN.1 variant)	A drug with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Expedited review]
Vaccines	Sep. 24, 2024	128	Mearubik II Subcutaneous Injection (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Live attenuated measles virus (Tanabe strain) and live attenuated rubella virus (Matsuura/J16 strain)	A new combination drug with a new active ingredient indicated for the prevention of measles and rubella.
Vaccines	Nov. 22, 2024	129	Arexvy Intramuscular Injection (GlaxoSmithKline K.K.)	Change	Recombinant respiratory syncytial virus PreF3 antigen	A drug with a new dosage indicated for the prevention of disease caused by RS virus infection in individuals aged 50 years or older who are considered to be at a high risk of developing severe RS virus infection.
Vaccines	Dec. 27, 2024	130	Efluelda intramuscular injection (Sanofi K.K.)	Approval	Influenza virus (type A and type B) HA fraction	A drug with a new active ingredient indicated for the prevention of influenza.
Vaccines	Mar. 27, 2025	131	Daichirona for Intramuscular Injection (Daiichi Sankyo Company, Limited)	Change	mRNA encoding the spike protein of SARS-CoV-2	A drug with a new additional pediatric dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19).
Blood products	Jun. 24, 2024	132	Alhemo Subcutaneous Injection 15 mg Alhemo Subcutaneous Injection 60 mg Alhemo Subcutaneous Injection 150 mg Alhemo Subcutaneous Injection 300 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change	Concizumab (genetical recombination)	Drugs with a new indication for the control of bleeding tendency in patients with congenital haemophilia who do not have inhibitors against blood coagulation factor VIII or IX.
Blood products	Sep. 24, 2024	133	NovoSeven HI Syringe for I.V. Injection 1 mg NovoSeven HI Syringe for I.V. Injection 2 mg NovoSeven HI Syringe for I.V. Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new indication and a new dosage for the control of bleeding tendency in patients with Glantzmann thrombasthenia. [Public knowledge-based application]
Blood products	Dec. 27, 2024	134	HyQvia 10% S.C. Injection Set 5 g/50 mL HyQvia 10% S.C. Injection Set 10 g/100 mL HyQvia 10% S.C. Injection Set 20 g/200 mL (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Human normal immunoglobulin G (pH4-treated acidic normal human immunoglobulin [subcutaneous injection]) and Vorhyaluronidase alfa (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Dec. 27, 2024	135	Hympavzi S.C. Injection 150 mg Pen (Pfizer Japan Inc.)	Approval	Marstacimab (genetical recombination)	A drug with a new active ingredient indicated for the control of bleeding tendency in patients with congenital haemophilia who do not have inhibitors against blood coagulation factor VIII or IX.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jun. 26, 2023	1	Cortiment Tablets 9 mg (Ferring Pharmaceuticals Co., Ltd.)	Approval	Budesonide	A drug with a new route of administration indicated for the treatment of active ulcerative colitis (excluding severe cases).
1	Jun. 26, 2023	2	(1) Rinvoq Tablets 7.5 mg (2) Rinvoq Tablets 15 mg (3) Rinvoq Tablets 30 mg (4) Rinvoq Tablets 45 mg (AbbVie GK)	Change Change Change Change	Upadacitinib hydrate	(1) (2) (3) Drugs with a new indication and a new dosage for the remission induction therapy and the maintenance therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (4) A drug with a new indication and a new dosage for the remission induction therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Aug. 23, 2023	3	Jakavi Tablets 5 mg Jakavi Tablets 10 mg (Novartis Pharma K.K.)	Change Change	Ruxolitinib phosphate	Drugs with a new indication and a new dosage for the treatment of graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
1	Aug. 23, 2023	4	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of lupus nephritis in patients who have not responded sufficiently to conventional treatments. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Sep. 25, 2023	5	Phozevel Tablets 5 mg Phozevel Tablets 10 mg Phozevel Tablets 20 mg Phozevel Tablets 30 mg (Kyowa Kirin Co., Ltd.)	Approval Approval Approval Approval	Tenapanor hydrochloride	Drugs with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic kidney disease on dialysis.
1	Sep. 25, 2023	6	Romiplate for S.C. Injection 250 μg (Kyowa Kirin Co., Ltd.)	Change	Romiplostim (genetical recombination)	A drug with a new indication and a new dosage for the treatment of aplastic anemia.
1	Sep. 25, 2023	7	Entyvio Pens for S.C. Injection 108 mg Entyvio Syringes for S.C. Injection 108 mg (Takeda Pharmaceutical Company Limited)	Change Change	Vedolizumab (genetical recombination)	Drugs with a new indication for the maintenance therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Dec. 22, 2023	8	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the suppression of antibody-mediated rejection in the following organ transplantations: kidney transplantation, liver transplantation, heart transplantation, lung transplantation, pancreas transplantation, small intestine transplantation, and the treatment of antibody-mediated rejection in the following organ transplantations: kidney transplantation, liver transplantation, heart transplantation, lung transplantation, pancreas transplantation, small intestine transplantation. [Orphan drug]
1	Dec. 22, 2023	9	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (Novartis Pharma K.K.)	Change Change	Eltrombopag olamine	Drugs with a new additional pediatric dosage indicated for the treatment of aplastic anemia. [Orphan drug]
1	Dec. 22, 2023	10	Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Capsules 5 mg Prograf Granules 0.2 mg Prograf Granules 1 mg Graceptor Capsules 0.5 mg Graceptor Capsules 1 mg Graceptor Capsules 5 mg (Astellas Pharma Inc.)	Change Change Change Change Change Change Change Change	Tacrolimus hydrate	Drugs with a new dosage indicated for the suppression of rejection reaction associated with kidney transplantation. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jan. 18, 2024	11	(1) Rapalimus Granules 0.2% (2) Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Approval Change	Sirolimus	(1) A drug with a new indication and a new dosage in an additional dosage form and (2) a drug with a new indication and a new dosage, for the treatment of the following refractory vascular tumors and refractory vascular malformations: lymphangioma (lymphatic malformation), lymphangiomatosis, Gorham disease, lymphangiectasia, hemangioendothelioma, tufted angioma, venous malformation, blue rubber bleb nevus syndrome, mixed vascular malformation and Klippel-Trenaunay-Weber syndrome. [Orphan drug]
1	Jan. 18, 2024	12	Voydeya Tablets 50 mg (Alexion Pharma GK)	Approval	Danicopan	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal haemoglobinuria. [Orphan drug]
1	Feb. 9, 2024	13	Jardiance Tablets 10 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Empagliflozin	A drug with a new indication and a new dosage for the treatment of chronic kidney disease.
1	Feb. 9, 2024	14	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a new indication and a new dosage for the suppression of graft-versus-host disease in hematopoietic stem cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
1	Mar. 26, 2024	15	Zintus Tablets 25 mg Zintus Tablets 50 mg (Nobelpharma Co., Ltd.)	Approval Approval	Zinc histidine hydrate	Drugs with a new active ingredient indicated for the treatment of hypozincemia.
1	Mar. 26, 2024	16	Piasky for Injection 340 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Crovalimab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal haemoglobinuria.
1	Mar. 26, 2024	17	Rezurock Tablets 200 mg (Meiji Seika Pharma Co., Ltd.)	Approval	Belumosudil mesilate	A drug with a new active ingredient indicated for the treatment of chronic graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
6-2	Jun. 26, 2023	18	(1) Sogroya Subcutaneous Injection 5 mg (1) Sogroya Subcutaneous Injection 10 mg (2) Sogroya Subcutaneous Injection 15 mg (Novo Nordisk Pharma Ltd.)	Change Change Approval	Somapacitan (genetical recombination)	(1) Drugs with a new indication, a new dosage, and other characteristics for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure. (2) A drug with a new indication and a new dosage in an additional dosage form for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure.
6-2	Jun. 26, 2023	19	(1) Feburic Tablet 10 mg (2) Feburic Tablet 20 mg (2) Feburic Tablet 40 mg (Teijin Pharma Limited)	Change Change Change	Febuxostat	(1) A drug with a new additional pediatric dosage and other characteristics indicated for the treatment of gout and hyperuricemia. (2) Drugs with a new additional pediatric dosage indicated for the treatment of gout and hyperuricemia.
6-2	Jun. 26, 2023	20	Growject S.C. Injection 6 mg Growject S.C. Injection 12 mg (JCR Pharmaceuticals Co., Ltd.)	Change Change	Somatropin (genetical recombination)	Drugs with a new indication for the treatment of short stature in SHOX deficiency prior to epiphyseal closure.
6-2	Dec. 22, 2023	21	Genotropin TC Inj. 5.3 mg Genotropin TC Inj. 12 mg Genotropin GoQuick Inj. 5.3 mg Genotropin GoQuick Inj. 12 mg (Pfizer Japan Inc.)	Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new indication and a new dosage for the improvement of body composition in patients with Prader-Willi syndrome. [Orphan drug]
6-2	Jan. 18, 2024	22	Zokinvy Capsules 50 mg Zokinvy Capsules 75 mg (AnGes, Inc.)	Approval Approval	Lonafarnib	Drugs with a new active ingredient indicated for the treatment of Hutchinson-Gilford Progeria syndrome and processing-deficient progeroid laminopathies. [Orphan drug]
2	Jun. 26, 2023	23	Parmodia XR Tablets 0.2 mg Parmodia XR Tablets 0.4 mg (Kowa Company, Ltd.)	Approval Approval	Pemafibrate	Drugs in a new dosage form indicated for the treatment of hyperlipidaemia (including familial hyperlipidaemia).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Sep. 25, 2023	24	Leqvio for S.C. Injection Syringe 300 mg (Novartis Pharma K.K.)	Approval	Inclisiran sodium	A drug with a new active ingredient indicated for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who met all of the followings:) • High risk of developing cardiovascular events • Patients who have not sufficiently responded to an HMG-CoA reductase inhibitor or in whom treatment with HMG-CoA reductase inhibitors is not suitable.
2	Sep. 25, 2023	25	Leqembi for Intravenous Infusion 200 mg Leqembi for Intravenous Infusion 500 mg (Eisai Co., Ltd.)	Approval Approval	Lecanemab (genetical recombination)	Drugs with a new active ingredient indicated for slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease. [Priority review]
2	Sep. 25, 2023	26	Solu-Medrol for Intravenous Use 40 mg Solu-Medrol for Intravenous Use 125 mg Solu-Medrol for Intravenous Use 500 mg Solu-Medrol for Intravenous Use 1000 mg (Pfizer Japan Inc.)	Change Change Change Change	Methylprednisolone sodium succinate	Drugs with a new indication and a new dosage for the treatment of the acute phase of Kawasaki's disease (for patients with severe Kawasaki's disease who have the risk of developing coronary artery disorder). [Public knowledge-based application after PAFSC's preliminary assessment]
2	Nov. 24, 2023	27	Xarelto Tablets 10 mg Xarelto Fine Granules 10 mg Xarelto OD Tablets 10 mg Xarelto Dry Syrup for Pediatric 51.7 mg Xarelto Dry Syrup for Pediatric 103.4 mg Xarelto Tablets 2.5 mg (Bayer Yakuhin, Ltd.)	Change Change Change Change Change Change	Rivaroxaban	Drugs with a new indication and a new dosage for the inhibition of thrombus/embolization formation in patients after Fontan surgery.
2	Jan. 18, 2024	28	Evkeeza for intravenous infusion 345 mg (Ultragenyx Japan K.K.)	Approval	Evinacumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of homozygous familial hypercholesterolemia. [Orphan drug]
2	Feb. 9, 2024	29	Entresto Tablets 50 mg Entresto Tablets 100 mg Entresto Tablets 200 mg (Novartis Pharma K.K.)	Change Change Change	Sacubitril valsartan sodium hydrate	Drugs with a new indication and a new additional pediatric dosage for the treatment of chronic heart failure.
2	Mar. 26, 2024	30	Entresto Granules for Pediatric 12.5 mg Entresto Granules for Pediatric 31.25 mg (Novartis Pharma K.K.)	Approval Approval	Sacubitril valsartan sodium hydrate	Drugs with a new indication and a new additional pediatric dosage in an additional dosage form for the treatment of chronic heart failure.
2	Mar. 26, 2024	31	Vyvgart for Intravenous Infusion 400 mg (Argenx Japan K.K.)	Change	Efgartigimod alfa (genetical recombination)	A drug with a new indication and a new dosage for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]
2	Mar. 26, 2024	32	Adzynma Intravenous 1500 (Takeda Pharmaceutical Company Limited)	Approval	Apadamtase alfa (genetical recombination)/ Cinaxadamtase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of congenital thrombotic thrombocytopenic purpura. [Orphan drug]
5	Apr. 28, 2023	33	Mefeego Pack (Linepharma K.K.)	Approval	Mifepristone Misoprostol	A drug with a new active ingredient and a new route of administration indicated for medical abortion within 63 days of gestation (9 weeks and 0 days of gestation) in women whose intrauterine pregnancy was confirmed.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Radio-pharmaceuticals	Aug. 23, 2023	34	FDGscan Injectable (Nihon Medi-Physics Co., Ltd.)	Change	Fludeoxyglucose (^{18}F)	A drug with a new indication for the diagnosis of malignant tumors (pleural mesothelioma, esophageal cancer, gastric cancer, gastrointestinal stromal tumor, hepatic cancer, biliary tract cancer, pancreatic cancer, bladder cancer, renal pelvis/ureter cancer, uterine cancer, ovarian cancer, bone soft tissue tumor, skin cancer [when the diagnosis of disease stage and metastasis/recurrence cannot be confirmed by other tests/imaging diagnosis]; thymic tumor, renal cancer, testicular tumor, thyroid cancer [when the diagnosis of metastasis/recurrence cannot be confirmed by other tests/imaging diagnosis]; visualization of bone lesion or extramedullary lesion in patients suspected of multiple myeloma or with multiple myeloma [when the presence of bone lesion or extramedullary lesion is suspected by other tests/imaging diagnosis]); and the visualization of inflammatory sites in patients suspected of cardiac sarcoidosis or with cardiac sarcoidosis. [Public knowledge-based application]
Radio-pharmaceuticals	Aug. 31, 2023	35	Vizamyl Injection (Nihon Medi-Physics Co., Ltd.)	Change	Flutemetamol (^{18}F)	A drug with a new indication for the visualization of beta-amyloid plaques in the brain of patients suspected of mild cognitive impairment or dementia due to Alzheimer's disease. [Expedited review]
Radio-pharmaceuticals	Aug. 31, 2023	36	Amyvid Injection (PDRadiopharma Inc.)	Change	florbetapir (^{18}F)	A drug with a new indication for the visualization of beta-amyloid plaques in the brain of patients suspected of mild cognitive impairment or dementia due to Alzheimer's disease. [Expedited review]
Radio-pharmaceuticals	Dec. 22, 2023	37	MyoMIBG-I123 Injection (PDRadiopharma Inc.)	Change	3-Iodobenzylguanidine (^{123}I)	A drug with a new indication and a new dosage for cardiac scintigraphy in the diagnoses of Parkinson's disease and dementia with Lewy bodies.
In vivo diagnostics	Sep. 25, 2023	38	Diagnogreen for Injection 25 mg (Daiichi Sankyo Company, Limited)	Change	Indocyanine green	A drug with a new indication and a new dosage for the visualization of extrahepatic biliary ducts. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
3-1	May 25, 2023	39	Ultomiris for Intravenous Infusion 300 mg Ultomiris for Intravenous Infusion 300 mg/3 mL Ultomiris for Intravenous Infusion 1100 mg/11 mL (Alexion Pharma GK)	Change Change Change	Ravulizumab (genetical recombination)	Drugs with a new indication for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica).
3-1	Jun. 26, 2023	40	E Keppra Dry Syrup 50% E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Change Change	Levetiracetam	Drugs with a new additional pediatric dosage indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy.
3-1	Aug. 23, 2023	41	Soliris for Intravenous Infusion 300 mg (Alexion Pharma GK)	Change	Eculizumab (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of generalized myasthenia gravis (for use only in patients whose symptoms cannot be sufficiently controlled with high-dose intravenous immunoglobulin therapy or plasmapheresis). [Orphan drug]
3-1	Sep. 25, 2023	42	Zilbrysq Syringe for S.C. Injections 16.6 mg Zilbrysq Syringe for S.C. Injections 23.0 mg Zilbrysq Syringe for S.C. Injections 32.4 mg (UCB Japan Co., Ltd.)	Approval Approval Approval	Zilucoplan sodium	Drugs with a new active ingredient indicated for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants).
3-1	Sep. 25, 2023	43	Rystiggo for S.C. Injection 280 mg (UCB Japan Co., Ltd.)	Approval	Rozanolixizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 22, 2023	44	Rexulti Tablets 1 mg Rexulti Tablets 2 mg Rexulti OD Tablets 0.5 mg Rexulti OD Tablets 1 mg Rexulti OD Tablets 2 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Brexpiprazole	Drugs with a new indication and a new dosage for the treatment of depression (for use only in patients who have not sufficiently responded to conventional treatments).
3-1	Jan. 18, 2024	45	Fycompa for Intravenous Infusion 2 mg (Eisai Co., Ltd.)	Approval	Perampanel hydrate	A drug with a new route of administration indicated for the following treatment: partial seizures (including secondary generalized seizures) in patients with epilepsy and an adjunctive therapy with other antiepileptic drugs to treat tonic-clonic seizure in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs. It is used as an alternative therapy for perampanel oral formulation in patients who are temporarily unable to be administered orally.
3-1	Jan. 18, 2024	46	Vyvdura Combination Subcutaneous Injection (Argenx Japan K.K.)	Approval	Efgartigimod alfa (genetical recombination) and Vorhyaluronidase alfa (genetical recombination)	A new combination drug with a new active ingredient indicated for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants).
3-1	Mar. 26, 2024	47	Fintepla Oral Solution 2.2 mg/mL (UCB Japan Co., Ltd.)	Change	Fenfluramine hydrochloride	A drug with a new indication and a new dosage for use as an adjunctive therapy with other antiepileptic drugs to treat epileptic seizures in patients with Lennox-Gastaut syndrome who have not responded sufficiently to other antiepileptic drugs. [Orphan drug]
3-1	Mar. 26, 2024	48	Acenobel Extended Release Tablets 500 mg (Nobelpharma Co., Ltd.)	Approval	Aceneuramic acid	A drug with a new active ingredient indicated for delaying the progression of muscle weakness in patients with distal myopathy with rimmed vacuoles. [Orphan drug]
3-2	Sep. 25, 2023	49	Korsuva IV Injection Syringe for Dialysis 17.5 μg Korsuva IV Injection Syringe for Dialysis 25.0 μg Korsuva IV Injection Syringe for Dialysis 35.0 μg (Maruishi Pharmaceutical Co., Ltd.)	Approval Approval Approval	Difelikefalin acetate	Drugs with a new active ingredient indicated for the improvement of pruritus in patients on hemodialysis (for use only in patients who have not sufficiently responded to conventional treatments).
3-2	Jan. 18, 2024	50	Eylea 8 mg Solution for IVT Inj. 114.3 mg/mL (Bayer Yakuhin, Ltd.)	Approval	Aflibercept (genetical recombination)	A drug in a new dosage form indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema.
3-2	Mar. 26, 2024	51	Cystadrops Ophthalmic Solution 0.38% (Viatris Pharmaceuticals Japan Inc.)	Approval	Cysteamine hydrochloride	A drug with a new active ingredient indicated for the reduction of corneal cystine crystals in patients with cystinosis. [Orphan drug]
3-2	Mar. 26, 2024	52	Vabysmo Solution for Intravitreal Injection 120 mg/mL (Chugai Pharmaceutical Co., Ltd.)	Change	Faricimab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of macular edema following retinal vein occlusion.
4	Nov. 30, 2023	53	Fetroja for Intravenous Drip Infusion 1 g (Shionogi & Co., Ltd.)	Approval	Cefiderocol tosilate sulfate hydrate	A drug with a new active ingredient indicated for the treatment of infections caused by Cefiderocol-sensitive *Escherichia coli* , *Citrobacter* spp, *Klebsiella pneumoniae* , *Klebsiella* spp, *Enterobacter* spp, *Serratia marcescens* , *Proteus* spp, *Morganella morganii* , *Pseudomonas aeruginosa* , *Burkholderia* spp, *Stenotrophomonas maltophilia* , and *Acinetobacter* spp (limited to bacterial strains resistant to carbapenem antimicrobial drugs). [Orphan drug]
4	Mar. 5, 2024	54	Xocova Tablets 125 mg (Shionogi & Co., Ltd.)	Approval	Ensitrelvir fumaric acid	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
4	Mar. 26, 2024	55	Beyfortus 50 mg Solution for Intramuscular Injection in Syringe Beyfortus 100 mg Solution for Intramuscular Injection in Syringe (AstraZeneca K.K.)	Approval Approval	Nirsevimab (genetical recombination)	Drugs with a new active ingredient indicated for as follows: 1.The prevention of lower respiratory tract disease caused by respiratory syncytial (RS) virus infection in neonates, infants and children at risk of serious RS virus infection entering their first or second RS virus season after birth. 2.The prophylaxis of lower respiratory tract disease caused by RS virus infection in all neonates and infants other than those described in Item 1 entering their first RS virus season after birth.
4	Mar. 26, 2024	56	Rifxima Tablets 200 mg (Aska Pharmaceutical Co., Ltd.)	Change	Rifaximin	A drug with a new additional pediatric dosage indicated for the improvement of hyperammonemia in patients with hepatic encephalopathy. [Orphan drug]
4	Mar. 26, 2024	57	Synagis 50 mg solution for Intramuscular Administration Synagis 100 mg solution for Intramuscular Administration (AstraZeneca K.K.)	Change Change	Palivizumab (genetical recombination)	Drugs with a new indication for the prevention of serious lower respiratory tract disease caused by respiratory syncytial (RS) virus infection in neonates, infants, and children aged 24 months and younger with pulmonary hypoplasia, airway stenosis, congenital esophageal atresia, congenital metabolic disorder, or neuromuscular disease at the early stage of the RS virus season. [Priority review]
6-1	May 25, 2023	58	Skyrizi 150 mg for S.C. Injection Syringe 1 mL Skyrizi 150 mg for S.C. Injection Pen 1 mL Skyrizi 75 mg for S.C. Injection Syringe 0.83 mL (AbbVie GK)	Change Change Change	Risankizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of palmoplantar pustulosis in patients who have not responded sufficiently to conventional therapies.
6-1	Jun. 26, 2023	59	Dupixent 300 mg Syringe for S.C. Injection Dupixent 300 mg Pen for S.C. Injection (Sanofi K.K.)	Change Change	Dupilumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of prurigo nodularis in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 26, 2023	60	Litfulo Capsules 50 mg (Pfizer Japan Inc.)	Approval	Ritlecitinib tosilate	A drug with a new active ingredient indicated for the treatment of alopecia areata (for use only in patients with intractable and extensive alopecia areata).
6-1	Aug. 23, 2023	61	Lumicef Subcutaneous Injection 210 mg Syringe (Kyowa Kirin Co., Ltd.)	Change	Brodalumab (genetical recombination)	A drug with a new indication for the treatment of palmoplantar pustulosis in patients who have not responded sufficiently to conventional therapies.
6-1	Sep. 25, 2023	62	(1) Dupixent 200 mg Syringe for S.C. Injection (2) Dupixent 300 mg Syringe for S.C. Injection (3) Dupixent 300 mg Pen for S.C. Injection (Sanofi K.K.)	Approval Change Change	Dupilumab (genetical recombination)	(1) A drug with a new additional pediatric dosage in an additional dosage form and (2), (3) drugs with a new additional pediatric dosage, indicated for the treatment of atopic dermatitis in patients who have not sufficiently responded to conventional treatments.
6-1	Dec. 22, 2023	63	Bimzelx Syringe for S.C Injection 160 mg Bimzelx Autoinjector for S.C Injection 160 mg (UCB Japan Co., Ltd.)	Change Change	Bimekizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis in patients who have not sufficiently responded to conventional treatments.
6-1	Jan. 18, 2024	64	Ebglyss Subcutaneous Injection 250 mg Syringes Ebglyss Subcutaneous Injection 250 mg Autoinjectors (Eli Lilly Japan K.K.)	Approval Approval	Lebrikizumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 9, 2024	65	Dupixent 300 mg Syringe for S.C. Injection Dupixent 300 mg Pen for S.C. Injection Dupixent 200 mg Syringe for S.C. Injection (Sanofi K.K.)	Change Change Change	Dupilumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of chronic spontaneous urticaria in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 26, 2024	66	(1) Olumiant Tablets 2 mg (2) Olumiant Tablets 4 mg (3) Olumiant Tablets 1 mg (Eli Lilly Japan K.K.)	Change Change Approval	Baricitinib	(1), (2) Drugs with a new indication and a new dosage and (3) a drug with a new indication and a new dosage in an additional dosage form, for the treatment of polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional treatments.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Mar. 26, 2024	67	(1) Olumiant Tablets 2 mg (2) Olumiant Tablets 4 mg (3) Olumiant Tablets 1 mg (Eli Lilly Japan K.K.)	Change Change Approval	Baricitinib	(1), (2) Drugs with a new additional pediatric dosage and (3) a drug with a new additional pediatric dosage in an additional dosage form, indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 26, 2024	68	(1) Fasenra Subcutaneous Injection 30 mg Syringe (2) Fasenra Subcutaneous Injection 10 mg Syringe (AstraZeneca K.K.)	Change Approval	Benralizumab (genetical recombination)	(1) A drug with a new additional pediatric dosage and (2) a drug with a new additional pediatric dosage in an additional dosage form, indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Mar. 26, 2024	69	Mitchga Vials 30 mg (Maruho Co., Ltd.)	Approval	Nemolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of prurigo nodularis in patients who have not responded sufficiently to conventional treatments, and a new additional pediatric dosage in an additional dosage form, indicated for the treatment of pruritus associated with atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 26, 2024	70	Sargmalin for Inhalation 250 μg (Nobelpharma Co., Ltd.)	Approval	Sargramostim (genetical recombination)	A drug with a new active ingredient indicated for the treatment of autoimmune pulmonary alveolar proteinosis. [Orphan drug]
6-1	Mar. 26, 2024	71	Alesion Eyelid Cream 0.5% (Santen Pharmaceutical Co., Ltd.)	Approval	Epinastine hydrochloride	A drug in a new dosage form indicated for the treatment of allergic conjunctivitis.
AIDS drugs	Aug. 1, 2023	72	Sunlenca Subcutaneous Injection 463.5 mg Sunlenca Tablets 300 mg (Gilead Sciences, Inc.)	Approval Approval	Lenacapavir sodium	Drugs with a new active ingredient indicated for the treatment of multidrug-resistant HIV-1 infection. [Orphan drug]
Oncology drugs	May 25, 2023	73	Vanflyta Tablets 17.7 mg Vanflyta Tablets 26.5 mg (Daiichi Sankyo Company, Limited)	Change Change	Quizartinib hydrochloride	Drugs with a new indication and a new dosage for the treatment of newly diagnosed FLT3-ITD mutation-positive acute myeloid leukemia. [Orphan drug]
Oncology drugs	May 25, 2023	74	Cylocide Injection 20 mg Cylocide Injection 40 mg Cylocide Injection 60 mg Cylocide Injection 100 mg Cylocide Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Change Change Change Change Change	Cytarabine	Drugs with a new dosage indicated for the treatment of acute leukemia. [Public knowledge-based application, Expedited review]
Oncology drugs	May 25, 2023	75	Cylocide N Injection 400 mg Cylocide N Injection 1 g (Nippon Shinyaku Co., Ltd.)	Change Change	Cytarabine	Drugs with a new indication and a new dosage for the treatment of acute leukemia. [Public knowledge-based application, Expedited review]
Oncology drugs	Jun. 26, 2023	76	Oncaspar I.V. Infusion 3750 (Nihon Servier Co., Ltd.)	Approval	Pegaspargase	A drug with a new active ingredient indicated for the treatment of acute lymphocytic leukemia and malignant lymphoma.
Oncology drugs	Jun. 26, 2023	77	Lytgobi tablets 4 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Futibatinib	A drug with a new active ingredient indicated for the treatment of unresectable *FGFR2* fusion gene-positive biliary tract cancer that has progressed after cancer chemotherapy.
Oncology drugs	Jun. 26, 2023	78	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of relapsed or refractory primary mediastinal large B-cell lymphoma. [Orphan drug]
Oncology drugs	Aug. 23, 2023	79	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change	Trastuzumab deruxtecan (genetical recombination)	A drug with a new indication for the treatment of unresectable advanced or recurrent *HER2* (*ERBB2*) mutation-positive non-small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Aug. 23, 2023	80	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new dosage indicated for the treatment of *BRCA* mutation-positive, metastatic castration-resistant prostate cancer.
Oncology drugs	Sep. 25, 2023	81	Phesgo Combination for Subcutaneous Injection MA Phesgo Combination for Subcutaneous Injection IN (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Pertuzumab (genetical recombination), Trastuzumab (genetical recombination), and Vorhyaluronidase alfa (genetical recombination)	New combination drugs with a new active ingredient indicated for the treatment of HER2-positive breast cancer and unresectable advanced or recurrent HER2-positive colon or rectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 25, 2023	82	Epkinly Subcutaneous Injection 4 mg Epkinly Subcutaneous Injection 48 mg (Genmab K.K.)	Approval Approval	Epcoritamab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma, and primary mediastinal large B-cell lymphoma) or relapsed or refractory follicular lymphoma.
Oncology drugs	Sep. 25, 2023	83	(1) TS-1 Combination Capsules T20 (2) TS-1 Combination Capsules T25 (3) TS-1 Combination Granules T20 (4) TS-1 Combination Granules T25 (5) TS-1 Combination OD Tablets T20 (6) TS-1 Combination OD Tablets T25 (7) S-1 Taiho Combination OD Tablets T20 (8) S-1 Taiho Combination OD Tablets T25 ((1)-(6) Taiho Pharmaceutical Co., Ltd. (7)-(8) Okayama Taiho Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Tegafur Gimeracil Oteracil potassium	Drugs with a new dosage indicated for the treatment of gastric cancer, colon or rectal cancer, non-small cell lung cancer, pancreatic cancer, and biliary tract cancer. [Public knowledge-based application]
Oncology drugs	Sep. 25, 2023	84	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Tocilizumab (genetical recombination)	Drugs with a new indication for the treatment of cytokine release syndrome induced by the treatment for malignant tumor.
Oncology drugs	Nov. 24, 2023	85	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	A drug with a new indication and a new dosage for the treatment of relapsed or refractory CD30-positive cutaneous T-cell lymphoma.
Oncology drugs	Nov. 24, 2023	86	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of malignant mesothelioma (excluding malignant pleural mesothelioma). [Orphan drug]
Oncology drugs	Nov. 24, 2023	87	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Change Change	Dabrafenib mesilate	Drugs with a new indication and a new dosage for the treatment of advanced or recurrent *BRAF* mutation-positive solid tumor (excluding colon/rectal cancer) that is refractory or intolerant to standard therapies and relapsed or refractory *BRAF* mutation-positive hairy cell leukemia. [Orphan drug]
Oncology drugs	Nov. 24, 2023	88	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Change Change	Trametinib dimethyl sulfoxide	Drugs with a new indication and a new dosage for the treatment of advanced or recurrent *BRAF* mutation-positive solid tumor (excluding colon/rectal cancer) that is refractory or intolerant to standard therapies and relapsed or refractory *BRAF* mutation-positive hairy cell leukemia. [Orphan drug]
Oncology drugs	Nov. 24, 2023	89	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new dosage indicated for the maintenance treatment of locally-advanced, unresectable non-small cell lung cancer following definitive chemoradiation therapy.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jan. 18, 2024	90	(1) Talzenna Capsules 0.1 mg (2) Talzenna Capsules 0.25 mg (3) Talzenna Capsules 1 mg (Pfizer Japan Inc.)	Approval Approval Approval	Talazoparib tosilate	(1) A drug with a new active ingredient indicated for the treatment of *BRCA* mutation-positive, metastatic castration-resistant prostate cancer. (2) A drug with a new active ingredient indicated for the treatment of *BRCA* mutation-positive, metastatic castration-resistant prostate cancer and unresectable or recurrent *BRCA* mutation-positive and HER2-negative breast cancer in patients who have previously been treated with chemotherapy. (3) A drug with a new active ingredient indicated for the treatment of unresectable or recurrent *BRCA* mutation-positive and HER2-negative breast cancer in patients who have previously been treated with chemotherapy.
Oncology drugs	Jan. 18, 2024	91	Reblozyl for S.C. Injection 25 mg Reblozyl for S.C. Injection 75 mg (Bristol-Myers Squibb K.K.)	Approval Approval	Luspatercept (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of anemia associated with myelodysplastic syndrome. [Orphan drug]
Oncology drugs	Feb. 9, 2024	92	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent epithelial skin malignancies. [Orphan drug]
Oncology drugs	Mar. 26, 2024	93	Vyxeos Combination for I.V. Injection (Nippon Shinyaku Co., Ltd.)	Approval	Daunorubicin hydrochloride, Cytarabine	A new combination drug indicated for the treatment of high-risk acute myeloid leukemia. [Orphan drug]
Oncology drugs	Mar. 26, 2024	94	Truqap Tablets 160 mg Truqap Tablets 200 mg (AstraZeneca K.K.)	Approval Approval	Capivasertib	Drugs with a new active ingredient indicated for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer with *PIK3CA, AKT1,* or *PTEN* mutation that has progressed after endocrine therapy.
Oncology drugs	Mar. 26, 2024	95	Vyloy for I.V. Infusion 100 mg (Astellas Pharma Inc.)	Approval	Zolbetuximab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of CLDN18.2 (Claudin-18 splice variant 2)-positive unresectable advanced or recurrent gastric cancer.
Oncology drugs	Mar. 26, 2024	96	Elrexfio S.C. Injection 44 mg Elrexfio S.C. Injection 76 mg (Pfizer Japan Inc.)	Approval Approval	Elranatamab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma (for use only if refractory or intolerant to standard therapies). [Orphan drug]
Oncology drugs	Mar. 26, 2024	97	Besponsa Injection 1 mg (Pfizer Japan Inc.)	Change	Inotuzumab ozogamicin (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of relapsed or refractory CD22-positive acute lymphoblastic leukemia.
Oncology drugs	Mar. 26, 2024	98	Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)	Change	Fulvestrant	A drug with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Mar. 26, 2024	99	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. [Public knowledge-based application]
Bio-CMC	Sep. 25, 2023	100	(1) Pegfilgrastim BS Subcutaneous Injection 3.6 mg "Mochida" (2) Pegfilgrastim BS Subcutaneous Injection 3.6 mg "Nipro" ([1] Mochida Pharmaceutical Co., Ltd. [2] Mochida Pharmaceutical Sales Co., Ltd.)	Approval Approval	Pegfilgrastim (genetical recombination) [pegfilgrastim biosimilar 1]	Biosimilars indicated for the prevention of febrile neutropenia in patients receiving cancer chemotherapy.
Bio-CMC	Sep. 25, 2023	101	Ustekinumab BS 45 mg Syringe for S.C. Injection “F” (Fuji Pharma Co., Ltd.)	Approval	Ustekinumab (genetical recombination) [ustekinumab biosimilar 1]	A biosimilar indicated for the treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Bio-CMC	Sep. 25, 2023	102	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL "CTNK" Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL "CTNK" Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL "CTNK" Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL "CTNK" Adalimumab BS Subcutaneous Injection 80 mg Pen 0.8 mL "CTNK" (Nippon Kayaku Co., Ltd.)	Approval Approval Approval Approval Approval	Adalimumab (genetical recombination) [adalimumab biosimilar 4]	Biosimilars indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not sufficiently responded to conventional treatments: polyarticular-course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, intestinal Behcet' s disease, non-infectious intermediate uveitis, posterior uveitis, and panuveitis; the remission induction therapy and maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional therapies), and the treatment of moderate or severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
Vaccines	Jun. 26, 2023	103	Vaxneuvance Aqueous Suspension Syringes (MSD K.K.)	Change	Pneumococcal polysaccharides of serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F conjugated to CRM197 carrier protein	A drug with a new indication and a new additional pediatric dosage for the prophylaxis of pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F) in individuals who are considered to be at a high risk of pneumococcal disease and invasive pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) in children.
Vaccines	Jun. 26, 2023	104	Shingrix for I.M. Injection (Glaxo SmithKline K.K.)	Change	Varicella zoster virus gE antigen	A drug with a new dosage indicated for the prevention of herpes zoster.
Vaccines	Aug. 2, 2023	105	Daichirona for Intramuscular Injection (Daiichi Sankyo Company, Limited)	Approval	Ufrenmeran	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]
Vaccines	Aug. 2, 2023	106	Spikevax Intramuscular Injection (Moderna Japan Co., Ltd.)	Change	Elasomeran, Elasomeran and Imelasomeran, Elasomeran and Davesomeran	A drug with a new additional pediatric dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Aug. 2, 2023	107	(1) Comirnaty RTU Intramuscular Injection (2) Comirnaty RTU Intramuscular Injection for 1 person (3) Comirnaty Intramuscular Injection for 5 to 11 years old (4) Comirnaty Intramuscular Injection for 6 months to 4 years old (Pfizer Japan Inc.)	Change Change Change Change	(1) Tozinameran, Tozinameran and Famtozinameran, Tozinameran and Riltozinameran (2)-(4) Tozinameran, Tozinameran and Famtozinameran	Drugs with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Sep. 25, 2023	108	Quintovac Aqueous Suspension Injection (KM Biologics Co., Ltd.)	Approval	Protective antigen of Bordetella pertussis Diphtheria toxoid Tetanus toxoid Inactivated poliovirus types 1-3 (Sabin strain) Haemophilus influenzae type b polysaccharide-tetanus toxoid conjugate	A new combination drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, acute poliomyelitis, and infections caused by *Haemophilus influenzae type b* .
Vaccines	Sep. 25, 2023	109	Arexvy Intramuscular Injection (GlaxoSmithKline K.K.)	Approval	Recombinant respiratory syncytial virus PreF3 antigen	A drug with a new active ingredient indicated for the prevention of disease caused by RS virus infection.
Vaccines	Oct. 24, 2023	110	Spikevax Intramuscular Injection (Moderna Japan Co., Ltd.)	Change	Elasomeran, Elasomeran and Imelasomeran, Elasomeran and Davesomeran, Andusomeran	A drug with a new dosage for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Nov. 28, 2023	111	Kostaive Intramuscular Injection (Meiji Seika Pharma Co., Ltd.)	Approval	Zapomeran	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Nov. 28, 2023	112	Daichirona for Intramuscular Injection (Daiichi Sankyo Company, Limited)	Change	Ufrenmeran, MAFB-7256a	A drug with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19).
Vaccines	Jan. 18, 2024	113	Abrysvo Intramuscular Injection (Pfizer Japan Inc.)	Approval	Respiratory syncytial virus-A prefusion F protein Respiratory syncytial virus-B prefusion F protein	A drug with a new active ingredient indicated for active immunization of pregnant individuals for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in neonates and infants.
Vaccines	Mar. 26, 2024	114	Ticovac Suspension Liquid for Intramuscular Injection 0.5 mL Ticovac Junior Suspension Liquid for Intramuscular Injection 0.25 mL (Pfizer Japan Inc.)	Approval Approval	Inactivated tick-borne encephalitis virus	Drugs with a new active ingredient indicated for the prevention of tick-borne encephalitis.
Vaccines	Mar. 26, 2024	115	Prevenar 20 Suspension Liquid for Injection (Pfizer Japan Inc.)	Approval	Pneumococcal polysaccharide conjugated to CRM197 carrier protein	A drug with a new active ingredient indicated for the prophylaxis of invasive pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) in children.
Vaccines	Mar. 26, 2024	116	Abrysvo Intramuscular Injection (Pfizer Japan Inc.)	Change	Respiratory syncytial virus-A prefusion F protein Respiratory syncytial virus-B prefusion F protein	A drug with a new indication and a new dosage for the prevention of disease caused by respiratory syncytial virus infection in individuals 60 years of age and older.
Blood products	Jun. 26, 2023	117	Hizentra 20% S.C. Injection 1 g/5 mL Hizentra 20% S.C. Injection 2 g/10 mL Hizentra 20% S.C. Injection 4 g/20 mL (CSL Behring K.K.)	Change Change Change	Human normal immunoglobulin G (pH4-treated acidic normal human immunoglobulin [subcutaneous injection])	Drugs with a new dosage indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Jun. 26, 2023	118	Adynovate Intravenous Kit 250 Adynovate Intravenous Kit 500 Adynovate Intravenous Kit 1000 Adynovate Intravenous Kit 1500 Adynovate Intravenous Kit 2000 Adynovate Intravenous Kit 3000 (Takeda Pharmaceutical Company Limited)	Change Change Change Change Change Change	Rurioctocog alfa pegol (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Sep. 25, 2023	119	Alhemo Subcutaneous Injection 15 mg Alhemo Subcutaneous Injection 60 mg Alhemo Subcutaneous Injection 150 mg Alhemo Subcutaneous Injection 300 mg (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval	Concizumab (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with congenital haemophilia who have inhibitors against blood coagulation factor VIII or IX. [Orphan drug]
Blood products	Sep. 25, 2023	120	Altuviiio Intravenous 250 Altuviiio Intravenous 500 Altuviiio Intravenous 1000 Altuviiio Intravenous 2000 Altuviiio Intravenous 3000 Altuviiio Intravenous 4000 (Sanofi K.K.)	Approval Approval Approval Approval Approval Approval	Efanesoctocog alfa (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Sep. 25, 2023	121	Cuvitru 20% S.C. Injection 1 g/5 mL Cuvitru 20% S.C. Injection 2 g/10 mL Cuvitru 20% S.C. Injection 4 g/20 mL Cuvitru 20% S.C. Injection 8 g/40 mL Cuvitru 20% S.C. Injection 10 g/50 mL (Takeda Pharmaceutical Company, Limited)	Approval Approval Approval Approval Approval	Human normal immunoglobulin G (pH4-treated acidic normal human immunoglobulin [subcutaneous injection])	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Mar. 26, 2024	122	Ceprotin for Intravenous Injection 1000 IU (Takeda Pharmaceutical Company Limited)	Approval	Human protein C	A drug with a new active ingredient indicated for the treatment of venous thromboembolism and purpura fulminans and for the control of thrombophilia, in patients with congenital protein C deficiency.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Blood products	Mar. 26, 2024	123	Obizur Intravenous Injection 500 (Takeda Pharmaceutical Company Limited)	Approval	Susoctocog alfa (genetical recombination)	A drug with a new active ingredient indicated for the control of bleeding episodes in patients with acquired hemophilia A. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2022

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	May 26, 2022	1	Rozex Gel 0.75% (Maruho Co., Ltd.)	Change	Metronidazole	A drug with a new indication and a new dosage for the treatment of rosacea.
1	Jun. 20, 2022	2	Enjaymo for I.V. Infusion 1.1 g (Sanofi K.K.)	Approval	Sutimlimab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of cold agglutinin disease. [Orphan drug]
1	Sep. 26, 2022	3	(1) Rinvoq Tablets 7.5 mg (2) Rinvoq Tablets 15 mg (3) Rinvoq Tablets 30 mg (4) Rinvoq Tablets 45 mg (AbbVie GK)	Change Change Change Approval	Upadacitinib hydrate	(1) (2) (3) Drugs with a new indication and a new dosage for the remission induction and maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (4) A drug with a new indication and a new dosage in an additional dosage form for the remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Sep. 26, 2022	4	(1) Skyrizi Intravenous Infusion 600 mg (2) Skyrizi for Subcutaneous Injection 360 mg Auto Dosers (AbbVie GK)	Approval Approval	Risankizumab (genetical recombination)	(1) A drug with a new route of administration indicated for the remission induction therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (2) A drug with a new indication and a new dosage in an additional dosage form for the maintenance therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Dec. 23, 2022	5	NexoBrid Gel 5 g (Kaken Pharmaceutical Co., Ltd.)	Approval	Purified pineapple stem juice	A drug with a new active ingredient indicated for the removal of necrotic tissue of deep dermal burn or deep burn. [Orphan drug]
1	Mar. 27, 2023	6	Entyvio Pens for S.C. Injection 108 mg Entyvio Syringes for S.C. Injection 108 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Vedolizumab (genetical recombination)	Drugs with a new route of administration indicated for the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Mar. 27, 2023	7	Apohide Lotion 20% (Hisamitsu Pharmaceutical Co., Inc.)	Approval	Oxybutynin hydrochloride	A drug with a new indication in a new dosage form for the treatment of primary palmar hyperhidrosis.
1	Mar. 27, 2023	8	Renail Gel 10% (Maruho Co., Ltd.)	Approval	Acetylcysteine	A drug with a new route of administration indicated for the support of pincer nail correction.
1	Mar. 27, 2023	9	Empaveli for Subcutaneous Ingection 1080 mg (Swedish Orphan Biovitrum Japan Co., Ltd.)	Approval	Pegcetacoplan	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal haemoglobinuria.
1	Mar. 27, 2023	10	(1) Omvoh Intravenous Infusion 300 mg (2) Omvoh Subcutaneous Injection 100 mg Autoinjectors (3) Omvoh Subcutaneous Injection 100 mg Syringes (Eli Lilly Japan K.K.)	Approval Approval Approval	Mirikizumab (genetical recombination)	(1) A drug with a new active ingredient indicated for the remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (2) (3) Drugs with a new active ingredient indicated for the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
6-2	Jun. 20, 2022	11	Canaglu Tablets 100 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Canagliflozin hydrate	A drug with a new indication for the treatment of chronic kidney disease associated with type 2 diabetes mellitus (excluding patients who have end-stage renal failure or are undergoing dialysis).
6-2	Jun. 20, 2022	12	Voxzogo for Subcutaneous Injection 0.4 mg Voxzogo for Subcutaneous Injection 0.56 mg Voxzogo for Subcutaneous Injection 1.2 mg (BioMarin Pharmaceutical K.K.)	Approval Approval Approval	Vosoritide (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of achondroplasia prior to epiphyseal closure. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-2	Sep. 26, 2022	13	Mounjaro Subcutaneous Injection 2.5 mg Ateos Mounjaro Subcutaneous Injection 5 mg Ateos Mounjaro Subcutaneous Injection 7.5 mg Ateos Mounjaro Subcutaneous Injection 10 mg Ateos Mounjaro Subcutaneous Injection 12.5 mg Ateos Mounjaro Subcutaneous Injection 15 mg Ateos (Eli Lilly Japan K.K.)	Approval Approval Approval Approval Approval Approval	Tirzepatide	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Dec. 23, 2022	14	Galafold Capsules 123 mg (Amicus Therapeutics, Inc.)	Change	Migalastat hydrochloride	A drug with a new additional pediatric dosage indicated for the treatment of Fabry disease in patients with GLA mutations categorized as amenable to treatment with migalastat. [Orphan drug]
6-2	Mar. 27, 2023	15	(1) Wegovy Subcutaneous Injection 0.25 mg SD (1) Wegovy Subcutaneous Injection 0.5 mg SD (1) Wegovy Subcutaneous Injection 1.0 mg SD (2) Wegovy Subcutaneous Injection 1.7 mg SD (2) Wegovy Subcutaneous Injection 2.4 mg SD (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	Semaglutide (genetical recombination)	(1) Drugs with a new indication, a new dosage and other characteristics for the treatment of obesity. (2) Drugs with a new indication and a new dosage in an additional dosage form for the treatment of obesity. For use only in patients with any of hypertension, hyperlipidemia or type 2 diabetes mellitus who have not responded sufficiently to diet therapy and exercise therapy, and meet the following conditions: • BMI of 27 kg/m^2 or greater in the presence of at least two obesity-related comorbidities or • BMI of 35 kg/m^2 or greater
6-2	Mar. 27, 2023	16	Palynziq Subcutaneous Injection 2.5 mg Palynziq Subcutaneous Injection 10 mg Palynziq Subcutaneous Injection 20 mg (BioMarin Pharmaceutical Japan K.K.)	Approval Approval Approval	Pegvaliase (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of phenylketonuria. [Orphan drug]
6-2	Mar. 27, 2023	17	Orphacol 50 mg Capsules (ReqMed Company, Ltd.)	Approval	Cholic acid	A drug with a new active ingredient indicated for the treatment of inborn errors of bile acid metabolism. [Orphan drug]
2	Jun. 20, 2022	18	Epadel EM Capsules 2 g (Mochida Pharmaceutical Co., Ltd.)	Approval	Ethyl Icosapentate	A drug in a new dosage form indicated for the treatment of hyperlipidemia.
2	Jun. 20, 2022	19	Xarelto Tablets 2.5 mg (Bayer Yakuhin, Ltd.)	Approval	Rivaroxaban	A drug with a new indication and a new dosage in an additional dosage form for the inhibition of thrombus/embolization formation in patients with peripheral arterial disease after lower extremity revascularization.
2	Aug. 24, 2022	20	Onoact for Intravenous Infusion 50 mg Onoact for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Landiolol hydrochloride	Drugs with a new indication and a new additional pediatric dosage for the treatment of the following tachyarrhythmia in patients with low cardiac function: supraventricular tachycardia, atrial fibrillation, and atrial flutter.
2	Sep. 26, 2022	21	Livazebe Combination Tablets LD Livazebe Combination Tablets HD (Kowa Company, Ltd.)	Approval Approval	Pitavastatin calcium hydrate/Ezetimibe	New combination drugs indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Sep. 26, 2022	22	Cablivi Injection 10 mg (Sanofi K.K.)	Approval	Caplacizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of acquired thrombotic thrombocytopenic purpura. [Orphan drug]
2	Dec. 23, 2022	23	Allydone Patches 27.5 mg Allydone Patches 55 mg (Teikoku Seiyaku Co., Ltd.)	Approval Approval	Donepezil	Drugs with a new active ingredient indicated for inhibiting progression of symptoms of dementia in patients with Alzheimer's disease.
2	Dec. 23, 2022	24	Treprost Inhalation Solution 1.74 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Treprostinil	A drug with a new route of administration indicated for the treatment of pulmonary arterial hypertension.
2	Dec. 23, 2022	25	Vyalev Combination Subcutaneous infusion (AbbVie GK)	Approval	Foslevodopa, Foscarbidopa hydrate	A new combination drug with new active ingredients indicated for the improvement of wearing-off phenomenon in the symptoms of Parkinson's disease in patients who have not responded sufficiently to conventional levodopa-containing drug therapies.
2	Dec. 23, 2022	26	Tavalisse Tablets 100 mg Tavalisse Tablets 150 mg (Kissei Pharmaceutical Co., Ltd.)	Approval Approval	Fostamatinib sodium hydrate	Drugs with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Mar. 27, 2023	27	Doptelet Tablets 20 mg (Swedish Orphan Biovitrum Japan Co., Ltd.)	Approval	Avatrombopag maleate	A drug with a new active ingredient indicated for the improvement of thrombocytopenia in patients with chronic liver disease for whom an elective invasive procedure is planned.
5	Aug. 24, 2022	28	(1) Human Menopausal Gonadotrophin for Injection 75 Units "F" (2) Human Menopausal Gonadotrophin for Injection 150 Units "F" (3) HMG Injection 75 Units "Aska" (4) HMG Injection 150 Units "Aska" (5) HMG for Injection 75 IU "Ferring" (6) HMG for Injection 150 IU "Ferring" ((1) (2) Fuji Pharma Co., Ltd. (3) (4) ASKA Pharmaceutical Co., Ltd. (5) (6) Ferring Pharmaceuticals Co., Ltd.)	Change Change Change Change Change Change	Human menopausal gonadotrophin	Drugs with a new route of administration indicated for controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
5	Aug. 24, 2022	29	(1) Human Chorionic Gonadotrophin for Injection 5000 Units "F" (2) Human Chorionic Gonadotrophin for Injection 10000 Units "F" (3) HCG Mochida for Injection 5000 units (4) HCG Mochida for Injection 10000 units (5) Gonatropin for Injection 5000 Units ((1) (2) Fuji Pharma Co., Ltd. (3) (4) Mochida Pharmaceutical Co., Ltd (5) ASKA Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Human chorionic gonadotrophin	(1) (2) (3) (4) Drugs with a new route of administration indicated for the induction of final follicular maturation and luteinization as part of assisted reproductive technology as well as induction of ovulation and luteinization in general infertility treatment (fertility treatment for in vivo fertilization). [Public knowledge-based application after PAFSC's preliminary assessment] (5) A drug with a new indication and a new dosage for the induction of final follicular maturation and luteinization as part of assisted reproductive technology as well as induction of ovulation and luteinization in general infertility treatment (fertility treatment for in vivo fertilization). [Public knowledge-based application after PAFSC's preliminary assessment]
5	Aug. 24, 2022	30	Nasanyl Nasal Spray 0.2% (Pfizer Japan Inc.)	Change	Nafarelin acetate hydrate	A drug with a new indication and a new dosage for the prevention of premature ovulation in assisted reproductive technology. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Aug. 24, 2022	31	(1) Suprecur Nasal Solution 0.15% (2) Buserelin Nasal Solution 0.15% "F" ((1) Clinigen K.K. (2) Fuji Pharma Co., Ltd.)	Change Change	Buserelin acetate	Drugs with a new indication and a new dosage for the prevention of premature ovulation in assisted reproductive technology. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	32	Duphaston Tablets 5 mg (Mylan EPD G.K.)	Change	Dydrogesterone	A drug with a new indication and a new dosage indicated for luteal support as part of assisted reproductive technology for infertile women. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	33	Cetrotide for Injection 0.25 mg (Nippon Kayaku Co., Ltd.)	Change	Cetrorelix acetate	A drug with a new dosage indicated for the prevention of premature ovulation during controlled ovarian stimulation. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	34	(1) Metgluco Tablets 250 mg (2) Metgluco Tablets 500 mg (3) Metformin Hydrochloride Tablets 250 mg MT "DSEP" (4) Metformin Hydrochloride Tablets 500 mg MT "DSEP" (5) Metformin Hydrochloride Tablets 250 mg MT "DSPB" (6) Metformin Hydrochloride Tablets 500 mg MT "DSPB" ((1) (2) Sumitomo Pharma Co., Ltd. (3) (4) Daiichi Sankyo Espha Co., Ltd. (5) (6) Sumitomo Pharma Promo Co., Ltd.)	Change Change Change Change Change Change	Metformin hydrochloride	Drugs with new indications and a new dosage for the induction of ovulation in patients with polycystic ovarian syndrome and for controlled ovarian stimulation in assisted reproductive technology in patients with polycystic ovarian syndrome (only for the patients with any of obesity, impaired glucose tolerance or insulin resistance). [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
5	Sep. 16, 2022	35	(1) Femara Tablets 2.5 mg (2) Letrozole Tablets 2.5 mg “NK” (3) Letrozole Tablets 2.5 mg “F” ((1) Novartis Pharma K.K. (2) Nippon Kayaku Co., Ltd. (3) Fuji Pharma Co., Ltd.)	Change Change Change	Letrozole	(1) A drug with new indications for the induction of ovulation in patients with polycystic ovary syndrome and with unexplained infertility. (2) (3) Drugs with new indications and a new dosage for the induction of ovulation in patients with polycystic ovary syndrome and with unexplained infertility. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	36	(1) Folyrmon-P Injection 75 (2) Folyrmon-P Injection 150 (3) uFSH Injection 75 IU "Aska" (4) uFSH Injection 150 IU "Aska" ((1) (2) Fuji Pharma Co., Ltd. (3) (4) ASKA Pharmaceutical Co., Ltd.)	Change Change Change Change	Purified human menopausal gonadotrophin	Drugs with a new indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	37	Clomid Tablets 50 mg (Fuji Pharma Co., Ltd.)	Change	Clomifene Citrate	A drug with a new indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 16, 2022	38	Cabaser Tab. 0.25 mg (Pfizer Japan Inc.)	Change	Cabergoline	A drug with a new indication and a new dosage for the prevention of ovarian hyperstimulation syndrome associated with assisted reproductive technology. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Sep. 26, 2022	39	Toviaz Tablets 4 mg Toviaz Tablets 8 mg (Pfizer Japan Inc.)	Change Change	Fesoterodine fumarate	Drugs with a new indication and a new additional pediatric dosage for the control of urination in patients with neurogenic bladder.
Radio-pharmaceuticals	Mar. 27, 2023	40	Techne Phytate Kit (PDRadiopharma Inc.)	Change	Sodium phytate	A drug with a new route of administration indicated for the sentinel lymph node mapping and lymphoscintigraphy in cervical cancer, uterine neoplasms, and head and neck cancer. A drug with a new indication for the sentinel lymph node mapping and lymphoscintigraphy in vulvar cancer. [Public knowledge-based application]
3-1	Jun. 20, 2022	41	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]
3-1	Aug. 24, 2022	42	Ultomiris for Intravenous Infusion 300 mg Ultomiris for Intravenous Infusion 300 mg/3 mL Ultomiris for Intravenous Infusion 1100 mg/11 mL (Alexion Pharma GK)	Change Change Change	Ravulizumab (genetical recombination)	Drugs with a new indication for the treatment of generalized myasthenia gravis (for use only in patients whose symptoms cannot be sufficiently controlled with high-dose intravenous immunoglobulin therapy or plasmapheresis).
3-1	Sep. 26, 2022	43	Koselugo Capsules 10 mg Koselugo Capsules 25 mg (Alexion Pharma GK)	Approval Approval	Selumetinib sulfate	Drugs with a new active ingredient indicated for the treatment of plexiform neurofibroma in patients with neurofibromatosis type 1. [Orphan drug]
3-1	Sep. 26, 2022	44	Amvuttra Subcutaneous Injection 25 mg Syringe (Alnylam Japan, K.K.)	Approval	Vutrisiran sodium	A drug with a new active ingredient indicated for the treatment of transthyretin familial amyloid polyneuropathy. [Orphan drug]
3-1	Sep. 26, 2022	45	Fintepla Oral Solution 2.2 mg/mL (UCB Japan Co., Ltd.)	Approval	Fenfluramine hydrochloride	A drug with a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat epileptic seizures in patients with Dravet syndrome who have not responded sufficiently to other antiepileptic drugs. [Orphan drug]
3-1	Dec. 23, 2022	46	Radicut Oral Suspension 2.1% (Mitsubishi Tanabe Pharma Corporation)	Approval	Edaravone	A drug with a new route of administration indicated for delaying the functional disorder in patients with amyotrophic lateral sclerosis (ALS).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 23, 2022	47	E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Change	Levetiracetam	A drug with a new indication and a new dosage for the treatment of status epilepticus. [Public knowledge-based application after PAFSC's preliminary assessment]
3-2	May 26, 2022	48	Twotram Tab. 50 mg Twotram Tab. 100 mg Twotram Tab. 150 mg (Nippon Zoki Pharmaceutical Co., Ltd.)	Change Change Change	Tramadol hydrochloride	Drugs with a new indication for analgesia in various types of cancer with pain that cannot be managed by treatment with non-opioid analgesics.
3-2	Jun. 20, 2022	49	Beovu kit for intravitreal injection 120 mg/mL (Novartis Pharma K.K.)	Change	Brolucizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of diabetic macular edema.
3-2	Aug. 24, 2022	50	Remifentanil for Intravenous Injection 2 mg "Daiichi Sankyo" Remifentanil for Intravenous Injection 5 mg "Daiichi Sankyo" (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Remifentanil hydrochloride	Drugs with a new indication and a new dosage for analgesia during artificial respiration in the intensive care setting.
3-2	Sep. 26, 2022	51	Eylea Intravitreal Injection 40 mg/mL (Bayer Yakuhin, Ltd.)	Change	Aflibercept (genetical recombination)	A drug with a new indication and a new dosage for the treatment of retinopathy of prematurity.
3-2	Sep. 26, 2022	52	Gla-alpha Combination Ophthalmic Solution (Kowa Company, Ltd.)	Approval	Ripasudil hydrochloride hydrate, Brimonidine tartrate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs.
3-2	Dec. 23, 2022	53	Mitomycin 2 mg for Ophthalmic Topical Use (Kyowa Kirin Co., Ltd.)	Approval	Mitomycin C	A drug with a new route of administration indicated for an adjunct to incisional glaucoma surgery.
3-2	Dec. 23, 2022	54	Scandonest Cartridge 3% (Nippon Shika Yakuhin Co., Ltd.)	Change	Mepivacaine hydrochloride	A drug with a new indication for nerve block in the fields of dentistry and oral surgery. [Public knowledge-based application after PAFSC's preliminary assessment]
3-2	Feb. 24, 2023	55	Precedex Intravenous Solution 200 µg "Pfizer" Precedex Intravenous Solution 200 µg/50 mL Syringe "Pfizer" (Pfizer Japan Inc.)	Change Change	Dexmedetomidine hydrochloride	Drugs with a new indication and a new dosage for sedation of non-intubated pediatric patients during non-invasive procedures and examinations. [Drugs for specific use]
4	Jun. 20, 2022	56	Cubicin IV 350 mg (MSD K.K.)	Change	Daptomycin	A drug with a new additional pediatric dosage indicated for the treatment of sepsis, deep skin infection, secondary infection of trauma, burn, and surgical wounds and secondary infection of erosion and ulcer caused by daptomycin-sensitive methicillin-resistant *Staphylococcus aureus* (MRSA).
4	Jun. 20, 2022	57	Maviret Combination Tablets Maviret Combination Granules for Pediatric Use (AbbVie GK)	Change Approval	Glecaprevir hydrate/Pibrentasvir	A drug with an additional pediatric dosage (aged 3 years to 11 years) and a drug with an additional pediatric dosage (aged 3 years to 11 years) in an additional dosage form, indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C.
4	Aug. 24, 2022	58	Epclusa Combination Tablets (Gilead Sciences, K.K.)	Change	Sofosbuvir/ Velpatasvir	A drug with a new indication and a new dosage for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C who are naïve or have not previously been treated.
4	Aug. 30, 2022	59	Evusheld Intramuscular Injection Set (AstraZeneca K.K.)	Approval	Tixagevimab (genetical recombination), Cilgavimab (genetical recombination)	A drug with new active ingredients indicated for the treatment and suppression of development of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Nov. 22, 2022	60	Xocova Tablets 125 mg (Shionogi & Co., Ltd.)	Approval	Ensitrelvir fumaric acid	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Emergency Approval]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
4	Dec. 23, 2022	61	Cresemba Capsules 100 mg Cresemba for I.V. Infusion 200 mg (Asahi Kasei Pharma Corporation)	Approval Approval	Isavuconazonium sulfate	Drugs with a new active ingredient indicated for the treatment of the following mycoses: • Aspergillosis (invasive aspergillosis, chronic progressive pulmonary aspergillosis, simple pulmonary aspergilloma) • Mucormycosis • Cryptococcosis (pulmonary cryptococcosis, disseminated cryptococcosis [including cryptococcal meningitis])
4	Feb. 24, 2023	62	Amenalief Tablets 200 mg (Maruho Co., Ltd.)	Change	Amenamevir	A drug with a new indication and a new dosage for the treatment of recurrent herpes simplex.
4	Mar. 27, 2023	63	Comlex Otic Solution 1.5% (Ceolia Pharma Co., Ltd.)	Approval	Levofloxacin hydrate	A drug with a new route of administration indicated for the treatment of otitis externa and otitis media caused by Comlex-senstive *Staphylococcus* spp., *Streptococcus* spp., *Streptococcus pneumoniae*, *Moraxella (Branhamella) catarrhalis*, *Klebsiella pneumoniae*, *Enterobacter* spp., *Serratia* spp., *Haemophilus influenzae*, *Pseudomonas aeruginosa*, and *Acinetobacter* spp.
4	Mar. 27, 2023	64	Valixa Dry Syrup 5000 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Valganciclovir hydrochloride	A drug with a new indication and a new dosage for the treatment of symptomatic congenital cytomegalovirus infection. [Orphan drug]
6-1	May 26, 2022	65	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 20, 2022	66	Olumiant Tablets 2 mg Olumiant Tablets 4 mg (Eli Lilly Japan K.K.)	Change Change	Baricitinib	Drugs with a new indication and a new dosage for the treatment of alopecia areata (for use only in patients with intractable and extensive alopecia areata).
6-1	Jun. 20, 2022	67	Zicthoru Tapes 75 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change	Diclofenac sodium	A drug with a new indication and a new dosage for the analgesia and anti-inflammation in patients with lumbago, periarthritis scapulohumeralis, neck-shoulder-arm syndrome, and tenosynovitis.
6-1	Jun. 20, 2022	68	Diquas LX Ophthalmic Solution 3% (Santen Pharmaceutical Co., Ltd.)	Approval	Diquafosol sodium	A drug in a new dosage form indicated for the treatment of dry eye.
6-1	Aug. 24, 2022	69	Firazyr Subcutaneous Injection 30 mg Syringe (Takeda Pharmaceutical Company Limited)	Change	Icatibant acetate	A drug with a new additional pediatric dosage indicated for the treatment of acute attacks of hereditary angioedema. [Orphan drug]
6-1	Sep. 26, 2022	70	Nanozora 30 mg Syringes for S.C. Injection (Taisho Pharmaceutical Co., Ltd.)	Approval	Ozoralizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 26, 2022	71	Spevigo 450 mg for I.V. Infusion (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Spesolimab (genetical recombination)	A drug with a new active ingredient indicated for the improvement of acute symptoms in patients with pustular psoriasis.
6-1	Sep. 26, 2022	72	Tezspire Subcutaneous Injection 210 mg Syringe (AstraZeneca K.K.)	Approval	Tezepelumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with severe or intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Sep. 26, 2022	73	Sotyktu Tablets 6 mg (Bristol-Myers Squibb K.K.)	Approval	Deucravacitinib	A drug with a new active ingredient indicated for the treatment of plaque psoriasis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Sep. 26, 2022	74	Metoject Subcutaneous Injection 7.5 mg Syringe 0.15 mL Metoject Subcutaneous Injection 10 mg Syringe 0.20 mL Metoject Subcutaneous Injection 12.5 mg Syringe 0.25 mL Metoject Subcutaneous Injection 15 mg Syringe 0.30 mL (nippon medac Co., Ltd.)	Approval Approval Approval Approval	Methotrexate	Drugs with a new indication and a new dosage in an additional dosage form for the treatment of rheumatoid arthritis.
6-1	Dec. 23, 2022	75	Adtralza S.C. Injection 150 mg Syringe (Leo Pharma K.K.)	Approval	Tralokinumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 24, 2023	76	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of non-radiographic axial spondyloarthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 24, 2023	77	(1) Calonal Fine Gran.20% (2) Calonal Fine Gran. 50% (3) Calonal Powder (4) Calonal Tablets 200 (5) Calonal Tablets 300 (6) Calonal Tablets 500 (7) Acetaminophen Tab. 200 mg “Maruishi” (8) Acetaminophen Tab. 300 mg “Maruishi” (9) Acetaminophen Tab. 500 mg “Maruishi” ((1) (2) (3) (4) (5) (6)Ayumi Pharmaceutical Corporation, (7) (8) (9) Maruishi Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change Change	Acetaminophen	Drugs with a new indication for the analgesia in various diseases and symptoms. [Public knowledge-based application after PAFSC's preliminary assessment]
AIDS drugs	May 31, 2022	78	1) Vocabria Aqueous Suspension for IM Injection 400 mg 2) Vocabria Aqueous Suspension for IM Injection 600 mg 3) Vocabria Tablets 30 mg 4) Rekambys Aqueous Suspension for IM Injection 600 mg 5) Rekambys Aqueous Suspension for IM Injection 900 mg (1) 2) 3) ViiV Healthcare K.K. 4) 5) Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval	1) 2) Cabotegravir 3) Cabotegravir sodium 4) 5) Rilpivirine	Drugs with new active ingredients indicated for the treatment of HIV-1 infection. [Orphan drug]
Oncology drugs	May 26, 2022	79	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of CD30-positive Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	May 26, 2022	80	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage for the postoperative adjuvant treatment for PD-L1-positive non-small cell lung cancer.
Oncology drugs	May 26, 2022	81	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent esophageal cancer. [Priority review]
Oncology drugs	May 26, 2022	82	Yervoy Injection 20 mg Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change Change	Ipilimumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent esophageal cancer. [Priority review]
Oncology drugs	Jun. 20, 2022	83	Darvias Injection 135 mg (Solasia Pharma K.K.)	Approval	Darinaparsin	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma.
Oncology drugs	Jun. 20, 2022	84	Jeselhy Tablets 40 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Pimitespib	A drug with a new active ingredient indicated for the treatment of gastrointestinal stromal tumor that has progressed after cancer chemotherapy.
Oncology drugs	Jun. 20, 2022	85	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of ovarian cancer. Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 20, 2022	86	Neutrogin for Injection 50 μg Neutrogin for Injection 100 μg Neutrogin for Injection 250 μg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Lenograstim (genetical recombination)	Drugs with a new indication and a new dosage for use as an adjunctive therapy with antineoplastic agents for the treatment of relapsed or refractory acute myeloid leukemia. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 20, 2022	87	Gran Injection 75 Gran Injection 150 Gran Injection M300 Gran Syringe 75 Gran Syringe 150 Gran Syringe M300 (Kyowa Kirin Co., Ltd.)	Change Change Change Change Change Change	Filgrastim (genetical recombination)	Drugs with a new indication and a new dosage for use as an adjunctive therapy with antineoplastic agents for the treatment of relapsed or refractory acute myeloid leukemia. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 20, 2022	88	Fludara I.V.Infusion 50 mg (Sanofi K.K.)	Change	Fludarabine phosphate	A drug with a new indication and a new dosage for the treatment of relapsed or refractory acute myeloid leukemia. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Aug. 24, 2022	89	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication and a new dosage for the postoperative adjuvant treatment of *BRCA* mutation-positive and HER2-negative breast cancer with a high risk of recurrence. [Orphan drug]
Oncology drugs	Aug. 24, 2022	90	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Change Change	Osimertinib mesilate	Drugs with a new indication, a new dosage, and other characteristics for postoperative adjuvant treatment for epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer.
Oncology drugs	Aug. 24, 2022	91	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for postoperative adjuvant treatment for renal cell carcinoma.
Oncology drugs	Aug. 24, 2022	92	Polivy for Intravenous Infusion 30 mg Polivy for Intravenous Infusion 140 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Polatuzumab vedotin (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of diffuse large B-cell lymphoma. [Orphan drug]
Oncology drugs	Sep. 26, 2022	93	Ezharmia Tablets 50 mg Ezharmia Tablets 100 mg (Daiichi Sankyo Company, Limited)	Approval Approval	Valemetostat tosilate	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory adult T-cell leukemia/lymphoma. [Orphan drug]
Oncology drugs	Sep. 26, 2022	94	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	(1) A drug with a new indication for the treatment of advanced or recurrent cervical cancer. (2) A drug with a new indication and a new dosage for the preoperative and postoperative adjuvant treatment of hormone receptor (HR)-negative and human epidermal growth factor receptor 2 (HER2)-negative breast cancer with a high risk of recurrence.
Oncology drugs	Sep. 26, 2022	95	Erbitux Injection 100 mg (Merck Biopharma Co., Ltd.)	Change	Cetuximab (genetical recombination)	A drug with a new additional dosage indicated for the treatment of unresectable, advanced or recurrent colon or rectal cancer with wild-type *RAS* and head and neck cancer. [Public knowledge-based application]
Oncology drugs	Sep. 26, 2022	96	Carboplatin Injection 50 mg "NK" Carboplatin Injection 150 mg "NK" Carboplatin Injection 450 mg "NK" (Mylan Seiyaku Ltd.)	Change Change Change	Carboplatin	Drugs with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Sep. 26, 2022	97	Paclitaxel Inj. 30 mg/5 mL "NK" Paclitaxel Inj. 100 mg/16.7 mL "NK" (Nippon Kayaku Co., Ltd.)	Change Change	Paclitaxel	Drugs with a new dosage indicated for thetreatment of advanced or recurrent cervical cancer. [Public knowledge-based application]
Oncology drugs	Nov. 24, 2022	98	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change	Trastuzumab deruxtecan (genetical recombination)	A drug with a new indication for the treatment of unresectable or recurrent HER2-positive breast cancer in patients who have previously been treated with chemotherapy.
Oncology drugs	Nov. 24, 2022	99	Adriacin Injection 10 Adriacin Injection 50 (Sandoz Pharma K.K.)	Change Change	Doxorubicin hydrochloride	Drugs with a new dosage indicated for the treatment of breast cancer (preoperative or postoperative chemotherapy in patients with operable breast cancer). [Public knowledge-based application]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 24, 2022	100	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a new dosage indicated for the treatment of breast cancer (preoperative or postoperative chemotherapy in patients with operable breast cancer). [Public knowledge-based application]
Oncology drugs	Nov. 24, 2022	101	(1) TS-1 Combination CapsulesT20 TS-1 Combination Capsules T25 (2) TS-1 Combination Granules T20 TS-1 Combination Granules T25 (3) TS-1 Combination OD Tablets T20 TS-1 Combination OD Tablets T25 (4) S-1 Taiho Combination OD Tablets T20 S-1 Taiho Combination OD Tablets T25 ((1) (2) (3) Taiho Pharmaceutical Co., Ltd. (4) Okayama Taiho Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Tegafur Gimeracil Oteracil potassium	Drugs with a new indication and a new dosage for the postoperative adjuvant treatment of hormone receptor(HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer with a high risk of recurrence.
Oncology drugs	Dec. 23, 2022	102	Imjudo Injection 25 mg Imjudo Injection 300 mg (AstraZeneca K.K.)	Approval Approval	Tremelimumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer and unresectable hepatocellular carcinoma.
Oncology drugs	Dec. 23, 2022	103	Libtayo I.V. Infusion 350 mg (Sanofi K.K.)	Approval	Cemiplimab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of advanced or recurrent cervical cancer that has progressed after cancer chemotherapy.
Oncology drugs	Dec. 23, 2022	104	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable biliary tract cancer. [Orphan drug]
Oncology drugs	Dec. 23, 2022	105	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with new indications for the treatment of Waldenström's macroglobulinemia and lymphoplasmacytic lymphoma. [Orphan drug]
Oncology drugs	Dec. 23, 2022	106	Calquence Capsules 100 mg (AstraZeneca K.K.)	Change	Acalabrutinib	A drug with a new indication for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma).
Oncology drugs	Dec. 23, 2022	107	Gazyva Intravenous Infusion 1000 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Obinutuzumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of CD20-positive chronic lymphocytic leukemia (including small lymphocytic lymphoma).
Oncology drugs	Dec. 23, 2022	108	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	(1) Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent non-small-cell lung cancer. (2) Drugs with a new indication and a new dosage for the treatment of unresectable hepatocellular carcinoma.
Oncology drugs	Feb. 24, 2023	109	Nubeqa Tablets 300 mg (Bayer Yakuhin, Ltd.)	Change	Darolutamide	A drug with a new indication and a new dosage for the treatment of metastatic prostate cancer.
Oncology drugs	Feb. 24, 2023	110	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new indication and a new dosage for the treatment of mantle cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 27, 2023	111	Besremi Subcutaneous Injection 250 μg Syringes Besremi Subcutaneous Injection 500 μg Syringes (PharmaEssence Japan K.K.)	Approval Approval	Ropeginterferon alfa-2b (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of polycythaemia vera (use only when conventional therapies are not sufficiently effective or inappropriate).
Oncology drugs	Mar. 27, 2023	112	Pemazyre Tablets 4.5 mg (Incyte Biosciences Japan G.K.)	Change	Pemigatinib	A drug with a new indication and a new dosage for the treatment of *FGFR1* fusion gene-positive myeloid/lymphoid neoplasms. [Orphan drug]
Oncology drugs	Mar. 27, 2023	113	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the preoperative adjuvant treatment for non-small-cell lung cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 27, 2023	114	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change	Trastuzumab deruxtecan (genetical recombination)	A drug with a new indication for the treatment of unresectable or recurrent HER2-low breast cancer in patients who have previously been treated with chemotherapy. [Priority review]
Oncology drugs	Mar. 27, 2023	115	Pemetrexed for I.V. Infusion 100 mg "NK" Pemetrexed for I.V. Infusion 500 mg "NK" Pemetrexed for I.V. Infusion 800 mg "NK" Pemetrexed Solution for I.V. Infusion 100 mg "NK" Pemetrexed Solution for I.V. Infusion 500 mg "NK" Pemetrexed Solution for I.V. Infusion 800 mg "NK" (Nippon Kayaku Co., Ltd.)	Change Change Change Change Change Change	Pemetrexed sodium hemipentahydrate	Drugs with a new indication and a new dosage for the preoperative adjuvant treatment for non-squamous non-small-cell lung cancer. [Expedited review]
Oncology drugs	Mar. 27, 2023	116	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 27, 2023	117	(1) Elplat I.V. Infusion Solution 50 mg (1) Elplat I.V. Infusion Solution 100 mg (1) Elplat I.V. Infusion Solution 200 mg (2) Oxaliplatin Intravenous Infusion 50 mg/10 mL "Sandoz" (2) Oxaliplatin Intravenous Infusion 100 mg/20 mL "Sandoz" (2) Oxaliplatin Intravenous Infusion 200 mg/40 mL "Sandoz" ((1) Yakult Honsha Co., Ltd., (2) Sandoz K.K.)	Change Change Change Change Change Change	Oxaliplatin	Drugs with a new indication and a new dosage for the treatment of gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 27, 2023	118	Isovorin Injection 25 mg Isovorin Injection 100 mg (Pfizer Japan Inc.)	Change Change	Calcium levofolinate hydrate	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. [Public knowledge-based application after PAESC's preliminary assessment]
Bio-CMC	Sep. 26, 2022	119	Bevacizumab BS for Intravenous Infusion 100 mg "CTNK" Bevacizumab BS for Intravenous Infusion 400 mg "CTNK" (Nippon Kayaku Co., Ltd.)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 4]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer, unresectable advanced or recurrent non-squamous non-small cell lung cancer, and unresectable or recurrent breast cancer.
Vaccines	Apr. 19, 2022	120	Nuvaxovid Intramuscular Injection (Takeda Pharmaceutical Company Limited)	Approval	Recombinant coronavirus (SARS-CoV-2) vaccine	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]
Vaccines	Jun. 20, 2022	121	Jcovden Intramuscular Injection (Janssen Pharmaceutical K.K.)	Approval	COVID-19 (SARS-CoV-2) vaccine (recombinant adenovirus vector)	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]
Vaccines	Aug. 2, 2022	122	Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 "KMB" (KM Biologics Co., Ltd.)	Change	Live vaccinia virus (LC16m8 strain)	A drug with a new indication for the prevention of monkeypox.
Vaccines	Aug. 30, 2022	123	Comirnaty Intramuscular Injection for 5 to 11 years old (Pfizer Japan Inc.)	Change	Tozinameran	A drug with a new dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Sep. 12, 2022	124	Comirnaty RTU Intramuscular Injection (Pfizer Japan Inc.)	Change	Tozinameran Tozinameran and Riltozinameran	A drug with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Sep. 12, 2022	125	Spikevax Intramuscular Injection (Moderna Japan Co., Ltd.)	Change	Elasomeran Elasomeran and Imelasomeran	A drug with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Sep. 26, 2022	126	MenQuadfi intramuscular injection (Sanofi K.K.)	Approval	Neisseria meningitidis polysaccharides conjugated to tetanus toxoid (serogroups A, C, W, and Y)	A drug with a new active ingredient indicated for the prophylaxis of invasive meningococcal disease caused by *Neisseria meningitidis* (serogroups A, C, W and Y).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Sep. 26, 2022	127	Vaxneuvance Aqueous Suspension Syringes (MSD K.K.)	Approval	Pneumococcal polysaccharides of serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F conjugated to CRM197 carrier protein	A drug with a new active ingredient indicated for the prophylaxis of pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F) in the elderly or in adults who are considered to be at a high risk of pneumococcal disease.
Vaccines	Oct. 5, 2022	128	Comirnaty Intramuscular Injection for 6 months to 4 years old (Pfizer Japan Inc.)	Approval	Tozinameran	A drug with a new additional pediatric dosage in an additional dosage form indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Feb. 28, 2023	129	Comirnaty Intramuscular Injection for 5 to 11 years old (Pfizer Japan Inc.)	Change	Tozinameran Tozinameran and Famtozinameran	A drug with a new indication, a new dosage, and other characteristics for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Mar. 8, 2023	130	Silgard 9 Aqueous Suspension for Intramuscular Injection Syringes (MSD K.K.)	Change	Human papillomavirus L1 protein virus-like particles (types 6, 11, 16, 18, 31, 33, 45, 52, and 58)	A drug with a new dosage indicated for the prevention of the following diseases caused by infection with human papillomavirus types 6, 11, 16, 18, 31, 33, 45, 52, and 58: • Cervical cancer (squamous cell carcinoma and adenosquamous carcinoma) and its precursor lesions (cervical intraepithelial neoplasia [CIN] 1, 2, and 3, and adenocarcinoma in situ [AIS]) • Vulvar intraepithelial neoplasia (VIN) 1, 2, and 3, and vaginal intraepithelial noeplasia (VaIN) 1, 2, and 3 • Condyloma acuminatum [Expedited review]
Vaccines	Mar. 27, 2023	131	Fulmist Intranasal Spray (Daiichi Sankyo Company, Limited)	Approval	Live attenuated influenza virus (type A and type B)	A drug with a new active ingredient indicated for the prevention of influenza.
Vaccines	Mar. 27, 2023	132	Gobik Aqueous Suspension Syringes (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Protective antigen of *Bordetella pertussis* Diphtheria toxoid Tetanus toxoid Inactivated poliovirus types 1-3 (Sabin strain) Haemophilus influenzae type b oligosaccharide - diphtheria CRM_{197} conjugate	A new combination drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, acute poliomyelitis, and infections caused by *Haemophilus influenzae type b* .
Blood products	Jun. 20, 2022	133	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Emicizumab (genetical recombination)	Drugs with a new indication and a new dosage for the control of bleeding tendency in patients with acquired hemophilia A. [Orphan drug]
Blood products	Aug. 24, 2022	134	Byclot Combination Intravenous Injection (KM Biologics Co., Ltd.)	Change	Freeze-dried activated human blood coagulation factor VII concentrate containing factor X	A drug with a new indication and a new dosage for the control of bleeding tendency in patients who have inhibitors against blood coagulation factor VIII or IX.
Blood products	Sep. 26, 2022	135	Berinert S.C. Injection 2000 (CSL Behring K.K.)	Approval	Human C1-inactivator	A drug with a new route of administration indicated for the prophylaxis of acute attacks of hereditary angioedema. [Orphan drug]
Blood products	Mar. 27, 2023	136	Atgam Intravenous Infusion 250 mg (Pfizer Japan Inc.)	Approval	Anti-human thymocyte immunoglobulin, equine	A drug with a new active ingredient indicated for the treatment of moderate to severe aplastic anemia. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2021

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
1	May 27, 2021	1	Aloxi I.V. Injection 0.75 mg Aloxi I.V. Infusion Bag 0.75 mg (Taiho Pharmaceutical Co., Ltd.)	Change Change	Palonosetron hydrochloride	Drugs with a new additional pediatric dosage indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.).
1	Jun. 23, 2021	2	Upasita IV Injection 25 μg Syringe for Dialysis Upasita IV Injection 50 μg Syringe for Dialysis Upasita IV Injection 100 μg Syringe for Dialysis Upasita IV Injection 150 μg Syringe for Dialysis Upasita IV Injection 200 μg Syringe for Dialysis Upasita IV Injection 250 μg Syringe for Dialysis Upasita IV Injection 300 μg Syringe for Dialysis (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Upacicalcet sodium hydrate	Drugs with a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on hemodialysis.
1	Jun. 23, 2021	3	Revestive 3.8 mg for S.C. Injection (Takeda Pharmaceutical Company Limited)	Approval	Teduglutide (genetical recombination)	A drug with a new active ingredient indicated for the treatment of short bowel syndrome. [Orphan drug]
1	Jun. 25, 2021	4	(1) Cellcept Capsules 250 (2) Cellcept Powder for Oral Suspension 31.8% (3) Mycophenolate Mofetil Capsules 250 mg [Pfizer] ((1) (2) Chugai Pharmaceutical Co., Ltd. (3) Mylan Seiyaku Ltd.)	Change Change Change	Mycophenolate mofetil	Drugs with a new indication and a new dosage for the suppression of graft-versus-host disease in hematopoietic stem cell transplantation. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Aug. 25, 2021	5	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Orphan drug]
1	Aug. 25, 2021	6	Forxiga 5 mg Tablets Forxiga 10 mg Tablets (AstraZeneca K.K.)	Change Change	Dapagliflozin propylene glycolate hydrate	Drugs with a new indication for the treatment of chronic kidney disease. [Priority review]
1	Aug. 25, 2021	7	Darzquro Combination Subcutaneous Injection (Janssen Pharmaceutical K.K.)	Change	Daratumumab (genetical recombination)/ Vorhyaluronidase alfa (genetical recombination)	A drug with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Orphan drug]
1	Aug. 25, 2021	8	Decadron Tablets 0.5 mg Decadron Tablets 4 mg (Nichi-Iko Pharmaceutical Co., Ltd.)	Change Change	Dexamethasone	Drugs with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Expedited review]
1	Aug. 25, 2021	9	Endoxan for Injection 100 mg Endoxan for Injection 500 mg Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change Change Change	Cyclophosphamide hydrate	Drugs with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Expedited review]
1	Sep. 27, 2021	10	Moizerto Ointment 0.3% Moizerto Ointment 1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Difamilast	Drugs with a new active ingredient indicated for the treatment of atopic dermatitis.
1	Sep. 27, 2021	11	Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL Humira 20 mg for S.C. Injection Syringe 0.2 mL (AbbVie GK)	Change Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new indication and a new dosage, including a new additional pediatric dosage, for the treatment of moderate or severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Sep. 27, 2021	12	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new indication and a new dosage for the treatment of chronic graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
1	Sep. 27, 2021	13	Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Change	Sirolimus	A drug with a new indication and a new dosage for the treatment of refractory lymphatic disease (lymphangioma [lymphatic malformation], lymphangiomatosis, Gorham's disease, and lymphangiectasia). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
1	Jan. 20, 2022	14	Rapifort Wipes 2.5% (Maruho Co., Ltd.)	Approval	Glycopyrronium tosilate hydrate	A drug with a new active ingredient indicated for the treatment of primary axillary hyperhidrosis.
1	Feb. 25, 2022	15	(1) Neoral Oral Solution 10% (2) Neoral 10 mg Capsules (3) Neoral 25 mg Capsules (4) Neoral 50 mg Capsules (5) Ciclosporin Capsules 10 mg “TC” (6) Ciclosporin Capsules 25 mg “TC” (7) Ciclosporin Capsules 50 mg “TC” (8) Ciclosporin Capsules 10 mg “BMD” (9) Ciclosporin Capsules 25 mg “BMD” (10) Ciclosporin Capsules 50 mg “BMD” (11) Ciclosporin Capsules 10 mg “Nichi-Iko” (12) Ciclosporin Capsules 25 mg “Nichi-Iko” (13) Ciclosporin Capsules 50 mg “Nichi-Iko” (14) Ciclosporin Capsules 10 mg “Pfizer” (15) Ciclosporin Capsules 25 mg “Pfizer” (16) Ciclosporin Capsules 50 mg “Pfizer” (17) Ciclosporin Fine Granules 17% “Pfizer” (18) Ciclosporin Capsules 10 mg “Towa” (19) Ciclosporin Capsules 25 mg “Towa” (20) Ciclosporin Capsules 50 mg “Towa” [(1) to (4), Novartis Pharma K.K.; (5) to (7), Toyo Capsule Co., Ltd.; (8) to (10), Biomedix Co., Ltd.; (11) to (13), Nichi-Iko Pharmaceutical Co., Ltd.; (14) to (17), Mylan Seiyaku Ltd.; (18) to (20), Towa Pharmaceutical Co., Ltd.]	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Ciclosporin	Drugs with other characteristics indicated for the suppression of immunoreaction associated with cell transplantation. [Expedited review]
1	Feb. 25, 2022	16	Endoxan Tablets 50mg (Shionogi & Co., Ltd.)	Change	Cyclophosphamide hydrate	A drug with other characteristics indicated for the suppression of immunoreaction associated with cell transplantation. [Expedited review]
1	Feb. 25, 2022	17	Ondansetron Injection 4 mg Syringe “Maruishi” (Maruishi Pharmaceutical Co., Ltd.)	Change	Ondansetron hydrochloride hydrate	A drug with a new indication and a new dosage for the treatment of digestive symptoms (nausea and vomiting) after surgery. [Public knowledge-based application after PAFSC's preliminary assessment]
1	Feb. 25, 2022	18	Kytril Injection 1 mg Kytril Injection 3 mg Kytril Intravenous Bag 3 mg/50 mL Kytril Intravenous Bag 3 mg/100 mL (Taiyo Pharma Co., Ltd.)	Change Change Change Change	Granisetron hydrochloride	Drugs with a new indication and a new dosage for the treatment of digestive symptoms (nausea and vomiting) after surgery. [Public knowledge-based application after PAFSC's preliminary assessment]
1	Mar. 28, 2022	19	Arokaris I.V. Infusion 235 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Fosnetupitant chloride hydrochloride	A drug with a new active ingredient indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.).
1	Mar. 28, 2022	20	MonoVer for I.V. Injection 500 mg MonoVer for I.V. Injection 1000 mg (Nippon Shinyaku Co., Ltd.)	Approval Approval	Ferric derisomaltose	Drugs with a new active ingredient indicated for the treatment of iron-deficiency anemia.
1	Mar. 28, 2022	21	Jyseleca Tablets 100 mg Jyseleca Tablets 200 mg (Gilead Sciences K.K.)	Change Change	Filgotinib maleate	Drugs with a new indication and a new dosage for the treatment and the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Mar. 28, 2022	22	Carogra Tablets 120 mg (EA Pharma Co., Ltd.)	Approval	Carotegrast methyl	A drug with a new active ingredient indicated for the treatment of moderate ulcerative colitis (for use only in patients who have not sufficiently responded to 5-aminosalicylic acid preparation).
6-2	Jun. 23, 2021	23	Twymeeg Tablets 500 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Approval	Imeglimin hydrochloride	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jun. 23, 2021	24	Givlaari Subcutaneous Injection 189 mg (Alnylam Japan K.K.)	Approval	Givosiran sodium	A drug with a new active ingredient indicated for the treatment of acute hepatic porphyria. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
6-2	Sep. 27, 2021	25	Nexviazyme for I.V. Infusion 100 mg (Sanofi K.K.)	Approval	Avalglucosidase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of Pompe disease. [Orphan drug]
6-2	Jan. 20, 2022	26	Mepsevii Intravenous Infusion 10 mg (Amicus Therapeutics, Inc.)	Approval	Vestronidase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type VII. [Orphan drug]
6-2	Jan. 20, 2022	27	Ngenla Inj. 24 mg Pens Ngenla Inj. 60 mg Pens (Pfizer Japan Inc.)	Approval Approval	Somatrogon (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure.
6-2	Mar. 28, 2022	28	Xenpozyme for I.V. Infusion 20 mg (Sanofi K.K.)	Approval	Olipudase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of acid sphingomyelinase deficiency. [SAKIGAKE designation, orphan drug]
2	Jun. 23, 2021	29	Verquvo Tablets 2.5 mg Verquvo Tablets 5 mg Verquvo Tablets 10 mg (Bayer Yakuhin, Ltd.)	Approval Approval Approval	Vericiguat	Drugs with a new active ingredient indicated for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Jun. 23, 2021	30	Ajovy Syringes for S.C. Injection 225 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Fremanezumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of migraine attacks.
2	Jun. 23, 2021	31	Aimovig Subcutaneous Injection 70 mg Pens (Amgen K.K.)	Approval	Erenumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of migraine attacks.
2	Aug. 25, 2021	32	Uptravi Tablets 0.2 mg Uptravi Tablets 0.4 mg (Nippon Shinyaku Co., Ltd.)	Change Change	Selexipag	Drugs with a new indication for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH. [Orphan drug]
2	Aug. 25, 2021	33	Lixiana Tablets 15 mg Lixiana OD Tablets 15 mg (Daiichi Sankyo Company, Limited)	Change Change	Edoxaban tosilate hydrate	Drugs with a new dosage indicated for the prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation.
2	Aug. 25, 2021	34	Nitopro Continuous Intravenous Solution 6 mg Nitopro Continuous Intravenous Solution 30 mg (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Sodium nitroprusside hydrate	Drugs with a new indication and a new dosage for the treatment of acute heart failure (including chronic heart failure in the exacerbation period) and hypertensive emergencies. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Sep. 27, 2021	35	Entresto Tablets 100 mg Entresto Tablets 200 mg (Novartis Pharma K.K.)	Change Change	Sacubitril valsartan sodium hydrate	Drugs with a new indication and a new dosage for the treatment of hypertension.
2	Sep. 27, 2021	36	Vynmac Capsules 61 mg (Pfizer Japan Inc.)	Approval	Tafamidis	A drug with a new active ingredient indicated for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary).
2	Sep. 27, 2021	37	Azilva Granules 1% Azilva Tablets 10 mg Azilva Tablets 20 mg Azilva Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval Change Change Change	Azilsartan	Drugs with a new additional pediatric dosage and a drug in an additional dosage form indicated for the treatment of hypertension.
2	Nov. 25, 2021	38	Jardiance Tablets 10 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Empagliflozin	A drug with a new indication and a new dosage for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Dec. 24, 2021	39	Efient Tablets 2.5 mg Efient Tablets 3.75 mg (Daiichi Sankyo Company, Limited)	Change Change	Prasugrel hydrochloride	Drugs with a new indication and a new dosage for the prevention of recurrence after ischemic cerebrovascular disease (associated with large artery atherosclerosis or small vessel occlusion) (for use only in patients having a high risk of cerebral infarction).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
2	Jan. 20, 2022	40	Reyvow Tablets 50 mg Reyvow Tablets 100 mg (Eli Lilly Japan K.K.)	Approval Approval	Lasmiditan succinate	Drugs with a new active ingredient indicated for the treatment of migraine.
2	Jan. 20, 2022	41	Pivlaz I.V. Infusion liquid 150 mg (Idorsia Pharmaceuticals Japan Ltd.)	Approval	Clazosentan sodium	A drug with a new active ingredient indicated for the prevention of cerebrovascular spasm after surgery for subarachnoid hemorrhage caused by cerebral aneurysm, and cerebral infarctions and cerebral ischemic symptoms accompanying the cerebrovascular spasm.
2	Mar. 28, 2022	42	Ondexxya for Intravenous Injection 200 mg (Alexion Pharma G.K.)	Approval	Andexanet alfa (genetical recombination)	A drug with a new active ingredient indicated for the reversal of anticoagulant effect in life-threatening or uncontrolled bleeding in patients treated with a direct-acting factor Xa inhibitor (apixaban, rivaroxaban, or edoxaban tosilate hydrate). [Orphan drug]
2	Mar. 28, 2022	43	Kerendia Tablets 10 mg Kerendia Tablets 20 mg (Bayer Yakuhin, Ltd.)	Approval Approval	Finerenone	Drugs with a new active ingredient indicated for the treatment of chronic kidney disease associated with type 2 diabetes mellitus (excluding patients who have end-stage renal failure or are undergoing dialysis).
2	Mar. 28, 2022	44	Samtasu for I.V. Infusion 8 mg Samtasu for I.V. Infusion 16 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Tolvaptan sodium phosphate	Drugs with a new active ingredient indicated for the treatment of fluid retention in heart failure patients who have not responded sufficiently to other diuretics to such as loop diuretics.
5	Sep. 27, 2021	45	F-meno Capsules 100 mg (Fuji Pharma Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for the prevention of endometrial hyperplasia when estrogen preparations were administered for climacteric disturbance or ovarian deficiency symptoms.
5	Dec. 24, 2021	46	Relumina Tablets 40 mg (ASKA Pharmaceutical Co., Ltd.)	Change	Relugolix	A drug with a new indication for the alleviation of pain associated with endometriosis.
5	Feb. 25, 2022	47	Femara Tablets 2.5 mg (Novartis Pharma K.K.)	Change	Letrozole	A drug with a new indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Feb. 25, 2022	48	Suprecur Nasal Solution 0.15% (Sanofi K.K.)	Change	Buserelin acetate	A drug with a new indication and a new dosage for the induction of final follicular maturation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	49	Clomid Tablets 50 mg (Fuji Pharma Co., Ltd.)	Change	Clomiphene citrate	A drug with a new indication and a new dosage for the induction of spermatogenesis in oligozoospermia. [Public knowledge-based application]
5	Mar. 11, 2022	50	l'estrogel 0.06% (Fuji Pharma Co., Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	51	Julina Tablets 0.5 mg (Bayer Yakuhin, Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	52	Divigel 1 mg (Sun Pharma Japan Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
5	Mar. 11, 2022	53	(1) Estrana Tape 0.72 mg (2) Estrana Tape 0.36 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change	Estradiol	(1) A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. (2) A drug with a new indication and a new dosage for hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	54	Jemina Tablets (Nobelpharma Co., Ltd.)	Change	Levonorgestrel/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	55	Lunabell Tablets LD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	56	Lunabell Tablets ULD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	57	Yaz Flex Combination Tablets (Bayer Yakuhin, Ltd.)	Change	Drospirenone/ Ethinylestradiol betadex	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	58	Hysron Tablets 5 (Kyowa Kirin Co., Ltd.)	Change	Medroxyprogesterone acetate	A drug with a new indication and a new dosage for the prevention of premature ovulation during controlled ovarian stimulation. [Public knowledge-based application]
5	Mar. 11, 2022	59	Duphaston Tablets 5mg (Mylan EPD G.K.)	Change	Dydrogesterone	A drug with a new indication and a new dosage for the prevention of premature ovulation during controlled ovarian stimulation. [Public knowledge-based application]
5	Mar. 28, 2022	60	Lympack TA5 (Nipro Corporation)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used as perfusion fluids for hemodialysis in patients with chronic renal failure (use in any of the following cases: ○ when bicarbonate dialysate with high bicarbonate concentration may cause excessive alkalosis; ○ when the patient's blood sugar level is difficult to control with sugarless dialysate; ○ when other bicarbonate dialysate is not sufficiently effective to improve hyperkalemia and hypermagnesemia or may cause hypercalcemia).
In vivo diagnostics	Aug. 25, 2021	61	Inulead Injection (Fuji yakuhin Co., Ltd.)	Change	Inulin	A drug with a new dosage indicated for renal function tests based on measurement of glomerular filtration rate.
3-1	Jun. 23, 2021	62	Evrysdi Dry Syrup 60 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Risdiplam	A drug with a new active ingredient indicated for the treatment of spinal muscular atrophy. [Orphan drug]
3-1	Jun. 23, 2021	63	Xeomin 50 Units for Intramuscular Injection Xeomin 100 Units for Intramuscular Injection Xeomin 200 Units for Intramuscular Injection (Teijin Pharma Limited)	Change Change Change	Incobotulinumtoxin A	Drugs with a new indication and a new dosage for the treatment of lower limb spasticity.
3-1	Sep. 27, 2021	64	Midafresa Injection 0.1% (Alfresa Pharma Corporation)	Change	Midazolam	A drug with a new dosage indicated for the treatment of status epilepticus.
3-1	Jan. 20, 2022	65	Vyvgart for Intravenous Infusion 400 mg (Argenx Japan K.K.)	Approval	Efgartigimod alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
3-1	Mar. 28, 2022	66	Dysval Capsules 40 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	Valbenazine tosilate	A drug with a new active ingredient indicated for the treatment of tardive dyskinesia.
3-1	Mar. 28, 2022	67	Tarlige Tablets 2.5 mg Tarlige Tablets 5 mg Tarlige Tablets 10 mg Tarlige Tablets 15 mg (Daiichi Sankyo Company, Limited)	Change Change Change Change	Mirogabalin besilate	Drugs with a new indication for the treatment of neuropathic pain.
3-1	Mar. 28, 2022	68	Spinraza Intrathecal Injection 12 mg (Biogen Japan Ltd.)	Change	Nusinersen sodium	A drug with a new indication for the treatment of spinal muscular atrophy without any clinical manifestations that is predicted to develop with genetic test. [Orphan drug]
3-2	Aug. 25, 2021	69	Fentos Tape 0.5 mg Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change Change Change Change Change	Fentanyl citrate	Drugs with a new indication and a new additional pediatric dosage for the analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics (for use only in patients who switch from other opioid analgesics).
3-2	Mar. 28, 2022	70	Vabysmo Solution for Intravitreal Injection 120 mg/mL (Chugai Pharmaceutical Co., Ltd.)	Approval	Faricimab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema.
4	Jun. 23, 2021	71	Recarbrio Combination for Intravenous Drip Infusion (MSD K.K.)	Approval	Relebactam hydrate/Imipenem hydrate/Cilastatin sodium	A new combination drug with a new active ingredient indicated for the treatment of infections caused by Recarbrio-sensitive *Escherichia coli* , *Citrobacter* spp. , *Klebsiella* spp. , *Enterococcus* spp., *Serratia* spp., *Pseudomonas aeruginosa* , and *Acinetobacter* spp. (limited to the bacterial strains resistant to carbapenem antimicrobial drugs) [Orphan drug]
4	Jul. 19, 2021	72	Ronapreve for Intravenous Infusion Set 300 Ronapreve for Intravenous Infusion Set 1332 (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Casirivimab (genetical recombination), Imdevimab (genetical recombination)	Drugs with new active ingredients indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Sep. 27, 2021	73	Stelues Suspension Liquid for Intramuscular Injection 600,000 Units Stelues Suspension Liquid for Intramuscular Injection 2,400,000 Units (Pfizer Japan Inc.)	Approval Approval	Benzylpenicillin benzathine hydrate	Drugs with a new route of administration indicated for the treatment of syphilis (excluding neurosyphilis) caused by *Treponema pallidum* .
4	Sep. 27, 2021	74	Xevudy for Intravenous Injection 500 mg (GlaxoSmithKline K.K.)	Approval	Sotrovimab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Sep. 27, 2021	75	Noxafil Tablets 100 mg Noxafil for Intravenous Infusion 300 mg (MSD K.K.)	Change Change	Posaconazole	Drugs with a new indication for the treatment of invasive aspergillosis.
4	Nov. 5, 2021	76	Ronapreve for Intravenous Infusion Set 300 Ronapreve for Intravenous Infusion Set 1332 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Casirivimab (genetical recombination), Imdevimab (genetical recombination)	Drugs with a new route of administration and a new indication for the treatment and suppression of development of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Dec. 24, 2021	77	Lagevrio Capsules 200 mg (MSD K.K.)	Approval	Molnupiravir	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Feb. 10, 2022	78	Paxlovidpack (Pfizer Japan Inc.)	Approval	Nirmatrelvir/Ritonavir	A drug with new active ingredients indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
6-1	Apr 23, 2021	79	Olumiant Tablets 2 mg Olumiant Tablets 4 mg (Eli Lilly Japan K.K.)	Change Change	Baricitinib	Drugs with a new indication and a new dosage for the treatment of pneumonia caused by SARS-CoV-2 (only for the patients requiring supplemental oxygen). [Priority review]
6-1	May 27, 2021	80	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of psoriatic arthritis in patients who have not responded sufficiently to conventional therapies.
6-1	Aug. 25, 2021	81	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	82	Rinvoq Tablets 30 mg (AbbVie GK)	Approval	Upadacitinib hydrate	A drug in an additional dosage form indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	83	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg Pen Cosentyx for S.C. Injection 75 mg Syringe (Novartis Pharma K.K.)	Change Change Approval	Secukinumab (genetical recombination)	Drugs with a new additional pediatric dosage and a drug in an additional dosage form indicated for the treatment of plaque psoriasis, psoriatic arthritis, and pustular psoriasis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	84	Cibinqo Tablets 50 mg Cibinqo Tablets 100 mg Cibinqo Tablets 200 mg (Pfizer Japan Inc.)	Approval Approval Approval	Abrocitinib	Drugs with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	85	Saphnelo for I.V. Infusion 300 mg (AstraZeneca K.K.)	Approval	Anifrolumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	86	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of systemic sclerosis. [Orphan drug]
6-1	Sep. 27, 2021	87	Tavneos Capsules 10 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	Avacopan	A drug with a new active ingredient indicated for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis. [Orphan drug]
6-1	Dec. 24, 2021	88	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of refractory pemphigus vulgaris and pemphigus foliaceus. [Orphan drug]
6-1	Jan. 20, 2022	89	Lyfnua Tablets 45 mg (MSD K.K.)	Approval	Gefapixant citrate	A drug with a new active ingredient indicated for the treatment of refractory chronic cough.
6-1	Jan. 20, 2022	90	Bimzelx Syringe for S.C Injection 160 mg Bimzelx Autoinjector for S.C Injection 160 mg (UCB Japan Co., Ltd.)	Approval Approval	Bimekizumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Jan. 21, 2022	91	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Tocilizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of pneumonia caused by SARS-CoV-2 (only for the patients requiring supplemental oxygen). [Priority review]
6-1	Mar. 28, 2022	92	Mitchga Syringes 60 mg (Maruho Co., Ltd.)	Approval	Nemolizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of pruritus associated with atopic dermatitis (for use only in patients who have not responded sufficiently to conventional treatments).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
6-1	Mar. 28, 2022	93	Takhzyro Subcutaneous Injection 300 mg Syringes (Takeda Pharmaceutical Company Limited)	Approval	Lanadelumab (genetical recombination)	A drug with a new active ingredient indicated for the prophylaxis of acute attacks of hereditary angioedema. [Orphan drug]
6-1	Mar. 28, 2022	94	Unitalc Intrapleural 4 g (Nobelpharma Co., Ltd.)	Change	Talc	A drug with a new indication for the treatment of inoperable secondary intractable pneumothorax. [Orphan drug]
Oncology drugs	May 27, 2021	95	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma. [Orphan drug]
Oncology drugs	May 27, 2021	96	Ninlaro Capsules 2.3 mg Ninlaro Capsules 3 mg Ninlaro Capsules 4 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Ixazomib citrate	Drugs with a new indication for the maintenance therapy of multiple myeloma.
Oncology drugs	May 27, 2021	97	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma. [Orphan drug]
Oncology drugs	Jun. 23, 2021	98	Tazverik Tablets 200 mg (Eisai Co., Ltd.)	Approval	Tazemetostat hydrobromide	A drug with a new active ingredient indicated for the treatment of relapsed or refractory *EZH* 2 gene mutation-positive follicular lymphoma (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Jun. 23, 2021	99	Lutathera Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	Lutetium (^{177}Lu) oxodotreotide	A drug with a new active ingredient indicated for the treatment of somatostatin receptor-positive neuroendocrine tumor.
Oncology drugs	Jun. 23, 2021	100	Lysakare Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	L-Lysine hydrochloride, L-Arginine hydrochloride	A new combination drug indicated for the reduction of renal radiation exposure from Lutetium (^{177}Lu) oxodotreotide.
Oncology drugs	Jun. 23, 2021	101	Unituxin I.V. Injection 17.5 mg/5 mL (Ohara Pharmaceutical Co.,Ltd.)	Approval	Dinutuximab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of neuroblastoma following high-dose chemotherapy. [Orphan drug]
Oncology drugs	Jun. 23, 2021	102	Hiyasta Tablets 10 mg (Huya Japan G.K.)	Approval	Tucidinostat	A drug with a new active ingredient indicated for the treatment of relapsed or refractory adult T-cell leukemia-lymphoma. [Orphan drug]
Oncology drugs	Jun. 23, 2021	103	Gran Injection 75 Gran Injection 150 Gran Injection M300 Gran Syringe 75 Gran Syringe 150 Gran Syringe M300 (Kyowa Kirin Co., Ltd.)	Change Change Change Change Change Change	Filgrastim (genetical recombination)	Drugs with a new indication and a new dosage for the enhancement of an antitumor effect of dinutuximab (genetical recombination) for neuroblastoma. [Expedited review]
Oncology drugs	Jun. 23, 2021	104	Imunace 35 for Injection (Shionogi & Co., Ltd.)	Change	Teceleukin (genetical recombination)	A drug with a new indication and a new dosage for the enhancement of an antitumor effect of dinutuximab (genetical recombination) for neuroblastoma. [Expedited review]
Oncology drugs	Aug. 25, 2021	105	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	(1) A drug with a new indication for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer. (2) A drug with a new indication and a new dosage for the treatment of PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Aug. 25, 2021	106	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 25, 2021	107	Cabometyx Tablets 20 mg (Takeda Pharmaceutical Company Limited)	Change	Cabozantinib malate	A drug with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 25, 2021	108	Carboplatin Injection 50 mg "NK" Carboplatin Injection 150 mg "NK" Carboplatin Injection 450 mg "NK" (Mylan Seiyaku Ltd.)	Change Change Change	Carboplatin	Drugs with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 25, 2021	109	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 25, 2021	110	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Busulfan	A drug with a new dosage indicated for the conditioning treatments prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem-cell transplantation for Ewing's sarcoma family of tumors and neuroblastoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 27, 2021	111	Retevmo Capsules 40 mg Retevmo Capsules 80 mg (Eli Lilly Japan K.K.)	Approval Approval	Selpercatinib	Drugs with a new active ingredient indicated for the treatment of *RET* fusion gene-positive unresectable advanced or recurrent non-small cell lung cancer. [Orphan drug]
Oncology drugs	Sep. 27, 2021	112	Raiatt MIBG-I 131 Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	3-Iodobenzylguanidine (^{131}I)	A drug with a new active ingredient indicated for the treatment of unresectable MIBG-positive pheochromocytoma/paraganglioma. [Orphan drug]
Oncology drugs	Sep. 27, 2021	113	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of relapsed or refractory classical Hodgkin lymphoma. [Orphan drug]
Oncology drugs	Sep. 27, 2021	114	Padcev for I.V. infusion 30 mg (Astellas Pharma Inc.)	Approval	Enfortumab vedotin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable urothelial carcinoma that has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Sep. 27, 2021	115	Megludase for Intravenous Use 1000 (Ohara Pharmaceutical Co., Ltd.)	Approval	Glucarpidase (genetical recombination)	A drug with a new active ingredient indicated to reduce toxic plasma methotrexate concentration in patients with delayed clearance of methotrexate due to methotrexate/leucovorin salvage therapy. [Orphan drug]
Oncology drugs	Nov. 25, 2021	116	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive salivary gland tumors. [Orphan drug]
Oncology drugs	Nov. 25, 2021	117	Hiyasta Tablets 10 mg (Huya Japan G.K.)	Change	Tucidinostat	A drug with a new indication for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Nov. 25, 2021	118	Leucovorin Tablets 5 mg (Pfizer Japan Inc.)	Change	Calcium folinate	A drug with a new dosage indicated for the alleviation of toxicity of antifolates.
Oncology drugs	Nov. 25, 2021	119	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent esophageal cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Nov. 25, 2021	120	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	1) Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. 2) Drugs with a new indication and a new dosage for postoperative adjuvant therapy for esophageal cancer.
Oncology drugs	Nov. 25, 2021	121	Lorbrena Tablets 25 mg Lorbrena Tablets 100 mg (Pfizer Japan Inc.)	Change Change	Lorlatinib	Drugs with a new indication for the treatment of unresectable or advanced/recurrent anaplastic lymphoma kinase (ALK) fusion gene-positive non-small cell lung cancer.
Oncology drugs	Nov. 25, 2021	122	Sarclisa 100 mg I.V. Infusion Sarclisa 500 mg I.V. Infusion (Sanofi K.K.)	Change Change	Isatuximab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma.
Oncology drugs	Nov. 25, 2021	123	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of esophageal cancer. [Public knowledge-based application]
Oncology drugs	Dec. 24, 2021	124	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of carcinoma of unknown primary. [Orphan drug]
Oncology drugs	Dec. 24, 2021	125	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent endometrial carcinoma that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 24, 2021	126	Lenvima Capsules 4 mg Lenvima Capsules 10 mg (Eisai Co., Ltd.)	Change Change	Lenvatinib mesilate	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent endometrial carcinoma that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 24, 2021	127	Verzenio Tablets 50 mg Verzenio Tablets 100 mg Verzenio Tablets 150 mg (Eli Lilly Japan K.K.)	Change Change Change	Abemaciclib	Drugs with a new indication and a new dosage for the postoperative adjuvant treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer with a high risk of recurrence.
Oncology drugs	Jan. 20, 2022	128	Lumakras Tablets 120 mg (Amgen K.K.)	Approval	Sotorasib	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent KRAS G12C mutation-positive non-small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Feb. 25, 2022	129	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Kirin Co., Ltd.)	Change	Pegfilgrastim (genetical recombination)	A drug with a new indication and a new dosage for the mobilization of hematopoietic stem cell to the peripheral blood for allogenic peripheral blood stem cell transplantation.
Oncology drugs	Feb. 25, 2022	130	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of advanced or recurrent solid tumors with tumor mutation burden-high (TMB-high) that have progressed after cancer chemotherapy (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Feb. 25, 2022	131	Retevmo Capsules 40 mg Retevmo Capsules 80 mg (Eli Lilly Japan K.K.)	Change Change	Selpercatinib	Drugs with a new indication and a new dosage for the treatment of *RET* fusion gene-positive unresectable thyroid cancer and *RET* gene mutation-positive unresectable medullary thyroid cancer. [Orphan drug]
Oncology drugs	Feb. 25, 2022	132	Lenvima Capsules 4 mg Lenvima Capsules 10 mg (Eisai Co., Ltd.)	Change Change	Lenvatinib mesilate	Drugs with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Feb. 25, 2022	133	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Feb. 25, 2022	134	Treakisym Injection Solution 100 mg/4 mL (SymBio Pharmaceuticals Limited)	Change	Bendamustine hydrochloride hydrate	A drug with a new dosage indicated for the treatment of low-grade B-cell non-Hodgkin's lymphoma, mantle cell lymphoma, chronic lymphocytic leukemia, and relapsed or refractory diffuse large B-cell lymphoma.
Oncology drugs	Mar. 28, 2022	135	Scemblix Tablets 20 mg Scemblix Tablets 40 mg (Novartis Pharma K.K.)	Approval Approval	Asciminib hydrochloride	Drugs with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies. [Orphan drug]
Oncology drugs	Mar. 28, 2022	136	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the postoperative adjuvant therapy for urothelial carcinoma.
Oncology drugs	Mar. 28, 2022	137	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Change	Pertuzumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive colon or rectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Mar. 28, 2022	138	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive colon or rectal cancer that has progressed after cancer chemotherapy.
Bio-CMC	Sep. 27, 2021	139	Ranibizumab BS Intravitreal Injection kit 10 mg/mL "Senju" (Senju Pharmaceutical Co., Ltd.)	Approval	Ranibizumab (genetical recombination) [ranibizumab biosimilar 1]	Follow-on biologics indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization or choroidal neovascularization in patients with pathologic myopia.
Bio-CMC	Jan. 20, 2022	140	Bevacizumab BS Intravenous Infusion 100 mg "Nichi-Iko" Bevacizumab BS Intravenous Infusion 400 mg "Nichi-Iko" (Nichi-Iko Pharmaceutical Co., Ltd.)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 3]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer and unresectable advanced or recurrent non-squamous non-small cell lung cancer.
Vaccines	May 21, 2021	141	COVID-19 Vaccine Moderna Intramuscular Injection (Takeda Pharmaceutical Company Limited)	Approval	CX-024414	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	May 21, 2021	142	Vaxzevria Intramuscular Injection (AstraZeneca K.K.)	Approval	COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Nov.11, 2021	143	Comirnaty Intramuscular Injection (Pfizer Japan Inc.)	Change	Tozinameran	A drug with a new dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Dec. 16, 2021	144	Spikevax Intramuscular Injection (previously COVID-19 Vaccine Moderna Intramuscular Injection) (Takeda Pharmaceutical Company Limited)	Change	Elasomeran (former ingredient name: CX-024414)	A drug with a new dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Jan. 21, 2022	145	Comirnaty Intramuscular Injection for 5 to 11 years old (Pfizer Japan Inc.)	Approval	Tozinameran	A drug with a new pediatric dosage and a drug in an additional dosage form indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Blood products	Mar. 28, 2022	146	Fibrinogen HT I.V. 1 g “JB” (Japan Blood Products Organization)	Change	Freeze-dried human fibrinogen	A drug with a new indication and a new dosage for the replacement of fibrinogen in patients with acquired hypofibrinogenemia associated with critical obstetrical hemorrhage. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jun. 29, 2020	1	Vafseo Tablets 150 mg Vafseo Tablets 300 mg (Mitsubishi Tanabe Pharma Corporation)	Approval Approval	Vadadustat	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Jun. 29, 2020	2	Duvroq Tablets 1 mg Duvroq Tablets 2 mg Duvroq Tablets 4 mg Duvroq Tablets 6 mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Daprodustat	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Sep. 25, 2020	3	Ultomiris for intravenous Infusion 300 mg (Alexion Pharma GK)	Change	Ravulizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of atypical hemolytic uremic syndrome (aHUS).
1	Sep. 25, 2020	4	Ecclock Gel 5% (Kaken Pharmaceutical Co., Ltd.)	Approval	Sofpironium bromide	A drug with a new active ingredient indicated for the treatment of primary axillary hyperhidrosis.
1	Sep. 25, 2020	5	Enaroy Tablets 2 mg Enaroy Tablets 4 mg (Japan Tobacco Inc.)	Approval Approval	Enarodustat	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Nov. 27, 2020	6	Evrenzo Tablets 20 mg Evrenzo Tablets 50 mg Evrenzo Tablets 100 mg (Astellas Pharma Inc.)	Change Change Change	Roxadustat	Drugs with a new indication for the treatment of renal anemia.
1	Jan. 22, 2021	7	Sulprep Combination Solution (Nihon Pharmaceutical Co., Ltd.)	Approval	Anhydrous sodium sulfate, Potassium sulfate, Magnesium sulfate hydrate	A new combination drug indicated for bowel cleansing preparation for colonoscopy.
1	Jan. 22, 2021	8	Musredo Tablets 5 mg Musredo Tablets 12.5 mg Musredo Tablets 25 mg Musredo Tablets 50 mg Musredo Tablets 75 mg (Bayer Yakuhin, Ltd.)	Approval Approval Approval Approval Approval	Molidustat sodium	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Jan. 22, 2021	9	(1) Nobelzin Granules 5% (2) Nobelzin Tablets 25 mg (3) Nobelzin Tablets 50 mg (Nobelpharma Co., Ltd.)	Approval Change Change	Zinc acetate hydrate	Drugs with a new dosage and a drug in an additional dosage form for the treatment of hypozincemia.
1	Jan. 22, 2021	10	Adlumiz Tablets 50 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Anamorelin hydrochloride	A drug with a new active ingredient indicated for the treatment of cancer cachexia in the following malignancies: non-small cell lung cancer, gastric cancer, pancreatic cancer, and colorectal cancer.
1	Feb. 24, 2021	11	Comclo Shampoo 0.05% (Maruho Co., Ltd.)	Change	Clobetasol propionate	A drug with a new indication for the treatment of eczema/dermatitis of the scalp.
1	Mar. 23, 2021	12	Riona Tab. 250 mg (Japan Tobacco Inc.)	Change	Ferric citrate hydrate	A drug with a new indication and a new dosage for the treatment of iron deficiency anemia.
1	Mar. 23, 2021	13	Corectim Ointment 0.25% Corectim Ointment 0.5% (Japan Tobacco Inc.)	Approval Change	Delgocitinib	Drugs with a new additional pediatric dosage and a drug in an additional dosage form indicated for the treatment of atopic dermatitis.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-2	Jun. 29, 2020	14	Rybelsus Tablets 3 mg Rybelsus Tablets 7 mg Rybelsus Tablets 14 mg (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	Semaglutide (genetical recombination)	Drugs with a new route of administration indicated for the treatment of type 2 diabetes mellitus.
6-2	Aug. 21, 2020	15	[1] Sandostatin for S.C. Injection 50 μg Sandostatin for S.C. Injection 100 μg [2] Octreotide Acetate for S.C. Injection 50 μg “SANDOZ” Octreotide Acetate for S.C. Injection 100 μg “SANDOZ” ([1] Novartis Pharma K.K. [2] Sandoz K.K.)	Change Change Change Change	Octreotide acetate	Drugs with a new additional indication and a new dosage for the treatment of hypoglycemia associated with congenital hyperinsulinism (for use only in patients who have not sufficiently responded to other pharmaceutical therapies). [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
6-2	Dec. 25, 2020	16	Somatuline 60 mg for s.c. Injection Somatuline 90 mg for s.c. Injection Somatuline 120 mg for s.c. Injection (Teijin Pharma Limited)	Change Change Change	Lanreotide acetate	Drugs with a new indication for the treatment of thyroid-stimulating hormone secreting pituitary tumour. [Orphan drug]
6-2	Jan. 22, 2021	17	Sogroya Subcutaneous Injection 5 mg Sogroya Subcutaneous Injection 10 mg (Novo Nordisk Pharma Ltd.)	Approval Approval	Somapacitan (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of adult growth hormone deficiency (used only for severe cases).
6-2	Jan. 22, 2021	18	Hunterase ICV Injection 15 mg (Clinigen K.K.)	Approval	Idursulfase beta (genetical recombination)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type II. [Orphan drug]
6-2	Mar. 23, 2021	19	Isturisa Tablets 1 mg Isturisa Tablets 5 mg (Recordati Rare Diseases Japan K.K.)	Approval Approval	Osilodrostat phosphate	Drugs with a new active ingredient indicated for the treatment of Cushing's syndrome (when surgical therapies are not sufficiently effective or are difficult to be performed).
6-2	Mar. 23, 2021	20	Ostabalo Subcutaneous Injection Cart 3 mg (Teijin Pharma Limited)	Approval	Abaloparatide acetate	A drug with a new active ingredient indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Mar. 23, 2021	21	Izcargo for I.V. Infusion 10 mg (JCR Pharmaceuticals Co., Ltd.)	Approval	Pabinafusp alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type II. [SAKIGAKE review, orphan drug]
2	Jun. 29, 2020	22	Entresto Tablets 50 mg Entresto Tablets 100 mg Entresto Tablets 200 mg (Novartis Pharma K.K.)	Approval Approval Approval	Sacubitril valsartan sodium hydrate	Drugs with a new active ingredient indicated for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Jun. 29, 2020	23	Ongentys Tablets 25 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Opicapone	A drug with a new active ingredient indicated for the improvement of wearing-off phenomenon in patients with Parkinson’s disease in combination with levodopa/carbidopa or levodopa/benserazide hydrochloride.
2	Jun. 29, 2020	24	Onoact for Intravenous Infusion 50 mg Onoact for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Landiolol hydrochloride	Drugs with a new indication and a new dosage for the treatment of the following tachyarrhythmia associated with sepsis: atrial fibrillation, atrial flutter, sinus tachycardia.
2	Jun. 29, 2020	25	Samsca Tablets 7.5 mg Samsca Tablets 15 mg Samsca Tablets 30 mg Samsca OD Tablets 7.5 mg Samsca OD Tablets 15 mg Samsca OD Tablets 30 mg Samsca Granules 1% (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Tolvaptan	Drugs with a new indication and a new dosage for the improvement of hyponatraemia in patients with syndrome of inappropriate secretion of antidiuretic hormone (SIADH). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Nov. 27, 2020	26	Forxiga 5 mg Tablets Forxiga 10 mg Tablets (AstraZeneca K.K.)	Change Change	Dapagliflozin propylene glycolate hydrate	Drugs with a new indication and a new dosage for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Jan. 22, 2021	27	Emgality Subcutaneous Injection 120 mg Autoinjectors Emgality Subcutaneous Injection 120 mg Syringe (Eli Lilly Japan K.K.)	Approval Approval	Galcanezumab (genetical recombination)	Drugs with a new active ingredient indicated for the prevention of migraine attacks.
2	Jan. 22, 2021	28	(1) Xarelto Dry Syrup for Pediatric 51.7 mg (2) Xarelto Dry Syrup for Pediatric 103.4 mg (3) Xarelto Tablets 15 mg (4) Xarelto Tablets 10 mg (5) Xarelto Fine Granules 15 mg (6) Xarelto Fine Granules 10 mg (7) Xarelto OD Tablets 15 mg (8) Xarelto OD Tablets 10 mg (Bayer Yakuhin, Ltd.)	Approval Approval Change Change Change Change Change Change	Rivaroxaban	Drugs ([1-8]) with a new indication and a new additional pediatric dosage for the treatment and prevention of recurrent venous thromboembolism. In addition, drugs ([1, 2]) are in an additional dosage form.
2	Mar. 23, 2021	29	Volibris Tablets 2.5 mg (GlaxoSmithKline K.K.)	Change	Ambrisentan	A drug with a new additional pediatric dosage indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
5	Jun. 29, 2020	30	Kindaly AF-5 Kindaly AF-5P Kindaly 5E (Fuso Pharmaceutical Industries, Ltd.)	Approval Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations to be used as perfusion fluids for hemodialysis in patients with chronic renal failure (use in any of the following cases: 1. when the patient's blood sugar level is not controlled well with sugarless dialysate, 2. when other bicarbonate dialysate is not sufficiently effective to improve hyperkalemia, 3. when other bicarbonate dialysate is not sufficiently effective to improve hypermagnesemia, 4. when other bicarbonate dialysate may cause hypercalcemia).
5	Sep. 25, 2020	31	Enefluid Injection (Otsuka Pharmaceutical Factory, Inc.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for the supplementation of amino acids, electrolytes, calories, fatty acids, water-soluble vitamin, and water in the following conditions. •When patients with insufficient oral intake and mild hypoproteinemia or mild undernutrition. •When patients in the perioperative period
5	Jan. 22, 2021	32	Zymso Intravesical Solution 50% (Kyorin Pharmaceutical Co., Ltd.)	Approval	Dimethyl sulfoxide	A drug with a new active ingredient indicated for the improvement of symptoms (chronic pelvic pain, pressure and discomfort perceived to be related to the urinary bladder; lower urinary tract symptoms such as persistent urge to void and urinary frequency) in patients with interstitial cystitis (Hunner type). [Orphan drug]
5	Mar. 23, 2021	33	Rekovelle Pen for S.C. Injection 12 µg Rekovelle Pen for S.C. Injection 36 µg Rekovelle Pen for S.C. Injection 72 µg (Ferring Pharmaceuticals Co., Ltd.)	Approval Approval Approval	Follitropin delta (genetical recombination)	Drugs with a new active ingredient indicated for controlled ovarian stimulation in assisted reproductive technology.
Radio-pharmaceuticals	Mar. 23, 2021	34	Axumin Injection (Nihon Medi-Physics Co., Ltd.)	Approval	Fluciclovine (18F)	A drug with a new active ingredient indicated for the visualization of tumors in patients with suspected to be newly identified malignant glioma, (for use only in supporting determination of the extent of tumor resection during tumor resection planning using magnetic resonance imaging).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Jun. 29, 2020	35	Mayzent Tablets 0.25 mg Mayzent Tablets 2 mg (Novartis Pharma K.K.)	Approval Approval	Siponimod fumaric acid	Drugs with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in secondary progressive multiple sclerosis (SPMS). [Orphan drug]
3-1	Jun. 29, 2020	36	Xeomin 50 Units for Intramuscular Injection Xeomin 100 Units for Intramuscular Injection Xeomin 200 Units for Intramuscular Injection (Teijin Pharma Limited)	Approval Approval Approval	Incobotulinumtoxin A	Drugs with a new active ingredient indicated for the treatment of upper limb spasticity.
3-1	Jun. 29, 2020	37	Enspryng Syringes for Subcutaneous Injection 120 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Satralizumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]
3-1	Sep. 25, 2020	38	Xeplion TRI Aqueous Suspension for IM Injection 175 mg Syringe Xeplion TRI Aqueous Suspension for IM Injection 263 mg Syringe Xeplion TRI Aqueous Suspension for IM Injection 350 mg Syringe Xeplion TRI Aqueous Suspension for IM Injection 525 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval	Paliperidone palmitate	Drugs with a new indication in a new dosage form for the treatment of schizophrenia (for use only in patients after they have been adequately treated with 4-week paliperidone extended-release intramuscular injectable suspension).
3-1	Sep. 25, 2020	39	ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg Syringes ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg Syringes (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change	Aripiprazole hydrate	Drugs with a new indication for the prevention of recurrence/relapse of mood episodes in patients with bipolar I disorder.
3-1	Sep. 25, 2020	40	Buccolam Oromucosal Solution 2.5 mg Buccolam Oromucosal Solution 5 mg Buccolam Oromucosal Solution 7.5 mg Buccolam Oromucosal Solution 10 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval Approval	Midazolam	Drugs with a new route of administration indicated for the treatment of status epilepticus. [Orphan drug]
3-1	Dec. 25, 2020	41	(1) Vimpat Tablets 50 mg (2) Vimpat Tablets 100 mg (3) Vimpat Dry Syrup 10% (4) Vimpat for I.V. Infusion 100 mg (5) Vimpat for I.V. Infusion 200 mg (UCB Japan Co., Ltd.)	Change Change Change Change Change	Lacosamide	(1)-(3) Drugs with a new indication for use as an adjunctive therapy with other antiepileptic drugs to treat tonic-clonic seizure in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs. (4), (5) Drugs with a new indication for use as an adjunctive therapy with other antiepileptic drugs to treat tonic-clonic seizure in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs. It is used as an alternative therapy for lacosamide oral formulation in patients who are temporarily unable to be administered orally.
3-1	Feb. 24, 2021	42	Thaled Capsules 25 Thaled Capsules 50 Thaled Capsules 100 (Fujimoto Pharmaceutical Corporation)	Change Change Change	Thalidomide	Drugs with a new indication and a new dosage for the treatment of Crow-Fukase (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes [POEMS]) syndrome. [Orphan drug]
3-1	Mar. 23, 2021	43	Lonasen Tablets 2 mg Lonasen Tablets 4 mg Lonasen Tablets 8 mg Lonasen Powder 2% (Sumitomo Dainippon Pharma Co., Ltd.)	Change Change Change Change	Blonanserin	Drugs with a new additional pediatric dosage indicated for the treatment of schizophrenia.
3-1	Mar. 23, 2021	44	Uplizna for Intravenous Infusion 100 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	Inebilizumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Mar. 23, 2021	45	Kesimpta for s.c.injection 20 mg Pen (Novartis Pharma K.K.)	Approval	Ofatumumab (genetical recombination)	A drug with a new route of administration and new indications for the prevention of relapse and for delaying the accumulation of physical disability in relapsing-remitting multiple sclerosis (RRMS) and active secondary progressive multiple sclerosis (active SPMS). [Orphan drug]
3-2	Jun. 29, 2020	46	Fentos Tape 0.5 mg Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change Change Change Change Change	Fentanyl citrate	Drugs with a new indication and a new dosage for the analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics and weak opioid analgesics.
3-2	Sep. 25, 2020	47	Twotram Tab. 50 mg Twotram Tab. 100 mg Twotram Tab. 150 mg (Nippon Zoki Pharmaceutical Co., Ltd.)	Approval Approval Approval	Tramadol hydrochloride	Drugs in a new dosage form indicated for analgesia in chronic pain that cannot be managed by treatment with non-opioid analgesics.
3-2	Oct. 29, 2020	48	Oxycontin TR Tablets 5 mg Oxycontin TR Tablets10 mg Oxycontin TR Tablets 20 mg Oxycontin TR Tablets 40 mg (Shionogi Pharma Co., Ltd)	Change Change Change Change	Oxycodone hydrochloride hydrate	Drugs with a new indication and a new dosage for analgesia in moderate to severe chronic pain which cannot be managed by treatment with non-opioid analgesics or other opioid analgesics.
4	May 7, 2020	49	Veklury for Intravenous Injection 100 mg (Solution) Veklury for Intravenous Injection 100 mg (Lyophilized powder) (Gilead Sciences K.K.)	Approval	Remdesivir	Drugs with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Nov. 27, 2020	50	Xofluza Tablets 20 mg Xofluza Granules 2% (Shionogi & Co., Ltd.)	Change Change	Baloxavir marboxil	Drugs with a new indication and a new dosage for the prophylaxis of influenza A or B virus infection.
4	Nov. 27, 2020	51	Lasvic Intravenous Drip Infusion Kit 150 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	Lascufloxacin hydrochloride	A drug with a new route of administration indicated for the treatment of pneumonia, lung abscess, and secondary infection of chronic respiratory disease caused by Lasvic-sensitive *Staphylococcus* spp, *Streptococcus* spp, *Streptococcus pneumoniae*, *Enterococcus* spp, *Moraxella* (*Branhamella*) *catarrhalis*, *Escherichia coli, Klebsiella* spp, *Enterobacter* spp, *Haemophilus influenzae*, *Legionella pneumophila*, *Peptostreptococcus* spp, *Veillonella* spp, *Bacteroides* spp, *Prevotella* spp, *Porphyromonas* spp, *Fusobacterium* spp, and *Mycoplasma pneumoniae*.
4	Mar. 23, 2021	52	Arikayce inhalation solution 590 mg (Insmed GK)	Approval	Amikacin sulfate	A drug with a new route of administration indicated for the treatment of nontuberculous mycobacterial pulmonary disease caused by amikacin-sensitive *Mycobacterium avium* complex (MAC).
6-1	May 29, 2020	53	Ofev Capsules 100 mg Ofev Capsules 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change Change	Nintedanib ethanesulfonate	Drugs with a new indication for the treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype. [Priority review]
6-1	May 29, 2020	54	Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL (AbbVie GK)	Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of hidradenitis suppurativa. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Jun. 29, 2020	55	Ilumya Subcutaneous Injection 100 mg Syringe (Sun Pharma Japan Ltd.)	Approval	Tildrakizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Jun. 29, 2020	56	Flutiform 50 Aerosol 56 Puffs Flutiform 50 Aerosol 120 Puffs (Kyorin Pharmaceutical Co., Ltd.)	Change Change	Fluticasone propionate/Formoterol fumarate hydrate	Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Jun. 29, 2020	57	Atectura Inhalation Capsules Low Dose Atectura Inhalation Capsules Medium Dose Atectura Inhalation Capsules High Dose (Novartis Pharma K.K.)	Approval Approval Approval	Indacaterol acetate/Mometasone furoate	New combination drugs with a new active ingredient indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Jun. 29, 2020	58	Enerzair Inhalation Capsules Medium Dose Enerzair Inhalation Capsules High Dose (Novartis Pharma K.K.)	Approval Approval	Indacaterol acetate/Glycopyrronium bromide/Mometasone furoate	New combination drugs with a new active ingredient indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid, a long-acting beta-2 agonist and a long-acting inhaled anticholinergic agent is needed).
6-1	Aug. 21, 2020	59	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg Pen (Novartis Pharma K.K.)	Change Change	Secukinumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of non-radiographic axial spondyloarthritis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Sep. 25, 2020	60	Jyseleca Tablets 100 mg Jyseleca Tablets 200 mg (Gilead Sciences K.K.)	Approval Approval	Filgotinib maleate	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 25, 2020	61	Taltz 80 mg Syringe for SC Injection Taltz 80 mg Auto-injector for SC Injection (Eli Lilly Japan K.K.)	Change Change	Ixekizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of non-radiographic axial spondyloarthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Nov. 27, 2020	62	(1) Trelegy 200 Ellipta 30 doses (2) Trelegy 200 Ellipta 14 doses (3) Trelegy 100 Ellipta 30 doses (4) Trelegy 100 Ellipta 14 doses (GlaxoSmithKline K.K.)	Approval Approval Change Change	Fluticasone furoate/Umeclidinium bromide/Vilanterol trifenatate	(1), (2) New combination drugs indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid, a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist is needed). (3), (4) Drugs with a new indication and a new dosage for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid, a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist is needed).
6-1	Nov. 27, 2020	63	Lumicef Subcutaneous Injection 210 mg Syringe (Kyowa Kirin Co., Ltd.)	Change	Brodalumab (genetical recombination)	A drug with new indications for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Nov. 27, 2020	64	Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL (AbbVie GK)	Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of pyoderma gangrenosum. [Orphan drug]
6-1	Dec. 25, 2020	65	Olumiant Tablets 4 mg Olumiant Tablets 2 mg (Eli Lilly Japan K.K.)	Change Change	Baricitinib	Drugs with a new indication for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Jan. 22, 2021	66	Orladeyo Capsules 150 mg (OrphanPacific, Inc.)	Approval	Berotralstat hydrochloride	A drug with a new active ingredient indicated for the prophylaxis of acute attacks of hereditary angioedema. [SAKIGAKE review, orphan drug]
6-1	Mar. 23, 2021	67	Joyclu 30 mg Intra-articular Injection (Seikagaku Corporation)	Approval	Diclofenac etalhyaluronate sodium	A drug with a new active ingredient indicated for the treatment of knee and hip osteoarthritis.
6-1	Mar. 23, 2021	68	Zicthoru Tapes 75 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval	Diclofenac sodium	A drug with a new indication in a new dosage form for analgesia in various types of cancer.
Oncology drugs	May 29, 2020	69	Erleada Tablets 60 mg (Janssen Pharmaceutical K.K.)	Change	Apalutamide	A drug with a new indication for the treatment of metastatic prostate cancer.
Oncology drugs	May 29, 2020	70	Xtandi Tablets 40 mg Xtandi Tablets 80 mg (Astellas Pharma Inc.)	Change Change	Enzalutamide	Drugs with a new indication for the treatment of metastatic prostate cancer.
Oncology drugs	Jun. 29, 2020	71	Sarclisa 100 mg I.V. Infusion Sarclisa 500 mg I.V. Infusion (Sanofi K.K.)	Approval Approval	Isatuximab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma.
Oncology drugs	Jun. 29, 2020	72	Tabrecta Tablets 150 mg Tabrecta Tablets 200 mg (Novartis Pharma K.K.)	Approval Approval	Capmatinib hydrochloride hydrate	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent *MET* exon 14 (METex14) skipping mutation-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	Jun. 29, 2020	73	Bosulif Tablets 100 mg (Pfizer Japan Inc.)	Change	Bosutinib hydrate	A drug with a new indication and a new dosage for the treatment of newly-diagnosed chronic phase chronic myeloid leukemia.
Oncology drugs	Aug. 21, 2020	74	Kadcyla for Intravenous Infusion 100 mg Kadcyla for Intravenous Infusion 160 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab emtansine (genetical recombination)	Drugs with a new indication and a new dosage for the postoperative adjuvant treatment for HER2-positive breast cancer.
Oncology drugs	Aug. 21, 2020	75	Cylocide Injection 20 mg Cylocide Injection 40 mg Cylocide Injection 60 mg Cylocide Injection 100 mg Cylocide Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Change Change Change Change Change	Cytarabine	Drugs with a new dosage indicated for the treatment of acute leukemia (including erythroleukemia and blast crisis of chronic myeloid leukemia). [Public knowledge-based application]
Oncology drugs	Aug. 21, 2020	76	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent PD-L1-positive esophageal squamous cell carcinoma that has progressed after cancer chemotherapy.
Oncology drugs	Aug. 21, 2020	77	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of extensive-stage small-cell lung cancer.
Oncology drugs	Aug. 21, 2020	78	Velexbru Tablets 80 mg (Ono Pharmaceutical Co., Ltd.)	Change	Tirabrutinib hydrochloride	A drug with new indications for the treatment of Waldenström's macroglobulinemia and lymphoplasmacytic lymphoma. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Sep. 25, 2020	79	Zejula Capsules 100 mg (Takeda Pharmaceutical Company Limited)	Approval	Niraparib tosilate hydrate	A drug with a new active ingredient indicated for the maintenance treatment of ovarian cancer in patients who have received first chemotherapy, the maintenance treatment of recurrent ovarian cancer in patients who are in a complete or partial response to platinum-based chemotherapy, and the treatment of homologous recombination deficiency (HRD)-positive recurrent ovarian cancer in patients who are in a complete or partial response to platinum-based chemotherapy.
Oncology drugs	Sep. 25, 2020	80	Akalux IV Infusion 250 mg (Rakuten Medical Japan K.K.)	Approval	Cetuximab sarotalocan sodium (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable locally advanced or recurrent head and neck cancer. [SAKIGAKE designation, Conditional early approval]
Oncology drugs	Sep. 25, 2020	81	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new indication for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 25, 2020	82	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change	Nivolumab (genetical recombination)	1) Drugs with a new dosage for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy. 2) Drugs with a new dosage for the treatment of melanoma, unresectable advanced or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable advanced or recurrent gastric cancer that has progressed after cancer chemotherapy, unresectable advanced or recurrent malignant pleural mesothelioma that have progressed after cancer chemotherapy, unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy, and unresectable advanced or recurrent esophageal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 25, 2020	83	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable hepatocellular carcinoma. [Priority review]
Oncology drugs	Sep. 25, 2020	84	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable hepatocellular carcinoma. [Priority review]
Oncology drugs	Sep. 25, 2020	85	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change	Trastuzumab deruxtecan (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive gastric cancer that has progressed after cancer chemotherapy. [SAKIGAKE designation]
Oncology drugs	Nov. 27, 2020	86	Braftovi Capsules 50 mg Braftovi Capsules 75 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Encorafenib	Drugs with a new indication and a new dosage for the treatment of unresectable, advanced or recurrent BRAF mutation-positive colorectal cancer that has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Nov. 27, 2020	87	Mektovi Tablets 15 mg (Ono Pharmaceutical Co., Ltd.)	Change	Binimetinib	A drug with a new indication and a new dosage for the treatment of unresectable, advanced or recurrent BRAF mutation-positive colorectal cancer that has progressed after cancer chemotherapy. [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 27, 2020	88	Xeloda Tablets 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new dosage indicated for the treatment of unresectable or recurrent breast cancer and colorectal cancer. [Public knowledge-based application]
Oncology drugs	Nov. 27, 2020	89	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer. Drugs with a new dosage indicated for the treatment of unresectable advanced or recurrent gastric cancer, unresectable advanced or recurrent colon or rectal cancer, unresectable advanced or recurrent non-small cell lung cancer, and unresectable hepatocellular carcinoma whose serum AFP level is greater than 400 ng/mL and conditions have progressed after cancer chemotherapy.
Oncology drugs	Nov. 27, 2020	90	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 240 mg Opdivo Intravenous Infusion 120 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
Oncology drugs	Nov. 27, 2020	91	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
Oncology drugs	Nov. 27, 2020	92	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Change Change	Daratumumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Nov. 27, 2020	93	Cabometyx Tablets 20 mg Cabometyx Tablets 60 mg (Takeda Pharmaceutical Company Limited)	Change Change	Cabozantinib malate	Drugs with a new indication for the treatment of unresectable hepatocellular carcinoma that has progressed after cancer chemotherapy.
Oncology drugs	Dec. 25, 2020	94	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
Oncology drugs	Dec. 25, 2020	95	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with new indications and new dosage for the maintenance treatment of homologous recombination deficiency (HRD)-positive ovarian cancer in patients who have received first chemotherapy including treatment with bevacizumab (genetical recombination) and the treatment of metastatic, BRCA mutation-positive, castration-resistant prostate cancer.
Oncology drugs	Dec. 25, 2020	96	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new dosage indicated for the treatment of CD20-positive B-cell non-Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	Dec. 25, 2020	97	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication and a new dosage for maintenance therapy of unresectable BRCA mutation-positive pancreatic cancer after chemotherapy including treatment with platinum-based antineoplastic drugs. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 25, 2020	98	MabCampath I.V. Infusion 30 mg (Sanofi K.K.)	Change	Alemtuzumab (genetical recombination)	A drug with a new indication and a new dosage for a conditioning regimen prior to allogeneic hematopoietic stem cell transplantation. [Orphan drug]
Oncology drugs	Jan. 22, 2021	99	Calquence Capsules 100 mg (AstraZeneca K.K.)	Approval	Acalabrutinib	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.
Oncology drugs	Jan. 22, 2021	100	Alunbrig Tablets 30 mg Alunbrig Tablets 90 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Brigatinib	Drugs with a new active ingredient indicated for the treatment of unresectable advanced/recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer.
Oncology drugs	Feb. 24, 2021	101	Daunomycin 20 mg for Injection (Meiji Seika Pharma Co., Ltd.)	Change	Daunorubicin hydrochloride	A drug with a new dosage indicated for the treatment of acute leukemia (including blast crisis of chronic myeloid leukemia). [Public knowledge-based application]
Oncology drugs	Feb. 24, 2021	102	Bavencio Injection 200 mg (Merck Biopharma Co., Ltd.)	Change	Avelumab (genetical recombination)	A drug with a new indication for the maintenance therapy of unresectable urothelial carcinoma in patients who have received chemotherapy. [Priority review]
Oncology drugs	Mar. 23, 2021	103	Remitoro for Intravenous Drip Infusion 300 μg (Eisai Co., Ltd.)	Approval	Denileukin diftitox (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma and relapsed or refractory cutaneous T-cell lymphoma.
Oncology drugs	Mar. 23, 2021	104	Vitrakvi Capsules 25 mg Vitrakvi Capsules 100 mg Vitrakvi Oral Solution 20 mg/mL (Bayer Yakuhin, Ltd.)	Approval Approval Approval	Larotrectinib sulfate	Drugs with a new active ingredient indicated for the treatment of *NTRK* fusion gene-positive advanced or recurrent solid tumors. [Orphan drug]
Oncology drugs	Mar. 23, 2021	105	Darzquro Combination Subcutaneous Injection (Janssen Pharmaceutical K.K.)	Approval	Daratumumab (genetical recombination)/ Vorhyaluronidase alfa (genetical recombination)	A new combination drug with a new active ingredient indicated for the treatment of multiple myeloma.
Oncology drugs	Mar. 23, 2021	106	Venclexta Tablets 10 mg Venclexta Tablets 50 mg Venclexta Tablets 100 mg (AbbVie GK)	Change Change Change	Venetoclax	Drugs with a new indication and a new dosage for the treatment of acute myeloid leukemia. [Orphan drug]
Oncology drugs	Mar. 23, 2021	107	Polivy for Intravenous Infusion 140 mg Polivy for Intravenous Infusion 30 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Polatuzumab vedotin (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory diffuse large B-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 23, 2021	108	Lenvima Capsule 4 mg Lenvima Capsule 10 mg (Eisai Co., Ltd.)	Change Change	Lenvatinib mesilate	Drugs with a new indication for the treatment of unresectable thymic carcinoma. [Orphan drug]
Oncology drugs	Mar. 23, 2021	109	Pemazyre Tablets 4.5 mg (Incyte Biosciences Japan GK)	Approval	Pemigatinib	A drug with a new active ingredient indicated for the treatment of unresectable FGFR2 fusion gene-positive biliary tract cancer that has progressed after cancer chemotherapy. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 23, 2021	110	Treakisym Injection 25 mg Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change Change	Bendamustine hydrochloride	Drugs with a new indication and a new dosage for the treatment of relapsed or refractory diffuse large B-cell lymphoma. [Expedited review]
Oncology drugs	Mar. 23, 2021	111	Vidaza for Injection 100 mg (Nippon Shinyaku Co., Ltd.)	Change	Azacitidine	A drug with a new indication for the treatment of acute myeloid leukemia. [Expedited review]
Oncology drugs	Mar. 23, 2021	112	Lanthanum Carbonate Granules 250 mg "Nipro" Lanthanum Carbonate Granules 500 mg "Nipro" (Nipro Corporation)	Change Change	Lanthanum carbonate hydrate	Drugs with a new indication for the improvement of hyperphosphatemia associated with administration of FGFR inhibitor. [Expedited review]
Bio-CMC	Jun. 29, 2020	113	Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.8 mL “FKB” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.8 mL “FKB” Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.4 mL “FKB” (Fujifilm Kyowa Kirin Biologics Co., Ltd.)	Approval Approval Approval	Adalimumab (genetical recombination) [adalimumab biosimilar 1]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments; polyarticular-course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis and intestinal Behcet’s disease; and the remission induction therapy and maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional therapies).
Bio-CMC	Jan. 22, 2021	114	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.4 mL ”Daiichi Sankyo” Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.8 mL ”Daiichi Sankyo” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.8 mL ”Daiichi Sankyo” (Daiichi Sankyo Company, Limited)	Approval Approval Approval	Adalimumab (genetical recombination) [adalimumab biosimilar 2]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments: plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, polyarticular-course juvenile idiopathic arthritis, and intestinal Behcet’s disease.
Bio-CMC	Mar. 23, 2021	115	Insulin Aspart BS Injection SoloStar NR "Sanofi" Insulin Aspart BS Injection Cart NR "Sanofi" Insulin Aspart BS Injection 100 I.U./mL NR "Sanofi" (Sanofi K.K.)	Approval Approval Approval	Insulin aspart (genetical recombination) [insulin aspart biosimilar 1]	Follow-on biologics indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
Bio-CMC	Mar. 23, 2021	116	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL "MA" Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL "MA" Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL "MA" Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL "MA" (Mochida Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Adalimumab (genetical recombination) [adalimumab biosimilar 3]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments; polyarticular-course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis and intestinal Behçet's disease; the remission induction therapy and maintenance therapy for moderate to severe active Crohn's disease, and treatment of moderate to severe ulcerative colitis.
Vaccines	May 29, 2020	117	Prevenar 13 Suspension Liquid for Injection (Pfizer Japan Inc.)	Change	Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM_{197} conjugate)	A drug with a new indication for the prophylaxis of pneumococcal disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) in individuals who are considered to be at high risk of pneumococcal disease.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Jul. 21, 2020	118	Silgard9 Aqueous Suspension for Intramuscular Injection Syringes (MSD K.K.)	Approval	Recombinant adsorbed 9-valent human papillomavirus virus-like particle vaccine (yeast origin)	A drug with a new active ingredient indicated for the prevention of the following diseases caused by infection with human papillomavirus types 6, 11, 16, 18, 31, 33, 45, 52, and 58: • Cervical cancer (squamous cell carcinoma and adenosquamous carcinoma) and its precursor lesions (cervical intraepithelial neoplasia [CIN] 1, 2, and 3, and adenocarcinoma in situ [AIS]) • Vulvar intraepithelial neoplasia (VIN) 1, 2, and 3, and vaginal intraepithelial noeplasia (VaIN) 1, 2, and 3 • Condyloma acuminatum
Vaccines	Dec. 25, 2020	119	Gardasil Aqueous Suspension for Intramuscular Injection Syringes (MSD K.K.)	Change	Recombinant adsorbed 4-valent human papillomavirus virus-like particle vaccine (yeast origin)	A drug with a new indication for the prevention of the following diseases caused by infection with human papillomavirus types 6, 11, 16, and 18: • Cervical cancer (squamous cell carcinoma and adenosquamous carcinoma) and its precursor lesions (cervical intraepithelial neoplasia [CIN] 1, 2, and 3, and adenocarcinoma in situ [AIS]) • Vulvar intraepithelial neoplasia (VIN) 1, 2, and 3, and vaginal intraepithelial noeplasia (VaIN) 1, 2, and 3 • Anal cancer (squamous cell carcinoma) and its precursor lesions (anal intraepithelial neoplasia [AIN] 1, 2, and 3) • Condyloma acuminatum
Vaccines	Feb. 14, 2021	120	Comirnaty intramuscular injection (Pfizer Japan Inc.)	Approval	Tozinameran	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Blood products	Aug. 21, 2020	121	Idelvion I.V. Injection 250 Idelvion I.V. Injection 500 Idelvion I.V. Injection 1000 Idelvion I.V. Injection 2000 Idelvion I.V. Injection 3500 (CSL Behring K.K.)	Change Change Change Change Change	Albutrepenonacog alfa (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with blood coagulation factor IX deficiency.
Blood products	Jan. 22, 2021	122	Nuwiq for I.V. Injection 250 Nuwiq for I.V. Injection 500 Nuwiq for I.V. Injection 1000 Nuwiq for I.V. Injection 2000 Nuwiq for I.V. Injection 2500 Nuwiq for I.V. Injection 3000 Nuwiq for I.V. Injection 4000 (Fujimoto Pharmaceutical Corporation)	Approval Approval Approval Approval Approval Approval Approval	Simoctocog alfa (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Jan. 22, 2021	123	Lynspad for Intravenous Infusion 1000 mg (Grifols Therapeutics LLC)	Approval	Lyophilized human alpha1-proteinase inhibitor concentrate	A drug with a new active ingredient indicated for the augmentation and maintenance therapy of severe alpha 1-antitrypsin deficiency. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2019

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	May 22, 2019	1	Entyvio for I.V. Infusion 300 mg (Takeda Pharmaceutical Company Limited)	Change	Vedolizumab (genetical recombination)	A drug with a new additional indication for the treatment and maintenance therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jun. 18, 2019	2	Ultomiris for intravenous Infusion 300 mg (Alexion Pharma G.K.)	Approval	Ravulizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal hemoglobinuria. [Orphan drug]
1	Jun. 18, 2019	3	Romiplate for S.C. Injection 250 μg (Kyowa Hakko Kirin Co., Ltd.)	Change	Romiplostim (genetical recombination)	A drug with a new indication and a new dosage for the treatment of aplastic anemia in patients who have not responded sufficiently to conventional treatments.
1	Sep. 20, 2019	4	Evrenzo Tablets 20 mg Evrenzo Tablets 50 mg Evrenzo Tablets 100 mg (Astellas Pharma Inc.)	Approval Approval Approval	Roxadustat	Drugs with a new active ingredient indicated for the treatment of renal anaemia in patients who are undergoing dialysis.
1	Dec. 20, 2019	5	Venoglobulin IH 5% I.V. 0.5 g/10 mL Venoglobulin IH 5% I.V. 1 g/20 mL Venoglobulin IH 5% I.V. 2.5 g/50 mL Venoglobulin IH 5% I.V. 5 g/100 mL Venoglobulin IH 5% I.V. 10 g/200 mL Venoglobulin IH 10% I.V. 0.5 g/5 mL Venoglobulin IH 10% I.V. 2.5 g/25 mL Venoglobulin IH 10% I.V. 5 g/50 mL Venoglobulin IH 10% I.V. 10 g/100 mL Venoglobulin IH 10% I.V. 20 g/200 mL (Japan Blood Products Organization)	Change Change Change Change Change Change Change Change Change Change Change	Polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication and a new dosage for the preoperative desensitization therapy for kidney transplantation in donor-specific antibodies (DSA) positive patients. [Orphan drug]
1	Dec. 20, 2019	6	Orkedia Tablets 1 mg Orkedia Tablets 2 mg (Kyowa Kirin Co., Ltd.)	Change Change	Evocalcet	Drugs with new additional indications and a new dosage for the treatment of hypercalcemia in patients with parathyroid carcinoma or patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy. [Orphan drug]
1	Jan. 23, 2020	7	Corectim Ointment 0.5% (Japan Tobacco Inc.)	Approval	Delgocitinib	A drug with a new active ingredient indicated for the treatment of atopic dermatitis.
1	Mar. 25, 2020	8	Lokelma 5 g Powder for Suspension (Single-dose package) Lokelma 10 g Powder for Suspension (Single-dose package) (AstraZeneca K.K.)	Approval Approval	Sodium zirconium cyclosilicate hydrate	Drugs with a new active ingredient indicated for the treatment of hyperkalaemia.
1	Mar. 25, 2020	9	1) Stelara Intravenous Infusion 130 mg 2) Stelara Subcutaneous Injection 45 mg Syringe (Janssen Pharmaceutical K.K.)	Change Change	Ustekinumab (genetical recombination)	1) A drug with a new indication for the remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). 2) A drug with a new indication for the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
6-2	May 22, 2019	10	Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.)	Change	Liraglutide (genetical recombination)	A drug with a new dosage and other characteristics indicated for the treatment of type 2 diabetes mellitus.
6-2	Jun. 18, 2019	11	Xultophy Combination Injection FlexTouch (Novo Nordisk Pharma Ltd.)	Approval	Insulin degludec (genetical recombination) /Liraglutide (genetical recombination)	A new combination drug indicated for the treatment of type 2 diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 20, 2019	12	Fiasp Injection FlexTouch Fiasp Injection Penfill Fiasp Injection 100 U/mL (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	Insulin aspart (genetical recombination)	Drugs in new dosage forms indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 20, 2019	13	Brineura Intracerebroventricular Injectable Solution 150 mg (BioMarin Pharmaceutical Japan K.K.)	Approval	Cerliponase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-2	Sep. 20, 2019	14	Crysvita Subcutaneous Injection 10 mg Crysvita Subcutaneous Injection 20 mg Crysvita Subcutaneous Injection 30 mg (Kyowa Kirin Co., Ltd.)	Approval Approval Approval	Burosumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of FGF23-related hypophosphatemic rickets/osteomalacia. [Orphan drug]
6-2	Sep. 20, 2019	15	Teribone 28.2 μg Subcutaneous Autoinjector (Asahi Kasei Pharma Corporation)	Approval	Teriparatide acetate	A drug with a new dosage in an additional dosage form indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Jan. 23, 2020	16	Urece Tablets 0.5 mg Urece Tablets 1 mg Urece Tablets 2 mg (Fuji Yakuhin Co., Ltd.)	Approval Approval Approval	Dotinurad	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.
6-2	Jan. 23, 2020	17	Thyradin-S Intravenous Injection 200 μg (Aska Pharmaceutical Co., Ltd.)	Approval	Levothyroxine sodium hydrate	A drug with a new route of administration indicated for the treatment of myxedema coma and hypothyroidism (for hypothyroidism, only in patients ineligible for oral levothyroxine sodium therapy).
6-2	Mar. 25, 2020	18	Lyumjev Cart Lyumjev MirioPen Lyumjev MirioPen HD Lyumjev Injection 100 units/mL (Eli Lilly Japan K.K.)	Approval Approval Approval Approval	Insulin lispro (genetical recombination)	Drugs in new dosage forms indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Mar. 25, 2020	19	Baqsimi Nasal Powder 3 mg (Eli Lilly Japan K.K.)	Approval	Glucagon	A drug with a new route of administration indicated for the emergency treatment of hypoglycemia.
6-2	Mar. 25, 2020	20	Soliqua Injection Solostar (Sanofi K.K.)	Approval	Insulin glargine (genetical recombination)/ Lixisenatide	A new combination drug indicated for the treatment of type 2 diabetes mellitus in cases where insulin therapy is indicated.
2	May 22, 2019	21	Blopress Tablets 2 Blopress Tablets 4 Blopress Tablets 8 Blopress Tablets 12 (Teva Takeda Pharma Ltd.) Candesartan Tablets 2 mg “Aska” Candesartan Tablets 4 mg “Aska” Candesartan Tablets 8 mg “Aska” Candesartan Tablets 12 mg “Aska” (Aska Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Candesartan cilexetil	Drugs with a new additional pediatric dosage indicated for the treatment of hypertension. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Jun. 18, 2019	22	Defitelio Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Approval	Defibrotide sodium	A drug with a new active ingredient indicated for the treatment of sinusoidal obstruction syndrome (SOS) /hepatic veno-occlusive disease (VOD). [Orphan drug]
2	Jun. 18, 2019	23	Repatha SC Injection 140 mg Syringe Repatha SC Injection 140 mg Pen Repatha SC Injection 420 mg Auto Mini-doser (Amgen Astellas BioPharma K.K.)	Change Change Change	Evolocumab (genetical recombination)	Drugs with a new additional indication for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular events, and in whom treatment with HMG-CoA reductase inhibitors is not suitable).
2	Sep. 20, 2019	24	Haruropi Tape 8 mg Haruropi Tape 16 mg Haruropi Tape 24 mg Haruropi Tape 32 mg Haruropi Tape 40 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Approval Approval Approval Approval	Ropinirole hydrochloride	Drugs with a new route of administration indicated for the treatment of Parkinson's disease.
2	Sep. 20, 2019	25	Equfina Tablets 50 mg (Meiji Seika Pharma Co., Ltd.)	Approval	Safinamide mesilate	A drug with a new active ingredient indicated for the improvement of wearing-off phenomenon in patients with Parkinson’s disease under the treatment with levodopa-containing preparations.
2	Sep. 20, 2019	26	Coralan Tablets 2.5 mg Coralan Tablets 5 mg Coralan Tablets 7.5 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	Ivabradine hydrochloride	Drugs with a new active ingredient indicated for the treatment of chronic heart failure with sinus rhythm and a resting heart rate of 75 bpm or greater at baseline (for use only in patients receiving standard treatment of chronic heart failure, including β-blocker).
2	Feb. 21, 2020	27	Neoral Oral Solution 10% (Novartis Pharma K.K.)	Change	Ciclosporin	A drug with a new indication and a new dosage for the treatment of the acute phase of Kawasaki's disease (for patients with severe Kawasaki's disease who have the risk of developing coronary artery disorder).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Feb. 21, 2020	28	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of acquired thrombotic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 25, 2020	29	Cabpirin Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Aspirin/Vonoprazan fumarate	A new combination drug indicated for inhibiting thrombus/embolization formation in the following diseases or post-operations (for use only in patients with a history of gastric ulcer or duodenal ulcer): • Angina pectoris (chronic stable angina, unstable angina), myocardial infarction, or ischemic cerebrovascular disease (transient ischemic attack [TIA], cerebral infarction) • Coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
5	Jun. 18, 2019	30	Minirinmelt OD Tablets 25 μg Minirinmelt OD Tablets 50 μg (Ferring Pharmaceuticals Co., Ltd.)	Approval Approval	Desmopressin acetate hydrate	Drugs with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of nocturia due to nocturnal polyuria in males.
5	Dec. 20, 2019	31	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new route of administration indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder or urinary incontinence due to neurogenic bladder, in patients who have not responded sufficiently to conventional therapies or in whom conventional therapies are not suitable.
5	Jan. 23, 2020	32	Propess Vaginal Inserts 10 mg (Ferring Pharmaceuticals Co., Ltd.)	Approval	Dinoprostone	A drug with a new route of administration indicated for the initiation of cervical ripening in patients with unfavourable cervix from 37 completed weeks of gestation.
5	Jan. 23, 2020	33	Dinagest Tablets 0.5 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Dienogest	A drug with a new indication and a new dosage in an additional dosage form for the treatment of dysmenorrhea.
3-1	Jun. 18, 2019	34	Lonasen Tape 20 mg Lonasen Tape 30 mg Lonasen Tape 40 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Approval Approval Approval	Blonanserin	Drugs with a new route of administration indicated for the treatment of schizophrenia.
3-1	Jun. 18, 2019	35	Onpattro for Intravenous Infusion 2 mg/mL (Alnylam Japan K.K.)	Approval	Patisiran sodium	A drug with a new active ingredient indicated for the treatment of transthyretin familial amyloid polyneuropathy. [Orphan drug]
3-1	Jun. 18, 2019	36	Intuniv Tablets 1 mg Intuniv Tablets 3 mg (Shionogi & Co., Ltd.)	Change Change	Guanfacine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Aug. 22, 2019	37	Afinitor Tablets 2.5 mg Afinitor Tablets 5 mg Afinitor Dispersible Tablets 2 mg Afinitor Dispersible Tablets 3 mg (Novartis Pharma K.K.)	Change Change Change Change	Everolimus	Drugs with a new indication and a new dosage for the treatment of tuberous sclerosis complex. [Orphan drug]
3-1	Aug. 22, 2019	38	Kenketsu Venilon-I for Intravenous Injection 500 mg Kenketsu Venilon-I for Intravenous Injection 1000 mg Kenketsu Venilon-I for Intravenous Injection 2500 mg Kenketsu Venilon-I for Intravenous Injection 5000 mg (KM Biologics Co., Ltd.)	Change Change Change Change	Freeze-dried sulfonated human normal immunoglobulin	Drugs with a new additional indication and a new dosage for the improvement of muscle weakness in patients with chronic inflammatory demyelinating polyneuropathy (including multifocal motor neuropathy).
3-1	Sep. 20, 2019	39	Trintellix Tablets 10 mg Trintellix Tablets 20 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Vortioxetine hydrobromide	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Nov. 22, 2019	40	Soliris for Intravenous Infusion 300 mg (Alexion Pharma GK)	Change	Eculizumab (genetical recombination)	A drug with a new additional indication for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 20, 2019	41	Kenketsu Venilon-I for Intravenous Injection 500 mg Kenketsu Venilon-I for Intravenous Injection 1000 mg Kenketsu Venilon-I for Intravenous Injection 2500 mg Kenketsu Venilon-I for Intravenous Injection 5000 mg (KM Biologics Co., Ltd.)	Change Change Change Change	Freeze-dried sulfonated human normal immunoglobulin	Drugs with a new additional indication and a new dosage for the treatment of acute-phase optic neuritis (for use when steroid drugs are not sufficiently effective). [Orphan drug]
3-1	Dec. 20, 2019	42	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new dosage indicated for the treatment of upper limb spasticity.
3-1	Jan. 23, 2020	43	Fycompa Fine Granules 1% Fycompa Tablets 2 mg Fycompa Tablets 4 mg (Eisai Co., Ltd.)	Approval Change Change	Perampanel hydrate	A drug in an additional dosage form and drugs with a revised indication and a new additional pediatric dosage for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy.
3-1	Jan. 23, 2020	44	Dayvigo Tablets 2.5 mg Dayvigo Tablets 5 mg Dayvigo Tablets 10 mg (Eisai Co., Ltd.)	Approval Approval Approval	Lemborexant	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Feb. 21, 2020	45	Modiodal Tablets 100 mg (Alfresa Pharma Corporation)	Change	Modafinil	A drug with a new indication for the treatment of excessive daytime sleepiness associated with idiopathic hypersomnia. [Orphan drug]
3-1	Mar. 25, 2020	46	Melatobel Granules 0.2% for Pediatric (Nobelpharma Co., Ltd.)	Approval	Melatonin	A drug with a new active ingredient indicated for the improvement of difficulty falling asleep associated with pediatric neurodevelopmental disorder.
3-1	Mar. 25, 2020	47	Latuda Tablets 20 mg Latuda Tablets 40 mg Latuda Tablets 60 mg Latuda Tablets 80 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Approval Approval Approval Approval	Lurasidone hydrochloride	Drugs with a new active ingredient indicated for the treatment of schizophrenia and the improvement of depressive symptoms in patients with bipolar disorder.
3-1	Mar. 25, 2020	48	Viltepso Intravenous Infusion 250 mg (Nippon Shinyaku Co., Ltd.)	Approval	Viltolarsen	A drug with a new active ingredient indicated for the treatment of Duchenne muscular dystrophy (DMD) with a confirmed deficiency of the dystrophin gene amenable to exon 53 skipping therapy. [SAKIGAKE designation] [Conditional early approval] [Orphan drug]
3-2	Sep. 20, 2019	49	Retympa 250 μg Set for Otology (Nobelpharma Co., Ltd.)	Approval	Trafermin (genetical recombination)	A drug with a new route of administration indicated for the treatment of tympanic membrane perforation.
3-2	Sep. 20, 2019	50	Aibeta Combination Ophthalmic Solution (Senju Pharmaceutical Co., Ltd.)	Approval	Brimonidine tartrate/Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs.
3-2	Nov. 22, 2019	51	Lucentis Solution for Intravitreal Injection 10 mg/mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of retinopathy of prematurity. [Orphan drug]
3-2	Jan. 23, 2020	52	Anerem 50 mg for I.V. Injection (Mundipharma K.K.)	Approval	Remimazolam besilate	A drug with a new active ingredient indicated for the induction and maintenance of general anesthesia.
3-2	Mar. 25, 2020	53	Beovu Kit for Intravitreal Injection 120 mg/mL (Novartis Pharma K.K.)	Approval	Brolucizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization.
3-2	Mar. 25, 2020	54	Ailamide Combination Ophthalmic Suspension (Senju Pharmaceutical Co., Ltd.)	Approval	Brimonidine tartrate/ Brinzolamide	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs.
3-2	Mar. 25, 2020	55	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of neovascular glaucoma. [Orphan drug]
4	Jun. 18, 2019	56	Inavir for Inhalation Suspension 160 mg Set (Daiichi Sankyo Company, Limited)	Approval	Laninamivir octanoate hydrate	A drug in a new dosage form indicated for the treatment of influenza A or B virus infection.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
4	Jun. 18, 2019	57	Azimycin Ophthalmic Solution 1% (Senju Pharmaceutical Co., Ltd.)	Approval	Azithromycin hydrate	A drug with a new route of administration indicated for the treatment of conjunctivitis, blepharitis, hordeolum and dacryocystitis caused by azithromycin-sensitive *Staphylococcus* spp., *Streptococcus* spp., *Streptococcus pneumoniae*, *Corynebacterium* spp., *Haemophilus influenzae* or *Propionibacterium acnes*.
4	Aug. 22, 2019	58	Maviret Combination Tablets (AbbVie GK)	Change	Glecaprevir hydrate/Pibrentasvir	A drug with a new additional pediatric dosage indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C. [Priority review]
4	Sep. 20, 2019	59	Lasvic Tablets 75 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	Lascufloxacin hydrochloride	A drug with a new active ingredient indicated for the treatment of laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, otitis media, and sinusitis caused by Lasvic-sensitive *Staphylococcus* spp., *Streptococcus* spp., *Streptococcus pneumoniae* , *Moraxella (Branhamella) catarrhalis* , *Klebsiella* spp., *Enterobacter* spp., *Haemophilus influenzae* , *Legionella pneumophila* , *Prevotella* spp., and *Mycoplasma pneumoniae* .
4	Dec. 20, 2019	60	Zerbaxa Combination for Intravenous Drip Infusion (MSD K.K.)	Change	Ceftolozane sulfate/Tazobactam sodium	A drug with new additional indications and a new dosage for the treatment of sepsis and pneumonia caused by *Serratia* and *Haemophilus influenzae* .
4	Jan. 23, 2020	61	Noxafil Tablets 100 mg Noxafil for Intravenous Infusion 300 mg (MSD K.K.)	Approval Approval	Posaconazole	Drugs with a new active ingredient indicated for the •prophylaxis of deep mycosis in hematopoietic stem cell transplantation recipients or patients with hematologic malignancy who are predicated to decrease neutrophil. •treatment of the following mycoses: Fusariosis, mucormycosis, coccidioidomycosis, chromoblastomycosis, and mycetoma.
AIDS drugs	May 22, 2019	62	Genvoya Combination Tablets (Japan Tobacco Inc.)	Change	Elvitegravir/Cobicistat /Emtricitabine/Tenofovir alafenamide fumarate	A drug with a new additional pediatric dosage indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Jun. 18, 2019	63	Symtuza Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Darunavir ethanolate/Cobicistat /Emtricitabine/Tenofovir alafenamide fumarate	A new combination drug indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Jan. 14, 2020	64	Dovato Combination Tablets (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium/Lamivudine	A new combination drug indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Jan. 14, 2020	65	Pifeltro Tablets 100 mg (MSD K.K.)	Approval	Doravirine	A drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
6-1	May 22, 2019	66	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Tocilizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of adult Still's disease in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 18, 2019	67	Breztri Aerosphere 56 Inhalations Breztri Aerosphere 120 Inhalations (AstraZeneca K.K.)	Approval Approval	Budesonide /Glycopyrronium bromide/Formoterol fumarate hydrate	New combination drugs with a new active ingredient indicated for the relief of symptoms in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with an inhaled corticosteroid, a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist).
6-1	Jun. 18, 2019	68	Bevespi Aerosphere 28 Inhalations Bevespi Aerosphere 120 Inhalations (AstraZeneca K.K.)	Approval Approval	Glycopyrronium bromide/Formoterol fumarate hydrate	New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist).
6-1	Sep. 20, 2019	69	Otezla Tablets 10 mg Otezla Tablets 20 mg Otezla Tablets 30 mg (Celgene K.K.)	Change Change Change	Apremilast	Drugs with a new indication for the treatment of oral ulcer associated with Behcet’s disease in patients who have not responded sufficiently to local treatment.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Sep. 20, 2019	70	Alesion LX Ophthalmic Solution 0.1% (Santen Pharmaceutical Co., Ltd.)	Approval	Epinastine hydrochloride	A drug with a new dosage in an additional dosage form indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 20, 2019	71	Benlysta for I.V. Infusion 120 mg Benlysta for I.V. Infusion 400 mg (GlaxoSmithKline K.K.)	Change Change	Belimumab (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Nov. 22, 2019	72	Taltz 80 mg Syringe for SC Injection Taltz 80 mg Auto-injector for SC Injection (Eli Lilly Japan K.K.)	Change Change	Ixekizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments.
6-1	Dec. 11, 2019	73	Xolair for S.C. Injection 75 mg Xolair for S.C. Injection 150 mg Xolair for S.C. Injection 75 mg Syringe Xolair for S.C. Injection 150 mg Syringe (Novartis Pharma K.K.)	Change Change Change Change	Omalizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of seasonal allergic rhinitis (for use only in severe or the most severe patients who have not responded sufficiently to conventional therapies).
6-1	Dec. 20, 2019	74	Cimzia 200 mg Syringe for S.C. Injection Cimzia 200 mg AutoClicks for S.C. Injection (UCB Japan Co., Ltd.)	Change Change	Certolizumab pegol (genetical recombination)	Drugs with new additional indications and a new dosage for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Dec. 20, 2019	75	Ofev Capsules 100 mg Ofev Capsules 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change Change	Nintedanib ethanesulfonate	Drugs with a new additional indication for the treatment of systemic sclerosis associated interstitial lung disease. [Orphan drug]
6-1	Jan. 23, 2020	76	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Approval Approval	Upadacitinib hydrate	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 21, 2020	77	Orencia for I.V. Infusion 250 mg Orencia SC 125 mg Syringe 1 mL Orencia SC 125 mg Autoinjector 1 mL (Bristol-Myers Squibb K.K.)	Change Change Change	Abatacept (genetical recombination)	Drugs with a new additional indication for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 25, 2020	78	Dupixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Change	Dupilumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of chronic rhinosinusitis with nasal polyps (for use only in patients who have not responded sufficiently to conventional treatments).
6-1	Mar. 25, 2020	79	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Change	Mepolizumab (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
Oncology drugs	May 22, 2019	80	Pomalyst Capsules 1 mg Pomalyst Capsules 2 mg Pomalyst Capsules 3 mg Pomalyst Capsules 4 mg (Celgene K.K.)	Change Change Change Change	Pomalidomide	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Jun. 18, 2019	81	Portrazza Injection 800 mg (Eli Lilly Japan K.K.)	Approval	Necitumumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent squamous non-small cell lung cancer.
Oncology drugs	Jun. 18, 2019	82	Vanflyta Tablets 17.7 mg Vanflyta Tablets 26.5 mg (Daiichi Sankyo Company, Limited)	Approval Approval	Quizartinib hydrochloride	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory FLT3-ITD mutation-positive acute myeloid leukemia. [Orphan drug]
Oncology drugs	Jun. 18, 2019	83	Rozlytrek Capsules 100 mg Rozlytrek Capsules 200 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Entrectinib	Drugs with a new active ingredient indicated for the treatment of *NTRK* fusion gene positive advanced or recurrent solid tumors. [SAKIGAKE designation, Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 18, 2019	84	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change Change	Gemcitabine hydrochloride	Drugs with a new dosage indicated for the treatment of non-small cell lung cancer.
Oncology drugs	Jun. 18, 2019	85	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new indication for the treatment of patients with unresectable hepatocellular carcinoma whose serum AFP level is greater than 400 ng/mL and conditions have progressed after cancer chemotherapy.
Oncology drugs	Jun. 18, 2019	86	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication for maintenance treatment of BRCA mutation-positive ovarian cancer in patients who have received first chemotherapy. [Orphan drug]
Oncology drugs	Aug. 22, 2019	87	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of extensive-stage small-cell lung cancer. [Orphan drug]
Oncology drugs	Aug. 22, 2019	88	Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.)	Change Change	Trifluridine/Tipiracil hydrochloride	Drugs with a new indication for the treatment of unresectable advanced or recurrent gastric cancer that have progressed after chemotherapy.
Oncology drugs	Aug. 22, 2019	89	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Change Change	Daratumumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Aug. 22, 2019	90	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new dosage indicated for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 20, 2019	91	Venclexta Tablets 10 mg Venclexta Tablets 50 mg Venclexta Tablets 100 mg (AbbVie GK)	Approval Approval Approval	Venetoclax	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.
Oncology drugs	Sep. 20, 2019	92	Tecentriq Intravenous Infusion 840 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer.
Oncology drugs	Sep. 20, 2019	93	Erbitux Injection 100 mg (Merck Biopharma Co., Ltd.)	Change	Cetuximab (genetical recombination)	A drug with a new indication for the treatment of unresectable, advanced or recurrent colon or rectal cancer with wild-type *RAS*.
Oncology drugs	Sep. 20, 2019	94	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Nov. 22, 2019	95	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Nov. 22, 2019	96	Empliciti for I.V. Infusion 300 mg Empliciti for I.V. Infusion 400 mg (Bristol-Myers Squibb K.K.)	Change Change	Elotuzumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Nov. 22, 2019	97	Kyprolis for Intravenous Injection 10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Carfilzomib	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Dec. 20, 2019	98	Bavencio Injection 200 mg (Merck Biopharma Co., Ltd.)	Change	Avelumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Dec. 20, 2019	99	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	1) Drugs with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma. 2) Drugs with a new indication for the treatment of recurrent or metastatic head and neck cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 20, 2019	100	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	1) A drug with a new indication and a new dosage for the treatment of CD30-positive peripheral T-cell lymphoma. 2) A drug with a new additional pediatric dosage indicated for the treatment of relapsed or refractory CD30-positive Hodgkin's lymphoma and peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Dec. 20, 2019	101	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Change Change	Daratumumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Jan. 23, 2020	102	Nubeqa Tablets 300 mg (Bayer Yakuhin, Ltd.)	Approval	Darolutamide	A drug with a new active ingredient indicated for the treatment of non-metastatic, castration-resistant prostate cancer.
Oncology drugs	Jan. 23, 2020	103	Ibrance 25 mg Tablets Ibrance 125 mg Tablets (Pfizer Japan Inc.)	Approval Approval	Palbociclib	Drugs with a new indication in a new dosage form for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer.
Oncology drugs	Feb. 21, 2020	104	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	Lenalidomide hydrate	Drugs with new indications and a new dosage for the treatment of relapsed or refractory follicular lymphoma and marginal zone lymphoma.
Oncology drugs	Feb. 21, 2020	105	Alecensa Capsule 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Alectinib hydrochloride	A drug with a new indication and a new dosage for the treatment of relapsed or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma. [Orphan drug]
Oncology drugs	Feb. 21, 2020	106	Rozlytrek Capsules 100 mg Rozlytrek Capsules 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Entrectinib	Drugs with a new indication and a new dosage for the treatment of ROS1 fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Feb. 21, 2020	107	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change	Nivolumab (genetical recombination)	1) Drugs with a new indication for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy. 2) Drugs with a new indication for the treatment of unresectable advanced or recurrent oesophageal cancer that has progressed after cancer chemotherapy. 2) [Priority review]
Oncology drugs	Mar. 25, 2020	108	Onivyde I.V. Infusion 43 mg (Nihon Servier Co., Ltd.)	Approval	Irinotecan hydrochloride hydrate	A drug with a new indication in a new dosage form for the treatment of unresectable pancreatic cancer that has progressed after cancer chemotherapy.
Oncology drugs	Mar. 25, 2020	109	Cabometyx Tablets 20 mg Cabometyx Tablets 60 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Cabozantinib malate	Drugs with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Mar. 25, 2020	110	Velexbru Tablets 80 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Tirabrutinib hydrochloride	A drug with a new active ingredient indicated for the treatment of relapsed or refractory primary central nervous system (CNS) lymphoma. [Orphan drug]
Oncology drugs	Mar. 25, 2020	111	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Approval	Trastuzumab deruxtecan (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer in patients who have previously been treated with chemotherapy (for use only if refractory or intolerant to standard therapies). [Conditional early approval]
Oncology drugs	Mar. 25, 2020	112	Steboronine 9000 mg/300 mL for infusion (Stella Pharma Corporation)	Approval	Borofalan (^{10}B)	A drug with a new active ingredient indicated for the treatment of locally unresectable recurrent or unresectable advanced head and neck cancer. [SAKIGAKE designation]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 25, 2020	113	Tepmetko Tablets 250 mg (Merck Biopharma Co., Ltd.)	Approval	Tepotinib hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent *MET* exon 14 (METex14) skipping mutation-positive non-small cell lung cancer. [SAKIGAKE designation] [Orphan drug]
Oncology drugs	Mar. 25, 2020	114	Rethio 100 mg for Intravenous Infusion (Sumitonmo Dainippon Pharma Co., Ltd.)	Change	Thiotepa	A drug with a new indication and a new dosage for the conditioning treatment of malignant lymphoma in patients prior to autologous hematopoietic stem-cell transplantation.
Oncology drugs	Mar. 25, 2020	115	Ninlaro Capsules 2.3 mg Ninlaro Capsules 3 mg Ninlaro Capsules 4 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Ixazomib citrate	Drugs with a new indication and a new dosage for the maintenance treatment of multiple myeloma in patients after autologous hematopoietic stem-cell transplantation.
Oncology drugs	Mar. 25, 2020	116	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Busulfan	A drug with a new indication and a new dosage for the conditioning treatment of malignant lymphoma in patients prior to autologous hematopoietic stem-cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 20, 2019	117	Esperoct for I.V. Injection 500 Esperoct for I.V. Injection 1000 Esperoct for I.V. Injection 1500 Esperoct for I.V. Injection 2000 Esperoct for I.V. Injection 3000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	Turoctocog alfa pegol (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Feb. 21, 2020	118	Privigen 10% I.V. Drip Infusion 5 g/50 mL Privigen 10% I.V. Drip Infusion 10 g/100 mL Privigen 10% I.V. Drip Infusion 20 g/200 mL (CSL Behring K.K.)	Change Change Change	pH4-treated acidic normal human immunoglobulin	Drugs with new indications and a new dosage for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Mar. 25, 2020	119	Vonvendi Intravenous 1300 (Shire Japan K.K.)	Approval	Vonicog alfa (genetical recombination)	A drug with a new active ingredient indicated for the control of bleeding tendency in patients with von Willebrand disease (VWD). [Orphan drug]
Bio-CMC	Jun. 18, 2019	120	Bevacizumab BS Intravenous Infusion 100 mg [Pfizer] Bevacizumab BS Intravenous Infusion 400 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 1]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colorectal cancer.
Bio-CMC	Sep. 20, 2019	121	Teriparatide BS Subcutaneous Injection Kit 600 μg "MOCHIDA" (Mochida Pharmaceutical Co., Ltd.)	Approval	Teriparatide (genetical recombination) [teriparatide biosimilar 1]	A follow-on biologic indicated for the treatment of osteoporosis with a high risk of fracture.
Bio-CMC	Sep. 20, 2019	122	Darbepoetin Alfa BS Injection 5 μg Syringe [JCR] Darbepoetin Alfa BS Injection 10 μg Syringe [JCR] Darbepoetin Alfa BS Injection 15 μg Syringe [JCR] Darbepoetin Alfa BS Injection 20 μg Syringe [JCR] Darbepoetin Alfa BS Injection 30 μg Syringe [JCR] Darbepoetin Alfa BS Injection 40 μg Syringe [JCR] Darbepoetin Alfa BS Injection 60 μg Syringe [JCR] Darbepoetin Alfa BS Injection 120 μg Syringe [JCR] Darbepoetin Alfa BS Injection 180 μg Syringe [JCR] (JCR Pharmaceuticals Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [darbepoetin alfa biosimilar 1]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.
Bio-CMC	Sep. 20, 2019	123	Darbepoetin Alfa BS 5 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 10 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 15 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 20 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 30 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 40 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 60 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 120 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 180 μg Syringe for Injection “Sanwa” (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [darbepoetin alfa biosimilar 2]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Bio-CMC	Sep. 20, 2019	124	Darbepoetin Alfa BS Injection 5 μg Syringe "MYL" Darbepoetin Alfa BS Injection 10 μg Syringe "MYL" Darbepoetin Alfa BS Injection 15 μg Syringe "MYL" Darbepoetin Alfa BS Injection 20 μg Syringe "MYL" Darbepoetin Alfa BS Injection 30 μg Syringe "MYL" Darbepoetin Alfa BS Injection 40 μg Syringe "MYL" Darbepoetin Alfa BS Injection 60 μg Syringe "MYL" Darbepoetin Alfa BS Injection 120 μg Syringe "MYL" Darbepoetin Alfa BS Injection 180 μg Syringe "MYL" (Mylan EPD G.K.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [darbepoetin alfa biosimilar 3]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.
Bio-CMC	Sep. 20, 2019	125	Bevacizumab BS Intravenous Drip Infusions 100 mg “Daiichi Sankyo” Bevacizumab BS Intravenous Drip Infusions 400 mg “Daiichi Sankyo” (Daiichi Sankyo Company, Limited)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 2]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer.
Bio-CMC	Sep. 20, 2019	126	Rituximab BS Intravenous Infusion 100 mg [Pfizer] Rituximab BS Intravenous Infusion 500 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Rituximab (genetical recombination) [rituximab biosimilar 2]	Follow-on biologics indicated for the treatment of CD20-positive B-cell non-Hodgkin’s lymphoma, CD20-positive B-cell lymphoproliferative disorder associated with immunosuppression, granulomatosis with polyangiitis, and microscopic polyangiitis.
Bio-CMC	Mar. 25, 2020	127	Insulin Lispro BS Injection HU Solostar "Sanofi" Insulin Lispro BS Injection HU Cart "Sanofi" Insulin Lispro BS Injection HU 100 U/mL "Sanofi" (Sanofi K.K.)	Approval Approval Approval	Insulin lispro (genetical recombination) [Insulin lispro biosimilar 1]	Follow-on biologics indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2018

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
1	May 25, 2018	1	Xeljanz Tablets 5 mg (Pfizer Japan Inc.)	Change	Tofacitinib citrate	A drug with a new additional indication and a new dosage for the remission induction and maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jul. 2, 2018	2	Entyvio for I.V. Infusion 300 mg (Takeda Pharmaceutical Company Limited)	Approval	Vedolizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment and maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Aug. 21, 2018	3	Linzess Tablets 0.25 mg (Astellas Pharma Inc.)	Change	Linaclotide	A drug with a new additional indication for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Sep. 21, 2018	4	Movicol Combination Oral Solution (EA Pharma Co., Ltd.)	Approval	Macrogol 4000/Sodium chloride/Sodium bicarbonate/Potassium chloride	A new combination drug indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Sep. 21, 2018	5	Lagnos NF Jelly for Oral Administration Divided Pack 12 g (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval	Lactulose crystal	A drug with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Feb. 21, 2019	6	Imuran Tablets 50 mg (Aspen Japan K.K.) Azanin Tablets 50 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Azathioprine	Drugs with a new additional indication for the treatment of autoimmune hepatitis. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Mar. 26, 2019	7	Ferinject Solution for Injection/Infusion 500 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	Ferric carboxymaltose	A drug with a new active ingredient indicated for the treatment of iron-deficiency anemia.
1	Mar. 26, 2019	8	Aselend Injection 100 μg (Fujimoto Pharmaceutical Corporation)	Approval	Sodium selenite	A drug with a new active ingredient indicated for the treatment of hyposelenemia.
2	Jul. 2, 2018	9	Trerief Tablets 25 mg Trerief OD Tablets 25 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Change Change	Zonisamide	Drugs with a new additional indication and a new dosage for the treatment of parkinsonism in patients with dementia with Lewy bodies (in the cases where parkinsonism persists after using levodopa-containing products).
2	Nov. 21, 2018	10	Praluent 75 mg solution for injection in pre-filled pen Praluent 150 mg solution for injection in pre-filled pen (Sanofi K.K.)	Change Change	Alirocumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular events, and in whom treatment with HMG-CoA reductase inhibitors is not suitable).
2	Jan. 8, 2019	11	Minnebro Tablets 1.25 mg Minnebro Tablets 2.5 mg Minnebro Tablets 5 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval	Esaxerenone	Drugs with a new active ingredient indicated for the treatment of hypertension.
2	Jan. 8, 2019	12	Demser Capsules 250 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Metirosine	A drug with a new active ingredient indicated for the improvement of the status of excessive catecholamine secretion in patients with pheochromocytoma. [Orphan drug]
2	Jan. 8, 2019	13	(1) Bisono Tape 2 mg (2) Bisono Tape 4 mg (3) Bisono Tape 8 mg (Toa Eiyo Ltd.)	Approval Change Change	Bisoprolol	(1) A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of tachycardiac atrial fibrillation. (2)(3) Drugs with a new additional indication, a new dosage, and other characteristics indicated for the treatment of tachycardiac atrial fibrillation.
2	Mar. 26, 2019	14	Rosuzet Combination Tablets LD Rosuzet Combination Tablets HD (MSD K.K.)	Approval Approval	Ezetimibe/Rosuvastatin calcium	New combination drugs indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Mar. 26, 2019	15	Onoact for Intravenous Infusion 50 mg Onoact for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Landiolol hydrochloride	Drugs with new additional indications and a new dosage for the following life-threatening cardiac arrhythmia in refractory and urgent cases: ventricular fibrillation and hemodynamically unstable ventricular tachycardia. [Orphan drug]
2	Mar. 26, 2019	16	Vyndaqel Capsules 20 mg (Pfizer Japan Inc.)	Change	Tafamidis meglumine	A drug with a new additional indication and a new dosage for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary). [SAKIGAKE designation, Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
3-1	May 25, 2018	17	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of spasmodic dysphonia.
3-1	Sep. 21, 2018	18	Lora-Pita Intravenous Injection 2 mg (Pfizer Japan Inc.)	Approval	Lorazepam	A drug with a new route of administration indicated for the treatment of status epilepticus.
3-1	Jan. 8, 2019	19	Selincro Tablets 10 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Nalmefene hydrochloride hydrate	A drug with a new active ingredient indicated to reduce alcohol consumption in patients with alcohol dependence.
3-1	Jan. 8, 2019	20	(1) Vimpat Dry Syrup 10% (2) Vimpat Tablets 50 mg (3) Vimpat Tablets 100 mg (4) Vimpat for I.V. Infusion 200 mg (UCB Japan Co., Ltd.)	Approval Change Change Approval	Lacosamide	(1)-(3) A drug in an additional dosage form and drugs with a new additional pediatric dosage indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. (4) A drug with a new route of administration indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. It is used as an alternative therapy for lacosamide oral formulation in patients who are temporarily unable to be administered orally.
3-1	Jan. 8, 2019	21	Tarlige Tablets 2.5 mg Tarlige Tablets 5 mg Tarlige Tablets 10 mg Tarlige Tablets 15 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval Approval	Mirogabalin besilate	Drugs with a new active ingredient indicated for the treatment of peripheral neuropathic pain.
3-1	Feb. 21, 2019	22	Taurine powder 98% “Taisho” (Taisho Pharmaceutical Co., Ltd.)	Change	Taurine	A drug with a new additional indication and a new dosage for the inhibition of stroke-like episodes in patients with mitochondrial myopathy, encephalopathy, lactic acidosis and stroke-like episodes (MELAS). [Orphan drug]
3-1	Mar. 26, 2019	23	Vyvanse Capsules 20 mg Vyvanse Capsules 30 mg (Shionogi & Co., Ltd.)	Approval Approval	Lisdexamfetamine mesilate	Drugs with a new active ingredient indicated for the treatment of pediatric attention deficit/hyperactivity disorder (AD/HD).
3-1	Mar. 26, 2019	24	Privigen 10% I.V. Drip Infusion 5 g/50 mL Privigen 10% I.V. Drip Infusion 10 g/100 mL Privigen 10% I.V. Drip Infusion 20 g/200 mL (CSL Behring K.K.)	Approval Approval Approval	pH4-treated acidic normal human immunoglobulin	Drugs with a new active ingredient indicated for the improvement of muscle weakness in chronic inflammatory demyelinating polyneuropathy and for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (in the cases where patients show an improvement in their acute phase treatment).
3-1	Mar. 26, 2019	25	Hizentra 20% S.C. Injection 1 g/5 mL Hizentra 20% S.C. Injection 2 g/10 mL Hizentra 20% S.C. Injection 4 g/20 mL (CSL Behring K.K.)	Change Change Change	pH4-treated acidic normal human immunoglobulin (subcutaneous injection)	Drugs with a new additional indication and a new dosage for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (in the cases where patients show an improvement in their acute phase treatment).
3-2	Jul. 2, 2018	26	Fentos Tape 0.5 mg Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Change Change Change Change Change	Fentanyl citrate	Drugs with a new dosage and in additional dosage form indicated for: (1) analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics or weak opioid analgesics (for use only in patients who switch from other opioid analgesics); or (2) analgesia in moderate to severe chronic pain (for use only in patients who switch from other opioid analgesics).
3-2	Sep. 21, 2018	27	Eybelis Ophthalmic Solution 0.002% (Santen Pharmaceutical Co., Ltd.)	Approval	Omidenepag isopropyl	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3-2	Nov. 29, 2018	28	Precedex Intravenous Solution 200 μg "Pfizer" Precedex Intravenous Solution 200 μg/50 mL Syringe "Pfizer" (Pfizer Japan Inc.) Precedex Intravenous Solution 200 μg "Maruishi" Precedex Intravenous Solution 200 μg/50 mL Syringe "Maruishi" (Maruishi Pharmaceutical Co., Ltd.)	Change Change Change Change	Dexmedetomidine hydrochloride	Drugs with a new additional pediatric dosage indicated for sedation during artificial respiration and after weaning in patients in intensive care.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
3-2	Mar. 26, 2019	29	Lafenta Tape 1.38 mg Lafenta Tape 2.75 mg Lafenta Tape 5.5 mg Lafenta Tape 8.25 mg Lafenta Tape 11 mg (Nippon Zoki Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Fentanyl	Drugs in a new dosage form indicated for analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics or weak opioid analgesics (for use only in patients who switch from other opioid analgesics).
4	Jul. 2, 2018	30	Dafclir Tablets 200 mg (Astellas Pharma Inc.)	Approval	Fidaxomicin	A drug with a new active ingredient indicated for the treatment of infectious enteritis (including pseudomembranous colitis) caused by *C. difficile* .
4	Jul. 2, 2018	31	Spiramycin Tablets 1.5M IU "Sanofi" (Sanofi K.K.)	Approval	Spiramycin	A drug with a new active ingredient indicated for the prophylaxis of congenital toxoplasmosis. [Orphan drug]
4	(1) Aug. 21, 2018 (2) Aug. 22, 2018	32	(1) Valixa Tablets 450 mg (2) Valixa Dry Syrup 5000 mg (Mitsubishi Tanabe Pharma Corporation)	(1) Change (2) Approval	Valganciclovir hydrochloride	Drugs with a new additional pediatric dosage and a drug in an additional dosage form of dry syrup, indicated for the prevention of cytomegalovirus disease in organ transplant patients (excluding hematopoietic stem cell transplantation). [Public knowledge-based application after PAFSC's preliminary assessment]
4	Sep. 21, 2018	33	Oravi Mucoadhesive Tablets 50 mg (Sosei Co., Ltd.)	Approval	Miconazole	A drug in a new dosage form indicated for the treatment of oropharyngeal candidiasis caused by *Candida* .
4	Jan. 8, 2019	34	Zerbaxa Combination for Intravenous Drip Infusion (MSD K.K.)	Approval	Ceftolozane sulfate/Tazobactam sodium	A new combination drug with new active ingredients indicated for the treatment of cystitis, pyelonephritis, peritonitis, intra-abdominal abscess, cholecystitis, and liver abscess caused by Zerbaxa-sensitive *Streptococcus* spp., *Escherichia coli* , *Citrobacter* spp., *Klebsiella* spp., *Enterobacter* spp., *Proteus* spp., or *Pseudomonas aeruginosa* .
4	Jan. 8, 2019	35	Epclusa Combination Tablets (Gilead Sciences K.K.)	Approval	Sofosbuvir/Velpatasvir	A new combination drug with a new active ingredient indicated for: - Improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C who have previously been treated. - Improvement of viremia in patients with decompensated cirrhosis type C. [Priority review]
4	Jan. 8, 2019	36	Rebetol Capsules 200 mg (MSD K.K.)	Change	Ribavirin	A drug with a new additional indication and a new dosage, used in combination with sofosbuvir and velpatasvir, for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C who have previously been treated. [Expedited review]
4	Feb. 21, 2019	37	Famvir Tab. 250 mg (Asahi Kasei Pharma Corporation)	Change	Famciclovir	A drug with a new dosage indicated for the treatment of herpes simplex.
4	Mar. 26, 2019	38	Foscavir Infusion Solution 24 mg/mL (Clinigen K.K.)	Change	Foscarnet sodium hydrate	A drug with a new additional indication and a new dosage indicated for the treatment of human herpesvirus 6 encephalitis after hematopoietic stem cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 2, 2018	39	Jemina Tablets (Nobelpharma Co., Ltd.)	Approval	Levonorgestrel/Ethinylestradiol	A new combination drug indicated for the treatment of dysmenorrhea.
5	Sep. 21, 2018	40	Beova Tablets 50 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	Vibegron	A drug with a new active ingredient indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
5	Jan. 8, 2019	41	Relumina Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval	Relugolix	A drug with a new active ingredient indicated for the alleviation of menorrhagia, lower abdominal pain, backache, and anemia that are associated with uterine fibroids.
5	Feb. 21, 2019	42	Gonalef for Subcutaneous Injection 75 Gonalef for Subcutaneous Injection 150 Gonalef for Subcutaneous Injection Pen 300 Gonalef for Subcutaneous Injection Pen 450 Gonalef for Subcutaneous Injection Pen 900 (Merck Serono Co., Ltd.)	Change Change Change Change Change	Follitropin alfa (genetical recombination)	Drugs with changes in dosage regimen indicated for the induction of spermatogenesis in male hypogonadotropic hypogonadism (MHH) and with a new additional indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
5	Mar. 26, 2019	43	Enoras Liquid for Enteral Use (EN Otsuka Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding, especially for patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
6-1	May 25, 2018	44	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Change	Mepolizumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of eosinophilic granulomatosis with polyangiitis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Jul. 2, 2018	45	Ilaris for S.C. Injection 150 mg Ilaris Solution for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change Change	Canakinumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of systemic juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Aug. 21, 2018	46	Taltz 80 mg Syringe for SC Injection Taltz 80 mg Auto-Injector for SC Injection (Eli Lilly Japan K.K.)	Change Change	Ixekizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Sep. 21, 2018	47	Firazyr Subcutaneous Injection 30 mg Syringe (Shire Japan KK)	Approval	Icatibant acetate	A drug with a new active ingredient indicated for the treatment of acute attacks of hereditary angioedema. [Orphan drug]
6-1	Nov. 21, 2018	48	Tremfya Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Change	Guselkumab (genetical recombination)	A drug with a new additional indication for the treatment of palmoplantar pustulosis in patients who have not responded sufficiently to conventional therapies.
6-1	Dec. 21, 2018	49	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg Pen (Novartis Pharma K.K.)	Change Change	Secukinumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 21, 2019	50	Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL (AbbVie GK)	Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of hidradenitis suppurativa. [Orphan drug]
6-1	Mar. 26, 2019	51	Skyrizi 75 mg for S.C. Injection Syringe 0.83 mL (AbbVie GK)	Approval	Risankizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 26, 2019	52	Trelegy 100 Ellipta 14 doses Trelegy 100 Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval	Fluticasone furoate/Umeclidinium bromide/Vilanterol trifenatate	New combination drugs indicated for the relief of symptoms in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with an inhaled corticosteroid, a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist).
6-1	Mar. 26, 2019	53	Smyraf Tablets 50 mg Smyraf Tablets 100 mg (Astellas Pharma Inc.)	Approval Approval	Peficitinib hydrobromide	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 26, 2019	54	Dupixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Change	Dupilumab (genetical recombination)	A drug with a new additional indication, a new dosage and other characteristics for the treatment of bronchial asthma (for use only in patients with severe or intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Mar. 26, 2019	55	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Tocilizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of cytokine release syndrome induced by tumor-specific T-cell infusion therapy. [Expedited review]
6-1	Mar. 26, 2019	56	Rheumatrex Capsules 2 mg (Pfizer Japan Inc.)	Change	Methotrexate	A drug with new additional indications and a new dosage for the treatment of plaque psoriasis in patients who have not responded sufficiently to topical therapy, or psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis . [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
6-2	Sep. 21, 2018	57	Tradiance Combination Tablets AP Tradiance Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Empagliflozin/Linagliptin	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of empagliflozin with linagliptin is deemed appropriate).
6-2	Sep. 21, 2018	58	Metoana Combination Tablets LD Metoana Combination Tablets HD (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval	Anagliptin/Metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of anagliptin with metformin hydrochloride is deemed appropriate).
6-2	Dec. 21, 2018	59	Suglat Tablets 25 mg Suglat Tablets 50 mg (Astellas Pharma Inc.)	Change Change	Ipragliflozin L-proline	Drugs with a new additional indication and a new dosage for the treatment of type 1 diabetes mellitus.
6-2	Jan. 8, 2019	60	Evenity Subcutaneous Injection 105 mg Syringe (Amgen Astellas BioPharma K.K.)	Approval	Romosozumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Mar. 26, 2019	61	Revcovi 2.4 mg for Intramuscular Injection (Teijin Pharma Limited)	Approval	Elapegademase (genetical recombination)	A drug with a new active ingredient indicated for the treatment of adenosine deaminase deficiency. [Orphan drug]
6-2	Mar. 26, 2019	62	Forxiga 5 mg Tablets Forxiga 10 mg Tablets (AstraZeneca K.K.)	Change Change	Dapagliflozin propylene glycolate hydrate	Drugs with a new additional indication and a new dosage for the treatment of type 1 diabetes mellitus.
In vivo diagnostics	Jul. 2, 2018	63	Diagnogreen for Injection 25 mg (Daiichi Sankyo Company, Limited)	Change	Indocyanine green	A drug with a new additional indication and a new dosage for the evaluation of vascular and tissue blood flow. [Public knowledge-based application after PAFSC's preliminary assessment]
In vivo diagnostics	Sep. 21, 2018	64	Dobutrex Injection 100 mg Dobutrex Kit for Intravenous Infusion 200 mg Dobutrex Kit for Intravenous Infusion 600 mg (Kyowa Pharmaceutical Industry Co., Ltd.) Dobutamine Injection 100 mg [Pfizer] Dobutamine Injection 200 mg Kit [Pfizer] Dobutamine Injection 600 mg Kit [Pfizer] (Mylan Seiyaku Ltd.)	Change Change Change Change Change Change	Dobutamine hydrochloride	Drugs with a new additional indication and a new dosage for stress echocardiography. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	May 25, 2018	65	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	May 25, 2018	66	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Jul. 2, 2018	67	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Approval Approval	Durvalumab (genetical recombination)	Drugs with a new active ingredient indicated for the maintenance treatment of locally-advanced, unresectable non-small cell lung cancer following definitive chemoradiation therapy.
Oncology drugs	Jul. 2, 2018	68	Gazyva Intravenous Infusion 1000 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Obinutuzumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of CD20-positive follicular lymphoma.
Oncology drugs	Jul. 2, 2018	69	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new additional indication for the treatment of unresectable or recurrent BRCA mutation-positive and HER2-negative breast cancer in patients who have previously been treated with chemotherapy. [Orphan drug]
Oncology drugs	Jul. 2, 2018	70	Treakisym Injection 25 mg Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change Change	Bendamustine hydrochloride	Drugs with a new dosage indicated for the treatment of low-grade B-cell non-Hodgkin's lymphoma.
Oncology drugs	Jul. 2, 2018	71	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Change Change	Dabrafenib mesilate	Drugs with a new additional indication and a new dosage indicated for the treatment of BRAF mutation-positive melanoma. [Orphan drug]
Oncology drugs	Jul. 2, 2018	72	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Change Change	Trametinib dimethyl sulfoxide	Drugs with a new additional indication and a new dosage indicated for the treatment of BRAF mutation-positive melanoma. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jul. 2, 2018	73	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new additional indication for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma). [Orphan drug]
Oncology drugs	Aug. 21, 2018	74	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	(1) Drugs with new indications and a new dosage for the treatment of unresectable or recurrent malignant pleural mesothelioma and melanoma that have progressed after chemotherapy. [Orphan drug] (2) Drugs with a new dosage indicated for the treatment of melanoma, unresectable or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable or recurrent gastric cancer that has progressed after chemotherapy, and (3) unresectable or metastatic renal cell carcinoma. [(3) Priority review]
Oncology drugs	Aug. 21, 2018	75	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Aug. 21, 2018	76	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Change Change	Osimertinib mesilate	Drugs with a new indication for the treatment of inoperable or recurrent epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer. [Priority review]
Oncology drugs	Aug. 21, 2018	77	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Change	Mogamulizumab (genetical recombination)	A drug with new indications and a new dosage for the treatment of relapsed or refractory cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Sep. 21, 2018	78	Verzenio Tablets 50 mg Verzenio Tablets 100 mg Verzenio Tablets 150 mg (Eli Lilly Japan K.K.)	Approval Approval Approval	Abemaciclib	Drugs with a new active ingredient indicated for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer.
Oncology drugs	Sep. 21, 2018	79	Blincyto for Drip Infusion 35 μg (Amgen Astellas BioPharma K.K.)	Approval	Blinatumomab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Sep. 21, 2018	80	Lorbrena Tablets 25 mg Lorbrena Tablets 100 mg (Pfizer Japan Inc.)	Approval Approval	Lorlatinib	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer with resistance or intolerance to ALK tyrosine kinase inhibitors. [Conditional early approval]
Oncology drugs	Sep. 21, 2018	81	Xospata Tablets 40 mg (Astellas Pharma Inc.)	Approval	Gilteritinib fumarate	A drug with a new active ingredient indicated for the treatment of relapsed or refractory FLT3 mutation-positive acute myeloid leukemia. [Orphan drug, SAKIGAKE designation]
Oncology drugs	Sep. 21, 2018	82	Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Nivolumab (genetical recombination)	(1) A drug with new indications and a new dosage in an additional dosage form for the treatment of unresectable or recurrent malignant pleural mesothelioma and melanoma that have progressed after chemotherapy. [Orphan drug] (2) A drug with a new dosage in an additional dosage form indicated for the treatment of melanoma, unresectable or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable or recurrent gastric cancer that has progressed after chemotherapy, and (3) unresectable or metastatic renal cell carcinoma. [(3) Priority review]
Oncology drugs	Sep. 21, 2018	83	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	A drug with a new indication and a new dosage for the treatment of CD30-positive Hodgkin's lymphoma [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Sep. 21, 2018	84	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.) Oxaliplatin i.v. Infusion 50 mg "Sawai" Oxaliplatin i.v. Infusion 100 mg "Sawai" Oxaliplatin i.v. Infusion 200 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Oxaliplatin I.V. Infusion Solution 50 mg "NK" Oxaliplatin I.V. Infusion Solution 100 mg "NK" Oxaliplatin I.V. Infusion Solution 200 mg "NK" (Nippon Kayaku Co., Ltd.) Oxaliplatin I.V. Infusion 50 mg "Nipro" Oxaliplatin I.V. Infusion 100 mg "Nipro" Oxaliplatin I.V. Infusion 200 mg "Nipro" (Nipro Corporation) Oxaliplatin I.V. Drip Infusion 50 mg "DSEP" Oxaliplatin I.V. Drip Infusion 100 mg "DSEP" Oxaliplatin I.V. Drip Infusion 200 mg "DSEP" (Daiichi Sankyo Espha Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Oxaliplatin	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	85	(1) Isovorin Injection 25 mg Isovorin Injection 100 mg (Pfizer Japan Inc.) (2) Levofolinate for I.V. Drip Infusion 25 "Ohara" Levofolinate for I.V. Drip Infusion 100 "Ohara" (Ohara Pharmaceutical Co., Ltd.) (3) Levofolinate for I.V. Infusion 25 mg “Yakult” Levofolinate for I.V. Infusion 100 mg “Yakult” (Yakult Honsha Co., Ltd.) (4) Levofolinate for I.V. Infusion 25 mg "NK" Levofolinate for I.V. Infusion100 mg "NK" (Takata Pharmaceutical Co.,Ltd.) (5) Levofolinate for I.V. Infusion 25 mg "NP" Levofolinate for I.V. Infusion 100 mg "NP" (Nipro Corporation)	Change Change Change Change Change Change Change Change Change Change	Except (2): Levofolinate calcium (2): Calcium levofolinate hydrate	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	86	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	87	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Busulfan	A drug with a new additional once-daily dosage indicated for a conditioning regimen prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem cell transplantation for Ewing's sarcoma (ES) family tumors and neuroblastoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Oct. 10, 2018	88	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Change	Pertuzumab (genetical recombination)	A drug with a new indication for the treatment of HER2-positive breast cancer.
Oncology drugs	Dec. 21, 2018	89	Keytruda Injection 100 mg Keytruda Injection 20 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with new indications and a new dosage for the treatment of: (1) advanced or recurrent microsatellite instability-high (MSI-High) solid tumors that have progressed after cancer chemotherapy (for use only if refractory or intolerant to standard therapies), (2) melanoma, and (3) unresectable advanced or recurrent non-small cell lung cancer. [(1) Conditional early approval, (2) Orphan drug, (3) Priority review]
Oncology drugs	Dec. 21, 2018	90	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer. [Priority review]
Oncology drugs	Jan. 8, 2019	91	Braftovi Capsules 50 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Encorafenib	A drug with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF gene mutation. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jan. 8, 2019	92	Mektovi Tablets 15 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Binimetinib	A drug with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF gene mutation. [Orphan drug]
Oncology drugs	Jan. 8, 2019	93	Vizimpro Tablets 15 mg Vizimpro Tablets 45 mg (Pfizer Japan Inc.)	Approval Approval	Dacomitinib hydrate	Drugs with a new active ingredient indicated for the treatment of inoperable or recurrent non-small cell lung cancer with EGFR gene mutation. [Priority review]
Oncology drugs	Jan. 8, 2019	94	Gonax 80 mg for Subcutaneous Injection Gonax 120 mg for Subcutaneous Injection Gonax 240 mg for Subcutaneous Injection (Astellas Pharma Inc.)	Change Change Approval	Degarelix acetate	Drugs with a new dosage and a drug in an additional dosage form indicated for the treatment of prostate cancer.
Oncology drugs	Feb. 21, 2019	95	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Change	Ceritinib	A drug with a new dosage indicated for the treatment of unresectable advanced/relapsed *ALK* fusion gene-positive non-small-cell lung cancer.
Oncology drugs	Feb. 21, 2019	96	Temodal Capsules 20 mg Temodal Capsules 100 mg Temodal Infusion 100 mg (MSD K.K.) Temozolomide Tab. 20 mg “NK” Temozolomide Tab. 100 mg “NK” (Nippon Kayaku Co., Ltd.)	Change Change Change Change Change	Temozolomide	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory Ewing's sarcoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 26, 2019	97	Erleada Tablets 60 mg (Janssen Pharmaceutical K.K.)	Approval	Apalutamide	A drug with a new active ingredient indicated for the treatment of non-metastatic, castration-resistant prostate cancer.
Oncology drugs	Mar. 26, 2019	98	Rethio 100 mg for Intravenous Infusion (Sumitomo Dainippon Pharma Co., Ltd.)	Approval	Thiotepa	A drug with a new active ingredient indicated for the conditioning treatment of solid tumors in pediatric patients prior to autologous hematopoietic stem-cell transplantation. [Expedited review]
Oncology drugs	Mar. 26, 2019	99	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of CD20-positive chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Mar. 26, 2019	100	Vepesid Injection 100 mg (Bristol-Myers Squibb K.K.) Lastet Inj. 100 mg/5 mL (Nippon Kayaku Co., Ltd.) Etoposide Intravenous Infusion 100 mg "Sandoz" (Sandoz K.K.) Etoposide Intravenous Infusion 100 mg "Taiyo" (Teva Takeda Pharma Ltd.) Etoposide Intravenous Infusion 100 mg "SN" (Shiono Chemical Co., Ltd.)	Change Change Change Change Change	Etoposide	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	101	Fludara 50 mg for Intravenous Infusion (Sanofi K.K.)	Change	Fludarabine phosphate	A drug with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	102	Cylocide N Injection 400 mg Cylocide N Injection 1 g (Nippon Shinyaku Co., Ltd.) Cytarabine for I.V. Infusion 400 mg “Teva” Cytarabine for I.V. Infusion 1 g “Teva” (Teva Takeda Pharma Ltd.)	Change Change Change Change	Cytarabine	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	103	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	104	Treakisym Injection 25 mg Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change Change	Bendamustine hydrochloride	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
AIDS drugs	May 14, 2018	105	Isentress Tablets 600 mg (MSD K.K.)	Approval	Raltegravir potassium	A drug with a new dosage and in an additional dosage form indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Aug. 21, 2018	106	Odefsey Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Rilpivirine hydrochloride /Emtricitabine/Tenofovir alafenamide fumarate	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
AIDS drugs	Nov. 26, 2018	107	Juluca Combination Tablets (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium/Rilpivirine hydrochloride	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Mar. 26, 2019	108	Biktarvy Combination Tablets (Gilead Sciences K.K.)	Approval	Bictegravir sodium/ Emtricitabine/Tenofovir alafenamide fumarate	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
Vaccines	Mar. 26, 2019	109	Rabipur Intramuscular Injection (GlaxoSmithKline K.K.)	Approval	Freeze-dried inactivated tissue culture rabies vaccine	A drug with a new active ingredient indicated for the pre-exposure and post-exposure prophylaxis against rabies.
Blood products	Jul. 2, 2018	110	Refixia I.V. Injection 500 Refixia I.V. Injection 1000 Refixia I.V. Injection 2000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	Nonacog beta pegol (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with coagulation factor IX deficiency.
Blood products	Sep. 21, 2018	111	Jivi for iv injection 250 Jivi for iv injection 500 Jivi for iv injection 1000 Jivi for iv injection 2000 Jivi for iv injection 3000 (Bayer Yakuhin, Ltd.)	Approval Approval Approval Approval Approval	Damoctocog alfa pegol (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Dec. 21, 2018	112	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Emicizumab (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with congenital blood coagulation factor VIII deficiency with blood coagulation factor VIII inhibitors. [Orphan drug]
Blood products	Dec. 21, 2018	113	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Emicizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency without blood coagulation factor VIII inhibitors.
Bio-CMC	Jul. 2, 2018	114	Infliximab BS for I.V. Infusion 100 mg [Pfizer] (Pfizer Japan Inc.)	Approval	Infliximab (genetical recombination) [infliximab biosimilar 3]	Follow-on biologics indicated for the treatment of rheumatoid arthritis, psoriasis, Crohn’s disease, and ulcerative colitis.
Bio-CMC	Sep. 21, 2018	115	Agalsidase Beta BS I.V. Infusion 5 mg [JCR] Agalsidase Beta BS I.V. Infusion 35 mg [JCR] (JCR Pharmaceuticals Co., Ltd.)	Approval Approval	Agalsidase beta (genetical recombination) [agalsidase beta biosimilar 1]	Follow-on biologics indicated for the treatment of Fabry disease.
Bio-CMC	Sep. 21, 2018	116	Trastuzumab BS for Intravenous Drip Infusions 60 mg "Daiichi Sankyo" Trastuzumab BS for Intravenous Drip Infusions 150 mg "Daiichi Sankyo" (Daiichi Sankyo Company, Limited)	Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 2]	Follow-on biologics indicated for the treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2.
Bio-CMC	Sep. 21, 2018	117	Trastuzumab BS for Intravenous Infusion 60 mg [Pfizer] Trastuzumab BS for Intravenous Infusion 150 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 3]	Follow-on biologics indicated for the treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2.
Bio-CMC	Mar. 26, 2019	118	Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. “TY” Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. “TY” Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. “TY” Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. “TY” (YL Biologics Limited) Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. “Nichiiko” Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. “Nichiiko” Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. “Nichiiko” Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. “Nichiiko” (Kyowa Pharmaceutical Industry Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval	Etanercept (genetical recombination) [etanercept biosimilar 2]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) and polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2017

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	May 18, 2017	1	Asacol Tablets 400 mg (Zeria Pharmaceutical Co., Ltd.)	Change	Mesalazine	A drug with a new dosage indicated for the treatment of ulcerative colitis (excluding severe cases).
1	May 18, 2017	2	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new dosage indicated for the treatment of Crohn's disease. [Orphan drug]
1	Jun. 26, 2017	3	Oldamin for Injection 1 g (Fuji Chemical Industries Co., Ltd.)	Change	Monoethanolamine oleate	A drug with a new additional indication and a new dosage indicated for the regression of gastric varices.
1	Jul. 3, 2017	4	Jadenu Granules Sachet 90 mg Jadenu Granules Sachet 360 mg (Novartis Pharma K.K.)	Approval Approval	Deferasirox	Drugs in a new dosage form indicated for the treatment of chronic iron overload due to blood transfusions (in patients for whom injection of iron chelating agents is inappropriate).
1	Aug. 25, 2017	5	Kenketu Nonthron 500 for injection Kenketu Nonthron 1500 for injection (Nihon Pharmaceutical Co., Ltd.)	Change Change	Lyophilized human antithrombin III concentrate	Drugs with a new additional indication and a new dosage for the treatment of portal vein thrombosis associated with decreased antithrombin III.
1	Aug. 25, 2017	6	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (Novartis Pharma K.K.)	Change Change	Eltrombopag olamine	Drugs with a new additional indication and a new dosage for the treatment of aplastic anemia. [Orphan drug]
1	Aug. 25, 2017	7	Neoral Oral Solution 10% Neoral 10 mg Capsules Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Ciclosporin	Drugs with a revised indication and a new dosage for the treatment of aplastic anemia which is not severe. [Expedited review]
1	Sep. 22, 2017	8	Pariet Tablets 5 mg Pariet Tablets 10 mg (Eisai Co., Ltd.)	Change Change	Rabeprazole sodium	Drugs with a new dosage indicated for the treatment of reflux esophagitis.
1	Sep. 27, 2017	9	Rectabul 2 mg Rectal Foam 14 Doses (EA Pharma Co., Ltd.)	Approval	Budesonide	A drug with a new route of administration indicated for the treatment of ulcerative colitis which is not severe.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Dec. 25, 2017	10	Zyprexa Tablets 2.5 mg Zyprexa Tablets 5 mg Zyprexa Tablets 10 mg Zyprexa Fine Granules 1% Zyprexa Zydis Tablets 2.5 mg Zyprexa Zydis Tablets 5 mg Zyprexa Zydis Tablets 10 mg (Eli Lilly Japan K.K.) Olanzapine Tablets 2.5 mg "DSEP" Olanzapine Tablets 5 mg "DSEP" Olanzapine Tablets 10 mg "DSEP" Olanzapine Fine Granules 1% "DSEP" Olanzapine OD Tablets 2.5 mg "DSEP" Olanzapine OD Tablets 5 mg "DSEP" Olanzapine OD Tablets 10 mg "DSEP" (Daiichi Sankyo Espha Co., Ltd.) Olanzapine Tablets 2.5 mg "Nichi-Iko" Olanzapine Tablets 5 mg "Nichi-Iko" Olanzapine Tablets 10 mg "Nichi-Iko" Olanzapine Fine Granules 1% "Nichi-Iko" Olanzapine OD Tablets 2.5 mg "Nichi-Iko" Olanzapine OD Tablets 5 mg "Nichi-Iko" Olanzapine OD Tablets 10 mg "Nichi-Iko" (Nichi-Iko Pharmaceutical Co., Ltd.) Olanzapine Fine Granules 1% "Pfizer" (Mylan Seiyaku Ltd.) Olanzapine Tablets 2.5 mg "Nipro" Olanzapine Tablets 5 mg "Nipro" Olanzapine Tablets 10 mg "Nipro" Olanzapine Fine Granules 1% "Nipro" Olanzapine OD Tablets 5 mg "Nipro" Olanzapine OD Tablets 10 mg "Nipro" (Nipro Corporation) Olanzapine Tablets 2.5 mg "Pfizer" Olanzapine Tablets 5 mg "Pfizer" Olanzapine Tablets 10 mg "Pfizer" Olanzapine OD Tablets 2.5 mg "Pfizer" Olanzapine OD Tablets 5 mg "Pfizer" Olanzapine OD Tablets 10 mg "Pfizer" (Daito Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Olanzapine	Drugs with a new additional indication and a new dosage indicated for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with the administration of antineoplastic drugs (cisplatin, etc.). [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Jan. 19, 2018	11	Nexium Capsules 10 mg Nexium Capsules 20 mg Nexium Granules for Suspension 10 mg Nexium Granules for Suspension 20 mg (AstraZeneca K.K.)	Change Change Approval Approval	Esomeprazole magnesium hydrate	Drugs with a new additional pediatric dosage and in additional dosage forms indicated for the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease, and Zollinger-Ellison syndrome.
1	Jan. 19, 2018	12	Goofice Tablets 5 mg (EA Pharma Co., Ltd.)	Approval	Elobixibat hydrate	A drug with a new active ingredient indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Feb. 23, 2018	13	Certican Tablets 0.25 mg Certican Tablets 0.5 mg Certican Tablets 0.75 mg (Novartis Pharma K.K.)	Change Change Change	Everolimus	Drugs with a new additional indication and a new dosage for the inhibition of rejection in liver transplantation.
1	Mar. 23, 2018	14	Orkedia Tablets 1 mg Orkedia Tablets 2 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval Approval	Evocalcet	Drugs with a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis.
1	Mar. 23, 2018	15	Rapalimus Gel 0.2% (Nobelpharma Co., Ltd.)	Approval	Sirolimus	A drug with a new route of administration indicated for the treatment of skin lesions associated with tuberous sclerosis complex. [Orphan drug, SAKIGAKE designation]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Jun. 26, 2017	16	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Jul. 3, 2017	17	Parmodia Tab. 0.1 mg (Kowa Company, Ltd.)	Approval	Pemafibrate	A drug with a new active ingredient indicated for the treatment of hyperlipidaemia (including familial hyperlipidaemia).
2	Sep. 27, 2017	18	Atozet Combination Tablets LD Atozet Combination Tablets HD (MSD K.K.)	Approval Approval	Ezetimibe/ Atorvastatin calcium hydrate	New combination drugs indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Sep. 27, 2017	19	Revatio Tablets 20 mg Revatio Dry Syrup for Suspension 900 mg Revatio OD Film 20 mg (Pfizer Japan Inc.)	Change Approval Approval	Sildenafil citrate	Drugs with a new additional pediatric dosage and in additional dosage forms indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Jan. 19, 2018	20	Ibulief I.V. Injection 20 mg (Senju Pharmaceutical Co., Ltd.)	Approval	Ibuprofen L-lysine	A drug with a new active ingredient indicated for the treatment of patent ductus arteriosus in premature infants when conservative treatment (fluid restriction, diuretic use, etc.) is not sufficiently effective.
2	Mar. 23, 2018	21	Azilect Tablets 0.5 mg Azilect Tablets 1 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Rasagiline mesilate	Drugs with a new active ingredient indicated for the treatment of Parkinson’s disease.
3-1	Jul. 3, 2017	22	Bipresso Extended Release Tablets 50 mg Bipresso Extended Release Tablets 150 mg (Astellas Pharma Inc.)	Approval Approval	Quetiapine fumarate	Drugs with a new indication in new dosage form indicated for the improvement of depressive symptoms in patients with bipolar disorder.
3-1	Jul. 3, 2017	23	Spinraza Intrathecal injection 12 mg (Biogen Japan Ltd.)	Approval	Nusinersen sodium	A drug with a new active ingredient indicated for the treatment of infantile spinal muscular atrophy. [Orphan drug]
3-1	Jul. 3, 2017	24	Depromel Tablets 25 Depromel Tablets 50 Depromel Tablets 75 (Meiji Seika Pharma Co., Ltd.) Luvox Tablets 25 Luvox Tablets 50 Luvox Tablets 75 (AbbVie GK)	Change Change Change Change Change Change	Fluvoxamine maleate	Drugs with a new additional pediatric dosage indicated for the treatment of obsessive-compulsive disorder.
3-1	Aug. 25, 2017	25	Leuplin SR for Injection Kit 11.25 mg (Takeda Pharmaceutical Company Limited)	Change	Leuprorelin acetate	A drug with a new additional indication for inhibiting progression of spinal and bulbar muscular atrophy. [Orphan drug]
3-1	Aug. 25, 2017	26	Vimpat Tablets 50 mg Vimpat Tablets 100 mg (UCB Japan Co., Ltd.)	Change Change	Lacosamide	Drugs with a revised indication for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy.
3-1	Sep. 22, 2017	27	Spinraza Intrathecal injection 12 mg (Biogen Japan Ltd.)	Change	Nusinersen sodium	A drug with a revised indication and a new dosage for the treatment of spinal muscular atrophy. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 25, 2017	28	Soliris for Intravenous Infusion 300 mg (Alexion Pharma G.K.)	Change	Eculizumab (genetical recombination)	A drug with a new additional indication and a new dosage indicated for the treatment of generalized myasthenia gravis (for use only in patients whose symptoms cannot be sufficiently controlled with high-dose intravenous immunoglobulin or plasmapheresis). [Orphan drug]
3-1	Jan. 19, 2018	29	Rexulti Tablets 1 mg Rexulti Tablets 2 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Brexpiprazole	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Mar. 23, 2018	30	Hernicore 1.25 Units for Intradiscal Inj. (Seikagaku Corporation)	Approval	Condoliase	A drug with a new active ingredient indicated for the treatment of lumbar disc herniation with subligamentous extrusion that has not adequately responded to conservative treatment.
3-2	Sep. 22, 2017	31	Remitch Capsules 2.5 μg Remitch OD Tablets 2.5 μg (Toray Industries, Inc.) Nopicor Capsules 2.5 μg (Toray Medical Co., Ltd.)	Change Change Change	Nalfurafine hydrochloride	Drugs with a revised indication for the improvement of pruritus in patients on peritoneal dialysis (for use only in patients who have not responded sufficiently to conventional treatments).
3-2	Jan. 19, 2018	32	Naruvein Injection 2 mg Naruvein Injection 20 mg (Daiichi Sankyo Propharma Co., Ltd.)	Approval Approval	Hydromorphone hydrochloride	Drugs with a new route of administration indicated for management of moderate to severe pain in various types of cancer.
4	May 18, 2017	33	Zosyn for Intravenous Injection 2.25 Zosyn for Intravenous Injection 4.5 Zosyn for I.V. Infusion bag 4.5 (Taiho Pharmaceutical Co., Ltd.)	Change Change Change	Tazobactam/Piperacillin hydrate	Drugs with additional indications and new dosages for the treatment of "bacterial skin infections mainly involving the dermis and/or subcutaneous tissues" and "secondary bacterial infections of pre-existing skin ulcers and/or erosion".
4	Jul. 3, 2017	34	Amenalief Tab. 200 mg (Maruho Co., Ltd.)	Approval	Amenamevir	A drug with a new active ingredient indicated for the treatment of herpes zoster.
4	Sep. 27, 2017	35	Zinplava for Intravenous Infusion 625 mg (MSD K.K.)	Approval	Bezlotoxumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of recurrent *Clostridium difficile* infection.
4	Sep. 27, 2017	36	Maviret Combination Tablets (AbbVie GK)	Approval	Glecaprevir hydrate/ Pibrentasvir	A new combination drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C. [Priority review]
4	Jan. 19, 2018	37	Nailin Capsules 100 mg (Sato Pharmaceutical Co., Ltd.)	Approval	Fosravuconazole L-lysine ethanolate	A drug with a new active ingredient indicated for the treatment of onychomycosis due to *Trichophyton* species.
4	Jan. 19, 2018	38	Sirturo Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval	Bedaquiline fumarate	A drug with a new active ingredient indicated for the treatment of pulmonary multidrug-resistant tuberculosis. [Orphan drug]
4	Feb. 16, 2018	39	Harvoni Combination Tablets (Gilead Sciences, Inc.)	Change	Ledipasvir acetonate/Sofosbuvir	A drug with a new additional indication for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
4	Feb. 23, 2018	40	Xofluza Tablets 10 mg Xofluza Tablets 20 mg (Shionogi & Co., Ltd.)	Approval Approval	Baloxavir marboxil	Drugs with a new active ingredient indicated for the treatment of influenza A or B virus infections. [SAKIGAKE designation]
4	Mar. 23, 2018	41	Sivextro Tablets 200 mg Sivextro Intravenous Infusion 200 mg (Bayer Yakuhin, Ltd.)	Approval Approval	Tedizolid phosphate	Drugs with a new active ingredient indicated for the treatment of bacterial skin infections mainly involving the dermis and/or subcutaneous tissues, secondary bacterial infections of pre-existing skin ulcers and/or erosion, and secondary bacterial infections of trauma, burn, and surgical wounds.
4	Mar. 23, 2018	42	Prevymis Tablets 240 mg Prevymis Intravenous Infusion 240 mg (MSD K.K.)	Approval Approval	Letermovir	Drugs with a new active ingredient indicated for the prophylaxis of cytomegalovirus disease in allogeneic hematopoietic stem cell transplant recipients. [Orphan drug]
5	Mar. 23, 2018	43	Onepal No. 1 Injection Onepal No. 2 Injection (AY Pharmaceuticals Co., Ltd.)	Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the supplementation of water, electrolytes, amino acids, calories, vitamins, zinc, iron, copper, manganese, and iodine in patients for whom receiving oral or enteral nutrition is impossible or insufficient and the total parenteral nutrition is the only choice.
6-1	Jun. 26, 2017	44	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Change Change	Tocilizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Jul. 3, 2017	45	Olumiant Tablets 4 mg Olumiant Tablets 2 mg (Eli Lilly Japan K.K.)	Approval Approval	Baricitinib	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Jul. 3, 2017	46	Prolia Subcutaneous Injection 60 mg Syringe (Daiichi Sankyo Company, Limited)	Change	Denosumab (genetical recombination)	A drug with a new additional indication and a new dosage indicated for inhibiting progression of bone erosion associated with rheumatoid arthritis.
6-1	Aug. 25, 2017	47	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Change Change	Tocilizumab (genetical recombination)	Drugs with new additional indications and a new dosage for the treatment of Takayasu arteritis and giant cell arteritis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Sep. 27, 2017	48	Cedarcure Japanese Cedar Pollen Sublingual Tablets 2,000 JAU Cedarcure Japanese Cedar Pollen Sublingual Tablets 5,000 JAU (Torii Pharmaceutical Co., Ltd.)	Approval Approval	Japanese cedar pollen extract bulk powder	Drugs with a new active ingredient indicated for the treatment of Japanese cedar pollinosis (desensitization therapy).
6-1	Sep. 27, 2017	49	Kevzara 150 mg Syringe for SC Injection Kevzara 200 mg Syringe for SC Injection Kevzara 150 mg Auto-injector for SC Injection Kevzara 200 mg Auto-injector for SC Injection (Sanofi K.K.)	Approval Approval Approval Approval	Sarilumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Sep. 27, 2017	50	Rupafin Tablets 10 mg (Teikoku Seiyaku Co., Ltd.)	Approval	Rupatadine fumarate	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	Sep. 27, 2017	51	Benlysta for I.V. Infusion 120 mg Benlysta for I.V. Infusion 400 mg Benlysta for S.C. Injection 200 mg Autoinjector Benlysta for S.C. Injection 200 mg Syringe (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Belimumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 19, 2018	52	Allesaga Tape 4 mg Allesaga Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Approval	Emedastine fumarate	Drugs with a new route of administration indicated for the treatment of allergic rhinitis.
6-1	Jan. 19, 2018	53	Dupixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Approval	Dupilumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 19, 2018	54	Fasenra Subcutaneous Injection 30 mg Syringe (AstraZeneca K.K.)	Approval	Benralizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Feb. 16, 2018	55	Miticure House Dust Mite Sublingual Tablets 3,300 JAU Miticure House Dust Mite Sublingual Tablets 10,000 JAU (Torii Pharmaceutical Co., Ltd.)	Change Change	*Dermatophagoides farinae* extract, *Dermatophagoides pteronyssinus* extract	Drugs with a new additional pediatric dosage for children aged under 12 years. These drugs comprise allergen immunotherapy for the treatment of house dust mite antigen-induced allergic rhinitis.
6-1	Feb. 16, 2018	56	Actair 100 IR Sublingual Tablets-HDM Actair 300 IR Sublingual Tablets-HDM (Shionogi & Co., Ltd.)	Change Change	*Dermatophagoides farinae* extract bulk powder, *Dermatophagoides pteronyssinus* extract bulk powder	Drugs with a new additional pediatric dosage for children aged under 12 years. These drugs comprise allergen immunotherapy for the treatment of house dust mite antigen-induced allergic rhinitis.
6-1	Feb. 23, 2018	57	Orencia for I.V. Infusion 250 mg (Bristol-Myers Squibb K.K.)	Change	Abatacept (genetical recombination)	A drug with a new additional indication and a new dosage indicated for the treatment of polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 23, 2018	58	Tremfya Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Approval	Guselkumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 23, 2018	59	Humira 40 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL (AbbVie GK)	Change Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new additional indication and a new dosage indicated for the treatment of pustular psoriasis in patients who have not responded sufficiently to conventional therapies.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-2	May 18, 2017	60	Teribone Inj. 56.5 μg (Asahi Kasei Pharma Corporation)	Change	Teriparatide acetate	A drug with a new dosage indicated for the treatment of osteoporosis with high risk of fracture.
6-2	Jul. 3, 2017	61	Canalia Combination Tablets (Mitsubishi Tanabe Pharma Corporation)	Approval	Teneligliptin hydrobromide hydrate/Canagliflozin hydrate	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of teneligliptin hydrobromide hydrate with canagliflozin hydrate is deemed appropriate).
6-2	Nov. 30, 2017	62	Norditropin FlexPro Injection 5 mg Norditropin FlexPro Injection 10 mg Norditropin FlexPro Injection 15 mg Norditropin S Injection 10 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication for the treatment of short stature associated with Noonan syndrome with no epiphyseal closure.
6-2	Mar. 23, 2018	63	Ozempic Subcutaneous Injection 2 mg (Novo Nordisk Pharma Ltd.)	Approval	Semaglutide (genetical recombination)	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 23, 2018	64	Sujanu Combination Tablets (MSD K.K.)	Approval	Sitagliptin phosphate hydrate/Ipragliflozin L-proline	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of sitagliptin phosphate hydrate with ipragliflozin L-proline is deemed appropriate).
6-2	Mar. 23, 2018	65	Galafold Capsules 123 mg (Amicus Therapeutics, Inc.)	Approval	Migalastat hydrochloride	A drug with a new active ingredient indicated for the treatment of Fabry disease in patients with *GLA* mutations categorized as amenable to treatment with migalastat. [Orphan drug]
6-2	Mar. 23, 2018	66	Signifor LAR Kit for i.m. injection 10 mg Signifor LAR Kit for i.m. injection 30 mg Signifor LAR Kit for i.m. injection 20 mg Signifor LAR Kit for i.m. injection 40 mg (Novartis Pharma K.K.)	Approval Approval Change Change	Pasireotide pamoate	Drugs with a new additional indication and a new dosage and in additional dosage forms indicated for the treatment of Cushing's disease (when surgical therapies are not sufficiently effective or are difficult to perform). [Orphan drug]
In vivo diagnostics	Aug. 25, 2017	67	Ovisot for Injection 0.1 g (Daiichi Sankyo Company, Limited)	Change	Acetylcholine chloride	A drug with a new route of administration indicated for the induction of coronary spasm in a drug-induced coronary spasm provocation test during coronary angiography. [Public knowledge-based application after PAFSC's preliminary assessment]
In vivo diagnostics	Sep. 27, 2017	68	Alaglio Granules sachets1.5 g (SBI Pharmaceuticals Co., Ltd.)	Approval	Aminolevulinic acid hydrochloride	A drug with a new additional indication and a new dosage in an additional dosage form for the visualization of tumor tissues of the non-muscle invasive bladder cancer in transurethral resection of bladder tumor. [Orphan drug]
Radio-pharmaceuticals	Sep. 27, 2017	69	Vizamyl Intravenous Injectable (Nihon Medi-Physics Co., Ltd.)	Approval	Flutemetamol (18F)	A drug with a new active ingredient indicated for visualization of beta-amyloid plaques in the brains of patients with cognitive impairment suspected to be Alzheimer's disease.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Radiopharmaceuticals	Feb. 16, 2018	70	FDGscan Injectable (Nihon Medi-Physics Co., Ltd.)	Change	Fludeoxyglucose (^{18}F)	A drug with a new additional indication for visualization of inflammatory sites in the diagnosis of large-vessel vasculitis. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	May 18, 2017	71	Xalkori Capsules 200 mg Xalkori Capsules 250 mg (Pfizer Japan Inc.)	Change Change	Crizotinib	Drugs with a new additional indication for the treatment of unresectable advanced/relapsed ROS1 fusion gene-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	May 18, 2017	72	Kyprolis for Intravenous Injection 10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Carfilzomib	Drugs with a new dosage and other characteristics indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Jun. 26, 2017	73	Stivarga Tablets 40 mg (Bayer Yakuhin, Ltd.)	Change	Regorafenib hydrate	A drug with a new additional indication for the treatment of unresectable hepatocellular carcinoma which has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Jul. 3, 2017	74	Difolta Injection 20 mg (Mundipharma K.K.)	Approval	Pralatrexate	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Jul. 3, 2017	75	Istodax Injection 10 mg (Celgene K.K.)	Approval	Romidepsin	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Jul. 3, 2017	76	Somatuline 120 mg for s.c. Injection (Teijin Pharma Limited)	Change	Lanreotide acetate	A drug with a new additional indication and a new dosage indicated for the treatment of neuroendocrine tumors of the pancreas and gastrointestinal tract.
Oncology drugs	Aug. 25, 2017	77	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new dosage indicated for the treatment of gastric cancer.
Oncology drugs	Sep. 22, 2017	78	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Change	Ceritinib	A drug with a revised indication for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer.
Oncology drugs	Sep. 22, 2017	79	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable advanced or recurrent gastric cancer which has progressed after cancer chemotherapy. [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Sep. 27, 2017	80	Ibrance Capsules 25 mg Ibrance Capsules 125 mg (Pfizer Japan Inc.)	Approval Approval	Palbociclib	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Sep. 27, 2017	81	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Daratumumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 27, 2017	82	Bavencio Injection 200 mg (Merck Serono Co., Ltd.)	Approval	Avelumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable Merkel cell carcinoma. [Orphan drug]
Oncology drugs	Sep. 27, 2017	83	Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)	Change	Fulvestrant	A drug with a revised indication and a new dosage for the treatment of breast cancer. [Expedited review]
Oncology drugs	Nov. 30, 2017	84	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with a new additional indication for the treatment of relapsed or refractory classical Hodgkin's lymphoma.
Oncology drugs	Dec. 25, 2017	85	Tasigna Capsules 50 mg Tasigna Capsules 150 mg Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Change Change Change	Nilotinib hydrochloride hydrate	Drugs with a new pediatric dosage indicated for the treatment of chronic- or accelerated-phase chronic myeloid leukemia. [Expedited review (only Tasigna Capsules 50 mg)]
Oncology drugs	Dec. 25, 2017	86	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable urothelial cancer which progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Jan. 19, 2018	87	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Atezolizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Jan. 19, 2018	88	Besponsa Injection 1 mg (Pfizer Japan Inc.)	Approval	Inotuzumab ozogamicin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory CD22-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Jan. 19, 2018	89	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Approval Approval	Olaparib	Drugs with a new active ingredient indicated for the maintenance treament of recurrent ovarian cancer in patients who are in a complete or partial response to platinum-based chemotherapy.
Oncology drugs	Feb. 16, 2018	90	Zytiga Tablets 250 mg (Janssen Pharmaceutical K.K.)	Change	Abiraterone acetate	A drug with a new additional indication for the treatment of prostate cancer in patients with high-risk prognostic factors who have not received previous endocrine therapy. [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 23, 2018	91	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Change Change	Dabrafenib mesilate	Drugs with a new additional indication and a new dosage indicated for the treatment of unresectable advanced or recurrent BRAF mutation-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	Mar. 23, 2018	92	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Change Change	Trametinib dimethyl sulfoxide	Drugs with a new additional indication for the treatment of unresectable advanced or recurrent BRAF mutation-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	Mar. 23, 2018	93	Lenvima Capsule 4 mg (Eisai Co., Ltd.)	Change	Lenvatinib mesilate	A drug with a new additional indication and a new dosage indicated for the treatment of unresectable hepatic cell carcinoma.
Oncology drugs	Mar. 23, 2018	94	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new additional indication and a new dosage indicated for the treatment of Waldenströ m's macroglobulinemia and lymphoplasmacytic lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Vaccines	Mar. 23, 2018	95	Shingrix for Intramuscular Injection (Japan Vaccine Co., Ltd.)	Approval	Freeze-dried recombinant herpes zoster vaccine (prepared from Chinese hamster ovary cells)	A drug with a new active ingredient indicated for the prevention of herpes zoster.
Vaccines	Mar. 23, 2018	96	Emulsion-adjuvanted Cell-culture Derived Influenza HA Vaccine H5N1 for Intramuscular Injection “Kaketsuken” (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Emulsion-adjuvanted cell-culture derived influenza HA vaccine (H5N1)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 23, 2018	97	Emulsion-adjuvanted Cell-culture Derived Influenza HA Vaccine (prototype) for Intramuscular Injection “Kaketsuken” (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Emulsion-adjuvanted cell-culture derived influenza HA vaccine (prototype)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza. [Orphan drug]
Blood products	Mar. 23, 2018	98	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Emicizumab (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with congenital blood coagulation factor VIII deficiency with blood coagulation factor VIII inhibitors. [Orphan drug]
Blood products	Sep. 27, 2017	99	Afstyla I.V. Injection 250 Afstyla I.V. Injection 500 Afstyla I.V. Injection 1000 Afstyla I.V. Injection 1500 Afstyla I.V. Injection 2000 Afstyla I.V. Injection 2500 Afstyla I.V. Injection 3000 (CSL Behring K.K.)	Approval Approval Approval Approval Approval Approval Approval	Lonoctocog alfa (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Blood products	Nov. 30, 2017	100	Adynovate Intravenous 250 Adynovate Intravenous 500 Adynovate Intravenous 1000 Adynovate Intravenous 2000 (Baxalta Japan Limited)	Change Change Change Change	Rurioctocog alfa pegol (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Bio-CMC	Sep. 27, 2017	101	Infliximab BS for I.V. Infusion 100 mg "Nichiiko" (Nichi-Iko Pharmaceutical Co., Ltd.) Infliximab BS for I.V. Infusion 100 mg "AYUMI" (Yakuhan Pharmaceutical Co., Ltd.)	Approval Approval	Infliximab (genetical recombination) [Infliximab biosimilar 2]	Follow-on biologics indicated for the treatment of rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis.
Bio-CMC	Sep. 27, 2017	102	Rituximab BS Intravenous Infusion 100 mg [KHK] Rituximab BS Intravenous Infusion 500 mg [KHK] (Sandoz K.K.)	Approval Approval	Rituximab (genetical recombination) [Rituximab biosimilar 1]	Follow-on biologics indicated for the treatment of CD20-positive B-cell non-Hodgkin's lymphoma, CD20-positive B-cell lymphoproliferative disorder associated with immunosuppression, Wegener's granulomatosis, and microscopic polyangiitis.
Bio-CMC	Jan. 19, 2018	103	Etanercept BS 10 mg for S.C. Inj. "MA" Etanercept BS 25 mg for S.C. Inj. "MA" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "MA" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "MA" Etanercept BS 50 mg PEN 1.0 mL for S.C. Inj. "MA" (Mochida Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Etanercept (genetical recombination) [etanercept biosimilar 1]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) and polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies.
Bio-CMC	Mar. 23, 2018	104	Trastuzumab BS for I.V. Infusion 60 mg "NK" Trastuzumab BS for I.V. Infusion 150 mg "NK" (Nippon Kayaku Co., Ltd.) Trastuzumab BS for I.V. Infusion 60 mg "CTH" Trastuzumab BS for I.V. Infusion 150 mg "CTH" (Celltrion Inc.)	Approval Approval Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 1]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent gastric cancer with HER2 overexpression.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2016

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	May 13, 2016	1	Cellcept Capsules 250 Cellcept Powder for Oral Suspension 31.8% (Chugai Pharmaceutical Co., Ltd.) Mycophenolate Mofetil Cap. 250 mg "Teva" (Teva Pharma Japan Inc.) Mycophenolate Mofetil Capsules 250 mg [Pfizer] (Mylan Seiyaku Ltd.)	Change Change Change Change	Mycophenolate mofetil	Drugs with a new additional indication and a new dosage for the treatment of lupus nephritis. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Jun. 20, 2016	2	Humira 40 mg for S.C. Injection Syringe 0.8 mL (AbbVie GK)	Change	Adalimumab (genetical recombination)	A drug with a new dosage indicated for the treatment of Crohn's disease.
1	Jul. 4, 2016	3	Epiduo Gel (Galderma S.A.)	Approval	Adapalene/Benzoyl peroxide	A new combination drug indicated for the treatment of acne vulgaris.
1	Jul. 4, 2016	4	Picoprep Combination Powder (Ferring Pharmaceuticals Co.,Ltd)	Approval	Sodium picosulfate hydrate/ Magnesium oxide/ Anhydrous citric acid	A new combination drug indicated for bowel cleansing preparation for colonoscopy or colorectal surgery.
1	Jul. 4, 2016	5	Hemangiol Syrup for Pediatric 0.375% (Maruho Co., Ltd.)	Approval	Propranolol hydrochloride	A drug with a new indication in a new dosage form indicated for the treatment of infantile hemangioma. [Orphan drug]
1	Sep. 28, 2016	6	Regroth Dental Kit 600 μg Regroth Dental Kit 1200 μg (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	Trafermin (genetical recombination)	Drugs with a new route of administration indicated for the treatment of alveolar bone loss due to periodontitis.
1	Sep. 28, 2016	7	Zentacort Capsules 3 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	Budesonide	A drug with a new route of administration indicated for the treatment of mild to moderately active Crohn's disease.
1	Sep. 28, 2016	8	Lialda Tab. 1200 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Mesalazine	A drug in a new dosage form indicated for the treatment of ulcerative colitis (excluding severe cases).
1	Dec. 19, 2016	9	Parsabiv Intravenous Injection for Dialysis 2.5 mg Parsabiv Intravenous Injection for Dialysis 5 mg Parsabiv Intravenous Injection for Dialysis 10 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	Etelcalcetide hydrochloride	Drugs with a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on hemodialysis.
1	Dec. 19, 2016	10	Linzess Tablets 0.25 mg (Astellas Pharma Inc.)	Approval	Linaclotide	A drug with a new active ingredient indicated for the treatment of irritable bowel syndrome with constipation.
1	Mar. 24, 2017	11	Nobelzin Capsules 25 mg Nobelzin Capsules 50 mg Nobelzin Tablets 25 mg Nobelzin Tablets 50 mg (Nobelpharma Co., Ltd.)	Change Change Change Change	Zinc acetate dihydrate	Drugs with a new additional indication and a new dosage for the treatment of hypozincemia.
1	Mar. 30, 2017	12	Symproic Tablets 0.2 mg (Shionogi & Co., Ltd.)	Approval	Naldemedine tosilate	A drug with a new active ingredient indicated for the treatment of opioid-induced constipation.
1	Mar. 30, 2017	13	(1) Stelara Intravenous Infusion 130 mg (2) Stelara Subcutaneous Injection 45 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Change	Ustekinumab (genetical recombination)	(1) A drug with a new route of administration indicated for the induction therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (2) A drug with a new indication and a new dosage for the maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Mar. 30, 2017	14	(1) Simponi Subcutaneous Injection 50 mg Syringe (2) Simponi Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Change Approval	Golimumab (genetical recombination)	Drugs with a new additional indication and a new dosage, in a new additional dosage form for improvement and maintenance of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Mar. 30, 2017	15	Comclo Shampoo 0.05% (Maruho Co., Ltd.)	Approval	Clobetasol propionate	A drug in a new dosage form indicated for the treatment of psoriasis vulgaris of the scalp.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Jul. 4, 2016	16	Praluent 75 mg solution for injection in pre-filled pen Praluent 150 mg solution for injection in pre-filled pen Praluent 75 mg solution for injection in pre-filled syringe Praluent 150 mg solution for injection in pre-filled syringe (Sanofi K.K.)	Approval Approval Approval Approval	Alirocumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of familial hypercholesteremia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular event and have not responded sufficiently to HMG-CoA reductase inhibitors).
2	Jul. 4, 2016	17	Duodopa Enteral Combination Solution (AbbVie GK)	Approval	Levodopa/ Carbidopa hydrate	A new combination drug indicated for the improvement of wearing-off phenomenon in the symptoms of Parkinson's disease in patients who have not responded sufficiently to conventional levodopa-containing drug therapies. [Orphan drug]
2	Sep. 28, 2016	18	Micatrio Combination Tablets (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/ Amlodipine besilate/ Hydrochlorothiazide	A new combination drug indicated for the treatment of hypertension.
2	Sep. 28, 2016	19	(1) Brilinta Tablets 60 mg (2) Brilinta Tablets 90 mg (AstraZeneca K.K.)	Approval Approval	Ticagrelor	Drugs with a new active ingredient indicated for the treatment of: (1) Old myocardial infarction at especially high risk of developing atherothrombosis with at least one of the following risk factors: age of 65 years or older, with diabetes mellitus requiring drug therapy, history of two or more episodes of myocardial infarction, angiography-confirmed multivessel coronary artery disease, or non-end-stage chronic renal dysfunction. (2) Acute coronary syndrome (unstable angina, non-ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction) for which percutaneous coronary intervention (PCI) is indicated. (provided that dual antiplatelet therapy including aspirin is appropriate but the administration of other antiplatelet drugs in combination with aspirin is not suitable for the patient.)
2	Sep. 28, 2016	20	Uptravi Tablets 0.2 mg Uptravi Tablets 0.4 mg (Nippon Shinyaku Co., Ltd.)	Approval Approval	Selexipag	Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Sep. 28, 2016	21	Juxtapid Capsules 5 mg Juxtapid Capsules 10 mg Juxtapid Capsules 20 mg (Aegerion Pharmaceuticals K.K.)	Approval Approval Approval	Lomitapide mesilate	Drugs with a new active ingredient indicated for the treatment of homozygous familial hypercholesterolemia. [Orphan drug]
2	Sep. 28, 2016	22	Prizbind Intravenous Solution 2.5 g (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Idarucizumab (genetical recombination)	A drug with a new active ingredient indicated for the reversal of anticoagulant effect of dabigatran under the following situations: • In life-threatening or uncontrolled bleeding • When performing emergency surgery or procedures in which serious bleeding is expected. [Priority review]
2	Sep. 28, 2016	23	Polidocasklerol 1% Inj. 2 mL Polidocasklerol 3% Inj. 2 mL (Kaigen Pharma Co., Ltd.)	Change Change	Polidocanol	Drugs with a new indication and a new dosage for the use in sclerotherapy of primary varicose veins of lower extremity.
2	Dec. 19, 2016	24	Selara Tablets 25 mg Selara Tablets 50 mg (Pfizer Japan Inc.)	Change Change	Eplerenone	Drugs with a new additional indication and a new dosage for the treatment of chronic heart failure in patients receiving basic treatment with angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists, β-blockers, diuretics, etc.
2	Mar. 2, 2017	25	Epoprostenol ACT 0.5 mg Epoprostenol ACT 1.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change Change	Epoprostenol sodium	Drugs with a new additional pediatric dosage indicated for the treatment of pulmonary arterial hypertension.
3-1	May. 23, 2016	26	Botox Vista Injection 50 Units (Allergan Japan K.K.)	Change	Botulinum toxin type A	A drug with a new additional indication and a new dosage for the temporary improvement in the appearance of lateral canthal lines (crow's feet lines) in adults aged under 65 years.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-1	Jul. 4, 2016	27	Ocnobel Tablets 150 mg Ocnobel Tablets 300 mg Ocnobel Oral Suspension 6% (Nobelpharma Co., Ltd.)	Approval Approval Approval	Oxcarbazepine	Drugs with a new active ingredient indicated for the use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Jul. 4, 2016	28	Vimpat Tablets 50 mg Vimpat Tablets 100 mg (UCB Japan Co., Ltd.)	Approval Approval	Lacosamide	Drugs with a new active ingredient indicated for the use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Sep. 28, 2016	29	Abilify Tablets 1 mg Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Tablets 12 mg Abilify OD Tablets 3 mg Abilify OD Tablets 6 mg Abilify OD Tablets 12 mg Abilify Powder 1% Abilify Oral Solution 0.1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Change Change Change Change Change Change Change Change	Aripiprazole	Drugs with a new additional indication, dosage, and dosage form for the treatment of irritability associated with autism spectrum disorder in children and adolescents.
3-1	Sep. 28, 2016	30	Kenketu Glovenin-I for I.V. Injection 500 mg Kenketu Glovenin-I for I.V. Injection 2500 mg Kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication for the treatment of Guillain-Barré syndrome (severe cases in an acute exacerbation phase with difficulty in walking).
3-1	Dec. 19, 2016	31	Tecfidera Capsules 120 mg Tecfidera Capsules 240 mg (Biogen Japan Ltd.)	Approval Approval	Dimethyl fumarate	Drugs with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis. [Orphan drug]
3-1	Dec. 19, 2016	32	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication for the treatment of pain associated with osteoarthritis.
3-1	Dec. 19, 2016	33	Kenketu Glovenin-I for I.V. Injection 2500 mg Kenketu Glovenin-I for I.V. Injection 500 mg Kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Polyethylene glycol treated human normal immunoglobulin G	Drugs with a new additional indication and a new dosage for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (including multifocal motor neuropathy) (in the cases where patients show an improvement in their acute phase treatment) [Orphan drug]
3-1	Mar. 30, 2017	34	Intuniv Tablets 1 mg Intuniv Tablets 3 mg (Shionogi & Co., Ltd.)	Approval Approval	Guanfacine hydrochloride	Drugs with a new active ingredient indicated for the treatment of pediatric attention deficit/hyperactivity disorder (AD/HD).
3-2	Aug. 26, 2016	35	Ultiva Intravenous 2 mg Ultiva Intravenous 5 mg (Janssen Pharmaceutical K.K.)	Change Change	Remifentanil hydrochloride	Drugs with a new additional indication and a new dosage for use in pediatric patients for analgesia during maintenance of general anesthesia.
3-2	Sep. 28, 2016	36	Mikeluna Combination Ophthalmic Solution (Otsuka Pharmaceutical Co., Ltd.)	Approval	Carteolol hydrochloride/ Latanoprost	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Mar. 2, 2017	37	MaQaid Intravitreal Injection 40 mg (Wakamoto Co., Ltd.)	Change	Triamcinolone acetonide	A drug with a new route of administration indicated for alleviation of diabetic macular edema and macular edema associated with retinal vein occlusion or non-infectious uveitis.
3-2	Mar. 30, 2017	38	Narusus Tablets 2 mg Narusus Tablets 6 mg Narusus Tablets 12 mg Narusus Tablets 24 mg Narurapid Tablets 1 mg Narurapid Tablets 2 mg Narurapid Tablets 4 mg (Daiichi Sankyo Propharma Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Hydromorphone hydrochloride	Drugs with a new active ingredient indicated for management of moderate to severe pain in various types of cancer.
4	Aug. 26, 2016	39	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Change	Laninamivir octanoate hydrate	A drug with a new additional dosage and administration for the prophylaxis of influenza A or B virus infections in single inhalation doses for adults and children aged 10 years and older, and children aged under 10 years.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Aug. 26, 2016	40	Valixa Tablets 450 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Valganciclovir hydrochloride	A drug with a new additional indication and a new dosage for the prevention of cytomegalovirus disease in organ transplant patients (excluding hematopoietic stem cell transplantation). [Public knowledge-based application after PAFSC's preliminary assessment]
4	Sep. 28, 2016	41	Rifxima Tablets 200 mg (Aska Pharmaceutical Co., Ltd.)	Approval	Rifaximin	A drug with a new active ingredient indicated for the improvement of hyperammonemia in patients with hepatic encephalopathy. [Orphan drug]
4	Sep. 28, 2016	42	Grazyna Tablets 50 mg (MSD K.K.)	Approval	Grazoprevir hydrate	A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Sep. 28, 2016	43	Erelsa Tablets 50 mg (MSD K.K.)	Approval	Elbasvir	A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Sep. 28, 2016	44	Viekirax Combination Tablets (AbbVie GK)	Change	Ombitasvir hydrate/ Paritaprevir hydrate/ Ritonavir	A drug with a new additional indication and a new dosage for the improvement of viremia in patients with chronic hepatitis C in serogroup 2 (genotype 2).
4	Sep. 28, 2016	45	Rebetol Capsules 200 mg (MSD K.K.)	Change	Ribavirin	A drug with a new additional indication and a new dosage for the improvement of viremia in patients with chronic hepatitis C in serogroup 2 (genotype 2), for a combination use of ombitasvir hydrate, paritaprevir hydrate, and ritonavir.
4	Dec. 19, 2016	46	Ximency Combination Tablets (Bristol-Myers Squibb K.K.)	Approval	Daclatasvir hydrochloride/ Asunaprevir/ Beclabuvir hydrochloride	A new combination drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1).
4	Dec. 19, 2016	47	Riamet Combination Tablets (Novartis Pharma K.K.)	Approval	Artemether/ Lumefantrine	A new combination drug with new active ingredients indicated for the treatment of malaria.
4	Dec. 19, 2016	48	Vemlidy Tablets 25 mg (Gilead Sciences, Inc.)	Approval	Tenofovir alafenamide fumarate	A drug with a new active ingredient indicated for the suppression of proliferation of hepatitis B virus in patients with chronic liver disease with hepatitis B virus infection in whom abnormal liver function is confirmed along with hepatitis B virus proliferation. [Priority review]
4	Mar. 2, 2017	49	Ozex Fine Granules 15% for Pediatric (Toyama Chemical Co., Ltd.)	Change	Tosufloxacin tosilate hydrate	A drug with a new additional indication for the treatment of mycoplasma pneumonia caused by *Mycoplasma pneumoniae* .
4	Mar. 24, 2017	50	Sovaldi Tablets 400 mg (Gilead Sciences, Inc.)	Change	Sofosbuvir	A drug with a new additional indication and a new dosage for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]
4	Mar. 24, 2017	51	Rebetol Capsules 200 mg (MSD K.K.)	Change	Ribavirin	A drug with a new additional indication for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]
4	Mar. 24, 2017	52	Copegus Tablet 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Ribavirin	A drug with a new additional indication for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Mar. 24, 2017	53	Tamiflu Dry Syrup 3% (Chugai Pharmaceutical Co., Ltd.)	Change	Oseltamivir phosphate	A drug with a new additional dosage for newborns and infants for the treatment of influenza A or B virus infection. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 4, 2016	54	Onecrinone 90mg Progesterone vaginal gel (Merck Serono Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women.
5	Jul. 4, 2016	55	Elneopa-NF No. 1 Injection Elneopa-NF No. 2 Injection (Otsuka Pharmaceutical Factory Inc.)	Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the supplementation of water, electrolytes, calories, amino acids, vitamins, zinc, iron, copper, manganese, and iodine in patients for whom receiving oral or enteral nutrition is impossible or insufficient and the total parenteral nutrition is the only choice.
5	Sep. 28, 2016	56	Ovidrel Syringe 250 μg (Merck Serono Co., Ltd.)	Approval	Choriogonadotropin alfa (genetical recombination)	A drug with a new active ingredient indicated for: • Induction of ovulation and luteinization in patients with anovulation or oligoovulation associated with hypothalamic-pituitary dysfunction • Induction of final follicular maturation and luteinization as part of assisted reproductive technology for infertile women.
5	Dec. 2, 2016	57	Dinagest Tablets 1 mg Dinagest OD Tablets 1 mg (Mochida Pharmaceutical Co., Ltd.)	Change Change	Dienogest	Drugs with a new additional indication for the alleviation of pain associated with uterine adenomyosis.
5	Dec. 19, 2016	58	YazFlex Combination Tablets (Bayer Yakuhin Ltd.)	Approval	Drospirenone /Ethinylestradiol betadex	A drug with new indications and a new dosage in an additional dosage form indicated for the alleviation of pain associated with endometriosis, and dysmenorrhea.
5	Mar. 30, 2017	59	D Dry 2.75S (Nikkiso Co., Ltd.)	Approval	N/A for this combination drug	A prescription drug with similar formulations to approved combination drugs used as perfusion fluids for hemodialysis in patients with chronic renal failure.
6-1	May 13, 2016	60	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new dosage indicated for plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional treatments.
6-1	Jul. 4, 2016	61	Taltz 80mg Syringe for SC Injection Taltz 80mg Auto-Injector for SC Injection (Eli Lilly Japan K.K.)	Approval Approval	Ixekizumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Jul. 4, 2016	62	Lumicef Subcutaneous Injection 210 mg Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval	Brodalumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Aug. 26, 2016	63	Spiriva 2.5 μg Respimat 60 puffs Spiriva1.25 μg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Change Approval	Tiotropium bromide hydrate	Drugs with a new additional indication, dosage, and dosage form for the relief of symptoms secondary to airway obstructive disorders in mild to moderate persistent bronchial asthma.
6-1	Sep. 28, 2016	64	Desalex Tablets 5 mg (MSD K.K.)	Approval	Desloratadine	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	Sep. 28, 2016	65	Bilanoa Tablet 20 mg (Taiho Pharmaceutical Co. Ltd.)	Approval	Bilastine	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	Sep. 28, 2016	66	Humira 40 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL (AbbVie GK)	Change Change Change	Adalimumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of non-infectious intermediate, posterior, and panuveitis in patients who have not responded sufficiently to conventional therapies.
6-1	Sep. 28, 2016	67	Colchicine Tablets 0.5 mg "Takata" (Takata Pharmaceutical Co.,Ltd.)	Change	Colchicine	A drug with a new additional indication and a new dosage for the treatment of familial Mediterranean fever. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Dec. 2, 2016	68	Relvar 100 Ellipta 14 dose Relvar 100 Ellipta 30 dose (GlaxoSmithKline K.K.)	Change Change	Vilanterol trifenatate/ Fluticasone furoate	Drugs with a new additional indication and a new dosage for the relief of symptoms in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with an inhaled corticosteroid and a long-acting beta-2 agonist).
6-1	Dec. 19, 2016	69	Otezla Tablets 10 mg Otezla Tablets 20 mg Otezla Tablets 30 mg (Celgene K.K.)	Approval Approval Approval	Apremilast	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis in patients who have not responded sufficiently to topical therapy or psoriatic arthritis.
6-1	Dec. 19, 2016	70	Ilaris for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change	Canakinumab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of patients with familial Mediterranean fever who have not responded sufficiently to conventional therapies, TNF receptor-associated periodic syndrome, or hyper IgD syndrome (mevalonate kinase deficiency). [Orphan drug]
6-1	Mar. 24, 2017	71	Xolair for S.C. Injection 150 mg Xolair for S.C. Injection 75 mg (Novartis Pharma K.K.)	Change Change	Omalizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of chronic idiopathic urticaria (for use only in patients who have not responded sufficiently to conventional therapies).
6-1	Mar. 24, 2017	72	Berinert P I.V. Injection 500 (CSL Behring K.K.)	Change	Lyophilized human C1-inactivator concentrate	A drug with a new additional indication and a new dosage for inhibiting onset of acute attacks of hereditary angioedema caused by invasive procedures. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Mar. 30, 2017	73	Arnuity 100 µg Ellipta 14 doses Arnuity 100 µg Ellipta 30 doses Arnuity 200 µg Ellipta 14 doses Arnuity 200 µg Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Fluticasone furoate	Drugs with a new dosage and other characteristics indicated for the treatment of bronchial asthma.
6-2	May. 23, 2016	74	Feburic Tablets 10 mg Feburic Tablets 20 mg Feburic Tablets 40 mg (Teijin Pharma Limited)	Change Change Change	Febuxostat	Drugs with a new additional indication and a new dosage for the treatment of hyperuricemia in patients receiving cancer chemotherapy.
6-2	Sep. 28, 2016	75	Signifor LAR Kit for i.m. injection 20 mg Signifor LAR Kit for i.m. injection 40 mg Signifor LAR Kit for i.m. injection 60 mg (Novartis Pharma K.K.)	Approval Approval Approval	Pasireotide pamoate	Drugs with a new active ingredient indicated for the improvement of hypersecretion of growth hormone and IGF-I (somatomedin-C) and related symptoms in acromegaly and pituitary gigantism (when surgical therapies are not sufficiently effective or are difficult to perform).
6-2	Sep. 28, 2016	76	Inisync Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Alogliptin benzoate/ Metformin hydrochloride	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of alogliptin benzoate with metformin hydrochloride is deemed appropriate).
6-2	Sep. 28, 2016	77	Reclast for i.v. infusion 5 mg (Asahi Kasei Pharma Corporation)	Approval	Zoledronic acid hydrate	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of osteoporosis.
6-2	Sep. 28, 2016	78	Carbaglu Dispersible Tablets 200 mg (Pola Pharma Inc.)	Approval	Carglumic acid	A drug with a new active ingredient indicated for the treatment of hyperammonemia due to N-acetylglutamate synthetase deficiency, isovaleric acidemia, methylmalonic acidemia, and propionic acidemia. [Orphan drug]
6-2	Sep. 28, 2016	79	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Change Change	Insulin degludec (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Dec. 19, 2016	80	Lyxumia 300 µg solution for injection (Sanofi K.K.)	Change	Lixisenatide	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Dec. 19, 2016	81	Humalog Cart Humalog Miriopen (Eli Lilly Japan K.K.)	Change Change	Insulin lispro (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
In vivo diagnostics	Mar. 30, 2017	82	(1) Optiray 350 Injection 20 mL (2) Optiray 350 Injection 50 mL (3) Optiray 350 Injection 100 mL (4) Optiray 350 Injection Syringe 100 mL (5) Optiray 350 Injection Syringe 135 mL (Fuji Pharma Co., Ltd.)	Change Change Change Change Approval	Ioversol	Drugs with a new additional indication and a new dosage, and an additional dosage form used as contrast media in abdominal computed tomography.
Radio pharma ceuticals	Dec. 19, 2016	83	Amyvid Injection (Fujifilm RI Pharma Co., Ltd.)	Approval	Florbetapir (^{18}F)	A drug with a new active ingredient indicated for visualization of beta-amyloid plaques in the brain of patients with cognitive impairment suspected to be Alzheimer's disease.
Oncology drugs	May 23, 2016	84	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication for the treatment of advanced or recurrent cervical cancer. [Orphan drug]
Oncology drugs	May 23, 2016	85	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent colorectal cancer.
Oncology drugs	Jun. 20, 2016	86	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced/relapsed non-small cell lung cancer.
Oncology drugs	Jul. 4, 2016	87	Kyprolis for Intravenous Injection10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval	Carfilzomib	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Aug. 26, 2016	88	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Aug. 26, 2016	89	Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change	Bendamustine hydrochloride	A drug with a new additional indication and a new dosage for the treatment of chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Aug. 26, 2016	90	Afinitor Tablets 5 mg Afinitor Tablets 2.5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with a revised indication from "pancreatic neuroendocrine tumor" to "neuroendocrine tumor."
Oncology drugs	Aug. 26, 2016	91	Xeloda Tablets 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new additional indication and a new dosage for adjuvant chemotherapy for rectal cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 28, 2016	92	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Approval Approval	Pembrolizumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Sep. 28, 2016	93	Empliciti for I.V. Infusion 300 mg Empliciti for I.V. Infusion 400 mg (Bristol-Myers Squibb Company)	Approval Approval	Elotuzumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 28, 2016	94	Iclusig Tablets 15 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Ponatinib hydrochloride	A drug with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies, and recurrent or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Sep. 28, 2016	95	Treakisym Injection 25 mg (SymBio Pharmaceuticals Limited)	Approval	Bendamustine hydrochloride	A drug with a new additional indication, dosage, and dosage form for the treatment of chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Dec. 2, 2016	96	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of relapsed or refractory classical Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	Dec. 2, 2016	97	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new additional indication and a new dosage for the treatment of relapsed or refractory mantle cell lymphoma. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 19, 2016	98	Erwinase for Intramuscular Injection 10000 (Ohara Pharmaceutical Co., Ltd.)	Approval	Crisantaspase	A drug with a new active ingredient indicated for the treatment of acute leukemia (including blast crisis of chronic leukemia) and malignant lymphoma (only for patients who experienced hypersensitivity to L-asparaginase preparations).
Oncology drugs	Dec. 19, 2016	99	Mozobil Injection 24 mg (Sanofi K.K.)	Approval	Plerixafor	A drug with a new active ingredient indicated for the enhancement of mobilization of hematopoietic stem cells to the peripheral blood for autologous peripheral blood stem cell transplantation. [Orphan drug]
Oncology drugs	Dec. 19, 2016	100	Treakisym Injection 100 mg Treakisym Injection 25 mg (SymBio Pharmaceuticals Ltd.)	Change Change	Bendamustine hydrochloride	Drugs with a revised indication and a new dosage for the treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.
Oncology drugs	Dec. 19, 2016	101	Keytruda Injection 100 mg Keytruda Injection 20 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of patients with PD-L1-positive, unresectable, recurrent or advanced non-small cell lung cancer.
Oncology drugs	Mar. 2, 2017	102	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	Lenalidomide hydrate	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory adult T-cell leukemia/lymphoma. [Orphan drug]
Oncology drugs	Mar. 24, 2017	103	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of relapse or distant metastasis of head and neck cancer. [Priority review]
Oncology drugs	Mar. 30, 2017	104	Zaltrap 100 mg I.V. Infusion Zaltrap 200 mg I.V. Infusion (Sanofi K.K.)	Approval Approval	Aflibercept beta (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer.
Oncology drugs	Mar. 30, 2017	105	Mundesine Capsule 100 mg (Mundipharma K.K.)	Approval	Forodesine hydrochloride	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 30, 2017	106	Ninlaro Capsules 2.3 mg Ninlaro Capsules 3 mg Ninlaro Capsules 4 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Ixazomib citrate	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
AIDS drugs	Jun. 17, 2016	107	Genvoya Combination Tablets (Japan Tobacco Inc.)	Approval	Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir alafenamide fumarate	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Nov. 22, 2016	108	Prezcobix Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Darunavir ethanolate/ Cobicistat	A new combination drug with a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Dec. 9, 2016	109	Descovy Combination Tablets LT Descovy Combination Tablets HT (Japan Tobacco Inc.)	Approval Approval	Emtricitabine/ Tenofovir alafenamide fumarate	New combination drugs indicated for the treatment of HIV-1 infection. [Orphan drug]
Vaccines	Dec. 19, 2016	110	Vaxem Hib Suspension Liquid for Injection (Takeda Pharmaceutical Company Limited)	Change	*Haemophilus influenzae* type b vaccine adsorbed (mutated diphtheria toxin CRM197 conjugate)	A drug with a new dosage indicated for the prophylaxis of *Haemophilus influenzae* type b infections.
Blood products	Sep. 28, 2016	111	Idelvion I.V. Injection 250 Idelvion I.V. Injection 500 Idelvion I.V. Injection 1000 Idelvion I.V. Injection 2000 (CSL Behring K.K.)	Approval Approval Approval Approval	Albutrepenonacog alfa (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with coagulation factor IX deficiency.
Blood products	Mar. 30, 2017	112	Kcentra for I.V. Injection 500 Kcentra for I.V. Injection 1000 (CSL Behring K.K.)	Approval Approval	Freeze-dried human prothrombin complex concentrated	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients treated with vitamin K antagonists at the time of acute serious bleeding or an emergency surgery/procedures in which serious bleeding is expected. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2015

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	May 26, 2015	1	Irribow Tablets 2.5 μg Irribow Tablets 5 μg Irribow OD Tablets 2.5 μg Irribow OD Tablets 5 μg (Astellas Pharma Inc.)	Change Change Change Change	Ramosetron hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of diarrhea-predominant irritable bowel syndrome in women.
1	Jul. 3, 2015	2	Xiaflex Inj. (Asahi Kasei Pharma Corporation)	Approval	Collagenase (*Clostridium histolyticum*)	A drug with a new active ingredient indicated for the treatment of Dupuytren's contracture.
1	Sep. 28, 2015	3	P-Tol Chewable Tab. 250 mg P-Tol Chewable Tab. 500 mg (Kissei Pharmaceutical Co., Ltd.)	Approval Approval	Sucroferric oxyhydroxide	Drugs with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic kidney disease who are receiving dialysis.
1	Sep. 28, 2015	4	Zagallo Capsules 0.1 mg Zagallo Capsules 0.5 mg (GlaxoSmithKline K.K.)	Approval Approval	Dutasteride	A drug with a new indication and a new dosage in an additional dosage form, and a drug with a new indication and a new dosage, indicated for the treatment of the male pattern hair loss (androgenetic alopecia) in men.
1	Nov. 20, 2015	5	kenketu Glovenin-I for I.V. Injection 500 mg kenketu Glovenin-I for I.V. Injection 2500 mg kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication for the treatment of bullous pemphigoid (for use when steroid drugs are not sufficiently effective).
1	Feb. 29, 2016	6	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new additional indication and a new dosage for prophylaxis of antibody-mediated rejection in patients who underwent ABO-incompatible kidney or liver transplantation. [Orphan drug]
1	Feb. 29, 2016	7	Kiklin Capsules 250 mg (Astellas Pharma Inc.)	Change	Bixalomer	A drug with a new expanded indication for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Mar. 18, 2016	8	Proemend for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change	Fosaprepitant meglumine	A drug with new additional pediatric dosages indicated for the treatment of gastrointestinal symptoms (nausea and vomiting, including delayed phase) associated with administration of antineoplastic drugs (cisplatin, etc.).
1	Mar. 28, 2016	9	Marduox Ointment (Chugai Pharmaceutical Co., Ltd.)	Approval	Maxacalcitol / Betamethasone butyrate propionate	A new combination drug indicated for the treatment of psoriasis vulgaris.
2	Jun. 26, 2015	10	Livalo Tablets 1 mg Livalo Tablets 2 mg Livalo OD Tablets 1 mg Livalo OD Tablets 2 mg (Kowa Company, Ltd.)	Change Change Change Change	Pitavastatin calcium	Drugs with a new additional pediatric dosage indicated for the treatment of familial hypercholesterolemia.
2	Aug. 24, 2015	11	Tracleer Tablets 62.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change	Bosentan hydrate	A drug with a new additional indication for inhibiting development of digital ulcer in patients with systemic scleroderma (only for patients who currently have digital ulcers or have a history of digital ulcer.) [Orphan drug]
2	Aug. 24, 2015	12	INOflo for Inhalation 800 ppm (INO Therapeutics LLC)	Change	Nitric oxide	A drug with a new additional indication and a new dosage for the improvement of pulmonary hypertension in the perioperative period of cardiac surgery. [Orphan drug]
2	Aug. 24, 2015	13	Artist Tablets 2.5 mg Artist Tablets 10 mg Artist Tablets 20 mg (Daiichi Sankyo Company, Limited)	Change Change Change	Carvedilol	Drugs with a new additional indication and a new dosage for the treatment of tachycardiac atrial fibrillation.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Aug. 24, 2015	14	Exelon Patch 4.5 mg Exelon Patch 9 mg Exelon Patch 13.5 mg Exelon Patch 18 mg (Novartis Pharma K.K.) Rivastach Patch 4.5 mg Rivastach Patch 9 mg Rivastach Patch 13.5 mg Rivastach Patch 18 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Rivastigmine	Drugs with a new dosage indicated for inhibiting progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Sep. 24, 2015	15	Xarelto Tablets 10 mg Xarelto Tablets 15 mg (Bayer Yakuhin, Ltd.)	Change Change	Rivaroxaban	Drugs with a new additional indication and a new dosage for the treatment and prevention of recurrence of deep vein thrombosis and pulmonary thromboembolism.
2	Sep. 28, 2015	16	Mulpleta Tablets 3 mg (Shionogi & Co., Ltd.)	Approval	Lusutrombopag	A drug with a new active ingredient indicated for the improvement of thrombocytopenia in patients with chronic liver disease for whom an elective invasive procedure is planned.
2	Sep. 28, 2015	17	Ventavis inhalation solution 10 μg (Bayer Yakuhin, Ltd.)	Approval	Iloprost	A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension.
2	Sep. 28, 2015	18	Tracleer pediatric dispersible tablets 32 mg (Actelion Pharmaceuticals Japan Ltd.)	Approval	Bosentan hydrate	A drug with a new indication and a new dosage in a new additional dosage form indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Dec. 21, 2015	19	Eliquis Tablets 2.5 mg Eliquis Tablets 5 mg (Bristol-Myers K.K.)	Change Change	Apixaban	Drugs with a new additional indication and a new dosage for the treatment and prevention of the recurrence of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism).
2	Dec. 21, 2015	20	FP-OD Tablet 2.5 (FP Pharmaceutical Corporation)	Change	Selegiline hydrochloride	A drug with a revised indication and a new dosage for the treatment of Parkinson's disease (When used in combination with levodopa-containing products; patients are classified as Stage I to IV on the Hoehn and Yahr scale, and when not used in combination with levodopa-containing products; patients are classified as Stage I to III on the Hoehn and Yahr scale).
2	Jan. 22, 2016	21	Repatha･SC Injection 140 mg Syringe Repatha･SC Injection 140 mg Pen (Amgen Astellas BioPharma K.K.)	Approval Approval	Evolocumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular event and have not responded sufficiently to HMG-CoA reductase inhibitors).
3-1	May 26, 2015	22	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of pain associated with fibromyalgia.
3-1	Jun. 26, 2015	23	Botox for injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of strabismus.
3-1	Jun. 26, 2015	24	Radicut Inj. 30 mg Radicut Bag for I.V. Infusion 30 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Edaravone	Drugs with a new additional indication and a new dosage for delaying the functional disorder in patients with amyotrophic lateral sclerosis (ALS). [Orphan drug]
3-1	Sep. 24, 2015	25	Lamictal Tablets 2 mg for Children Lamictal Tablets 5 mg for Children Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Change Change Change Change	Lamotrigine	Drugs with a new additional indication and a new dosage for use in the monotherapy for the treatment of typical absence seizures in patients with epilepsy.
3-1	Sep. 28, 2015	26	Effexor SR Capsules 37.5 mg Effexor SR Capsules 75 mg (Pfizer Japan Inc.)	Approval Approval	Venlafaxine hydrochloride	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Sep. 28, 2015	27	Copaxone S.C. Injection 20 mg Syringe (Takeda Pharmaceutical Company Limited)	Approval	Glatiramer acetate	A drug with a new active ingredient indicated for the prevention of relapse in multiple sclerosis. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-1	Nov. 20, 2015	28	Lexapro Tablets 10 mg (Mochida Pharmaceutical Co., Ltd.)	Change	Escitalopram oxalate	A drug with a new additional indication for the treatment of social anxiety disorder.
3-1	Feb. 29, 2016	29	E Keppra Tablets 250 mg E Keppra Tablets 500 mg E Keppra Dry Syrup 50% E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Change Change Change Change	Levetiracetam	Drugs with a new additional indication for use as an adjunctive therapy with other antiepileptic drugs to treat tonic-clonic seizures in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Feb. 29, 2016	30	Risperdal Tablets 1 mg Risperdal Tablets 2 mg Risperdal Fine Granules 1% Risperdal OD Tablets 0.5 mg Risperdal OD Tablets 1 mg Risperdal OD Tablets 2 mg Risperdal Oral Solution 1 mg/mL (Janssen Pharmaceutical K.K.)	Change Change Change Change Change Change Change	Risperidone	Drugs with a new additional indication and a new dosage for the treatment of irritability associated with autism spectrum disorder in children and adolescents.
3-1	Feb. 29, 2016	31	Tryptanol Tablets 10 Tryptanol Tablets 25 (Nichi-Iko Pharmaceutical Co., Ltd.) Amitriptyline Hydrochloride Tablets 10 mg "Sawai" Amitriptyline Hydrochloride Tablets 25 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change Change Change Change	Amitriptyline hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of peripheral neuropathic pain. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
3-1	Mar. 18, 2016	32	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication for the treatment of pain associated with chronic low back pain.
3-1	Mar. 28, 2016	33	Sabril Granule Sachets 500 mg (Sanofi K.K.)	Approval	Vigabatrin	A drug with a new active ingredient indicated for the treatment of infantile spasms. [Orphan drug]
3-1	Mar. 28, 2016	34	Sycrest Sublingual Tablets 5 mg Sycrest Sublingual Tablets 10 mg (Meiji Seika Pharma Co., Ltd.)	Approval Approval	Asenapine maleate	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Mar. 28, 2016	35	Fycompa Tablets 2 mg Fycompa Tablets 4 mg (Eisai Co., Ltd.)	Approval Approval	Perampanel hydrate	Drugs with a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) and tonic-clonic seizures in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-2	Jun. 26, 2015	36	Emla Cream (Sato Pharmaceutical Co., Ltd.)	Change	Lidocaine/Propitocaine	A drug with a new additional indication and a new dosage for adults indicated for the relief of pain during pricking with injection needles and intravenous indwelling needles, and with a new pediatric dosage indicated for the relief of pain during skin laser radiation therapy and pricking with injection needles and intravenous indwelling needles.
3-2	Jun. 26, 2015	37	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a revised indication for the treatment of macular edema following retinal vein occlusion.
3-2	Dec. 21, 2015	38	(1) Xylocaine Injection Polyamp 0.5% (AstraZeneca K.K.) (2) Lidocaine Hydrochloride Injection 0.5% [Pfizer] (Mylan Seiyaku Ltd.)	Change Change	(1) Lidocaine hydrochloride monohydrate (2) Lidocaine hydrochloride	Drugs with a new additional indication and a new dosage for the intravenous regional anesthesia in upper extremity surgery. [Public knowledge-based application after PAFSC's preliminary assessment]
4	May 26, 2015	39	Diflucan Capsules 50 mg Diflucan Capsules 100 mg (Pfizer Japan Inc.)	Change Change	Fluconazole	Drugs with new additional indications and a new dosage for the treatment of vaginitis and vulvovaginitis caused by *Candida* .
4	May 26, 2015	40	Clavamox combination Dry Syrup for pediatric (GlaxoSmithKline K.K.)	Change	Clavulanate potassium/Amoxicillin hydrate	A drug with a new additional indication for the treatment of sinusitis.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Jun. 26, 2015	41	Zosyn for Intravenous Injection 2.25 Zosyn for Intravenous Injection 4.5 Zosyn for I.V. Infusion bag 4.5 (Taiho Pharmaceutical Co., Ltd.)	Change Change Change	Tazobactam/ Piperacillin hydrate	Drugs with a new additional indication and a new dosage for the treatment of febrile neutropenia.
4	Jul. 3, 2015	42	Harvoni Combination Tablets (Gilead Sciences, Inc.)	Approval	Ledipasvir acetonate/Sofosbuvir	A new combination drug with new active ingredients indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Jul. 3, 2015	43	Olanedine Antiseptic Solution 1.5% Olanedine Solution 1.5% Antiseptic Applicator 10 mL Olanedine Solution 1.5% Antiseptic Applicator 25 mL (Otsuka Pharmaceutical Factory, Inc.)	Approval Approval Approval	Olanexidine gluconate	Drugs with a new active ingredient indicated for skin antisepsis at surgical sites (in surgical fields).
4	Aug. 24, 2015	44	Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg Vfend Dry Syrup 2800 mg (Pfizer Japan Inc.)	Change Change Change Change	Voriconazole	Drugs with a new additional indication and new dosages for the prophylaxis of deep mycosis in patients after hematopoietic stem cell transplantation.
4	Aug. 24, 2015	45	(1) Cravit Tablets 250 mg (2) Cravit Tablets 500 mg (3) Cravit Fine Granules 10% (Daiichi Sankyo Company, Limited) (4) Levofloxacin Tablets 250 mg “DSEP” (5) Levofloxacin Tablets 500 mg “DSEP” (6) Levofloxacin Fine Granules 10% “DSEP” (Daiichi Sankyo Espha Co., Ltd.)	Change Change Change Change Change Change	Levofloxacin hydrate	Drugs with new additional indications and a new dosage for the treatment of pulmonary tuberculosis and other tuberculosis.
4	Sep. 24, 2015	46	Ciproxan-I.V. 200 (Bayer Yakuhin, Ltd.)	Change	Ciprofloxacin	A drug with a new increased dose for adults indicated for the treatment of sepsis, pneumonia, etc., and also with new indications and new dosages for children for both the treatment of complicated cystitis, pyelonephritis and anthrax, and the improvement of symptoms associated with respiratory infection caused by *Pseudomonas aeruginosa* in cystic fibrosis.
4	Sep. 24, 2015	47	Cravit Intravenous Drip Infusion 500 mg/100 mL Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Company, Limited)	Change Change	Levofloxacin hydrate	Drugs with new additional indications for the treatment of cystitis, pyelonephritis, secondary infection of trauma, burns or surgical wounds, and others.
4	Sep. 28, 2015	48	Zebiax Lotion 2% (Maruho Co., Ltd.)	Approval	Ozenoxacin	A drug with a new active ingredient indicated for the treatment of superficial skin infections and acne (accompanied by purulent inflammation).
4	Sep. 28, 2015	49	Viekirax Combination Tablets (AbbVie G.K.)	Approval	Ombitasvir hydrate/Paritaprevir hydrate/Ritonavir	A new combination drug with new active ingredients indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Jan. 22, 2016	50	Luconac Solution 5% (Sato Pharmaceutical Co., Ltd.)	Approval	Luliconazole	A drug with a new indication in a new dosage form indicated for the treatment of tinea unguium.
4	Mar. 28, 2016	51	Malarone Combination Tablets Malarone Pediatric Combination Tablets (GlaxoSmithKline K.K.)	Change Approval	Atovaquone / Proguanil hydrochloride	A drug with a revised pediatric dosage and an additional dosage form indicated for the treatment and prevention of malaria.
4	Mar. 28, 2016	52	Primaquine Tablets 15 mg "Sanofi" (Sanofi K.K.)	Approval	Primaquine phosphate	A drug with a new active ingredient indicated for the treatment of malaria caused by *Plasmodium vivax* and *Plasmodium oval* .
5	Jan. 22, 2016	53	Utrogestan Vaginal Capsules 200 mg (Fuji Pharma Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women.
5	Mar. 28, 2016	54	Luteum Vaginal Suppository 400 mg (Aska Pharmaceutical Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	May 26, 2015	55	Talion Tablets 5 mg Talion Tablets 10 mg Talion OD Tablets 5 mg Talion OD Tablets 10 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change Change Change	Bepotastine besilate	Drugs with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	May 26, 2015	56	Cimzia 200 mg Syringe for S.C. Injection (UCB Japan Co. Ltd.)	Change	Certolizumab pegol (genetical recombination)	A drug with a revised indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage).
6-1	May 26, 2015	57	Solu-Cortef Injection 100 mg Solu-Cortef for Intravenous Use 250 mg Solu-Cortef for Intravenous Use 500 mg (Pfizer Japan Inc.)	Change Change Change	Hydrocortisone sodium succinate	Drugs with a new additional indication and a new dosage for the treatment of bronchial asthma. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Jul. 3, 2015	58	Plaquenil Tablets 200 mg (Sanofi K.K.)	Approval	Hydroxychloroquine sulfate	A drug with a new active ingredient indicated for the treatment of cutaneous lupus erythematosus and systemic lupus erythematosus.
6-1	Jul. 3, 2015	59	Ofev Capsules 100 mg Ofev Capsules 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Nintedanib ethanesulfonate	Drugs with a new active ingredient indicated for the treatment of idiopathic pulmonary fibrosis. [Orphan drug]
6-1	Aug. 24, 2015	60	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of entero-Behcet's disease, neuro-Behcet's disease, and vasculo-Behcet's disease in patients who have not responded sufficiently to conventional therapies. [Orphan drug]
6-1	Sep. 28, 2015	61	Spiolto Respimat 28 puffs Spiolto Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Tiotropium bromide hydrate/Olodaterol hydrochloride	New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (when a combination treatment of an inhaled long-acting anticholinergic and a long-acting beta-2 agonist is needed).
6-1	Sep. 28, 2015	62	Loqoa Tape (Taisho Pharmaceutical Co., Ltd.)	Approval	Esflurbiprofen/Menthaoil	A new combination drug with a new active ingredient indicated for the relief of inflammation and pain associated with osteoarthritis.
6-1	Sep. 28, 2015	63	Miticure House Dust Mite Sublingual Tablets 3,300 JAU Miticure House Dust Mite Sublingual Tablets 10,000 JAU (Torii Pharmaceutical Co., Ltd.)	Approval Approval	*Dermatophagoides farinae* extract, *Dermatophagoides pteronyssinus* extract	Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis.
6-1	Dec. 21, 2015	64	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of acute-phase Kawasaki's disease in patients who have not responded sufficiently to conventional therapies. [Orphan drug]
6-1	Dec. 21, 2015	65	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change Change	Secukinumab (genetical recombination)	Drugs with a new additional indication for the treatment of pustular psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 28, 2016	66	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Approval	Mepolizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-2	Jul. 3, 2015	67	Lantus XR Inj. SoloStar (Sanofi K.K.)	Approval	Insulin glargine (genetical recombination)	A drug in a new dosage form indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Jul. 3, 2015	68	Trulicity Subcutaneous Injection 0.75 mg Ateos (Eli Lilly Japan K.K.)	Approval	Dulaglutide (genetical recombination)	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Jul. 3, 2015	69	Strensiq Subcutaneous Injection 12 mg/0.3 mL Strensiq Subcutaneous Injection 18 mg/0.45 mL Strensiq Subcutaneous Injection 28 mg/0.7 mL Strensiq Subcutaneous Injection 40 mg/1 mL Strensiq Subcutaneous Injection 80 mg/0.8 mL (Alexion Pharma G.K.)	Approval Approval Approval Approval Approval	Asfotase alfa (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of hypophosphatasia. [Orphan drug]
6-2	Aug. 24, 2015	70	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Change Change	Insulin degludec (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 28, 2015	71	Marizev Tablets 25 mg Marizev Tablets 12.5 mg (MSD K.K.)	Approval Approval	Omarigliptin	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Sep. 28, 2015	72	EquMet Combination Tablets LD EquMet Combination Tablets HD (Novartis Pharma K.K.)	Approval Approval	Vildagliptin/Metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of vildagliptin with metformin hydrochloride is deemed appropriate).
6-2	Dec. 21, 2015	73	Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change	Anagliptin	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Jan. 22, 2016	74	Bonviva Tablet 100 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Ibandronate sodium hydrate	A drug with a new route of administration indicated for the treatment of osteoporosis.
6-2	Mar. 28, 2016	75	Kanuma Intravenous Infusion 20 mg (Alexion Pharma G.K.)	Approval	Sebelipase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of lysosomal acid lipase deficiency. [Orphan drug]
In vivo diagnostics	Sep. 28, 2015	76	Allergen Scratch Extract Positive control “TORII” Histamine dihydrochloride (Japan Tobacco Inc.)	Approval	Histamine dihydrochloride	A drug with a new indication and a new dosage in a newly-added dosage form indicated for positive control in skin tests when diagnosing allergy.
In vivo diagnostics	Jan. 22, 2016	77	Provocholine Powder for Inhalation Solution 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Kenbran Powder for Inhalation Solution 100 mg (Santen Pharmaceutical Co., Ltd.)	Approval Approval	Methacholine chloride	Drugs with a new active ingredient indicated for tests in the diagnosis of bronchial airway hyperresponsiveness.
In vivo diagnostics	Mar. 28, 2016	78	ColomforT Oral Suspension 25% (Fushimi Pharmaceutical Co.,Ltd.)	Approval	Barium sulfate	A drug with a new indication and a new dosage in an additional dosage form indicated for the support of computed tomographic colonography with labelling of bowel contents.
Radio-pharmaceuticals	Sep. 28, 2015	79	Octreoscan Injection (Fujifilm RI Pharma Co.,Ltd.)	Approval	Indium pentetoreotide (^{111}In)	A drug with a new active ingredient indicated for the diagnosis of neuroendocrine tumor by using somatostatin receptor scintigraphy.
Oncology drugs	May 26, 2015	80	Laserphyrin 100 mg for Injection (Meiji Seika Pharma Co., Ltd)	Change	Talaporfin sodium	A drug with a new additional indication for the treatment of recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy. [Orphan drug]
Oncology drugs	May 26, 2015	81	Pegintron Powder for Injection 50 μg/0.5 mL Pegintron Powder for Injection 100 μg/0.5 mL Pegintron Powder for Injection 150 μg/0.5 mL (MSD K.K.)	Change Change Change	Peginterferon alfa-2b (genetical recombination)	Drugs with a new additional indication and a new dosage for the adjuvant treatment of melanoma. [Orphan drug]
Oncology drugs	May 26, 2015	82	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new dosage for the treatment of CD20-positive, B-cell non-Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	Jun. 26, 2015	83	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new additional indication and a new dosage for the treatment of patients with mantle cell lymphoma. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 26, 2015	84	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review]
Oncology drugs	Jun. 26, 2015	85	Prednisolone Tablets 5 mg "Takeda" Prednisolone Powder 1% "Takeda" (Takeda Pharmaceutical Company Limited) Predonine Tablets 5 mg (Shionogi & Co., Ltd.)	Change Change Change	Prednisolone	Drugs with revised indications and a new dosage for the treatment of malignant lymphoma and similar diseases (closely-related diseases). [Expedited review]
Oncology drugs	Jul. 3, 2015	86	Yervoy Injection 50 mg (Bristol-Myers K.K.)	Approval	Ipilimumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Jul. 3, 2015	87	Farydak Capsules 10 mg Farydak Capsules 15 mg (Novartis Pharma K.K.)	Approval Approval	Panobinostat lactate	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 24, 2015	88	Jakavi Tablets 5 mg (Novartis Pharma K.K.)	Change	Ruxolitinib phosphate	A drug with a new additional indication and a new dosage for the treatment of polycythemia vera (use only when conventional therapies are not sufficiently effective or inappropriate).
Oncology drugs	Sep. 24, 2015	89	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.) Paclitaxel Inj. 30 mg/5 mL "NK" Paclitaxel Inj. 100 mg/16.7 mL "NK" (Nippon Kayaku Co., Ltd.) Paclitaxel I.V. Infusion 30 mg/5 mL "Hospira" Paclitaxel I.V. Infusion 100 mg/16.7 mL "Hospira" (Hospira Japan Co., Ltd.) Paclitaxel Injection 30 mg "Sawai" Paclitaxel Injection 100 mg "Sawai" Paclitaxel Injection 150 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Paclitaxel Intravenous Infusion 30 mg "Sandoz" Paclitaxel Intravenous Infusion 100 mg "Sandoz" (Sandoz K.K.) Paclitaxel Injection 30 mg "NP" Paclitaxel Injection 100 mg "NP" (Nipro Corporation) Paclitaxel Injection 30 mg "Pfizer" Paclitaxel Injection 100 mg "Pfizer" (Mylan Seiyaku Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change	Paclitaxel	Drugs with a new dosage indicated for the treatment of gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 28, 2015	90	Caprelsa Tablets 100 mg (AstraZeneca K.K.)	Approval	Vandetanib	A drug with a new active ingredient indicated for the treatment of unresectable medullary thyroid cancer. [Orphan drug]
Oncology drugs	Sep. 28, 2015	91	Leuplin Pro for Injection Kit 22.5 mg (Takeda Pharmaceutical Company Limited)	Approval	Leuprorelin acetate	A drug in a new dosage form indicated for the treatment of prostate cancer and premenopausal breast cancer.
Oncology drugs	Sep. 28, 2015	92	Yondelis I.V. infusion 0.25 mg Yondelis I.V. infusion 1 mg (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	Trabectedin	Drugs with a new active ingredient indicated for the treatment of patients with soft tissue sarcoma. [Orphan drug]
Oncology drugs	Nov. 20, 2015	93	(1) Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.) (2) Elplat I.V. Infusion Solution 50 mg (3) Elplat I.V. Infusion Solution 100 mg (4) Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.)	Change Change Change Change	(1) Capecitabine (2) - (4) Oxaliplatin	Drugs with a revised indication for the treatment of gastric cancer.
Oncology drugs	Nov. 20, 2015	94	Hycamtin for Injection 1.1 mg (Nippon Kayaku Co., Ltd.)	Change	Nogitecan hydrochloride	A drug with a new additional indication and a new dosage for the treatment of advanced or recurrent cervical cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 20, 2015	95	Tykerb Tablets 250 mg (GlaxoSmithKline K.K.)	Change	Lapatinib tosilate hydrate	A drug with new dosages indicated for the treatment of inoperable or recurrent breast cancer with HER2 overexpression.
Oncology drugs	Dec. 17, 2015	96	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced/relapsed non-small-cell lung cancer. [Priority review]
Oncology drugs	Dec. 21, 2015	97	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	Lenalidomide hydrate	Drugs with a revised indication for the treatment of multiple myeloma.
Oncology drugs	Jan. 22, 2016	98	Targretin Capsules 75 mg (Minophagen Pharmaceutical Co., Ltd.)	Approval	Bexarotene	A drug with a new active ingredient indicated for the treatment of cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Feb. 29, 2016	99	Halaven Injection 1 mg (Eisai Co., Ltd.)	Change	Eribulin mesylate	A drug with a new additional indication for the treatment of soft tissue sarcoma. [Orphan drug]
Oncology drugs	Feb. 29, 2016	100	Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.)	Change	Sorafenib tosilate	A drug with a revised indication for the treatment of unresectable thyroid cancer. [Orphan drug]
Oncology drugs	Feb. 29, 2016	101	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Mar. 28, 2016	102	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Approval Approval	Dabrafenib mesilate	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF mutation. [Orphan drug]
Oncology drugs	Mar. 28, 2016	103	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Approval Approval	Trametinib dimethyl sulfoxide	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF mutation. [Orphan drug]
Oncology drugs	Mar. 28, 2016	104	Xofigo Injection (Bayer Yakuhin, Ltd.)	Approval	Radium（^{223}Ra）dichloride	A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer with bone metastases.
Oncology drugs	Mar. 28, 2016	105	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Approval	Ceritinib	A drug with a new active ingredient indicated for the treatment of unresectable advanced/relapsed anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer with resistance or intolerance to crizotinib.
Oncology drugs	Mar. 28, 2016	106	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Approval Approval	Osimertinib mesilate	Drugs with a new active ingredient indicated for the treatment of inoperable or recurrent epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer with resistance to EGFR tyrosine kinase inhibitors.
Oncology drugs	Mar. 28, 2016	107	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Approval	Ibrutinib	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.
Vaccines	Jan. 22, 2016	108	Vaxem Hib Suspension Liquid for Injection (Takeda Pharmaceutical Company Limited)	Approval	*Haemophilus influenzae* type b vaccine absorbed (mutated diphtheria CRM_{197} conjugate)	A drug with a new active ingredient indicated for the prophylaxis of *Haemophilus influenzae* type b infections.
Vaccines	Feb. 29, 2016	109	Tribik (The Research Foundation for Microbial Diseases of Osaka University)	Change	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	A drug with a new dosage indicated for the prevention of pertussis, diphtheria, and tetanus.
Vaccines	Mar. 18, 2016	110	Freeze-dried Live Attenuated Varicella Vaccine "Biken" (The Research Foundation for Microbial Diseases of Osaka University)	Change	Freeze-dried live attenuated varicella vaccine	A drug with a new additional indication for the prevention of herpes zoster in individuals 50 years of age and older.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Vaccines	Mar. 18, 2016	111	Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 30μg/mL "Kitasato Daiichi Sankyo" (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Change	Adsorbed cell culture-derived influenza vaccine (H5N1)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	Jul. 3, 2015	112	Acoalan Injection 600 (Kyowa Hakko Kirin Co., Ltd.)	Approval	Antithrombin gamma (genetical recombination)	A drug with a new active ingredient indicated for the treatment of thrombophilia due to congenital antithrombin (AT) deficiency (CAD) and disseminated intravascular coagulation (DIC) accompanied by a decrease in AT.
Blood products	Mar. 28, 2016	113	Adynovate Intravenous 250 Adynovate Intravenous 500 Adynovate Intravenous 1000 Adynovate Intravenous 2000 (Baxter Limited)	Approval Approval Approval Approval	Rurioctocog alfa pegol (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Mar. 28, 2016	114	Kovaltry for iv injection 250 Kovaltry for iv injection 500 Kovaltry for iv injection 1000 Kovaltry for iv injection 2000 Kovaltry for iv injection 3000 Kovaltry for iv injection Kit 250 Kovaltry for iv injection Kit 500 Kovaltry for iv injection Kit 1000 Kovaltry for iv injection Kit 2000 Kovaltry for iv injection Kit 3000 (Bayer Yakuhin, Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval Approval	Octocog beta (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Bio-CMC	Mar. 28, 2016	115	Insulin Glargine BS Injection Kit "FFP" Insulin Glargine BS Injection 100 Unit/mL "FFP" (Fujifilm Pharma Co., Ltd.)	Approval Approval	Insulin glargine (genetical recombination) [insulin glargine biosimilar 2]	Follow-on biologics indicated for the treatment of diabetes mellitus where insulin therapy is indicated.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Jul. 4, 2014	1	Dovobet Ointment (Leo Pharma K.K.)	Approval	(1) Calcipotriol hydrate/ (2) Betamethasone dipropionate	A new combination drug indicated for the treatment of psoriasis vulgaris.
1	Aug. 29, 2014	2	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of refractory nephrotic syndrome (for use in patients with frequent recurrence or steroid-dependent). [Orphan drug]
1	Sep. 19, 2014	3	Thymoglobuline for Intravenous Infusion 25 mg (Sanofi K.K.)	Change	Anti-human thymocyte immunoglobulin, rabbit	A drug with a new additional indication and a new dosage for the treatment of acute rejection after the liver, heart, lungs, pancreas, or small intestinal transplantation.
1	Sep. 26, 2014	4	Fomepizole Intravenous Infusion 1.5 g "Takeda" (Takeda Pharmaceutical Company Limited)	Approval	Fomepizole	A drug with a new active ingredient indicated for the treatment of ethylene glycol and methanol poisonings.
1	Dec. 26, 2014	5	Pariet Tablets 5 mg Pariet Tablets 10 mg (Eisai Co., Ltd.)	Approval Change	Rabeprazole sodium	A drug with a new additional indication and a new dosage in a newly-added dosage form, and a drug with a new additional indication and a new dosage for the prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with low-dose aspirin.
1	Dec. 26, 2014	6	Takecab Tablets 10 mg Takecab Tablets 20 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Vonoprazan fumarate	Drugs with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis, prevention of recurrence of gastric or duodenal ulcer in patients treated with low-dose aspirin, prevention of recurrence of gastric or duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs (NSAIDs), and aid to eradication of *Helicobacter pylori* in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, *Helicobacter pylori* gastritis,-and stomach after endoscopic treatment for early gastric cancer.
1	Dec. 26, 2014	7	Methylene Blue Intravenous Injection 50 mg "Daiichi Sankyo" (Daiichi Sankyo Company, Limited)	Approval	Methylthioninium chloride hydrate	A drug with a new active ingredient indicated for the treatment of toxic methemoglobinemia.
1	Dec. 26, 2014	8	Bepio Gel 2.5% (Maruho Co., Ltd.)	Approval	Benzoyl peroxide	A drug with a new active ingredient indicated for the treatment of acne vulgaris.
2	Jul. 4, 2014	9	Stalevo Combination Tablets L50 Stalevo Combination Tablets L100 (Novartis Pharma K.K.)	Approval Approval	Levodopa/ Carbidopa hydrate/ Entacapone	New combination drugs indicated for the treatment of Parkinson's disease [for use in patients having wearing-off phenomenon in the symptoms following administration of levodopa/carbidopa].
2	Sep. 19, 2014	10	Aricept Tablets 3 mg Aricept Tablets 5 mg Aricept Tablets 10 mg Aricept D Tablets 3 mg Aricept D Tablets 5 mg Aricept D Tablets 10 mg Aricept Fine Granules 0.5% Aricept Oral Jelly 3 mg Aricept Oral Jelly 5 mg Aricept Oral Jelly 10 mg Aricept Dry Syrup 1% (Eisai Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change	Donepezil hydrochloride	Drugs with a new additional indication and a new dosage for inhibiting progress of dementia symptoms in patients with dementia with Lewy bodies.
2	Sep. 26, 2014	11	Lixiana Tablets 15 mg Lixiana Tablets 30 mg Lixiana Tablets 60 mg (Daiichi Sankyo Company, Limited)	Change Change Approval	Edoxaban tosilate hydrate	Drugs with new additional indications and new dosages, and a drug with a newly-added dosage form indicated for prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation, or for the treatment and prevention of the recurrence of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism).
2	Nov. 18, 2014	12	Inderal Tablets 10 mg Inderal Tablets 20 mg (AstraZeneca K.K.)	Change Change	Propranolol hydrochloride	Drugs with a new additional indication and a new dosage for the prevention of hypoxic attack caused by right ventricular outflow tract obstruction. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Feb. 20, 2015	13	Adempas Tablets 0.5 mg Adempas Tablets 1.0 mg Adempas Tablets 2.5 mg (Bayer Yakuhin, Ltd.)	Change Change Change	Riociguat	Drugs with a new additional indication for the treatment of pulmonary arterial hypertension.
2	Mar. 26, 2015	14	Opsumit Tablet 10 mg (Actelion Pharmaceuticals Japan Ltd.)	Approval	Macitentan	A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension.
3-1	Jul. 4, 2014	15	E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Approval	Levetiracetam	A drug with a new route of administration indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizure (including secondary generalized seizure) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs. It is used as an alternative therapy for levetiracetam oral formulation in patients who are temporarily unable to be administered orally.
3-1	Aug. 29, 2014	16	Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Change Change	Lamotrigine	Drugs with a new additional indication and a new dosage for use in the monotherapy for treatment of partial seizures (including secondary generalized seizure) and tonic-clonic seizures in patients with epilepsy.
3-1	Sep. 26, 2014	17	Belsomra Tablets 15 mg Belsomra Tablets 20 mg (MSD K.K.)	Approval Approval	Suvorexant	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Sep. 26, 2014	18	Midafresa Injection 0.1% (Alfresa Pharma Corporation)	Approval	Midazolam	A drug with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of status epilepticus.
3-1	Feb. 20, 2015	19	E Keppra Tablets 250 mg E Keppra Tablets 500 mg E Keppra Dry Syrup 50% E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Change Change Change Change	Levetiracetam	Drugs with a revised indication and a new dosage for the treatment of partial seizure in patients with epilepsy (including secondary generalized seizure).
3-1	Mar. 20, 2015	20	J Zoloft Tablets 25 mg J Zoloft Tablets 50 mg J Zoloft Tablets 100 mg J Zoloft OD Tablets 25 mg J Zoloft OD Tablets 50 mg J Zoloft OD Tablets 100 mg (Pfizer Japan Inc.)	Change Change Change Change Change Change	Sertraline hydrochloride	Drugs with a new additional indication for the treatment of posttraumatic stress disorder.
3-1	Mar. 26, 2015	21	ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg Syringe ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg Syringe (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Aripiprazole hydrate	Drugs with a new route of administration indicated for the treatment of schizophrenia.
3-2	Jun. 20, 2014	22	Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change Change Change Change	Fentanyl citrate	Drugs with a new indication for analgesia in moderate to severe chronic pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Sep. 19, 2014	23	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new additional indication for the treatment of choroidal neovascularization in patients with pathologic myopia.
3-2	Sep. 26, 2014	24	Glanatec Ophthalmic Solution 0.4% (Kowa Company, Ltd.)	Approval	Ripasudil hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of glaucoma or ocular hypertension in patients who have not sufficiently responded to other therapeutic drugs for glaucoma or who are unable to use them.
3-2	Nov. 18, 2014	25	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of diabetic macular edema.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-2	Dec. 26, 2014	26	Nopicor Capsules 2.5 μg (Toray Medical Co., Ltd.)	Approval	Nalfurafine hydrochloride	A drug with a new active ingredient indicated for the improvement of pruritus in patients with chronic liver diseases (for use only when conventional therapies are not sufficiently effective).
3-2	Mar. 26, 2015	27	Onetram Tablets 100 mg (Nippon Shinyaku Co., Ltd.)	Approval	Tramadol hydrochloride	A drug in a new dosage form indicated for analgesia in patients with cancers-associated pain or chronic pain, which cannot be managed by treatments with non-opioid analgesics.
4	May 23, 2014	28	Vancomycin Hydrochloride for Intravenous Drip Infusion 0.5 g (Shionogi & Co., Ltd.)	Change	Vancomycin hydrochloride	A drug with new additional indications for the treatment of: (1) sepsis, infective endocarditis, secondary infection of trauma, burn or surgical wounds, osteomyelitis, arthritis, peritonitis and purulent meningitis caused by vancomycin-sensitive methicillin-resistant coagulase-negative *Staphylococcus* (MRCNS); or (2) febrile neutropenia which is suspected of MRSA or MRCNS infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jul. 4, 2014	29	Clenafin Topical Solution 10% for Nail (Kaken Pharmaceutical Co., Ltd.)	Approval	Efinaconazole	A drug with a new active ingredient indicated for the treatment of tinea unguium caused by dermatophyte (*trichophyton*).
4	Jul. 4, 2014	30	Deltyba Tablets 50 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Delamanid	A drug with a new active ingredient indicated for the treatment of multidrug-resistant pulmonary tuberculosis caused by delamanid-sensitive *Mycobacterium tuberculosis*. [Orphan drug]
4	Jul. 4, 2014	31	Anaemetro Intravenous Infusion 500 mg (Pfizer Japan Inc.)	Approval	Metronidazole	A drug with a new route of administration indicated for the treatment of different kinds of anaerobic bacterial infections, infectious enteritis, and amebic dysentery.
4	Jul. 4, 2014	32	Daklinza Tablets 60 mg (Bristol-Myers K.K.) Sunvepra Capsules 100 mg (Bristol-Myers K.K.)	Approval Approval	Daclatasvir hydrochloride Asunaprevir	Drugs with new active ingredients indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1) who are untreated and ineligible for, or are intolerant to therapy including interferon; or who did not respond to therapy including interferon. [Priority review]
4	Sep. 19, 2014	33	Telavic 250 mg Tablet (Mitsubishi Tanabe Pharma Corporation)	Change	Telaprevir	A drug with a new additional indication for the improvement of viremia in serogroup 2 (genotype III [2a] or IV [2b]) chronic hepatitis C in patients who did not respond to, or in whom the symptom relapsed with, interferon monotherapy or interferon-ribavirin combination therapy. [Priority review]
4	Sep. 26, 2014	34	Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg Vfend Dry Syrup 2800 mg (Pfizer Japan Inc.)	Change Change Change Approval	Voriconazole	Drugs with new additional pediatric dosages, and a drug with a new additional pediatric dosage in an additional dosage form of dry syrup indicated for the treatment of severe or refractory fungus infection.
4	Sep. 26, 2014	35	Vanihep Capsules 150 mg (MSD K.K.)	Approval	Vaniprevir	A drug with a new active ingredient indicated for the improvement of viremia in the following patients with serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C: Patients with high levels of blood HCV RNA who are treatment-naive, or Patients who are non-responders or relapsed to therapy including interferon. [Priority review]
4	Nov. 18, 2014	36	Valtrex Tablets 500 Valtrex Granules 50% (GlaxoSmithKline K.K.)	Change Change	Valaciclovir hydrochloride	Drugs with a new additional indication and revised indications with a new dosage for prevention of herpes simplex virus infection in adult or pediatric haematopoietic stem cell transplant patients, for treatment of herpes simplex /herpes zoster, and for prevention of recurrent genital herpes in pediatric patients.
4	Dec. 18, 2014	37	Cancidas for Intravenous Drip Infusion 50 mg Cancidas for Intravenous Drip Infusion 70 mg (MSD K.K.)	Change Change	Caspofungin acetate	Drugs with a new additional pediatric dosage indicated for the treatment of febrile neutropenia with suspected fungal infection, esophageal candidiasis, invasive candidiasis, and aspergillosis caused by *Candida* or *Aspergillus*.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Dec. 26, 2014	38	Rozex Gel 0.75% (Galderma S.A.)	Approval	Metronidazole	A drug with a new route of administration indicated for disinfection/deodorisation of odorous fungating tumours.
4	Mar. 20, 2015	39	Pentcillin for Injection 1 g Pentcillin for Injection 2 g Pentcillin Intravenous Injection 1 g Bag Pentcillin Intravenous Injection 2 g Bag (Toyama Chemical Co., Ltd.)	Approval Approval Approval Approval	Piperacillin sodium	Drugs with a new dosage indicated for the treatment of sepsis, acute bronchitis, pneumonia, lung abscess, thoracic empyema, secondary infection of chronic respiratory disease, cystitis, pyelonephritis, cholecystitis, choledochitis, bartholinitis, intrauterine infection, uterine adnexitis, parametritis, and purulent meningitis.
4	Mar. 20, 2015	40	Daklinza Tablets 60 mg (Bristol-Myers K.K.) Sunvepra Capsules 100 mg (Bristol-Myers K.K.)	Change Change	Daclatasvir hydrochloride Asunaprevir	Drugs with a revised indication for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Mar. 26, 2015	41	Duac Combination Gel (GlaxoSmithKline K.K.)	Approval	Clindamycin phosphate hydrate/ Benzoyl peroxide	A new combination drug with a new active ingredient indicated for the treatment of acne vulgaris.
4	Mar. 26, 2015	42	Sovaldi Tablets 400 mg (Gilead Sciences, Inc.)	Approval	Sofosbuvir	A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2) . [Priority review]
4	Mar. 26, 2015	43	Copegus Tablets 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Ribavirin	A drug with a new additional indication and a new dosage for the improvement of viremia with the concomitant use of sofosbuvir in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2) . [Expedited review]
4	Mar. 26, 2015	44	Aldreb for Injection 150 mg (GlaxoSmithKline K.K.)	Approval	Colistin sodium methanesulfonate	A drug with a new route of administration indicated for the treatment of infections caused by colistin-sensitive *Escherichia coli, Citrobacter, Klebsiella, Enterobacter, Pseudomonas aeruginosa,* and *Acinetobacter* (limited to the strains resistant to other antimicrobial drugs). [Orphan drug]
5	Jun. 20, 2014	45	Mirena 52 mg (Bayer Yakuhin, Ltd.)	Change	Levonorgestrel	A drug with a new additional indication for the treatment of hypermenorrhea. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 4, 2014	46	Pareplus for IV. Infusion (Ajinomoto Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for the supplementation of amino acids, electrolyte, hydrosoluble vitamins, and water. It is used in patients with mild hypoproteinemia or in a mild malnutrition state due to insufficient oral intake or used in perioperative patients.
5	Sep. 26, 2014	47	Lutinus Vaginal Tablet 100 mg (Ferring Pharmaceuticals Co.,Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women.
5	Nov. 18, 2014	48	Mirena 52 mg (Bayer Yakuhin, Ltd.)	Change	Levonorgestrel	A drug with a new additional indication for the treatment of dysmenorrhoea. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Jul. 4, 2014	49	Anoro Ellipta 7 doses Anoro Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval	(1) Umeclidinium bromide/ (2) Vilanterol trifenatate	New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (when a combination treatment of an inhaled long-acting anticholinergic and a long-acting beta-2 agonist is needed).
6-1	Jul. 4, 2014	50	Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Approval	Sirolimus	A drug with a new active ingredient indicated for the treatment of lymphangioleiomyomatosis. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Jul. 4, 2014	51	kenketu Glovenin-I for I.V. Injection 2500 mg kenketu Glovenin-I for I.V. Injection 500 mg kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	Drugs with new additional indications for the treatment of Stevens-Johnson syndrome and toxic epidermal necrolysis (for use when steroid drugs are not sufficiently effective). [Orphan drug]
6-1	Aug. 29, 2014	52	Solu-Medrol for Intravenous Use 40 mg Solu-Medrol for Intravenous Use 125 mg Solu-Medrol for Intravenous Use 500 mg Solu-Medrol for Intravenous Use 1000 mg (Pfizer Japan Inc.)	Change Change Change Change	Methylprednisolone sodium succinate	Drugs with new additional indications and a new dosage for the treatment of the following treatment-resistant rheumatic diseases: systemic vasculitis (including microscopic polyangiitis, Wegener's granulomatosis, polyarteritis nodosa, Churg-Strauss syndrome, aortitis syndrome), systemic lupus erythematosus, polymyositis, dermatomyositis, scleroderma, mixed connective tissue disease, and refractory rheumatic disease. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Sep. 26, 2014	53	Calonal Tab. 500 (Showa Yakuhin Kako Co., Ltd.)	Approval	Acetaminophen	A drug in an additional dosage form. Note: the product was submitted for an approval application as a drug with a new additional indication for the treatment of osteoarthrosis and with an expanded dosage of acetaminophen in an additional dosage form. The new additional indication and the expanded dosage were approved on January 21, 2011, whereas approval of the additional dosage form had been under review.
6-1	Nov. 18, 2014	54	Spiriva 2.5 µg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Tiotropium bromide hydrate	A drug with a new additional indication for the relief of symptoms secondary to airway obstructive disorders in bronchial asthma (for use only in patients with the severe persistent type).
6-1	Dec. 26, 2014	55	Allergen Extract for Subcutaneous Injection-HDM "TORII"100,000 JAU/mL Allergen Extract for Subcutaneous Injection-HDM "TORII"10,000 JAU/mL (Torii Pharmaceutical Co., Ltd.)	Approval Approval	*Dermatophagoides farinae* extract 10,000 AU/mL, *Dermatophagoides pteronyssinus* extract 10,000 AU/mL	Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis and bronchial asthma.
6-1	Dec. 26, 2014	56	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg (Novartis Pharma K.K.)	Approval Approval	Secukinumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional therapies.
6-1	Dec. 26, 2014	57	Allergen Extract for Scratch Test - HDM "TORII" 100,000 JAU/mL (Torii Pharmaceutical Co., Ltd.)	Approval	*Dermatophagoides farinae* extract 10,000 AU/mL, *Dermatophagoides pteronyssinus* extract 10,000 AU/mL	A drug with new active ingredients indicated for the identification of allergen in patients with allergic diseases.
6-1	Mar. 20, 2015	58	Dopram Injectable 400 mg (Kissei Pharmaceutical Co., Ltd.)	Change	Doxapram hydrochloride hydrate	A drug with a new additional indication and a new dosage for the treatment of primary apnoea (apnea of prematurity) in immature or low birth weight infants who have not responded sufficiently to conventional therapies.
6-1	Mar. 26, 2015	59	Eklira 400 µg Genuair 30 doses Eklira 400 µg Genuair 60 doses (Kyorin Pharmaceutical Co., Ltd.)	Approval Approval	Aclidinium bromide	Drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema).
6-1	Mar. 26, 2015	60	Actair 100 IR Sublingual Tablets-HDM Actair 300 IR Sublingual Tablets-HDM (Shionogi & Co., Ltd.)	Approval Approval	*Dermatophagoides farinae* extract bulk powder, *Dermatophagoides pteronyssinus* extract bulk powder	Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis.
6-1	Mar. 26, 2015	61	Encruse 62.5 µg Ellipta 7 doses Encruse 62.5 µg Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval	Umeclidinium bromide	Other drugs with a new dosage indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	May 23, 2014	62	Januvia Tablets 12.5 mg Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.) Glactiv Tablets 12.5 mg Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Sitagliptin phosphate hydrate	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	May 23, 2014	63	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Alogliptin benzoate	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	May 23, 2014	64	Aredia for I.V. Infusion 15 mg Aredia for I.V. Infusion 30 mg (Novartis Pharma K.K.)	Change Change	Pamidronate disodium hydrate	Drugs with a new additional indication and a new dosage for the treatment of osteogenesis imperfecta. [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Jul. 4, 2014	65	Canaglu Tablets 100 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	Canagliflozin hydrate	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jul. 4, 2014	66	Vpriv for Intravenous Injection 400 U (Shire Japan KK)	Approval	Velaglucerase alfa (genetical recombination)	A drug with a new active ingredient indicated for the improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone disease). [Orphan drug]
6-2	Jul. 4, 2014	67	Nicystagon Capsules 50 mg Nicystagon Capsules 150 mg (Mylan Seiyaku Ltd.)	Approval Approval	Cysteamine bitartrate	Drugs with a new active ingredient indicated for the treatment of nephropathic cystinosis. [Orphan drug]
6-2	Aug. 29, 2014	68	Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.)	Change	Liraglutide (genetical recombination)	A drug with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Aug. 29, 2014	69	Metgluco Tablets 250 mg Metgluco Tablets 500 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Change Change	Metformin hydrochloride	Drugs with a new dosage indicated for the treatment of type 2 diabetes mellitus (for pediatric use).
6-2	Nov. 18, 2014	70	Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Change Change	Repaglinide	Drugs with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Dec. 26, 2014	71	Orfadin Capsules 2 mg Orfadin Capsules 5 mg Orfadin Capsules 10 mg (Astellas Pharma Inc.)	Approval Approval Approval	Nitisinone	Drugs with a new active ingredient indicated for the treatment of type I hypertyrosinemia.
6-2	Dec. 26, 2014	72	Jardiance Tablets 25 mg Jardiance Tablets 10 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Empagliflozin	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Dec. 26, 2014	73	Vimizim Intravenous Infusion 5 mg (BioMarin Pharmaceutical Japan K.K.)	Approval	Elosulfase alfa (genetical recombination)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type IVA. [Orphan drug]
6-2	Mar. 26, 2015	74	Zafatek Tablets 50 mg Zafatek Tablets 100 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Trelagliptin succinate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 26, 2015	75	Cerdelga Capsule 100 mg (Genzyme Japan K.K)	Approval	Eliglustat tartrate	A drug with a new active ingredient indicated for the improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone disease). [Orphan drug]
In vivo diagnostics	Dec. 26, 2014	76	Patch Test Panel (S) (Sato Pharmaceutical Co., Ltd.)	Approval	N/A for this drug used for patch tests	A drug indicated for use in patch tests to identify allergens in patients with allergic dermatitis.
In vivo diagnostics	Mar. 26, 2015	77	Gadovist IV Inj. 1.0 mol/L 7.5 mL Gadovist IV Inj. 1.0 mol/L Syringe 5 mL Gadovist IV Inj. 1.0 mol/L Syringe 7.5 mL Gadovist IV Inj. 1.0 mol/L Syringe 10 mL (Bayer Yakuhin, Ltd.)	Approval Approval Approval Approval	Gadobutrol	Drugs with a new active ingredient indicated for visibility of brain/spinal cord and trunk/extremities in magnetic resonance computer tomographic imaging as a contrast agent.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	May 23, 2014	78	Imunomax-γ for Injection 50 Imunomax-γ for Injection 100 (Shionogi & Co., Ltd.)	Change Change	Interferon gamma-1a (genetical recombination)	Drugs with new additional indications and a new dosage for the treatment of mycosis fungoides and Sézary syndrome. [Orphan drug]
Oncology drugs	May 23, 2014	79	Ranmark Subcutaneous Injection 120 mg (Daiichi Sankyo Company, Limited)	Change	Denosumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of giant cell tumor of bone. [Orphan drug]
Oncology drugs	Jun. 20, 2014	80	Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.)	Change	Sorafenib tosilate	A drug with a new additional indication for the treatment of unresectable differentiated thyroid carcinoma. [Orphan drug]
Oncology drugs	Jul. 4, 2014	81	Zytiga Tablets 250 mg (Janssen Pharmaceutical K.K.)	Approval	Abiraterone acetate	A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer. [Priority review]
Oncology drugs	Jul. 4, 2014	82	Jevtana 60 mg I.V. Infusion (Sanofi K.K.)	Approval	Cabazitaxel acetonate	A drug with a new active ingredient indicated for the treatment of prostate cancer. [Priority review]
Oncology drugs	Jul. 4, 2014	83	Jakavi Tablets 5 mg (Novartis Pharma K.K.)	Approval	Ruxolitinib phosphate	A drug with a new active ingredient indicated for the treatment of myelofibrosis. [Orphan drug]
Oncology drugs	Jul. 4, 2014	84	Alecensa Capsule 20 mg Alecensa Capsule 40 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Alectinib hydrochloride	Drugs with a new active ingredient indicated for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	Jul. 4, 2014	85	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval	Nivolumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable malignant melanoma. [Orphan drug]
Oncology drugs	Sep. 26, 2014	86	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	Pegfilgrastim (genetical recombination)	A drug with a new active ingredient indicated for decreasing the incidence of cancer chemotherapy-induced febrile neutropenia.
Oncology drugs	Sep. 26, 2014	87	Agrylin Capsules 0.5 mg (Shire Japan KK)	Approval	Anagrelide hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of essential thrombocythemia. [Orphan drug]
Oncology drugs	Sep. 26, 2014	88	MabCampath Intravenous infusion 30 mg (Sanofi K.K.)	Approval	Alemtuzumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Sep. 26, 2014	89	Bosulif Tablets 100 mg (Pfizer Japan Inc.)	Approval	Bosutinib hydrate	A drug with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies. [Orphan drug]
Oncology drugs	Sep. 26, 2014	90	Zanosar for Intravenous Injection 1 g (Nobelpharma Co., Ltd.)	Approval	Streptozocin	A drug with a new active ingredient indicated for the treatment of neuroendocrine tumors of the pancreas and gastrointestinal tract. [Orphan drug]
Oncology drugs	Dec. 18, 2014	91	Nesp Injection 5 μg Plastic Syringe Nesp Injection 10 μg Plastic Syringe Nesp Injection 15 μg Plastic Syringe Nesp Injection 20 μg Plastic Syringe Nesp Injection 30 μg Plastic Syringe Nesp Injection 40 μg Plastic Syringe Nesp Injection 60 μg Plastic Syringe Nesp Injection 120 μg Plastic Syringe Nesp Injection 180 μg Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change Change Change	Darbepoetin alfa (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of anemia due to myelodysplastic syndrome. [Orphan drug]
Oncology drugs	Dec. 18, 2014	92	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review]
Oncology drugs	Dec. 18, 2014	93	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Change	Mogamulizumab (genetical recombination)	A drug with a revised indication and a new dosage for the treatment of CCR4-positive adult T-cell leukemia/lymphoma. [Expedited review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 18, 2014	94	Adriacin Injection 10 Adriacin Injection 50 (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Doxorubicin hydrochloride	Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review]
Oncology drugs	Dec. 18, 2014	95	Doxorubicin Hydrochloride for Injection 10 mg “NK” Doxorubicin Hydrochloride for Injection 50 mg “NK” (Nippon Kayaku Co., Ltd.)	Change Change	Doxorubicin hydrochloride	Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review]
Oncology drugs	Dec. 18, 2014	96	Cylocide Injection 20 mg Cylocide Injection 40 mg Cylocide Injection 60 mg Cylocide Injection 100 mg Cylocide Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Change Change Change Change Change	Cytarabine	Drugs with a new route of administration indicated for the treatment of acute leukemia (including acute erythroid leukemia and blast crisis of chronic myelogenous leukemia). [Expedited review]
Oncology drugs	Dec. 18, 2014	97	Cymerin 50 mg Injection Cymerin 100 mg Injection (Mitsubishi Tanabe Pharma Corporation)	Change Change	Ranimustine	Drugs with a new dosage indicated for the treatment of malignant lymphoma. [Expedited review]
Oncology drugs	Dec. 26, 2014	98	Zelboraf Tablet 240 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Vemurafenib	A drug with a new active ingredient indicated for the treatment of unresectable malignant melanoma with BRAF mutation. [Orphan drug]
Oncology drugs	Mar. 20, 2015	99	Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.)	Change Change	(1) Trifluridine (2) Tipiracil hydrochloride	Drugs with a revised indication for the treatment of unresectable advanced or recurrent colorectal cancer. [Expedited review]
Oncology drugs	Mar. 20, 2015	100	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.)	Change Change Change	Oxaliplatin	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 26, 2015	101	Lenvima Capsule 4 mg Lenvima Capsule 10 mg (Eisai Co., Ltd.)	Approval Approval	Lenvatinib mesilate	Drugs with a new active ingredient indicated for the treatment of unresectable thyroid cancer. [Orphan drug]
Oncology drugs	Mar. 26, 2015	102	Pomalyst Capsules 1 mg Pomalyst Capsules 2 mg Pomalyst Capsules 3 mg Pomalyst Capsules 4 mg (Celgene K.K.)	Approval Approval Approval Approval	Pomalidomide	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Mar. 26, 2015	103	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Approval Approval	Ramucirumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent gastric cancer. [Priority review]
HIV/AIDS drugs	Nov. 18, 2014	104	Complera Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Rilpivirine hydrochloride, Emtricitabine, Tenofovir disoproxil fumarate	A new combination drug indicated for the treatment of HIV-1 infection. [Orphan drug]
HIV/AIDS drugs	Mar. 16, 2015	105	Triumeq Combination Tablets (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium, Abacavir sulfate, Lamivudine	A new combination drug indicated for the treatment of HIV infection. [Orphan drug]
Vaccines	Jun. 20, 2014	106	Prevenar 13 Suspension Liquid for Injection (Pfizer Japan Inc.)	Change	Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM_{197} conjugate)	A drug with a new additional indication and a new dosage for the prophylaxis of pneumococcal disease. (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in the elderly.
Vaccines	Jul. 4, 2014	107	Menactra Intramuscular Injection (Sanofi K.K.)	Approval	Meningococcal quadrivalent vaccine (diphtheria toxoid conjugate)	A drug with a new active ingredient indicated for the prophylaxis of invasive meningococcal disease. (serotypes A, C, Y, and W-135).
Vaccines	Jul. 4, 2014	108	Squarekids Subcutaneous Injection Syringe (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Approval	Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (salk vaccine) combined vaccine	A new combination drug indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis.
Vaccines	Mar. 26, 2015	109	Cell Culture-derived Influenza Emulsion HA Vaccine (prototype) for Intramuscular Injection “Kaketsuken” (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Cell culture-derived influenza emulsion HA vaccines (prototype)	A drug with a new active ingredient indicated for the prevention of pandemic influenza. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Vaccines	Mar. 26, 2015	110	Synflorix Aqueous Suspension for Intramuscular Injection (Japan Vaccine Co., Ltd.)	Approval	Pneumococcal 10-valent conjugate vaccine adsorbed (Non-Typeable *Haemophilus influenzae* (NTHi) protein D, diphtheria or tetanus toxoid conjugates)	A drug with a new active ingredient indicated for the prophylaxis of pneumonia and pneumococcal invasive disease. (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F)
Blood products	Jun. 20, 2014	111	Feiba NF for Injection 500 Feiba NF for Injection 1000 (Baxter Limited)	Change Change	Anti-inhibitor coagulant complex	Drugs with a revised indication and a new dosage for inhibition of bleeding tendency by promoting the blood coagulation in the plasma in patients with inhibitors to blood coagulation factor VIII or factor IX.
Blood products	Jul. 4, 2014	112	Byclot Combination Intravenous Injection (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Freeze-dried activated human blood coagulation factor VII concentrate containing factor X	A new combination drug with a new active ingredient indicated for prevention of bleeding in patients who have inhibitors against blood coagulation factor VIII or IX. [Orphan drug]
Blood products	Jul. 4, 2014	113	Alprolix Intravenous 250 Alprolix Intravenous 500 Alprolix Intravenous 1000 Alprolix Intravenous 2000 Alprolix Intravenous 3000 (Biogen Idec Japan Ltd.)	Approval Approval Approval Approval Approval	Eftrenonacog alfa (genetical recombination)	Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with blood coagulation factor IX deficiency.
Blood products	Dec. 26, 2014	114	Rixubis Intravenous 250 Rixubis Intravenous 500 Rixubis Intravenous 1000 Rixubis Intravenous 2000 Rixubis Intravenous 3000 (Baxter Limited)	Approval Approval Approval Approval Approval	Nonacog gamma (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor IX deficiency.
Blood products	Dec. 26, 2014	115	Eloctate Intravenous 250 Eloctate Intravenous 500 Eloctate Intravenous 750 Eloctate Intravenous 1000 Eloctate Intravenous 1500 Eloctate Intravenous 2000 Eloctate Intravenous 3000 (Biogen Idec Japan Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Efraloctocog alfa (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Feb. 2, 2015	116	Venoglobulin IH 5% I.V. 2.5 g/50 mL (Japan Blood Products Organization)	Change	Polyethylene glycol treated human normal immunoglobulin	A drug with a new indication and a new dosage for the prevention of acute otitis media, acute bronchitis, or pneumonia caused by *Pneumococcus or Haemophilus influenzae* in patients associated with a decrease in serum IgG2 levels. (for use only in patients who have not responded sufficiently to prevention by vaccination and other appropriate treatments, and have repeated the relapse of these diseases).
Blood products	Mar. 26, 2015	117	NovoThirteen i.v.injection 2500 (Novo Nordisk Pharma Ltd.)	Approval	Catridecacog (genetical recombination)	A drug with a new active ingredient indicated for the control of bleeding tendency in patients with congenital blood coagulation factor XIII A-subunit deficiency. [Orphan drug]
Bio-CMC	Jul. 4, 2014	118	(1) Infliximab BS for I.V. Infusion 100 mg “NK” (Nippon Kayaku Co., Ltd.) (2) Infliximab BS for I.V. Infusion 100 mg “CTH” (Celltrion Inc.)	Approval Approval	Infliximab (genetical recombination) [infliximab biosimilar 1]	Follow-on biologics indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments (including prevention of structural joint damage), the treatment and maintenance therapy of Crohn's disease (for use only in patients in an active phase of moderate to severe Crohn's disease or with external fistula who have not responded sufficiently to conventional treatments), or the treatment of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
Bio-CMC	Dec. 26, 2014	119	Insulin Glargine BS Inj. Cartridges [Lilly] Insulin Glargine BS Inj. MirioPen [Lilly] (Eli Lilly Japan K.K.)	Approval Approval	Insulin glargine (genetical recombination) [Insulin glargine biosimilar 1]	Follow-on biologics indicated for the treatment of diabetes mellitus where insulin therapy is indicated.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2013

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 30, 2013	1	Potassium Iodide Pills 50 mg "Nichi-iko" (Nichi-Iko Pharmaceutical Co., Ltd.)	Change	Potassium iodide	A drug with a new additional indication and a new dosage for the prevention and reduction of internal exposure to radioactive iodine in the thyroid gland. [Expedited review]
1	May 16, 2013	2	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbvie G.K.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of intestinal Behcet's disease in patients who have not responded sufficiently to conventional treatments.
1	Jun. 14, 2013	3	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbvie G.K.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Aug. 20, 2013	4	Ora-Bliss Gargle Gran. 11% (Showa Yakuhin Kako Co., Ltd.) Miranor Granule 11% (Oriental Pharmaceutical and Synthetic Chemical Co., Ltd.)	Change Change	Sodium fluoride	Drugs with a new dosage indicated for the prevention of dental caries.
1	Aug. 20, 2013	5	Fosrenol Chewable Tablets 250 mg Fosrenol Chewable Tablets 500 mg Fosrenol Granules 250 mg Fosrenol Granules 500 mg (Bayer Yakuhin, Ltd.)	Change Change Change Change	Lanthanum carbonate hydrate	Drugs with a new indication to extend the indication for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Sep. 13, 2013	6	Lipiodol 480 Injection 10 mL (Guerbet Japan K.K.)	Change	Iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil	A drug with a new route of administration and a new dosage for a new additional indication for the adjustment of drugs or medical devices. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Sep. 13, 2013	7	Nesp Injection 10 μg Plastic Syringe Nesp Injection 15 μg Plastic Syringe Nesp Injection 20 μg Plastic Syringe Nesp Injection 30 μg Plastic Syringe Nesp Injection 40 μg Plastic Syringe Nesp Injection 60 μg Plastic Syringe Nesp Injection 120 μg Plastic Syringe Nesp Injection 180 μg Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change Change	Darbepoetin alfa (genetical recombination)	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of renal anemia.
1	Sep. 13, 2013	8	Soliris for Intravenous Infusion 300 mg (Alexion Pharma G.K.)	Change	Eculizumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
1	Sep. 20, 2013	9	Nesp Injection 5 μg Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval	Darbepoetin alfa (genetical recombination)	A drug with a new additional pediatric dosage in an additional dosage form. The drug is indicated for the treatment of renal anemia.
1	Sep. 20, 2013	10	Oblean Tablets 120 mg (Takeda Pharmaceutical Company Limited)	Approval	Cetilistat	A drug with a new active ingredient indicated for the treatment of obesity (for use only in patients who have both type 2 diabetes mellitus and dyslipidaemia and whose BMI level is 25kg/m^2 or more even with diet and exercise therapies).
1	Jan. 17, 2014	11	Riona Tab. 250 mg (Japan Tobacco Inc.)	Approval	Ferric citrate hydrate	A drug with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Jan. 17, 2014	12	Savene Injectable 500 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	Dexrazoxane	A drug with a new active ingredient indicated for the treatment of anthracycline extravasation.
1	Feb. 21, 2014	13	Regpara Tablets 25 mg Regpara Tablets 75 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Cinacalcet hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism (HPT) who are unable to undergo parathyroidectomy or who experience recurrent primary HPT after the surgery. [Orphan drug]
1	Mar. 24, 2014	14	Glash Vista Solution for external use 0.03% 3 mL Glash Vista Solution for external use 0.03% 5 mL (Allergan Japan K.K.)	Approval Approval	Bimatoprost	Drugs with a new route of administration for the treatment of eyelashe hypotrichosis.
2	May 31, 2013	15	Ancaron Inj. 150 (Sanofi K.K.)	Change	Amiodarone hydrochloride	A drug with a new additional indication and a new dosage indicated for the treatment of cardiac arrest due to ventricular fibrillation/pulseless ventricular tachycardia, resistant to electrical cardioversion.
2	Jun. 14, 2013	16	Adalat-CR Tablets 10 Adalat-CR Tablets 20 Adalat-CR Tablets 40 (Bayer Yakuhin, Ltd.)	Change Change Change	Nifedipine	Drugs with a new dosage indicated for the treatment of hypertension.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Jun. 14, 2013	17	Maintate Tablets 2.5 mg Maintate Tablets 5 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Bisoprolol fumarate	Drugs with a new additional indication and a new dosage for the treatment of tachycardiac atrial fibrillation.
2	Jun. 28, 2013	18	Bisono Tape 4 mg Bisono Tape 8 mg (Toa Eiyo Ltd.)	Approval Approval	Bisoprolol	Drugs with a new active ingredient indicated for the treatment of essential hypertension (mild to moderate).
2	Jun. 28, 2013	19	Irtra Combination Tablets LD Irtra Combination Tablets HD (Shionogi & Co., Ltd.)	Approval Approval	Irbesartan/ trichlormethiazide	New combination drugs indicated for the treatment of hypertension.
2	Aug. 20, 2013	20	Trerief Tablet 25 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change	Zonisamide	A drug with a new dosage indicated for the improvement of wearing-off phenomenon in symptoms of Parkinson's disease.
2	Sep. 13, 2013	21	Samsca Tablets 7.5 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Tolvaptan	A drug with a new additional indication and a new dosage for the treatment of fluid retention in patients with hepatic cirrhosis who have not responded sufficiently to other diuretics such as loop diuretics
2	Sep. 20, 2013	22	Complavin Combination Tablets (Sanofi K.K.)	Approval	(1) Clopidogrel sulfate (2) Aspirin	A new combination drug indicated for the treatment of ischemic heart diseases (acute coronary syndrome [unstable angina, non-ST-segment elevation myocardial infarction, ST-segment elevation myocardial infarction], stable angina, old myocardial infarction) to which percutaneous coronary intervention (PCI) is applicable.
2	Sep. 20, 2013	23	Preminent Tablets HD (MSD K.K.)	Approval	(1) Losartan potassium (2) Hydrochlorothiazide	A drug with a new dosage in an additional dosage form. The drug is indicated for the treatment of hypertension.
2	Nov. 22, 2013	24	Onoact 50 for injection (Ono Pharmaceutical Co., Ltd.)	Change	Landiolol hydrochloride	A drug with a new additional indication and a new dosage for the treatment of tachyarrhythmia including atrial fibrillation/flutter in patients with low cardiac function.
2	Jan. 17, 2014	25	Adempas Tablets 0.5 mg Adempas Tablets 1.0 mg Adempas Tablets 2.5 mg (Bayer Yakuhin, Ltd.)	Approval Approval Approval	Riociguat	Drugs with a new active ingredient indicated for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH. [Orphan drug]
2	Mar. 24, 2014	26	Takelda Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Lansoprazole/aspirin	A new combination drug indicated for the postoperative inhibition of thrombus and thrombus formation (limited to patients with previous history of gastric or duodenal ulcer) in patients with angina (chronic stable angina, unstable angina), myocardial infraction, ischemic cerebrovascular disorder (transient ischemic attack [TIA], cerebral infarction), and patients who have undergone coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA).
2	Mar. 24, 2014	27	Atedio Combination Tab. (Ajinomoto Pharmaceutical Co., Ltd.)	Approval	Valsartan/cilnidipine	A new combination drug indicated for the treatment of hypertension.
2	Mar. 24, 2014	28	Rasimlo Combination Tablet LD Rasimlo Combination Tablet HD (Novartis Pharma K.K.)	Approval Approval	Aliskiren fumarate/amlodipine besylate	New combination drugs indicated for the treatment of hypertension.
2	Mar. 24, 2014	29	Zacras Combination Tablets LD Zacras Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Azilsartan/amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	Mar. 24, 2014	30	Treprost 20 mg for injection Treprost 50 mg for injection Treprost 100 mg for injection Treprost 200 mg for injection (Mochida Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Treprostinil	Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension (WHO functionalclassification; Class II, III and IV).
2	Mar. 24, 2014	31	Samsca Tablets 7.5 mg Samsca Tablets 15 mg Samsca Tablets 30 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Approval	Tolvaptan	Drugs with a new additional indication and a new dosage, and a drug with a newly-added dosage form indicated for inhibiting the progression of autosomal dominant polycystic kidney disease in patients whose kidney volume already have increased and enlarged at a rapid rate. [Orphan drug]
2	Mar. 24, 2014	32	Efient Tablets 3.75 mg Efient Tablets 5 mg (Daiichi Sankyo Company, Limited)	Approval Approval	Prasugrel hydrochloride	Drugs with a new active ingredient indicated for the treatment of the following ischemic heart diseases managed with percutaneous coronary intervention (PCI): acute coronary syndrome (unstable angina, non ST-segment elevation myocardial infarction, ST-segment elevation myocardial infarction), stable angina, old myocardial infarction.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
(1) - (3) 2 (4) - (6) 2 3-1	Sep. 13, 2013	33	[1] Predonine 10 mg [2] Predonine 20 mg [3] Predonine 50 mg [4] Predonine Tablets 5 mg (Shionogi & Co., Ltd.) [5] Prednisolone Tablets 1 mg (Asahi Kasei) [6] Prednisolone Tablets 5 mg (Asahi Kasei) (Asahi Kasei Pharma Corporation)	Change Change Change Change Change Change	[1] - [3] Prednisolone sodium succinate [4] - [6] Prednisolone	Drugs with a new additional indication and a new dosage for the treatment of acute-phase Kawasaki's disease (cases where the disease is severe and at risk for coronary artery disorder) ([1] - [6]) and Duchenne muscular dystrophy ([4] - [6]). Duchenne muscular dystrophy: [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	May 31, 2013	34	E Keppra Tablets 250 mg E Keppra Tablets 500 mg (UCB Japan Co., Ltd.)	Change Change	Levetiracetam	Drugs with a new additional pediatric dosage indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Jun. 14, 2013	35	Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Tablets 12 mg Abilify OD Tablets 3 mg Abilify OD Tablets 6 mg Abilify OD Tablets 12 mg Abilify Powder 1% Abilify Oral Solution 0.1% (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Aripiprazole	Drugs with a new additional indication and a new dosage for the treatment of depression (for use only in patients who have an inadequate response to antidepressant therapy).
3-1	Jun. 28, 2013	36	E Keppra Dry Syrup 50% (UCB Japan Co., Ltd.)	Approval	Levetiracetam	A drug with a new additional pediatric dosage in an additional dosage form indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Sep. 20, 2013	37	Xeplion Aqueous Suspension for Intramuscular Injection 25 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 50 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 75 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 100 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 150 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval	Paliperidone palmitate	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Sep. 20, 2013	38	Vyndaqel Capsules 20 mg (Pfizer Japan Inc.)	Approval	Tafamidis meglumine	A drug with a new active ingredient indicated for delaying the peripheral neurologic impairment in transthyretin familial amyloid polyneuropathy. [Orphan drug]
3-1	Nov. 22, 2013	39	Paxil Tablets 5 mg Paxil Tablets 10 mg Paxil Tablets 20 mg (GlaxoSmithKline K.K.)	Change Change Change	Paroxetine hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of posttraumatic stress disorder.
3-1	Nov. 22, 2013	40	Anafranil Tablets 10 mg Anafranil Tablets 25 mg (Alfresa Pharma Corporation)	Change Change	Clomipramine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of cataplexy associated with narcolepsy. [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	Nov. 22, 2013	41	Topina Tablets 25 mg Topina Tablets 50 mg Topina Tablets 100 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change	Topiramate	Drugs with a new additional pediatric dosage. These drugs are indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Dec. 20, 2013	42	Concerta Tablets 18 mg Concerta Tablets 27 mg (Janssen Pharmaceutical K.K.)	Change Change	Methylphenidate hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Jan. 17, 2014	43	Topina Fine Granules 10% (Kyowa Hakko Kirin Co., Ltd.)	Approval	Topiramate	A drug with a new additional pediatric dosage in an additional dosage form. The drug is indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Jan. 17, 2014	44	Concerta Tablets 36 mg (Janssen Pharmaceutical K.K.)	Approval	Methylphenidate hydrochloride	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of attention deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Mar. 24, 2014	45	Tysabri for I.V. Infusion 300 mg (Biogen Idec Japan Ltd.)	Approval	Natalizumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-2	Jun. 14, 2013	46	Precedex Intravenous Solution 200 μg "Hospira" (Hospira Japan Co., Ltd.) Precedex Intravenous Solution 200 μg "Maruishi" (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Dexmedetomidine hydrochloride	Drugs with a new additional indication and a new dosage for sedation of non-intubated patients during surgical and other procedures under local anesthesia.
3-2	Jun. 14, 2013	47	Tramal Capsules 25 mg Tramal Capsules 50 mg (Nippon Shinyaku Co., Ltd.)	Change Change	Tramadol hydrochloride	Drugs with a new additional indication for analgesia in patients with chronic non-cancer pain which cannot be managed by treatments with non-opioid analgesics.
3-2	Jun. 14, 2013	48	Penles Tape 18 mg (Nitto Denko Corporation)	Change	Lidocaine	A drug with a new additional indication and a new dosage for the relief of pain during skin laser radiation therapy.
3-2	Jun. 28, 2013	49	E-fen Buccal Tablets 50 μg E-fen Buccal Tablets 100 μg E-fen Buccal Tablets 200 μg E-fen Buccal Tablets 400 μg E-fen Buccal Tablets 600 μg E-fen Buccal Tablets 800 μg (Teikoku Seiyaku Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Fentanyl citrate	Drugs with a new dosage in a new dosage form for the analgesia of breakthrough pain in patients with cancer receiving a potent opioid analgesic at a fixed time.
3-2	Aug. 20, 2013	50	Lucentis Solution for Intravitreal Injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of macular edema following retinal vein occlusion and choroidal neovascularisasion in pathologic myopia.
3-2	Sep. 20, 2013	51	Tapcom Combination Ophthalmic Solution (Santen Pharmaceutical Co., Ltd.)	Approval	(1) Tafluprost (2) Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Sep. 20, 2013	52	Abstral Sublingual Tablet 100 μg Abstral Sublingual Tablet 200 μg Abstral Sublingual Tablet 400 μg (Kyowa Hakko Kirin Co., Ltd.)	Approval Approval Approval	Fentanyl citrate	Drugs with a new dosage in a new dosage form indicated for analgesia of breakthrough pain in patients with cancer receiving a potent opioid analgesic at fixed time.
3-2	Sep. 20, 2013	53	Azorga Combination Ophthalmic Suspension (Alcon Japan Ltd.)	Approval	(1) Brinzolamide (2) Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other glaucoma drugs.
3-2	Nov. 22, 2013	54	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of macular edema following central retinal vein occlusion.
3-2	Dec. 20, 2013	55	Dormicum Injection 10 mg (Astellas Pharma Inc.)	Change	Midazolam	A drug with a new additional indication and a new dosage for sedation during surgeries and other procedures in the field of dentistry and oral surgery.
3-2	Dec. 20, 2013	56	OneDuro Patch 0.84 mg OneDuro Patch 1.7 mg OneDuro Patch 3.4 mg OneDuro Patch 5 mg OneDuro Patch 6.7 mg (Janssen Pharmaceutical K.K.)	Change Change Change Change Change	Fentanyl	Drugs with a new additional indication for analgesia in moderate to severe chronic pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Feb. 21, 2014	57	Lucentis solution for intravitreal injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with a new additional indication for the treatment of diabetic macular edema.
3-2	Mar. 24, 2014	58	Tapenta Tablets 25 mg Tapenta Tablets 50 mg Tapenta Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	Tapentadol hydrochloride	Drugs with a new active ingredient indicated for management of moderate to severe pain in various types of cancer.
4	Aug. 20, 2013	59	Cubicin IV 350 mg (MSD K.K.)	Change	Daptomycin	A drug with a new dosage indicated for the treatment of sepsis, infective endocarditis, deep skin infection, secondary infection of trauma, burn and surgical wound, and secondary infection of erosion and ulcer caused by daptomycin-sensitive methicillin-resistant *Staphylococcus aureus* (MRSA).
4	Aug. 20, 2013	60	Synagis for Intramuscular Injection 50 mg Synagis for Intramuscular Injection 100 mg Synagis for Intramuscular Solution 50 mg Synagis for Intramuscular Solution 100 mg (Abbvie G.K.)	Change Change Change Change	Palivizumab (genetical recombination)	Drugs with new indications for the suppression of development of serious lower respiratory tract disease caused by RS viral infection in newborns, infants, and children aged 24 months or less with immunodeficiency and Down syndrome. [Priority review]
4	Sep. 13, 2013	61	Gentacin Injection 10 Gentacin Injection 40 Gentacin Injection 60 (MSD K.K.)	Change Change Change	Gentamicin sulfate	Drugs with a new dosage indicated for the treatment of sepsis, secondary infection of trauma, burn, and surgical wound, pneumonia, cystitis, pyelonephritis, peritonitis, otitis media caused by following applicable microorganisms: Gentamicin-sensitive *Staphylococcus, Escherichia coli, Klebsiella, Enterobacter, Serratia, Proteus, Morganella morganii, Providencia, Pseudomonas aeruginosa*

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Sep. 27, 2013	62	Sovriad Capsules 100 mg (Janssen Pharmaceutical K.K.)	Approval	Simeprevir sodium	A drug with a new active ingredient indicated for the improvement of viraemia in following (1) or (2) patient with chronic hepatitis C serogroup 1 (genotype I [1a] or II [1b]): (1) Patient with high level of blood HCV RNA who have untreated or (2) Patients who have not respond to or relapsed with the treatment including interferon. [Priority review]
4	Dec. 20, 2013	63	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Change	Laninamivir octanoate hydrate	A drug with a new additional indication and a new dosage for prophylaxis of influenza A or B virus infections.
4	Dec. 20, 2013	64	Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Meropenem hydrate	Drugs with a new dosage (the daily dose has been changed) in patients with purulent meningitis.
4	Feb. 21, 2014	65	Streptomycin Sulfate 1 g ”Meiji” for Injection (Meiji Seika Pharma Co., Ltd.)	Change	Streptomycin sulfate	A drug with a new additional indication and new dosage for the treatment of non-tuberculous mycobacterial infection including mycobacterium avium complex (MAC) caused by streptomycin-sensitive *mycobacterium* as its applicable microorganism. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Feb. 21, 2014	66	Dalacin S Injection 300 mg Dalacin S Injection 600 mg (Pfizer Japan Inc.)	Change Change	Clindamycin phosphate	Drugs with a new additional indication for cellulitis around the jaw bone and jaw inflammation. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Mar. 24, 2014	67	Avigan Tablet 200 mg (Toyama Chemical Co., Ltd.)	Approval	Favipiravir	A drug with a new active ingredient indicated for novel or re-emerging influenza virus infections (for use only in patients who have not responded or not responded sufficiently to other anti-influenza virus drugs). [Priority review]
4	Mar. 24, 2014	68	Sumithrin Lotion 5% (Kracie Pharma, Ltd.)	Approval	Phenothrin	A drug with a new indication and a new dosage for the treatment of scabies. [Priority review]
4	Mar. 24, 2014	69	Tenozet Tablets 300 mg (GlaxoSmithKline K.K.)	Approval	Tenofovir disoproxil fumarate	A drug with a new active ingredient indicated for the growth inhibition of hepatitis B virus in patients with chronic hepatitis B who show liver dysfunction accompanied by proliferation of the virus. [Priority review]
5	May 16, 2013	70	Lunabell Tablets LD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ ethinylestradiol	A drug with a revised indication from "dysmenorrhea associated with endometriosis; functional dysmenorrhea" to "dysmenorrhea."
5	Jun. 28, 2013	71	Lunabell Tablets ULD (Nobelpharma Co., Ltd.)	Approval	Norethisterone/ ethinylestradiol	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of dysmenorrhea.
5	Sep. 20, 2013	72	(1) Reguneal HCa 1.5 Peritoneal Dialysis Solution Reguneal HCa 2.5 Peritoneal Dialysis Solution Reguneal HCa 4.25 Peritoneal Dialysis Solution (2) Reguneal LCa 1.5 Peritoneal Dialysis Solution Reguneal LCa 2.5 Peritoneal Dialysis Solution Reguneal LCa 4.25 Peritoneal Dialysis Solution (Baxter Limited)	 Approval Approval Approval Approval Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the treatment of (1) peritoneal dialysis in patients with chronic renal failure (used when the peritoneal dialysis is not sufficiently effective to improve hypermagnesemia), (2) peritoneal dialysis in patients with chronic renal failure (used when the peritoneal dialysis is not sufficiently effective to improve hypermagnesemia and when hypercalcaemia may occur due to the treatment with calcium preparation or active vitamin D preparation).
5	Jan. 17, 2014	73	Zalutia 2.5 mg Tablets Zalutia 5 mg Tablets (Eli Lilly Japan K.K.)	Approval Approval	Tadalafil	Drugs with a new indication and a new dosage in a new additional dosage form indicated for the treatment of dysuria associated with benign prostatic hypertrophy.
5	Feb. 21, 2014	74	Estrana Tape 0.72 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change	Estradiol	A drug with a new additional indication and new dosages for the treatment of hypoestrogenism caused by hypogonadism, gonadectomy or primary ovarian insufficiency. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Mar. 24, 2014	75	Racol-NF Semisolid for Enteral Use (EN Otsuka Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding for especially patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
5	Mar. 24, 2014	76	Enevo Liquid for Enteral Use (Abbott Japan Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding for especially patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
6-1	Jun. 14, 2013	77	Prograf Capsules 0.5 mg Prograf Capsules 1 mg (Astellas Pharma Inc.)	Change Change	Tacrolimus hydrate	Drugs with a new additional indication and new dosage for the treatment of interstitial pneumonia associated with polymyositis/dermatomyositis. [Orphan drug]
6-1	Jun. 28, 2013	78	Orencia SC 125 mg Syringe 1 mL (Bristol-Myers K.K.)	Approval	Abatacept (genetical recombination)	A drug with a new route of administration and a new dosage in a new dosage form indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 28, 2013	79	Accelio Intravenous Injection 1000 mg (Terumo Corporation)	Approval	Acetaminophen	A drug with a new route of administration indicated for the treatment of pain and pyrexia which cannnot be managed by oral preparations and suppositories.
6-1	Aug. 20, 2013	80	Xolair for S.C. Injection 150 mg Xolair for S.C. Injection 75 mg (Novartis Pharma K.K.)	Change Change	Omalizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Sep. 20, 2013	81	Flutiform 50 Aerosol 56 puffs Flutiform 125 Aerosol 56 puffs Flutiform 50 Aerosol 120 puffs Flutiform 125 Aerosol 120 puffs (Kyorin Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	(1) Fluticasone propionate (2) Formoterol fumarate hydrate	New combination drugs indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Sep. 20, 2013	82	Alesion Ophthalmic Solutoin 0.05% (Santen Pharmaceutical Co., Ltd.)	Approval	Epinastine hydrochloride	A drug with a new route of administration indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 20, 2013	83	Relvar 100 Ellipta 14 doses Relvar 100 Ellipta 30 doses Relvar 200 Ellipta 14 doses Relvar 200 Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	(1) Vilanterol trifenatate (2) Fluticasone furoate	New combination drugs with a new active ingredient indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Sep. 20, 2013	84	Ultibro Inhalation Capsules (Novartis Pharma K.K.)	Approval	(1) Indacaterol maleate (2) Glycopyrronium bromide	A new combination drug indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (when a combination treatment of an inhaled long-acting anticholinergic and a long-acting beta-2 agonist is needed).
6-1	Jan. 17, 2014	85	Allegra 5% Dry Syrup (Sanofi K.K.)	Approval	Fexofenadine hydrochloride	A drug with a new additional pediatric (6 months of age and older and less than 7 years of age) dosage in an additional dosage form of dry syrup. This drug is indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, pruritus cutaneous, atopic dermatitis).
6-1	Jan. 17, 2014	86	Cedartolen Sublingual Drop-Japanese Cedar Polllen 200 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Polllen 2,000 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Polllen 2,000 JAU/mL pack (Torii Pharmaceutical Co., Ltd.)	Approval Approval Approval	Standardized Japanese cedar pollen extract original solution 10,000 JAU/mL	Drugs with a new route of administration indicated for the treatment of Japanese cedar pollinosis. (Allergen immunotherapy).
6-1	Jan. 17, 2014	87	Xyzal Syrup 0.05% (GlaxoSmithKline K.K.)	Approval	Levocetirizine hydrochloride	A drug with a new additional pediatric (6 months of age and older and less than 7 years of age) dosage in an additional dosage form of dry syrup. This drug is indicated for the treatment of allergic rhinitis, urticaria and itching associated with skin disease. (eczema/dermatitis and pruritus cutaneous)
6-1	Mar. 17, 2014	88	Allermist 27.5 μg 56 metered Nasal Spray (GlaxoSmithKline K.K.)	Change	Fluticasone furoate	A drug with a new additional pediatric dosage indicated for the treatment of allergic rhinitis.
6-1	Mar. 24, 2014	89	Respia Injection or oral solution 60 mg (Nobelpharma Co., Ltd.)	Approval	Anhydrous caffeine	A drug with a new route of administration indicated for the treatment of primary apnea (apnea of prematurity) in immature or low birth weight infants. [Orphan drug]
6-2	Jun. 28, 2013	90	Topiloric Tablets 20 mg Topiloric Tablets 40 mg Topiloric Tablets 60 mg (Fujiyakuhin Co., Ltd.) Uriadec Tab. 20 mg Uriadec Tab. 40 mg Uriadec Tab. 60 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Topiroxostat	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Jun. 28, 2013	91	Lyxumia 300 µg solution for injection (Sanofi K.K.)	Approval	Lixisenatide	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either treatment (1) or (2): (1) Use of sulfonylureas (including combination with biguanides) in addition to diet and exercise therapies; (2) Use of long-acting soluble insulin or intermediate-acting insulin preparations (including combination with sulfonylureas) in addition to diet and exercise therapies.
6-2	Jun. 28, 2013	92	Bonviva IV Injection 1 mg Syringe (Chugai Pharmaceutical Co., Ltd.)	Approval	Ibandronate sodium hydrate	A drug with a new active ingredient indicated for the treatment of osteoporosis.
6-2	Sep. 13, 2013	93	Glufast Tab. 5 mg Glufast Tab. 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change Change	Mitiglinide calcium hydrate	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Dec. 20, 2013	94	Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Teneligliptin hydrobromide hydrate	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Jan. 17, 2014	95	Suglat Tablets 25 mg Suglat Tablets 50 mg (Astellas Pharma Inc.)	Approval Approval	Ipragliflozin L-proline	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jan. 17, 2014	96	Cystadane (ReqMed Company, Ltd.)	Approval	Betaine	A drug with a new active ingredient indicated for the treatment of homocystinuria. [Orphan drug]
6-2	Mar. 24, 2014	97	Forxiga Tablets 5 mg Forxiga Tablets 10 mg (Bristol-Myers K.K.)	Approval Approval	Dapagliflozin propylene glycolate hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 24, 2014	98	Lusefi Tab. 2.5 mg Lusefi Tab. 5 mg (Taisho Pharmaceutical Co., Ltd.)	Approval Approval	Luseogliflozin hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 24, 2014	99	Deberza Tablets 20 mg (Kowa Company, Ltd.) Apleway 20 mg Tablets (Sanofi K.K.)	Approval Approval	Tofogliflozin hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
Radio-pharmaceuticals	Sep. 20, 2013	100	DaTscan Intravenous Injection (Nihon Medi-Physics Co., Ltd.)	Approval	Ioflupane (123I)	A drug with a new active ingredient indicated for dopamine transporter scintigraphy in the diagnoses of Parkinson's syndrome and dementia with Lewy bodies.
Oncology drugs	Jun. 14, 2013	101	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of malignant glioma. [Orphan drug]
Oncology drugs	Jun. 14, 2013	102	Tarceva Tablet 25 mg Tarceva Tablet 100 mg Tarceva Tablet 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Erlotinib hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent non-small cell lung cancer with *EGFR* gene mutation in patients who have not been treated with chemotherapy.
Oncology drugs	Jun. 14, 2013	103	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new dosage for the treatment of breast cancer with HER2 overexpression. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 14, 2013	104	Hycamtin for Injection 1.1 mg (Nippon Kayaku Co., Ltd.)	Change	Nogitecan hydrochloride	A drug with a new additional indication and a new dosage for the treatment of pediatric malignant solid tumors. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 28, 2013	105	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Approval	Pertuzumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer.
Oncology drugs	Aug. 20, 2013	106	Stivarga Tablets 40 mg (Bayer Yakuhin, Ltd.)	Change	Regorafenib hydrate	A drug with a new additional indication for the treatment of gastrointestinal stromal tumor which has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Sep. 20, 2013	107	Unitalc Intrapleural 4 g (Nobelpharma Co., Ltd.)	Approval	Sterile talc	A drug with a new active ingredient indicated for the suppression of recurrence of malignant pleural effusions.
Oncology drugs	Sep. 20, 2013	108	Kadcyla Intravenous Infusion 100 mg Kadcyla Intravenous Infusion 160 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Trastuzumab emtansine (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer. [Priority review]
Oncology drugs	Sep. 20, 2013	109	Laserphyrin 100 mg for Injection (Meiji Seika Pharma Co., Ltd.)	Change	Talaporfin sodium	A drug with a new additional indication and a new dosage for the treatment of primary malignant brain tumor (only for the case where surgical excision of tumor is performed). [Orphan drug]
Oncology drugs	Nov. 22, 2013	110	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication for the treatment of ovarian cancer.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 22, 2013	111	Farmorubicin for Injection 10 mg Farmorubicin for Injection 50 mg (Pfizer Japan Inc.)	Change Change	Epirubicin hydrochloride	Drugs with a new additional dosage indicated for transcatheter arterial chemo-embolization (TACE) in hepatocellular carcinoma. [Public knowledge-based application]
Oncology drugs	Dec. 20, 2013	112	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.)	Change Change Change	Oxaliplatin	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	113	Campto 40 mg for I.V. Infusion Campto 100 mg for I.V. Infusion (Yakult Honsha Co., Ltd.)	Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	114	Topotecin Intravenous Drip Infusion 40 mg Topotecin Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	115	Isovorin Injection 25 mg Isovorin Injection 100 mg (Pfizer Japan Inc.)	Change Change	Levofolinate calcium	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	116	Levofolinate for I.V. Infusion 25 mg “Yakult” Levofolinate for I.V. Infusion 100 mg “Yakult” (Yakult Honsha Co., Ltd.)	Change Change	Levofolinate calcium	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	117	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Jan. 17, 2014	118	Giotrif Tablets 20 mg Giotrif Tablets 30 mg Giotrif Tablets 40 mg Giotrif Tablets 50 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval Approval Approval	Afatinib maleate	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer with EGFR gene mutation.
Oncology drugs	Jan. 17, 2014	119	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Approval	Brentuximab vedotin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory CD30-positive Hodgkin’s lymphoma and anaplastic large-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 17, 2014	120	Zoladex LA 10.8 mg depot (AstraZeneca K.K.)	Change	Goserelin acetate	A drug with a new additional indication for the treatment of premenopausal breast cancer.
Oncology drugs	Mar. 17, 2014	121	Afinitor Tablets 2.5 mg Afinitor Tablets 5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with a new additional indication and a new dosage for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Mar. 17, 2014	122	Votrient Tablets 200 mg (GlaxoSmithKline K.K.)	Change	Pazopanib hydrochloride	A drug with a new additional indication for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Mar. 17, 2014	123	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Change	Mogamulizumab (genetical recombination)	A drug with new additional indications for the treatment of relapsed or refractory CCR4-positive peripheral T-cell lymphoma and relapsed or refractory CCR4-positive cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 24, 2014	124	Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	Trifluridine/tipiracil hydrochloride	New combination drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Mar. 24, 2014	125	Xtandi Capsules 40 mg (Astellas Pharma Inc.)	Approval	Enzalutamide	A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer. [Priority review]
(1) Oncology drugs (2) 6-1	Jun. 14, 2013	126	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of (1) CD 20-positive B-cell lymphoproliferative disorders in immunocompromised patients and (2) Wegener's granulomatosis and microscopic polyangiitis. [Public knowledge-based application after PAFSC's preliminary assessment]
AIDS drugs	Mar. 24, 2014	127	Tivicay Tablets 50 mg (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium	A drug with a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
Vaccines	Apr. 26, 2013	128	Cell Culture-derived Influenza Vaccine (prototype) "Baxter" (Baxter Limited) Cell Culture-derived Influenza Vaccine (prototype) "Takeda" 5 mL (Takeda Pharmaceutical Company Limited)	Approval Approval	Cell culture-derived influenza vaccines (prototype)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Vaccines	Jun. 18, 2013	129	Prevenar 13 Suspension Liquid for Injection (Pfizer Japan Inc.)	Approval	Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM_{197} conjugate)	A drug with a new active ingredient indicated for the prophylaxis of pneumococcal invasive disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F).
Vaccines	Jun. 18, 2013	130	Cell Culture-derived Influenza Vaccine H5N1 "Baxter" (Baxter Limited) Cell Culture-derived Influenza Vaccine H5N1 "Takeda" 5 mL (Takeda Pharmaceutical Company Limited)	Approval Approval	Cell culture-derived influenza vaccine (H5N1)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 17, 2014	131	Heptavax-II (MSD K.K.) Bimmugen Bimmugen Injection 0.25 mL Bimmugen Injection 0.5 mL (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change Change Change Change	Recombinant adsorbed hepatitis B vaccine (prepared from yeast)	Drugs with a revised dosage indicated for the prevention of perinatal hepatitis B virus infection (concomitant use with anti-Hepatitis B surface [HBs] human immunoglobulin). [Public knowledge-based application after PAFSC's preliminary assessment]
Vaccines	Mar. 24, 2014	132	Cell Culture-derived Influenza Emulsion HA Vaccine H5N1 for Intramuscular Injection “Kaketsuken” (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Cell culture-derived influenza emulsion HA vaccine (H5N1)	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 24, 2014	133	Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 30μg/mL “Kitasato Daiichi Sankyo” Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 60μg/mL “Kitasato Daiichi sankyo” (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Approval Approval	Adsorbed cell culture-derived influenza vaccine (H5N1)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	May 16, 2013	134	NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new dosage to add single-dose administration for the prevention of bleeding in patients with congenital hemophilia who have inhibitors against blood coagulation factor VIII or IX. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 13, 2013	135	Fibrogammin P I.V. Injection (CSL Behring K.K.)	Change	Lyophilized human blood coagulation factor XIII concentrate	A drug with a new additional indication for the treatment of bleeding tendency caused by acquired blood coagulation factor XIII deficiency. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 27, 2013	136	Hizentra 20% S.C. Injection 1 g/5 mL Hizentra 20% S.C. Injection 2 g/10 mL Hizentra 20% S.C. Injection 4 g/20 mL (CSL Behring K.K.)	Approval Approval Approval	pH4-treated normal human immunoglobulin (subcutaneous injection)	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Jan. 17, 2014	137	NovoEight i.v.injection 250 NovoEight i.v.injection 500 NovoEight i.v.injection 1000 NovoEight i.v.injection 1500 NovoEight i.v.injection 2000 NovoEight i.v.injection 3000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval Approval	Turoctocog alpha (genetical recombination)	Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Bio-CMC	Mar. 24, 2014	138	Filgrastim BS Inj.75 μg Syringe “Sandoz” Filgrastim BS Inj.150 μg Syringe “Sandoz” Filgrastim BS Inj.300 μg Syringe “Sandoz” (Sandoz K.K.)	Approval Approval Approval	Filgrastim (genetical recombination) [Filgrastim biosimilar 3]	Follow-on biologics indicated for mobilization of hematopoietic stem cell to peripheral blood, promotion of increase in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia and congenital/idiopathic neutropenia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

New Drugs Approved in FY 2012

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Jun. 22, 2012	1	Nexium Capsules 10 mg Nexium Capsules 20 mg (AstraZeneca K.K.)	Change Change	Esomeprazole magnesium hydrate	Drugs with a new additional indication and a new dosage for the prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with low-dose aspirin.
1	Jun. 22, 2012	2	Emend Capsules 80 mg Emend Capsules 125 mg Emend Capsules Set (Ono Pharmaceutical Co., Ltd.)	Change Change Change	Aprepitant	Drugs with a new additional pediatric dosage for patients of 12 years or older. These drugs are indicated for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) (including delayed phase).
1	Jun. 29, 2012	3	Amitiza Capsules 24 μg (Sucampo Pharma. Ltd.)	Approval	Lubiprostone	A drug with a new active ingredient indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Aug. 24, 2012	4	Pentasa Tablets 250 mg Pentasa Tablets 500 mg (Kyorin Pharmaceutical Co., Ltd.)	Change Change	Mesalazine	Drugs with a new dosage. These drugs are indicated for the treatment of ulcerative colitis.
1	Dec. 21, 2012	5	Radiogardase Capsule 500 mg (Nihon Medi-Physics Co., Ltd.)	Change	Iron (III) hexacyanoferrate (II)	A drug with a new additional indication for the treatment of thallium and thallium compound poisoning.
1	Dec. 25, 2012	6	Moviprep Combination Oral Solution (Ajinomoto Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used for bowel cleansing as a preparation for colonoscopy and large intestine surgery.
1	Dec. 25, 2012	7	Phosribbon Combination Granules (Zeria Pharmaceutical Co., Ltd.)	Approval	Monobasic sodium phosphate monohydrate/dibasic sodium phosphate anhydrous	A drug with a new indication and a new dosage in an additional dosage form for the treatment of hypophosphatemia. [Orphan drug]
1	Feb. 28, 2013	8	Minclea Catapasm for Internal Use 0.8% (Nihon Pharmaceutical Co., Ltd.)	Change	*l*-Menthol	A drug with a new additional indication for the inhibition of gastric peristalsis in endoscopic therapy for the upper gastrointestinal tract.
1	Mar. 25, 2013	9	Pentasa Suppositories 1 g (Kyorin Pharmaceutical Co., Ltd.)	Approval	Mesalazine	A drug in a new dosage form indicated for the treatment of ulcerative colitis (excluding severe cases).
1	Mar. 25, 2013	10	Acofide Tablets 100 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	Acotiamide hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of postprandial fullness, upper abdominal bloating, and early satiation in functional dyspepsia.
2	May 25, 2012	11	Kaytwo Syrup 0.2% (Sannova Co., Ltd.)	Change	Menatetrenone	A drug with a new additional indication and a new dosage for the prevention of vitamin K-deficiency hemorrhage in neonates/infants. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	May 25, 2012	12	Inderal Tablets 10 mg Inderal Tablets 20 mg (AstraZeneca K.K.)	Change Change	Propranolol hydrochloride	Drugs with new additional pediatric dosages for extrasystole (supraventricular/ventricular), the prevention of paroxysmal tachycardia, atrial fibrillation with rapid ventricular response (bradycardiac effect), sinus tachycardia, atrial fibrillation, and the prevention of paroxysmal atrial fibrillation. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	13	Epadel Capsules 300 Epadel S300 Epadel S600 Epadel S900 (Mochida Pharmaceutical Co., Ltd.)	Change Change Change Change	Ethyl icosapentate	Drugs with a new dosage. These drugs are indicated for the treatment of hyperlipemia.
2	Jun. 22, 2012	14	Renivace Tablets 2.5 Renivace Tablets 5 Renivace Tablets 10 (MSD K.K.)	Change Change Change	Enalapril maleate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	15	Zestril Tablets 5 Zestril Tablets 10 Zestril Tablets 20 (AstraZeneca K.K.)	Change Change Change	Lisinopril hydrate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Jun. 22, 2012	16	Longes Tablets 5 mg Longes Tablets 10 mg Longes Tablets 20 mg (Shionogi & Co., Ltd.)	Change Change Change	Lisinopril hydrate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun.22, 2012	17	Norvasc Tablets 2.5 mg Norvasc Tablets 5 mg Norvasc OD Tablets 2.5 mg Norvasc OD Tablets 5 mg (Pfizer Japan Inc.) Amlodin Tablets 2.5 mg Amlodin Tablets 5 mg Amlodin OD Tablets 2.5 mg Amlodin OD Tablets 5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change Change Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	18	Amlodipine Tab. 2.5 mg "Amel" Amlodipine Tab. 5 mg "Amel" Amlodipine OD Tab. 2.5 mg "Amel" Amlodipine OD Tab. 5 mg "Amel" (Kyowa Pharmaceutical Industry Co., Ltd.)	Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosages. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	19	Enalart Fine Gran. 1% Enalart Tab. 2.5 mg Enalart Tab. 5 mg Enalart Tab. 10 mg (Kyowa Pharmaceutical Industry Co., Ltd.)	Change Change Change Change	Enalapril maleate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	20	Amlodipine Oral Jelly 2.5 mg "Towa" Amlodipine Oral Jelly 5 mg "Towa" Amlodipine OD Tablets 2.5 mg "Towa" Amlodipine OD Tablets 5 mg "Towa" Amlodipine Tablets 2.5 mg "Towa" Amlodipine Tablets 5 mg "Towa" (Towa Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 29, 2012	21	Requip CR Tablets 2 mg Requip CR Tablets 8 mg (GlaxoSmithKline K.K.)	Approval Approval	Ropinirole hydrochloride	Drugs in new dosage forms and with a new dosage. These drugs are indicated for the treatment of Parkinson's disease.
2	Aug. 24, 2012	22	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with a new additional indication for the treatment of the following ischemic heart disease for which percutaneous coronary intervention (PCI) is applied: ST elevation myocardial infarction.
2	Aug. 24, 2012	23	Diovan Tablets 20 mg Diovan Tablets 40 mg Diovan Tablets 80 mg Diovan Tablets 160 mg (Novartis Pharma K.K.)	Change Change Change Change	Valsartan	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Sep. 28, 2012	24	Lotriga Granular Capsule 2 g (Takeda Pharmaceutical Company Limited)	Approval	omega-3-acid ethyl esters	A drug with a new active ingredient indicated for the treatment of hyperlipidaemia.
2	Sep. 28, 2012	25	Aimix Combination Tablet LD Aimix Combination Tablet HD (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval	Irbesartan/ amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	Sep. 28, 2012	26	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with a new additional indication and a new dosage for the suppression of embolus/thrombus formation in peripheral arterial diseases.
2	Nov. 21, 2012	27	Tracleer Tablets 62.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change	Bosentan hydrate	A drug with a new additional indication for the treatment of pulmonary arterial hypertension (WHO functional class II). [Orphan drug]
2	Dec. 21, 2012	28	Micamlo Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/amlodipine besilate	A drug with a new dosage in an additional dosage form for the treatment of hypertension.
2	Dec. 25, 2012	29	Eliquis Tablets 2.5 mg Eliquis Tablets 5 mg (Bristol-Myers K.K.)	Approval Approval	Apixaban	Drugs with a new active ingredient indicated for prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Feb. 28, 2013	30	Livalo Tablets 1 mg Livalo Tablets 2 mg Livalo Tablets 4 mg (Kowa Company, Ltd.)	Change Change Change	Pitavastatin calcium	Drugs with a new dosage indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Feb. 28, 2013	31	Grtpa Inj. 6,000,000 Grtpa Inj. 12,000,000 Grtpa Inj. 24,000,000 (Mitsubishi Tanabe Pharma Corporation) Activacin for Injection 6,000,000 Activacin for Injection 12,000,000 Activacin for Injection 24,000,000 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change	Alteplase (genetical recombination)	Drugs with a new indication and a new dosage for the improvement of functional impairment in association with acute phase of ischemic cerebrovascular disorder (within 4.5 hours after onset). [Public knowledge-based application after PAFSC's preliminary assessment]
2	Feb. 28, 2013	32	Inderal Tablets 10 mg Inderal Tablets 20 mg (AstraZeneca K.K.)	Change Change	Propranolol hydrochloride	Drugs with a new additional indication and a new dosage for the prevention of migraine attack. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 25, 2013	33	Nouriast Tablets 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	Istradefylline	A drug with a new active ingredient indicated for the improvement of wearing-off phenomenon in patients with Parkinson's disease on treatment with levodopa-containing products.
2 & 3-1	Dec. 25, 2012	34	[1] Neupro Patch 2.25 mg [2] Neupro Patch 4.5 mg [3] Neupro Patch 9 mg [4] Neupro Patch 13.5 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Rotigotine	[1] [2] Drugs with a new active ingredient indicated for the treatment of Parkinson's disease and moderate to severe idiopathic restless legs syndrome. [3] [4] Drugs with a new active ingredient indicated for the treatment of Parkinson's disease.
3-1	Jun. 22, 2012	35	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Change Change Change	Pregabalin	Drugs with a new additional indication and a new dosage for the treatment of pain associated with fibromyalgia. [Priority review]
3-1	Aug. 24, 2012	36	Strattera Capsule 5 mg Strattera Capsule 10 mg Strattera Capsule 25 mg Strattera Capsule 40 mg (Eli Lilly Japan K.K.)	Change Change Change Change	Atomoxetine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Sep. 28, 2012	37	Zyprexa for Intramuscular Injection 10 mg (Eli Lilly Japan K.K.)	Approval	Olanzapine	A drug with a new route of administration indicated for the treatment of acute agitation associated with schizophrenia.
3-1	Sep. 28, 2012	38	Diacomit Drysyrup 250 mg Diacomit Drysyrup 500 mg Diacomit Capsules 250 mg (Meiji Seika Pharma Co., Ltd.)	Approval Approval Approval	Stiripentol	Drugs with a new active ingredient indicated for use in conjunction with clobazam and sodium valproate as adjunctive therapy of refractory generalized tonic-clonic and clonic seizures in patients with Dravet’s syndrome whose seizures are not adequately controlled with clobazam and sodium valproate. [Orphan drug]
3-1	Nov. 21, 2012	39	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new route of administration and an additional indication for the treatment of severe primary axillary hyperhidrosis.
3-1	Dec. 25, 2012	40	Choreazine Tablets 12.5 mg (Alfresa Pharma Corporation)	Approval	Tetrabenazine	A drug with a new active ingredient indicated for the treatment of chorea associated with Huntington's disease. [Orphan drug]
3-1	Feb. 28, 2013	41	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Change Change Change	Pregabalin	Drugs with a new indication for the treatment of neuropathic pain.
3-1	Mar. 25, 2013	42	Solu-Medrol for Intravenous Use 40 mg Solu-Medrol for Intravenous Use 125 mg Solu-Medrol for Intravenous Use 500 mg Solu-Medrol for Intravenous Use 1000 mg (Pfizer Japan Inc.)	Change Change Change Change	Methylprednisolone sodium succinate	Drugs with a new additional indication and a new dosage for the treatment of acute exacerbation of multiple sclerosis. [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	Mar. 25, 2013	43	Regtect Tablets 333 mg (Nippon Shinyaku Co., Ltd.)	Approval	Acamprosate calcium	A drug with a new active ingredient indicated for use as an aid for maintenance of abstinence in patients with alcohol dependence.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-1	Mar. 25, 2013	44	Inovelon Tablets 100 mg Inovelon Tablets 200 mg (Eisai Co., Ltd.)	Approval Approval	Rufinamide	Drugs with a new active ingredient indicated for use as a concomitant therapy with other antiepileptic drugs to treat tonic and atonic seizures in patients with Lennox-Gastaut syndrome who have not responded sufficiently to other antiepileptic drugs. [Orphan drug]
3-2	Jun. 22, 2012	45	Penles Tape 18 mg (Nitto Denko Corporation)	Change	Lidocaine	A drug with a new additional indication and a new dosage for pain relief at the resection of molluscum contagiosum.
3-2	Sep. 28, 2012	46	Eylea Intravitreal Injection 40 mg/mL, Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Approval Approval	Aflibercept (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization.
3-2	Sep. 28, 2012	47	Methapain Tablet 5 mg Methapain Tablet 10 mg (Teikoku Seiyaku Co., Ltd.)	Approval Approval	Methadone hydrochloride	Drugs with a new active ingredient indicated for achieving analgesia of moderate to severe pain associated with various types of cancer which can not be managed by treatment with other strong opioid analgesics.
4	May 25, 2012	48	Finibax for Intravenous Infusion 0.25 g Finibax for Intravenous Infusion 0.5 g Finibax Kit for Intravenous Infusion 0.25 g (Shionogi & Co., Ltd.)	Change Change Change	Doripenem hydrate	Drugs with a new additional pediatric dosage and with a new additional indication for the treatment of purulent meningitis.
4	May 25, 2012	49	Viccillin 0.25 g for Injection Viccillin 0.5 g for Injection Viccillin 1 g for Injection Viccillin 2 g for Injection (Meiji Seika Pharma Co., Ltd.)	Change Change Change Change	Ampicillin sodium	Drugs with a new additional indication for *Listeria monocytogenes* as an applicable microorganism and with new additional pediatric and neonate dosages. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jun. 22, 2012	50	Meiact MS Fine Granules 10% for Pediatric (Meiji Seika Pharma Co., Ltd.)	Change	Cefditoren pivoxil	A drug with a new additional dosage for the treatment of pneumonia, otitis media, and sinusitis.
4	Jun. 22, 2012	51	Zithromac Intravenous Use 500 mg Zithromac Tablets 250 mg (Pfizer Japan Inc.)	Change Change	Azithromycin hydrate	Drugs with a new additional indication and a new dosage for the treatment of pelvic inflammatory diseases.
4	Aug. 10, 2012	52	Flagyl Oral Tablet 250 mg (Shionogi & Co., Ltd.)	Change	Metronidazole	A drug with new additional indications and a new dosage for the treatment of anaerobic bacterial infection, infectious enteritis, amoebic dysentery, and *Giardia lamblia* infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Aug. 10, 2012	53	Baktar Combination Tablets Baktar Combination Granules (Shionogi & Co., Ltd.) Bactramin Combination Tablet Bactramin Combination Granule (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change	Sulfamethoxazole/ trimethoprim	Drugs with a new additional indication and a new dosage for the treatment and prevention of Pneumocystis pneumonia. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Aug. 10, 2012	54	Unasyn-S for Intravenous Use 0.75 g Unasyn-S for Intravenous Use 1.5 g Unasyn-S Kit for Intravenous Use 1.5 g Unasyn-S Kit for Intravenous Use 3 g (Pfizer Japan Inc.)	Change Change Change Change	Sulbactam sodium/ampicillin sodium	Drugs with new additional indications for *Streptococcus Pneumoniae* and *Moraxella catarrhalis* as applicable microorganisms. A new dosage has been added to enable high-dosage use for severe infections.
4	Sep. 28, 2012	55	Tobi Inhalation Solution 300 mg (Novartis Pharma K.K.)	Approval	Tobramycin	A drug with a new route of administration indicated for the improvement of symptoms associated with respiratory infection caused by *Pseudomonas aeruginosa* in cystic fibrosis patients.
4	Sep. 28, 2012	56	Zosyn for Intravenous Injection 2.25 Zosyn for Intravenous Injection 4.5 (Taiho Pharmaceutical Co., Ltd.)	Change Change	Tazobactam/ piperacillin hydrate	Drugs with new additional indications for the treatment of peritonitis, intraperitoneal abscess, cholecystitis, and cholangitis.
4	Sep. 28, 2012	57	Tygacil Injection 50 mg (Pfizer Japan Inc.)	Approval	Tigecycline	A drug with a new active ingredient indicated for the treatment of deep skin infection, chronic pyoderma, secondary infection of trauma, burn, and surgical wounds, secondary infection of erosion and ulcer, peritonitis, intraperitoneal abscess, and cholecystitis. [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Nov. 21, 2012	58	Zyvox Tablets 600 mg Zyvox Injection 600 mg (Pfizer Japan Inc.)	Change Change	Linezolid	Drugs with a new additional pediatric dosage. These drugs are indicated for sepsis, deep skin infection, chronic pyoderma, secondary infection of trauma, burn, and surgical wounds, and pneumonia. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Dec. 25, 2012	59	Malarone Combination Tablets (GlaxoSmithKline K.K.)	Approval	Atovaquone/proguanil hydrochloride	A new combination drug with a new active ingredient indicated for the treatment and prevention of malaria. [Priority review]
4	Dec. 25, 2012	60	Ameparomo Capsules 250 mg (Pfizer Japan Inc.)	Approval	Paromomycin sulfate	A drug with a new active ingredient indicated for the treatment of intestinal amoebiasis.
4	Feb. 21, 2013	61	Famvir Tab. 250 mg (Asahi Kasei Pharma Corporation)	Change	Famciclovir	A drug with a new additional indication and a new dosage for the treatment of herpes simplex.
4	Feb. 21, 2013	62	(1) Takepron capsules 15 Takepron capsules 30 (2) Takepron OD Tablets 15 Takepron OD Tablets 30 (Takeda Pharmaceutical Company Limited) (3) Omepral Tablets 10 Omepral Tablets 20 (AstraZeneca K.K.) (4) Omeprazon Tablets 10 mg Omeprazon Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation) (5) Omeprazole Tablets 10 mg "Mylan" Omeprazole Tablets 20 mg "Mylan" (Mylan Seiyaku Ltd.) (6) Pariet Tablets 10 mg (Eisai Co., Ltd.) (7) Rabeprazole Na Tablets 10 mg "Ohara" (Ohara Pharmaceutical Co., Ltd.) (8) Nexium Capsules 10 mg Nexium Capsules 20 mg (AstraZeneca K.K.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change	(1)(2) Lansoprazole (3)(4)(5) Omeprazole (6)(7) Rabeprazole sodium (8) Esomeprazole magnesium hydrate (9)(10)(11)(12)(13)(14) Amoxicillin hydrate (15)(16)(17)(18) Clarithromycin (19) Metronidazole (20) Lansoprazole/amoxicillin hydrate/clarithromycin	Drugs with a new additional indication for the treatment of gastritis induced by *Helicbacter pylori* infection.
			(9) Pasetocin Capsules 125 Pasetocin Capsules 250 (10) Pasetocin Tablets 250 (Kyowa Hakko Kirin Co., Ltd.) (11) Sawacillin Capsules 125 Sawacillin Capsules 250 (12) Sawacillin Tablets 250 (Astellas Pharma Inc.) (13) Amolin Capsules 125 Amolin Capsules 250 (14) 10% Amolin Fine Granules (Takeda Pharmaceutical Company Limited) (15) Clarith tab. 200 (Taisho Pharmaceutical Co., Ltd.) (16) Klaricid Tablets 200 mg (Abbott Japan Co., Ltd.) (17) Clarithromycin Tab. 200 mg "Mylan" (Mylan Seiyaku Ltd.) (18) Clarithromycin Tablets 200 mg "Takata" (Takata Seiyaku Co., Ltd.) (19) Flagyl Oral Tablet 250 mg (Shionogi & Co., Ltd.) (20) Lansap 400 Lansap 800 (21) Lampion Pack (Takeda Pharmaceutical Company Limited)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	(21) Lansoprazole/amoxicillin hydrate/metronidazole	
5	Dec. 21, 2012	63	Minirinmelt OD Tablets 120 μg Minirinmelt OD Tablets 240 μg (Ferring Pharmaceuticals Co., Ltd.)	Change Change	Desmopressin acetate hydrate	Drugs with a new indication and a new dosage for the treatment of central diabetes insipidus.
5	Dec. 25, 2012	64	Toviaz Tablet 4 mg Toviaz Tablet 8mg (Pfizer Japan Inc.)	Approval Approval	Fesoterodine fumarate	Drugs with a new active ingredient indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
5	Dec. 25, 2012	65	Minirinmelt OD Tablets 60 μg (Ferring Pharmaceuticals Co., Ltd.)	Approval	Desmopressin acetate hydrate	A drug with a new indication and a new dosage in an additional dosage form for the treatment of central diabetes insipidus.
5	Mar. 25, 2013	66	Magsent Injection 100 mL Magnesol for Intravenous Injection 20 mL Magsent Injection Syringe 40 mL (Toa Pharmaceuticals Co., Ltd.)	Change Change Change	Magnesium sulfate hydrate/glucose	Drugs with a new additional indication and a new dosage for the prevention and treatment of eclampsia in patients with severe pregnancy-induced hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Mar. 25, 2013	67	Voluven Solution for Infusion 6% (Fresenius Kabi Japan K.K.)	Approval	Hydroxyethylated starch 130000	A drug with a new active ingredient indicated for maintenance of circulating blood volume.
5	Mar. 25, 2013	68	Neoxy Tape 73.5 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval	Oxybutynin hydrochloride	A drug with a new route of administration and new indications for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
6-1	May 25, 2012	69	Thaled Capsule 50 Thaled Capsule 100 (Fujimoto Pharmaceutical Corporation)	Change Change	Thalidomide	Drugs with a new additional indication and a new dosage for the treatment of erythema nodosum leprosum. [Orphan drug]
6-1	May 25, 2012	70	Nasonex Nasal 50 μg 56 sprays Nasonex Nasal 50 μg 112 sprays (MSD K.K.)	Change Change	Mometasone furoate hydrate	Drugs with a new additional pediatric dosage for the treatment of allergic rhinitis.
6-1	Jun. 22, 2012	71	Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.)	Change Change	Budesonide/formoterol fumarate hydrate	Drugs with a new dosage for inhalation as needed in addition to periodic inhalation as a maintenance therapy. These drugs are indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Jun. 29, 2012	72	Kolbet Tablets 25 mg (Toyama Chemical Co., Ltd.) Careram Tablets 25 mg (Eisai Co., Ltd.)	Approval Approval	Iguratimod	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis.
6-1	Jun. 29, 2012	73	Oxis 9 μg Turbuhaler 28 doses Oxis 9 μg Turbuhaler 60 doses (AstraZeneca K.K.)	Approval Approval	Formoterol fumarate hydrate	Drugs with a new indication and a new dosage for the alleviation of various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
6-1	Aug. 10, 2012	74	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage).
6-1	Aug. 10, 2012	75	Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.)	Change Change	Budesonide/formoterol fumarate hydrate	Drugs with a new additional indication and a new dosage for the relief of symptoms of chronic obstructive pulmonary diseases (chronic bronchitis, emphysema).
6-1	Sep. 28, 2012	76	Seebri Inhalation Capsules 50 μg (Novartis Pharma K.K.)	Approval	Glycopyrronium bromide	A drug with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema).
6-1	Nov. 21, 2012	77	MaQaid Intravitreal Injection 40 mg (Wakamoto Pharmaceutical Co., Ltd.)	Change	Triamcinolone acetonide	A drug with a new additional indication and a new dosage for the treatment of diabetic macular edema.
6-1	Dec. 25, 2012	78	Cimzia 200 mg Syringe for S.C. Injection (UCB Japan Co., Ltd.)	Approval	Certolizumab pegol (genetical recombination)	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-1	Dec. 25, 2012	79	Dellegra Combination Tablets (Sanofi K.K.)	Approval	Fexofenadine hydrochloride/ pseudoephedrine hydrochloride	A new combination drug indicated for the treatment of allergic rhinitis.
6-1	Mar. 25, 2013	80	Neoral 10 mg Capsules Neoral Solution 10% Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Ciclosporin	Drugs with a new indication and a new dosage for the treatment of non-Behcet's, non-infectious uveitis (active non-infectious uveitis in the intermediate or posterior area in patients who have not responded sufficiently to conventional treatments and may involve deterioration of visual acuity). [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Mar. 25, 2013	81	Ciclosporin Cap. 10 mg "Mylan" Ciclosporin Cap. 25 mg "Mylan" Ciclosporin Cap. 50 mg "Mylan" Ciclosporin Fine Granules 17% "Mylan" (Mylan Seiyaku Ltd.)	Change Change Change Change	Ciclosporin	Drugs with a new indication and a new dosage for the treatment of non-Behcet's, non-infectious uveitis (active non-infectious uveitis in the intermediate or posterior area in patients who have not responded sufficiently to conventional treatments and may involve deterioration of visual acuity). [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Mar. 25, 2013	82	Xeljanz Tablets 5 mg (Pfizer Japan Inc.)	Approval	Tofacitinib citrate	A drug with a new active ingredient for the treatment of rheumatoid arthritis in patients who have not sufficiently responded to conventional treatments.
6-1	Mar. 25, 2013	83	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-Injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Tocilizumab (genetical recombination)	Drugs with a new route of administration indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-2	Jun. 22, 2012	84	NovoRapid 100 U/ml (Novo Nordisk Pharma Ltd.)	Change	Insulin aspart (genetical recombination)	A drug with a new route of administration and a new dosage. This drug is indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Jun. 29, 2012	85	Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	Teneligliptin hydrobromide hydrate	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jun. 29, 2012	86	Somatuline Subcutaneous Injection 60 mg Somatuline Subcutaneous Injection 90 mg Somatuline Subcutaneous Injection 120 mg (Teijin Pharma Limited)	Approval Approval Approval	Lanreotide acetate	Drugs with a new active ingredient for the improvement of hypersecretion of growth hormone and IGF-I (somatomedin-C) and related symptoms in acromegaly and pituitary gigantism (when surgical therapies are not sufficiently effective or are difficult to perform).
6-2	Aug. 24, 2012	87	Growject BC for Injection 8 mg Growject for Injection 8 mg Growject for Injection 1.33 mg (JCR Pharmaceuticals Co., Ltd.)	Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of SGA (small-for-gestational age) dwarfism not associated with epiphyseal closure.
6-2	Sep. 28, 2012	88	Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Beskoa Tab. 100 mg (Kowa Pharmaceutical Co. Ltd.)	Approval Approval	Anagliptin	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Sep. 28, 2012	89	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin degludec (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 28, 2012	90	Buphenyl Tablet 500 mg Buphenyl Granule 94% (CMIC Holdings, Co., Ltd.)	Approval Approval	Sodium phenylbutyrate	Drugs with a new active ingredient indicated for the treatment of urea cycle disorder. [Orphan drug]
6-2	Dec. 25, 2012	91	L-Cartin FF Oral Solution 10% L-Cartin FF Injection 1000 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Levocarnitine	Drugs with a new active ingredient indicated for the treatment of carnitine deficiency.
6-2	Dec. 25, 2012	92	Ryzodeg Combination Injection FlexTouch Ryzodeg Combination Injection Penfill (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin degludec (genetical recombination)/insulin aspart (genetical recombination)	New combination drugs indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Dec. 25, 2012	93	Actonel Tablets 75 mg (Ajinomoto Pharmaceutical Co., Ltd.) Benet Tablets 75 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Sodium risedronate hydrate	Drugs with a new dosage in a new additional dosage form. These drugs are indicated for the treatment of osteoporosis.
6-2	Feb. 28, 2013	94	Equa Tablets 50 mg (Novartis Pharma K.K.)	Change	Vildagliptin	A drug with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Feb. 28, 2013	95	Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change	Repaglinide	Drugs with a new indication for the improvement of postprandial changes of blood glucose in type 2 diabetes mellitus.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Feb. 28, 2013	96	Denotas Chewable Combination Tablets (Nitto Pharmaceutical Industries, Ltd.)	Approval	Precipitated calcium carbonate/cholecalciferol/ magnesium carbonate	A combination prescription drug with a similar formulation indicated for the treatment and prevention of hypocalcemia in association with administration of RANKL inhibitors (e.g. denosumab [genetical recombination]) [Expedited review]
6-2	Mar. 25, 2013	97	Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Linagliptin	A drug with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Mar. 25, 2013	98	Pralia Subcutaneous Injection 60 mg Syringe (Daiichi Sankyo Company, Limited)	Approval	Denosumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of osteoporosis.
6-2	Mar. 25, 2013	99	Onglyza Tablets 2.5 mg Onglyza Tablets 5 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Saxagliptin hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 25, 2013	100	Metreleptin for Subcutaneous Injection 11.25 mg "Shionogi" (Shionogi & Co., Ltd.)	Approval	Metreleptin (genetical recombination)	A drug with a new active ingredient for the treatment of lipodystrophy. [Orphan drug]
In vivo diagnostics	May 25, 2012	101	Thyrogen for Intramuscular Injection 0.9 mg (Sato Pharmaceutical Co., Ltd.)	Change	Thyrotropin human alfa (genetical recombination)	A drug with a new additional indication for adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. [Orphan drug]
In vivo diagnostics	Aug. 10, 2012	102	Sonazoid for Injection 16 µL (Daiichi Sankyo Company, Limited)	Change	Perflubutane	A drug with a new additional indication as a contrast agent for breast mass lesion in ultrasonography.
In vivo diagnostics	Mar. 25, 2013	103	Alabel Oral 1.5 g (Nobelpharma Co., Ltd.) Alaglio Internal Medicine 1.5 g (SBI Pharmaceuticals Co., Ltd.)	Approval Approval	Aminolevulinic acid hydrochloride	Drugs with a new active ingredient indicated for the visualization of tumor tissues during tumorectomy for malignant glioma. [Orphan drug]
Oncology drugs	Jun. 29, 2012	104	Gonax 80 mg for Subcutaneous Injection Gonax 120 mg for Subcutaneous Injection (Astellas Pharma Inc.)	Approval Approval	Degarelix acetate	Drugs with a new active ingredient indicated for the treatment of prostate cancer.
Oncology drugs	Jun. 29, 2012	105	Inlyta Tablets 1 mg Inlyta Tablets 5 mg (Pfizer Japan Inc.)	Approval Approval	Axitinib	Drugs with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 10, 2012	106	Sutent Capsule 12.5 mg (Pfizer Japan Inc.)	Change	Sunitinib malate	A drug with a new additional indication and a new dosage for pancreatic neuroendocrine tumour. [Orphan drug]
Oncology drugs	Sep. 28, 2012	107	Gliadel for Intracerebral Implant 7.7 mg (Nobelpharma Co., Ltd.)	Approval	Carmustine	A drug with a new active ingredient indicated for the treatment of malignant glioma. [Orphan drug]
Oncology drugs	Sep. 28, 2012	108	Votrient Tablets 200 mg (GlaxoSmithKline K.K.)	Approval	Pazopanib hydrochloride	A drug with a new active ingredient indicated for the treatment of soft tissue sarcoma. [Orphan drug]
Oncology drugs	Nov. 21, 2012	109	Afinitor Tablets 5 mg Afinitor Tablets 2.5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with new additional indications and a new dosage for the treatment of renal angiomyolipoma associated with tuberous sclerosis complex and subependymal giant cell astrocytoma associated with tuberous sclerosis complex. [Orphan drug]
Oncology drugs	Dec. 21, 2012	110	Erbitux Injection 100 mg (Merck Serono Co., Ltd.)	Change	Cetuximab (genetical recombination)	A drug with a new additional indication for the treatment of head and neck cancer. [Priority review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 21, 2012	111	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new route of administration indicated for the treatment of multiple myeloma.
Oncology drugs	Dec. 25, 2012	112	Afinitor Dispersible Tablet 2 mg Afinitor Dispersible Tablet 3 mg (Novartis Pharma K.K.)	Approval Approval	Everolimus	Drugs with a new additional indication and a new dosage in an additional dosage form for the treatment of subependymal giant cell astrocytoma associated with tuberous sclerosis complex (currently in the reexamination period). [Orphan drug]
Oncology drugs	Feb. 21, 2013	113	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with new additional indications and a new dosage for the treatment of gastric cancer and non-small cell lung cancer.
Oncology drugs	Feb. 21, 2013	114	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.) Gemcitabine for I.V. infusion 200 mg "Yakult" Gemcitabine for I.V. infusion 1 g "Yakult" (Takata Seiyaku Co., Ltd.) Gemcitabine for i.v. infusion 200 mg "Sawai" Gemcitabine for i.v. infusion 1 g "Sawai" (Sawai Pharmaceutical Co., Ltd.) Gemcitabine for I.V. Infusion 200 mg "NK" Gemcitabine for I.V. Infusion 1 g "NK" (Nippon Kayaku Co., Ltd.) Gemcitabine for I.V. Infusion 200 mg "Hospira" Gemcitabine for I.V. Infusion 1 g "Hospira" (Hospira Japan Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change	Gemcitabine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory malignant lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 21, 2013	115	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.) Paclitaxel Inj. 30 mg/5 mL "NK" Paclitaxel Inj. 100 mg/16.7 mL "NK" (Nippon Kayaku Co., Ltd.) Paclitaxel Injection 30 mg "Sawai" Paclitaxel Injection 100 mg "Sawai" Paclitaxel Injection 150 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Paclitaxel	Drugs with new additional indications and a new dosage for the treatment of relapsed or refractory germ cell tumors (testicular tumors, ovarian tumors, extragonadal tumors). [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 21, 2013	116	Leunase Injection 5000 Leunase Injection 10000 (Kyowa Hakko Kirin Co., Ltd.)	Change Change	L-Asparaginase	Drugs with a new route of administration. These drugs are indicated for acute leukemia (including blast crisis of chronic leukemia) and malignant lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	117	Campto 40 mg for I.V. infusion Campto 100 mg for I.V. infusion (Yakult Honsha Co., Ltd.) Topotecin Intravenous Drip Infusion 40 mg Topotecin Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited) Irinotecan Hydrochloride Intravenous Drip Infusion 40 mg "Sawai" Irinotecan Hydrochloride Intravenous Drip Infusion 100 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Irinotecan Hydrochloride I.V. Infusion 40 mg "Taiho" Irinotecan Hydrochloride I.V. Infusion 100 mg "Taiho" (Taiho Pharmaceutical Co., Ltd.) Irinotecan Hydrochloride I.V. Infusion 40 mg "Hospira" Irinotecan Hydrochloride I.V. Infusion 100 mg "Hospira" (Hospira Japan Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of pediatric malignant solid tumor. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	118	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 25, 2013	119	Dacarbazine Injection 100 (Kyowa Hakko Kirin Co., Ltd.)	Change	Dacarbazine	A drug with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	120	Oncovin for Inj. 1 mg (Nippon Kayaku Co., Ltd.)	Change	Vincristine sulfate	A drug with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	121	Hydrea Capsules 500 mg (Bristol-Myers K.K.)	Change	Hydroxycarbamide	A drug with new additional indications for the treatment of essential thrombocythemia and polycythemia vera. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	122	Arzerra for I.V. infusion 100 mg Arzerra for I.V. infusion 1000 mg (GlaxoSmithKline K.K.)	Approval Approval	Ofatumumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory CD20-positive chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Mar. 25, 2013	123	Evoltra Intravenous Drip Infusion 20 mg (Genzyme Japan K.K.)	Approval	Clofarabine	A drug with a new active ingredient for the treatment of recurrent or refractory acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Mar. 25, 2013	124	Stivarga tablets 40 mg (Bayer Yakuhin, Ltd.)	Approval	Regorafenib hydrate	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer. [Priority review]
AIDS drugs	May 18, 2012	125	Edurant Tablets 25 mg (Janssen Pharmaceutical K.K.)	Approval	Rilpivirine hydrochloride	A drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Mar. 25, 2013	126	Stribild Combination Tab. (Japan Tobacco Inc.)	Approval	Elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
Biologicals	Apr. 27, 2012	127	Imovax Polio Subcutaneous Injection (Sanofi Pasteur)	Approval	Inactivated poliomyelitis vaccine (Salk vaccine)	A drug with a new active ingredient indicated for the prevention of acute poliomyelitis. [Expedited review]
Biologicals	Jul. 27, 2012	128	Tetrabik Subcutaneous Injection Syringe (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (Sabin strain) combined vaccine	A drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis.
Biologicals	Jul. 27, 2012	129	Quattrovac Subcutaneous Injection Syringe (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (Sabin strain) combined vaccine	A drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis.
Vaccines	Mar. 15, 2013	130	Aimmugen (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Freeze-dried inactivated tissue culture hepatitis A vaccine	A drug with a new pediatric dosage. The drug is indicated for the prevention of hepatitis A.
Vaccines	Mar. 25, 2013	131	Adsorbed Influenza Vaccine (H5N1) "Seiken" 1 mL (Denka Seiken Co., Ltd.)	Approval	Adsorbed influenza vaccine (H5N1)	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	Mar. 25, 2013	132	Normosang Infusion 250 mg (CMIC Holdings Co., Ltd.)	Approval	Hemin	A drug with a new active ingredient indicated for the improvement of symptoms of acute attack in patients with acute porphyria. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Bio-CMC	Nov. 21, 2012	133	Filgrastim BS Injection 75 μg Syringe "Mochida" Filgrastim BS Injection 150 μg Syringe "Mochida" Filgrastim BS Injection 300 μg Syringe "Mochida" (Mochida Pharmaceutical Co., Ltd.) Filgrastim BS Injection 75 μg Syringe "F" Filgrastim BS Injection 150 μg Syringe "F" Filgrastim BS Injection 300 μg Syringe "F" (Fuji Pharma Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Filgrastim (genetical recombination)	Follow-on biologics indicated for mobilization of hematopoietic stem cells to peripheral blood, promotion of increases in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia, and congenital/idiopathic neutropenia.
Bio-CMC	Feb. 28, 2013	134	Filgrastim BS Inj. 75 μg Syringe "NK" Filgrastim BS Inj. 150 μg Syringe "NK" Filgrastim BS Inj. 300 μg Syringe "NK" (Nippon Kayaku Co., Ltd.) Filgrastim BS Injection 75 μg Syringe "Teva" Filgrastim BS Injection 150 μg Syringe "Teva" Filgrastim BS Injection 300 μg Syringe "Teva" (Teva Pharma Japan Inc.)	Approval Approval Approval Approval Approval Approval	Filgrastim (genetical recombination) [filgrastim biosimilar 2]	Follow-on biologics indicated for mobilization of hematopoietic stem cells to peripheral blood, promotion of increases in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia, and congenital/idiopathic neutropenia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Products Approved in FY 2011: New Drugs

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 22, 2011	1	Lipacreon Granules 300 mg Sachet Lipacreon Capsules 150 mg (Abbott Japan Co., Ltd.)	Approval Approval	Pancrelipase	Drugs with a new active ingredient indicated for the replacement of pancreatic digestive enzymes in pancreatic exocrine insufficiency.
1	Apr. 22, 2011	2	Mircera Injection Syringe 25 μg Mircera Injection Syringe 50 μg Mircera Injection Syringe 75 μg Mircera Injection Syringe 100 μg Mircera Injection Syringe 150 μg Mircera Injection Syringe 200 μg Mircera Injection Syringe 250 μg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Epoetin beta pegol (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Apr. 22, 2011	3	Thymoglobuline for Intravenous Infusion 25 mg (Genzyme Japan K.K.)	Change	Anti-human thymocyte immunoglobulin, rabbit	A drug with a new additional indication and a new dosage for the treatment of acute rejection after renal transplantation. [Expedited review]
1	May 20, 2011	4	Solu-Medrol for Intravenous Use 40 mg Solu-Medrol for Intravenous Use 125 mg Solu-Medrol for Intravenous Use 500 mg Solu-Medrol for Intravenous Use 1000 mg (Pfizer Japan Inc.) Sol-Melcort for Injection 40 Sol-Melcort for Injection 125 Sol-Melcort for Injection 500 Sol-Melcort for Injection 1,000 (Fuji Pharma Co., Ltd.)	Change Change Change Change Change Change Change Change	Methylprednisolone sodium succinate	Drugs with a new additional indication and a new dosage for the treatment of nephrotic syndrome. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Jul. 1, 2011	5	Nexium Capsules 10 mg (AstraZeneca K.K.)	Approval	Esomeprazole magnesium hydrate	A drug with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease and Zollinger-Ellison syndrome, prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal antiinflammatory drugs, and aid to eradication of *Helicobacter pylori* in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and stomach after endoscopic treatment for early gastric cancer.
			Nexium Capsules 20 mg (AstraZeneca K.K.)	Approval	Esomeprazole magnesium hydrate	A drug with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis and Zollinger-Ellison syndrome, prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal antiinflammatory drugs, and aid to eradication of *Helicobacter pylori* in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and stomach after endoscopic treatment for early gastric cancer.
1	Jul. 1, 2011	6	Pegasys S.C. 90 μg Copegus Tablets 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Peginterferon alfa-2a (genetical recombination) Ribavirin	Drugs with a new additional indication for the improvement of viremia in patients with compensated cirrhosis C. A new dosage of Pegasis S.C. 90 μg has also been approved. [Priority review]
1	Jul. 1, 2011	7	Ditripentat-Cal Injection 1000 mg Zinc-Tripentat Injection 1055 mg (Nihon Medi-Physics Co., Ltd.)	Approval Approval	Pentetate calcium trisodium Pentetate zinc trisodium	Drugs with a new active ingredient indicated for the reduction of internal contamination with transuranium elements (plutonium, americium, and curium). [Expedited review]
1	Aug. 17, 2011	8	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recom	A drug with a new dosage indicated for the treatment of Crohn's disease. [Orphan drug]
1	Sep. 16, 2011	9	Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change	Cyclophosphamide hydrate	A drug with a new additional indication and a new dosage for the treatment of nephrotic syndrome (for use only in patients who have not sufficiently responded to adequate treatment with corticosteroids). [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Sep. 16, 2011	10	Cellcept Capsule 250 (Chugai Pharmaceutical Co., Ltd.)	Change	Mycophenolate mofetil	A drug with a new additional pediatric dosage indicated for the prevention of rejection in renal transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
1	Sep. 26, 2011	11	Proemend for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Fosaprepitant meglumine	A drug with a new active ingredient indicated for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) (including delayed phase).
1	Sep. 26, 2011	12	Pegasys S.C. 180 µg Pegasys S.C. 90 µg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Peginterferon alfa-2a (genetical recombination)	Drugs with a new additional indication and a new dosage for the improvement of viremia in patients with chronic active hepatitis B. [Priority review]
1	Nov. 25, 2011	13	Beselna Cream 5% (Mochida Pharmaceutical Co., Ltd.)	Change	Imiquimod	A drug with a new additional indication and a new dosage for the treatment of actinic keratosis (limited to the face or baldness).
1	Dec. 22, 2011	14	Kytril Fine Granule 0.4% Kytril Tablet 1 mg Kytril Tablet 2 mg Kytril Injection 1 mg Kytril Injection 3 mg Kytril Intravenous Bag 3 mg/50 mL Kytril Intravenous Bag 3 mg/100 mL (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Granisetron hydrochloride	Drugs with a new additional indication for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with radiation. [Public knowledge-based application after PAFSC's preliminary assessment]
1	Dec. 22, 2011	15	Certican Tablets 0.25 mg Certican Tablets 0.5 mg Certican Tablets 0.75 mg (Novartis Pharma K.K.)	Change Change Change	Everolimus	Drugs with a new additional indication and a new dosage for the inhibition of rejection in renal transplantation.
1	Dec. 22, 2011	16	(1) Pegintron Powder for Injection 50 µg/0.5 mL Pegintron Powder for Injection 100 µg/0.5 mL Pegintron Powder for Injection 150 µg/0.5 mL (2) Rebetol Capsules 200 mg (MSD K.K.)	Change Change Change Change	(1) Peginterferon alfa-2b (genetical recombination) (2) Ribavirin	Drugs with a new additional indication and a new dosage for the improvement of viremia in patients with compensated cirrhosis C by concomitant use. [Priority review]
1	Mar. 30, 2012	17	Kiklin Capsules 250 mg (Astellas Pharma Inc.)	Approval	Bixalomer	A drug with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic renal failure under dialysis.
2	Apr. 22, 2011	18	Mirapex-LA Tablets 0.375 mg Mirapex-LA Tablets 1.5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Pramipexole hydrochloride hydrate	Drugs in new dosage forms and with new dosages indicated for the treatment of Parkinson's disease.
2	Apr. 22, 2011	19	Exelon Patch 4.5 mg Exelon Patch 9 mg Exelon Patch 13.5 mg Exelon Patch 18 mg (Novartis Pharma K.K.) Rivastach Patch 4.5 mg Rivastach Patch 9 mg Rivastach Patch 13.5 mg Rivastach Patch 18 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval	Rivastigmine	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Apr. 22, 2011	20	Lixiana Tablets 15 mg Lixiana Tablets 30 mg (Daiichi Sankyo Company, Limited)	Approval Approval	Edoxaban tosilate hydrate	Drugs with a new active ingredient indicated for prevention of venous thromboembolism in patients undergoing orthopedic surgery of lower limbs including total knee arthroplasty, total hip arthroplasty and hip fracture surgery.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	May 20, 2011	21	Novastan HI Inj. 10 mg/2 mL (Mitsubishi Tanabe Pharma Corporation) Slonnon HI Injection 10 mg/2 mL (Daiichi Sankyo Company, Limited)	Change Change	Argatroban hydrate	Drugs with new additional indications and new dosages for the prevention of perfusion blood coagulation during blood extracorporeal circulation (hemodialysis) in patients with heparin-induced thrombocytopenia (HIT) type II and in addition for the prevention of blood coagulation during percutaneous coronary intervention in HIT type II patients (including the patients who have the risk for HIT). [Orphan drug]
2	May 20, 2011	22	Vasolan for Intravenous Injection 5 mg (Eisai Co., Ltd.)	Change	Verapamil hydrochloride	A drug with a new additional dosage indicated for the treatment of tachyarrhythmia in pediatric patients (paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, paroxysmal atrial flutter). [Public knowledge-based application after PAFSC's preliminary assessment]
2	May 20, 2011	23	Vasolan Tablets 40 mg (Eisai Co., Ltd.)	Change	Verapamil hydrochloride	A drug with a new additional indication and a new dosage for the treatment of tachyarrhythmia in pediatric patients (atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia). [Public knowledge-based application after PAFSC's preliminary assessment]
2	May 20, 2011	24	Maintate Tablets 2.5 Maintate Tablets 5 Maintate Tablets 0.625 (Mitsubishi Tanabe Pharma Corporation)	Change Change Change	Bisoprolol fumarate	Drugs with a new additional indication and new dosages for the treatment of chronic heart failure secondary to ischemic heart disease or dilated cardiomyopathy in patients receiving basic treatment with angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists, diuretics, digitalis preparations, etc. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 16, 2011	25	Depakene Tablets 100 Depakene Tablets 200 Depakene Fine Granules 20% Depakene Fine Granules 40% Depakene-R Tablets 100 Depakene-R Tablets 200 Depakene Syrup 5% (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change	Sodium valproate	Drugs with a new additional indication and a new dosage for prevention of migraine attack. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 16, 2011	26	Selenica-R Granules 40% Selenica-R Tab.200 mg Selenica-R Tab.400 mg (Kowa Company, Ltd.)	Change Change Change	Sodium valproate	Drugs with a new additional indication and a new dosage for prevention of migraine attack.
2	Jul. 1, 2011	27	Corebeta for Intravenous 12.5 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Landiolol hydrochloride	A drug with a new indication, a new dosage, and an additional dosage form indicated for the improvement of visualization of coronary arteries at high heart rate in coronary angiography by computed tomography.
2	Dec. 22, 2011	28	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with new additional indications for the treatment of the following ischemic heart disease for which percutaneous coronary intervention (PCI) is applied: stable angina and old myocardial infarction.
2	Jan. 18, 2012	29	Azilva Tablets 20 mg Azilva Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Azilsartan	Drugs with a new active ingredient indicated for the treatment of hypertension.
2	Jan. 18, 2012	30	Xarelto Tablets 15 mg Xarelto Tablets 10 mg (Bayer Yakuhin, Ltd.)	Approval Approval	Rivaroxaban	Drugs with a new active ingredient indicated for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Mar. 30, 2012	31	Apokyn Subcutaneous Injection 30 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	Apomorphine hydrochloride hydrate	A drug with a new active ingredient indicated for the treatment of "off" episodes associated with Parkinson's disease (when levodopa-containing products that are frequently administered and other anti-Parkinson drugs at increased doses are not sufficiently effective). [Orphan drug]
3-1	Apr. 22, 2011	32	Lexapro Tablets 10 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Escitalopram oxalate	A drug with a new active ingredient indicated for the treatment of depression.
3-1	Jul. 1, 2011	33	Fostoin 750mg for injection (Nobelpharma Co., Ltd.)	Approval	Fosphenytoin sodium hydrate	A drug with a new active ingredient indicated for: 1. treatment of status epilepticus 2. prevention of seizures occurring in connection with neurosurgery, and/or consciousness disorder (head trauma, etc.) 3. temporary substitution of oral phenytoin therapy in epilepsy patients.
3-1	Jul. 1, 2011	34	Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Change Change	Lamotrigine	Drugs with a new additional indication and a new dosage for the prevention of recurrence/relapse of mood episodes in patients with bipolar disorder.
3-1	Jul. 1, 2011	35	Gabapen Tablets 200 mg Gabapen Tablets 300 mg Gabapen Tablets 400 mg Gabapen Syrop 5% (Pfizer Japan Inc.)	Change Change Change Approval	Gabapentine	Drugs with a new additional pediatric dosage and an additional dosage form indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Sep. 26, 2011	36	Venoglobulin IH 5% I.V. 0.5 g/10 mL Venoglobulin IH 5% I.V. 1 g/20 mL Venoglobulin IH 5% I.V. 2.5 g/50 mL Venoglobulin IH 5% I.V. 5 g/100 mL (Benesis Corporation)	Change Change Change Change	Polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants). [Orphan drug]
3-1	Sep. 26, 2011	37	Imusera Capsules 0.5 mg (Mitsubishi Tanabe Pharma Corporation) Gilenya Capsules 0.5 mg (Novartis Pharma K.K.)	Approval Approval	Fingolimod hydrochloride	Drugs with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis. [Orphan drug]
3-1	Nov. 25, 2011	38	Modiodal Tablets 100 mg (Alfresa Pharma Corporation)	Change	Modafinil	A drug with a new additional indication for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea syndrome who receive treatment of airway obstruction with continuous positive airway pressure (CPAP) therapy, etc.
3-1	Jan. 18, 2012	39	Lunesta Tablets 1 mg Lunesta Tablets 2 mg Lunesta Tablets 3 mg (Eisai Co., Ltd.)	Approval Approval Approval	Eszopiclone	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Jan. 18, 2012	40	Regnite Tablets 300 mg (Astellas Pharma Inc.)	Approval	Gabapentin enacarbil	A drug with a new active ingredient indicated for the treatment of moderate to severe idiopathic restless legs syndrome.
3-1	Jan. 18, 2012	41	[1] Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Tablets 12 mg Abilify Powder 1% Abilify Oral Solution 0.1% [2] Abilify OD Tablets 3 mg Abilify OD Tablets 6 mg Abilify OD Tablets 12 mg Abilify OD Tablets 24 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Change Approval Approval Approval Approval	Aripiprazole	Drugs with a new additional indication and a new dosage in new dosage forms for the improvement of manic symptoms in patients with bipolar disorder.
3-1	Feb. 22, 2012	42	Zyprexa Tablets 2.5 mg Zyprexa Tablets 5 mg Zyprexa Tablets 10 mg Zyprexa Fine Granule 1% Zyprexa Zydis Tablets 5 mg Zyprexa Zydis Tablets 10 mg (Eli Lilly Japan K.K.)	Change Change Change Change Change Change	Olanzapine	Drugs with a new additional indication and a new dosage for the improvement of depressive symptoms in patients with bipolar disorder.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-1	Feb. 22, 2012	43	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication for the treatment of pain associated with diabetic neuropathy.
3-2	Jan. 18, 2012	44	Aiphagan Ophthalmic Solution 0.1% (Senju Pharmaceutical Co., Ltd.)	Approval	Brimonidine tartrate	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension when other glaucoma drugs are not sufficiently effective or cannot be used.
3-2	Jan. 18, 2012	45	Emla Cream (Sato Pharmaceutical Co., Ltd.)	Approval	Lidocaine/propitocaine	A new combination drug with a new active ingredient indicated for the relief of pain in skin laser radiation therapy.
3-2	Jan. 18, 2012	46	OxyFast Injection 10 mg OxyFast Injection 50 mg (Shionogi & Co., Ltd.)	Approval Approval	Oxycodone hydrochloride hydrate	Drugs with a new route of administration indicated for analgesia in various types of cancer with moderate to severe pain.
3-2	Apr. 22, 2011	47	Suprane Liquid for Inhalation (Baxter Limited)	Approval	Desflurane	A drug with a new active ingredient indicated for the maintenance of general anesthesia.
3-2	Apr. 22, 2011	48	Tramcet Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Tramadol hydrochloride/ acetaminophen	A new combination drug indicated for analgesia of chronic non-cancer pain and pain after tooth extraction which are not managed by treatments with non-opioid analgesics.
3-2	Apr. 22, 2011	49	Popscaine 0.5% Inj. 50 mg/10 mL Popscaine 0.5% Inj. syringe 50 mg/10 mL Popscaine 0.25% Inj. 25 mg/10 mL Popscaine 0.25% Inj. syringe 25 mg/10 mL (Maruishi Pharmaceutical Co., Ltd.)	Approval Approval Change Change	Levobupivacaine hydrochloride	Drugs with a new route of administration, a new additional indication and new dosages indicated for conduction anesthesia.
4	Apr. 22, 2011	50	Finibax 0.25 g IV Solution Finibax 0.25 g IV Solution Kit (Shionogi & Co., Ltd.)	Change Change	Doripenem hydrate	Drugs with a new dosage that enables high-dose (1 g three times daily) use.
4	May 20, 2011	51	Rifadin Capsules 150 mg (Daiichi Sankyo Company, Limited) Rifampicin Capsules 150 mg "Sandoz" (Sandoz K.K.)	Change Change	Rifampicin	Drugs with a new additional indication and a new dosage for the treatment of nontuberculous mycobacteriosis including *Mycobacterium avium* complex (MAC) infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	May 20, 2011	52	Foscarvir Infusion Solution 24 mg/mL (AstraZeneca K.K.)	Change	Foscarnet sodium hydrate	A drug with new additional indications and a new dosage for the treatment of cytomegalovirus viremia and cytomegalovirus infection in patients undergoing hematopoietic stem cell transplantation.
4	May 20, 2011	53	Esanbutol Tablets 125 mg Esanbutol Tablets 250 mg (Sandoz K.K.) Ebutol 125 mg Tablets Ebutol 250 mg Tablets (Kaken Pharmaceutical Co., Ltd.)	Change Change Change Change	Ethambutol hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of nontuberculous mycobacteriosis including *Mycobacterium avium* complex (MAC) infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jul. 1, 2011	54	Cubicin IV 350 mg (MSD K.K.)	Approval	Daptomycin	A drug with a new active ingredient indicated for the treatment of sepsis, infective endocarditis, deep skin infection, secondary infection of trauma, burn, and surgical wounds, and secondary infection of erosion and ulcer caused by daptomycin-sensitive methicillin-resistant *Staphylococcus aureus* (MRSA).
4	Jul. 1, 2011	55	Zithromac Tablets 250 mg (Pfizer Japan Inc.)	Change	Azithromycin hydrate	A drug with a new additional indication for *Legionella pneumophila* as applicable microorganism.
			Zithromac Intravenous Use 500 mg (Pfizer Japan Inc.)	Approval		A drug with a new route of administration indicated for the treatment of pneumonia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Aug. 17, 2011	56	Gracevit Tablets 50 mg Gracevit Fine Granules 10% (Daiichi Sankyo Company, Limited)	Change Change	Sitafloxacin hydrate	Drugs with a new dosage indicated for the treatment of pharyngitis and laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, cystitis, pyelonephritis, urethritis, cervicitis, otitis media, sinusitis, periodontal inflammation, pericoronitis, and jaw inflammation.
4	Sep. 26, 2011	57	Telavic 250 mg Tablet (Mitsubishi Tanabe Pharma Corporation)	Approval	Telaprevir	A drug with a new active ingredient indicated for the improvement of viremia in serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C in: (1) untreated patients with high blood HCV RNA; or (2) patients who did not respond to, or in whom the symptom relapsed with, interferon monotherapy or interferon-ribavirin combination therapy. [Priority review]
4	Sep. 26, 2011	58	Itrizole Oral Solution 1% (Janssen Pharmaceutical K.K.)	Change	Itraconazole	A drug with new indications for (1) the treatment of fungal infection, (2) the treatment of febrile neutropenia with suspected fungal infection, and (3) the prevention of deep mycosis in patients with hematologic malignancy or hematopoietic stem cell transplantation in whom neutropenia is anticipated.
4	Nov. 25, 2011	59	Diflucan Intravenous Solution 50 mg Diflucan Intravenous Solution 100 mg Diflucan Intravenous Solution 200 mg Diflucan Capsules 50 mg Diflucan Capsules 100 mg (Pfizer Japan Inc.)	Change Change Change Change Change	Fluconazole	Drugs with a new additional pediatric dosage and a new additional indication for the prevention of deep mycosis in patients with hematopoietic stem cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Dec. 22, 2011	60	Claforan Injection 0.5 g Claforan Injection 1 g (Sanofi-Aventis K.K.) Cefotax Injection 0.5 g Cefotax Injection 1 g (Sanofi-Aventis Nichi-Iko K.K.)	Change Change Change Change	Cefotaxime sodium	Drugs with a new dosage for the treatment of pediatric purulent meningitis. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jan. 18, 2012	61	Samtirel Oral Suspension 15% (GlaxoSmithKline K.K.)	Approval	Atovaquone	A drug with a new active ingredient indicated for the treatment and prevention of Pneumocystis pneumonia. [Priority review]
4	Jan. 18, 2012	62	Cancidas for Intravenous Drip Infusion 50 mg Cancidas for Intravenous Drip Infusion 70 mg (MSD K.K.)	Approval Approval	Caspofungin acetate	Drugs with a new active ingredient indicated for the treatment of febrile neutropenia suspected of a fungal infection and fungal infections due to *Candida* or *Aspergillus* (esophageal candidiasis, invasive candidiasis, aspergillosis).
4	Feb. 22, 2012	63	Sawacillin Fine Granules 10% Sawacillin Capsules 125 Sawacillin Capsules 250 Sawacillin Tablets 250 (Astellas Pharma Inc.) Pasetocin Fine Granules 10% Pasetocin Capsules 125 Pasetocin Capsules 250 Pasetocin Tablets 250 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change Change	Amoxicillin hydrate	Drugs with a revised maximum dosage for pediatric patients indicated for the treatment of infections except *Helicobacter pylori* infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Feb. 22, 2012	64	Penicillin G Potassium 200000 Units for Injection Penicillin G Potassium 1000000 Units for Injection (Meiji Seika Pharma Co., Ltd.)	Change Change	Benzylpenicillin potassium	Drugs with a new route of administration and a new dosage for a new additional indication for the treatment of syphilis. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Mar. 21, 2012	65	Flagyl Oral Tablet 250 mg Flagyl Vaginal Tablet 250 mg (Shionogi & Co., Ltd.)	Change Change	Metronidazole	Drugs with a new indication and new dosages for the treatment of bacterial vaginosis. [Public knowledge-based application after PAFSC's preliminary assessment]
5	May 20, 2011	66	Anti-D Globulin for I.M. Injection 1000 "Nichiyaku" (Nihon Pharmaceutical Co., Ltd.)	Change	Dry anti-Rho(D) immune human globulin	A drug with a new indication and a new dosage for the prevention of sensitization to the D(Rho) factor in women who are D(Rho) negative and are not already sensitized to the D(Rho) factor, to be used at around 28 weeks of pregnancy or in the case of possible sensitization such as after delivery, miscarriage, artificial abortion, ectopic pregnancy, testing/procedure during pregnancy (e.g., amniocentesis, external cephalic version) or abdominal bruise. [Public knowledge-based application after PAFSC's preliminary assessment]
5	May 20, 2011	67	Anti-D Human Immunoglobulin I.M. 1000-Benesis (Benesis Corporation)	Change	Dry anti-Rho(D) immune human globulin	A drug with a new indication and a new dosage for the prevention of sensitization to the D(Rho) factor in women who are D(Rho) negative and are not already sensitized to the D(Rho) factor, to be used at around 28 weeks of pregnancy or in the case of possible sensitization such as after delivery, miscarriage, artificial abortion, ectopic pregnancy, testing/procedure during pregnancy (e.g., amniocentesis, external cephalic version) or abdominal bruise. [Public knowledge-based application after PAFSC's preliminary assessment]
5	May 20, 2011	68	Gonalef for Subcutaneous Injection 150 (Merck Serono Co., Ltd.)	Change	Follitropin alfa (genetical recombination)	A drug with a new additional indication and a new dosage for induction of ovulation in patients with anovulation and infrequent ovulation associated with hypothalamic-pituitary dysfunction or polycystic ovarian syndrome.
5	May 20, 2011	69	Leuplin for Injection 1.88 Leuplin for Injection 3.75 (Takeda Pharmaceutical Company Limited)	Change Change	Leuprorelin acetate	Drugs with a new additional dosage indicated for the treatment of central precocious puberty. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 1, 2011	70	Betanis Tablet 25 mg Betanis Tablet 50 mg (Astellas Pharma Inc.)	Approval Approval	Mirabegron	Drugs with a new active ingredient indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
5	Nov. 25, 2011	71	L'estrogel 0.06% (Shiseido Company, Limited)	Change	Estradiol	A drug with a new dosage. This drug is indicated for the treatment of vasomotor symptoms (hot flush and sweating) associated with menopausal disorder and ovarian deficiency symptoms.
5	Mar. 30, 2012	72	Minirinmelt OD Tablets 120 μg Minirinmelt OD Tablets 240 μg (Ferring Pharmaceuticals Co., Ltd.)	Approval Approval	Desmopressin acetate hydrate	Drugs with a new route of administration indicated for the treatment of nocturnal enuresis associated with decreased urine osmolality or urinary specific gravity.
6-1	May 20, 2011	73	Imuran Tablets 50 mg (GlaxoSmithKline K.K.) Azanin Tablets 50 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Azathioprine	Drugs with new additional indications and a new dosage for the treatment of the following treatment-resistant rheumatic diseases: systemic vasculitis (e.g., microscopic polyangiitis, Wegener granulomatosis, polyarteritis nodosa, Churg-Strauss syndrome, aortitis syndrome), systemic lupus erythematosus (SLE), polymyositis, dermatomyositis, pachyderma, mixed connective tissue disease and refractory rheumatic disease. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Jul. 1, 2011	74	Allelock Granule 0.5% (Kyowa Hakko Kirin Co., Ltd.)	Approval	Olopatadine hydrochloride	A drug with an additional dosage form of granules and with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin disease (eczema/dermatitis and pruritus cutaneous).
6-1	Jul. 1, 2011	75	Simponi Subcutaneous Injection 50 mg Syringe (Janssen Pharmaceutical K.K.)	Approval	Golimumab (genetical reco	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-1	Jul. 1, 2011	76	Onbrez Inhalation Capsules 150 μg (Novartis Pharma K.K.)	Approval	Indacaterol maleate	A drug with a new active ingredient indicated for the alleviation of various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
6-1	Jul. 1, 2011	77	Humira 40 mg for S.C. Injection Syringe 0.8 mL Humira 20 mg for S.C. Injection Syringe 0.4 mL (Abbott Japan Co., Ltd.)	Change Approval	Adalimumab (genetical recombination)	Drugs with a new additional indication, a new dosage, and an additional dosage form for the treatment of polyarticular-course juvenile idiopathic arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Aug. 17, 2011	78	Patanol EX Ophthalmic Solution 0.2% (Alcon Japan Ltd.)	Approval	Olopatadine hydrochloride	A drug with a new dosage and an additional dosage form indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 26, 2011	79	Ilaris for S.C. Injection 150 mg (Novartis Pharma K.K.)	Approval	Canakinumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of cryopyrin-associated periodic syndrome. [Orphan drug]
6-1	Sep. 26, 2011	80	Mucosta Ophthalmic Solution UD 2% (Otsuka Pharmaceutical Co., Ltd.)	Approval	Rebamipide	A drug with a new route of administration indicated for the treatment of dry eye.
6-1	Dec. 22, 2011	81	Celecox Tablets 100 mg Celecox Tablets 200 mg (Astellas Pharma Inc.)	Change Change	Celecoxib	Drugs with a new additional indication and a new dosage for the relief of inflammation and pain after operation, trauma, and tooth extraction.
6-1	Dec. 22, 2011	82	Onon Drysyrup 10% (Ono Pharmaceutical Co., Ltd.)	Change	Pranlukast hydrate	A drug with a new additional indication for the treatment of allergic rhinitis in pediatric patients.
6-1	Mar. 21, 2012	83	Enbrel 25 mg for S.C. Injection Enbrel 25 mg Syringe 0.5 mL for S.C. Injection Enbrel 10 mg for S.C. Injection Enbrel 50 mg Syringe 1.0 mL for S.C. Injection (Pfizer Japan Inc.)	Change	Etanercept (genetical recombination)	Drugs with a new additional indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-1	Mar. 30, 2012	84	Pulmozyme Inhalation Solution 2.5 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Dornase alfa (genetical recombination)	A drug with a new active ingredient indicated for the improvement of lung function in patients with cystic fibrosis. [Orphan drug]
6-2	Apr. 22, 2011	85	Glubes Combination Tab. (Kissei Pharmaceutical Co., Ltd.)	Approval	Mitiglinide calcium hydrate/voglibose	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of mitiglinide calcium hydrate with voglibose is deemed appropriate).
6-2	May 20, 2011	86	Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.) Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change	Sitagliptin phosphate hydrate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to alpha-glucosidase inhibitors along with diet and exercise therapies.
6-2	May 20, 2011	87	Forteo for S.C. Injection Kit 600 μg (Eli Lilly Japan K.K.)	Change	Teriparatide (genetical recombination)	A drug with a new dosage with a revised treatment period from "up to 18 months" to "up to 24 months" indicated for the treatment of osteoporosis with an increased risk for fracture.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Jul. 1, 2011	88	Liovel Combination Tablets LD Liovel Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Alogliptin benzoate/pioglitazone hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus.
6-2	Jul. 1, 2011	89	Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Linagliptin	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to diet and exercise therapies alone).
6-2	Jul. 1, 2011	90	Recalbon Tablets 50 mg (Ono Pharmaceutical Co., Ltd.) Bonoteo Tablets 50 mg (Astellas Pharma Inc.)	Approval Approval	Minodronic acid hydrate	Drugs with a new dosage and an additional dosage form indicated for the treatment of osteoporosis.
6-2	Sep. 16, 2011	91	Levemir Penfill Levemir FlexPen Levemir InnoLet (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	Insulin detemir (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated. This application applies only to the change in manufacturing method of the drug substance, and thus formulation, manufacturing method, indications and dosage and administration of the product are the same as the approved product.
6-2	Sep. 16, 2011	92	Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.) Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.)	Change Change Change Change Change Change	Sitagliptin phosphate hydrate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to insulin along with diet and exercise therapies.
6-2	Sep. 26, 2011	93	Teribone Inj. 56.5 μg (Asahi Kasei Pharma Corporation)	Approval	Teriparatide acetate	A drug with a new route of administration, a new indication, and a new dosage indicated for the treatment of osteoporosis with high risk of fracture.
6-2	Nov. 25, 2011	94	Metopirone Capsules 250 mg (Novartis Pharma K.K.)	Change	Metyrapone	A drug with a new additional indication and a new dosage for the treatment of Cushing's syndrome. [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Jan. 18, 2012	95	Bonalon Bag for I.V. Infusion 900 μg (Teijin Pharma Limited)	Approval	Alendronate sodium hydrate	A drug with a new dosage in a new additional dosage form indicated for the treatment of osteoporosis (not in the reexamination period).
6-2	Mar. 30, 2012	96	Brazaves Capsules 100 mg (Actelion Pharmaceuticals Japan Ltd.)	Approval	Miglustat	A drug with a new active ingredient indicated for the treatment of Niemann-Pick disease Type C. [Orphan drug]
6-2	Mar. 30, 2012	97	Bydureon for Subcutaneous Injection 2 mg (Eli Lilly Japan K.K.)	Approval	Exenatide	A drug with a new additional indication and a new dosage in a new dosage form for the treatment of type 2 diabetes mellitus.
Blood products	Jun. 16, 2011	98	NovoSeven for Injection 1.2 mg NovoSeven for Injection 4.8 mg NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new additional indication and a new dosage for inhibition of bleeding tendency in patients with Glanzmann thrombasthenia with alloantibodies against platelet, and with past or present refractoriness to platelet transfusions. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 26, 2011	99	TachoSil Tissue Sealing Sheet (CSL Behring K.K.)	Approval	Human fibrinogen/thrombin fraction	A new combination drug indicated for the adhesion and closure of wounds in tissues at surgery in the fields of hepatic surgery, pulmonary surgery, cardiovascular surgery, obstetrics and gynecology, and urologic surgery.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Apr. 22, 2011	100	Halaven Injection 1 mg (Eisai Co., Ltd.)	Approval	Eribulin mesylate	A drug with a new active ingredient indicated for the treatment of inoperable or recurrent breast cancer. [Priority review]
Oncology drugs	Jun. 16, 2011	101	Sprycel Tablets 20 mg Sprycel Tablets 50 mg (Bristol-Myers K.K.)	Change Change	Dasatinib hydrate	Drugs with a new additional indication and a new dosage for the treatment of chronic myelocytic leukemia.
Oncology drugs	Jul. 1, 2011	102	Tarceva Tablets 25 mg Tarceba Tablets 100 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Erlotinib hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer.
Oncology drugs	Jul. 1, 2011	103	Zolinza Capsules 100 mg (MSD K.K.)	Approval	Vorinostat	A drug with a new active ingredient indicated for the treatment of cutaneous T-cell lymphoma.
Oncology drugs	Sep. 16, 2011	104	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new indication and a new dosage for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 16, 2011	105	Predonine Tablets 5 mg (Shionogi & Co., Ltd.) Prednisolone Tablets 1 mg (Asahi Kasei) Prednisolone Tablets 5 mg (Asahi Kasei) (Asahi Kasei Pharma Corporation) Prednisolone Tablets 5 mg "Takeda" Prednisolone Powder 1% "Takeda" (Takeda Pharmaceutical Company Limited)	Change Change Change Change Change	Prednisolone	Drugs with a new indication for the treatment of multiple myeloma. [Expedited review]
Oncology drugs	Sep. 26, 2011	106	Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)	Approval	Fulvestrant	A drug with a new active ingredient indicated for the treatment of postmenopausal breast cancer.
Oncology drugs	Sep. 26, 2011	107	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Nov. 25, 2011	108	Paraplatin Injection 50 mg Paraplatin Injection 150 mg Paraplatin Injection 450 mg (Bristol-Myers K.K.)	Change Change Change	Carboplatin	Drugs with a new additional indication and new dosages for the treatment of breast cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	109	Sandostatin LAR for I.M. Injection 10 mg Sandostatin LAR for I.M. Injection 20 mg Sandostatin LAR for I.M. Injection 30 mg (Novartis Pharma K.K.)	Change Change Change	Octreotide acetate	Drugs with a new additional indication and a new dosage for the treatment of gastrointestinal neuroendocrine tumor. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	110	Elplat for Injection 50 mg Elplat for Injection 100 mg Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg (Yakult Honsha Co., Ltd.)	Change Change Change Change	Oxaliplatin	Drugs with a new dosage for post-operative adjuvant chemotherapy for colon cancer.
Oncology drugs	Nov. 25, 2011	111	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of breast cancer with HER2 overexpression. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	112	Iressa Tablets 250 (AstraZeneca K.K.)	Change	Gefitinib	A drug with a revised indication for the treatment of unresectable advanced or recurrent non-small cell lung cancer in patients with EGFR gene mutation.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 22, 2011	113	Afinitor Tablets 5 mg (Novartis Pharma K.K.)	Change	Everolimus	A drug with a new additional indication and a new dosage for the treatment of pancreatic neuroendocrine tumor.
Oncology drugs	Jan. 18, 2012	114	Ranmark Subcutaneous Injection 120 mg (Daiichi Sankyo Company, Limited)	Approval	Denosumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of bone lesions due to multiple myeloma and bone lesions due to bone metastasis of solid tumor.
Oncology drugs	Feb. 22, 2012	115	Vepesid Capsules 25 mg Vepesid Capsules 50 mg (Bristol-Myers K.K.) Lastet S Cap. 25 mg Lastet S Cap. 50 mg (Nippon Kayaku Co., Ltd.)	Change Change Change Change	Etoposide	Drugs with a new additional indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 22, 2012	116	Randa Inj. 10 mg/20 mL Randa Inj. 25 mg/50 mL Randa Inj. 50 mg/100 mL (Nippon Kayaku Co., Ltd.) Briplatin Injection 10 mg Briplatin Injection 25 mg Briplatin Injection 50 mg (Bristol-Myers K.K.) Cisplatin Injection 10 mg 'Nichi-iko' Cisplatin Injection 25 mg 'Nichi-iko' Cisplatin Injection 50 mg 'Nichi-iko' (Nichi-Iko Pharmaceutical Co., Ltd.) Cisplatin for I.V. Infusion 10 mg 'Maruko' Cisplatin for I.V. Infusion 25 mg 'Maruko' Cisplatin for I.V. Infusion 50 mg 'Maruko' (Nichi-Iko Pharmaceutical Co., Ltd.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Cisplatin	Drugs with a new additional indication and a new dosage for the treatment of biliary tract cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 22, 2012	117	Glivec Tablets 100 mg (Novartis Pharma K.K.)	Change	Imatinib mesilate	A drug with new additional indications and a new dosage for the treatment of FIP1L1-PDGFRα-positive hypereosinophilic syndrome or chronic eosinophilic leukemia. [Public knowledge-based application after PAFSC's preliminary assessment] [Orphan drug]
Oncology drugs	Mar. 21, 2012	118	Ifomide for Injection 1 g (Shionogi & Co., Ltd.)	Change	Ifosfamide	A drug with a new additional indication and a new dosage for the treatment of malignant lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 21, 2012	119	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.) Paclitaxel Inj. 30 mg/5 mL 'NK' Paclitaxel Inj. 100 mg/16.7 mL 'NK' (Nippon Kayaku Co., Ltd.) Paclitaxel Injection 30 mg 'Sawai' Paclitaxel Injection 100 mg 'Sawai' Paclitaxel Injection 150 mg 'Sawai' (Sawai Pharmaceutical Co., Ltd.) Paclitaxel Intravenous Infusion 30 mg 'Sandoz' Paclitaxel Intravenous Infusion 100 mg 'Sandoz' (Sandoz K.K.)	Change Change Change Change Change Change Change Change Change	Paclitaxel	Drugs with new additional indications and new dosages for the treatment of relapsed or metastatic head and neck cancer, relapsed or metastatic esophagus cancer, angiosarcoma, advanced or relapsed cervical cancer. A new dosage for once-weekly administration for ovarian cancer has also been added. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 30, 2012	120	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	Mogamulizumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of recurrent or relapsed CCR4-positive adult T-cell leukemia/lymphoma. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 30, 2012	121	Xalkori Capsules 200 mg Xalkori Capsules 250 mg (Pfizer Japan Inc.)	Approval	Crizotinib	Drugs with a new active ingredient indicated for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer. [Orphan drug]
Biologicals	Jul. 1, 2011	122	Rotarix Oral Solution (GlaxoSmithKline K.K.)	Approval	Live attenuated human rotavirus vaccine, oral	A drug with a new active ingredient indicated for the prevention of gastroenteritis due to rotavirus.
Biologicals	Jul. 1, 2011	123	Gardasil Aqueous Suspension for Intramuscular Injection Gardasil Aqueous Suspension for Intramuscular Injection Syringe (MSD K.K.)	Approval Approval	Recombinant adsorbed quadrivalent human papillomavirus virus-like particle vaccine (yeast origin)	Drugs with a new active ingredient indicated for the prevention of cervical cancer and its precursor lesions, vulvar intraepithelial neoplasia, vaginal intraepithelial neoplasia, and condyloma acuminatum caused by infection with human papillomavirus types 6, 11, 16 and 18.
Biologicals	Aug. 8, 2011	124	Influenza HA Vaccine "Kaketsuken" TF Influenza HA Vaccine "Kaketsuken" Influ "Kaketsuken" Syringe (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza. [Expedited review]
Biologicals	Aug. 8, 2011	125	Influenza HA Vaccine "Biken" Flubik HA Flubik HA Syringe (The Research Foundation for Microbial Diseases of Osaka University)	Change Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza. [Expedited review]
Biologicals	Aug. 8, 2011	126	Influenza HA Vaccine "Seiken" Flu-Syringe “Seiken” (Denka Seiken Co., Ltd.)	Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza. [Expedited review]
Biologicals	Aug. 8, 2011	127	Influenza HA Vaccine "Kitasatodaiichisankyo" Influenza HA Vaccine "S Hokken" Influenza HA Vaccine "Kitasatodaiichisankyo" Syringe (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Change Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza. [Expedited review]
Biologicals	Jan. 18, 2012	128	RotaTeq Oral Solution (MSD K.K.)	Approval	Live attenuated rotavirus vaccine, oral, pentavalent	A drug with a new active ingredient indicated for the prevention of gastroenteritis due to rotavirus.
In vivo diagnosis	Feb. 22, 2012	129	Diagnogreen for Injection 25 mg (Daiichi Sankyo Company, Limited)	Change	Indocyanine green	A drug with a new additional indication and a new dosage for the use of cerebral angiography (by fluorescence measurement in infrared-ray irradiation) in neurosurgical operation. [Public knowledge-based application after PAFSC's preliminary assessment]
Radio-pharmaceuticals	May 20, 2011	130	MyoMIBG-I123 Injection (Fujifilm RI Pharma Co., Ltd.)	Change	3-iodobenzylguanidine (^{123}I) injection	A drug with a new additional indication and a new dosage for diagnosis of melanocytoma in tumor scintigraphy. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Products Approved in FY 2010: New Drugs

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 16, 2010	1	Nesp Injection 10 µg/1 mL Plastic Syringe Nesp Injection 15 µg/1 mL Plastic Syringe Nesp Injection 20 µg/1 mL Plastic Syringe Nesp Injection 30 µg/1 mL Plastic Syringe Nesp Injection 40 µg/1 mL Plastic Syringe Nesp Injection 60 µg/0.6 mL Plastic Syringe Nesp Injection 120 µg/0.6 mL Plastic Syringe Nesp Injection 180 µg/0.9 mL Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination)	Drugs with a new route of administration and a new indication for the treatment of renal anemia.
1	Apr. 16, 2010	2	Soliris for Intravenous Infusion 300 mg (Alexion Pharma K.K. (currently Alexion Pharma G.K.))	Approval	Eculizumab (genetical recombination)	A drug with a new active ingredient indicated to reduce hemolysis in patients with paroxysmal nocturnal hemoglobinuria. [Orphan drug]
1	Jun. 18, 2010	3	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jun. 18, 2010	4	Pariet Tablets 10 mg (Eisai Co., Ltd.)	Change	Sodium rabeprazole	A drug with a new additional indication and a new dosage for the treatment of non-erosive reflux disease.
1	Jul. 23, 2010	5	Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company Limited)	Change Change	Lansoprazole	Drugs with a new additional indication and a new dosage for prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with low-dose aspirin.
1	Aug. 20, 2010	6	Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company Limited)	Change Change	Lansoprazole	Drugs with a new additional indication and a new dosage for prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal anti-inflammatory drugs.
1	Oct. 27, 2010	7	Humira 40mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.)	Change	Adalimumab (genetical recombination)	A drug with new additional indications and a new dosage for the remission induction and maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatment).
1	Oct. 27, 2010	8	Minclea Catapasm for Internal Use 0.8% (Nihon Pharmaceutical Co., Ltd.)	Approval	*l*-Menthol	A drug with a new additional indication and a new dosage and in an additional dosage form for the inhibition of gastric peristalsis in endoscopy of the upper gastrointestinal tract.
1	Oct. 27, 2010	9	Radiogardase Capsule 500 mg (Nihon Medi-Physics Co., Ltd.)	Approval	Iron(III)hexacyanoferrate(II)	A drug with a new active ingredient indicated for the reduction of internal contamination with radioactive cesium. [Expedited review]
1	Dec. 21, 2010	10	Pariet Tablets 10 mg Pariet Tablets 20 mg (Eisai Co., Ltd.)	Change Change	Sodium rabeprazole	Drugs with new dosages for the treatment of reflux esophagitis.
1	Jan. 21, 2011	11	Altat Capsules 37.5 Altat Capsules 75 (Aska Pharmaceutical Co., Ltd.)	Change Change	Roxatidine acetate hydrochloride	Drugs with new additional pediatric dosages. These drugs are indicated for gastric ulcer, duodenal ulcer, stomal ulcer, Zollinger-Ellison syndrome, reflux esophagitis, preanesthetic medication and improvement of gastric mucosal lesions (erosion, bleeding, redness, edema) during acute gastritis or acute exacerbation phase of chronic gastritis.
1	Mar. 10, 2011	12	Exal for Inj. 10 mg (Nippon Kayaku Co., Ltd.)	Change	Vinblastine sulfate	A drug with a new additional indication and a new dosage for the treatment of Langerhans cell histiocytosis. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Apr. 16, 2010	13	Unisia Combination Tablets LD Unisia Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Candesartan cilexetil/amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	May 13, 2010	14	Tambocor Tablets 50 mg Tambocor Tablets 100 mg (Eisai Co., Ltd.)	Change Change	Flecainide acetate	Drugs with a new additional indication and a new dosage for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia) in children. [Expedited review]
2	Jul. 23, 2010	15	Micamlo Combination Tablets AP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/amlodipine besilate	A new combination drug indicated for the treatment of hypertension.
2	Jul. 23, 2010	16	Volibris Tablets 2.5 mg (GlaxoSmithKline K.K.)	Approval	Ambrisentan	A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Sep. 10, 2010	17	Ancaron Tablets 100 (Sanofi-Aventis K.K.)	Change	Amiodarone hydrochloride	A drug with a new additional indication for the treatment of arterial fibrillation with cardiac failure (impaired cardiac function).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Oct. 27, 2010	18	Samsca Tablets 15 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	Tolvaptan	A drug with a new active ingredient indicated for the treatment of fluid retention in heart failure patients who have not responded sufficiently to other diuretics to such as loop diuretics.
2	Oct. 27, 2010	19	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (GlaxoSmithKline K.K.)	Approval Approval	Eltrombopag olamine	Drugs with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]
2	Jan. 21, 2011	20	Memary Tablets 5 mg Memary Tablets 10 mg Memary Tablets 20 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval	Memantine hydrochloride	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in moderate and severe Alzheimer's dementia.
2	Jan. 21, 2011	21	Reminyl Tablets 4 mg Reminyl Tablets 8 mg Reminyl Tablets 12 mg Reminyl OD Tablets 4 mg Reminyl OD Tablets 8 mg Reminyl OD Tablets 12 mg Reminyl Oral Solution 4 mg/mL (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval Approval Approval	Galantamine hydrobromide	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Jan. 21, 2011	22	Prazaxa Capsules 75 mg Prazaxa Capsules 110 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Dabigatran etexilate methanesulfonate	Drugs with a new active ingredient indicated for prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
2	Jan. 21, 2011	23	Romiplate for S.C. Injection 250 μg (Kyowa Hakko Kirin Co., Ltd.)	Approval	Romiplostim (genetical recombination)	A drug with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]
2	Jan. 21, 2011	24	Arixtra Injection 5 mg Arixtra Injection 7.5 mg (GlaxoSmithKline K.K.)	Approval Approval	Fondaparinux sodium	Drugs with new additional indications and new dosages for the treatment of acute pulmonary thromboembolism and acute deep vein thrombosis.
2	Feb. 23, 2011	25	Warfarin Tablets 0.5 mg Warfarin Tablets 1 mg Warfarin Tablets 5 mg (Eisai Co., Ltd.)	Change Change Change	Warfarin potassium	Drugs with new additional pediatric dosages. These drugs are indicated for the treatment and prophylaxis of thromboembolism (e.g., phlebothrombosis, myocardial infarction, pulmonary embolism, brain embolism, slowly-progressive cerebral thrombosis). [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 30, 2011	26	Lipidil Tablets 53.3 mg Lipidil Tablets 80 mg (Aska Pharmaceutical Co., Ltd.) Tricor Tablets 53.3 mg Tricor Tablets 80 mg (Abbott Japan Co., Ltd.)	Approval Approval Approval Approval	Fenofibrate	Drugs in new dosage forms and with new dosages indicated for the treatment of hyperlipemia (including familial hyperlipemia).
3-1	Apr. 16, 2010	27	Rozerem Tablets 8 mg (Takeda Pharmaceutical Company Limited)	Approval	Ramelteon	A drug with a new active ingredient indicated for the improvement of difficulty with sleep onset in insomnia.
3-1	Apr. 16, 2010	28	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Approval Approval Approval	Pregabalin	Drugs with a new active ingredient indicated for the treatment of postherpetic neuralgia.
3-1	Jul. 23, 2010	29	E Keppra Tablets 250 mg E Keppra Tablets 500 mg (UCB Japan Co., Ltd.)	Approval Approval	Levetiracetam	Drugs with a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Oct. 27, 2010	30	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with new additional indications and new dosages for the treatment of upper and lower limb spasticity.
3-1	Oct. 27, 2010	31	Zyprexa Tablets 2.5 mg Zyprexa Tablets 5 mg Zyprexa Tablets 10 mg Zyprexa Fine Granules 1% Zyprexa Zydis Tablets 5 mg Zyprexa Zydis Tablets 10 mg (Eli Lilly Japan K.K.)	Change Change Change Change Change Change	Olanzapine	Drugs with a new additional indication and a new dosage for the improvement of manic symptoms in patients with bipolar disorder.
3-1	Oct. 27, 2010	32	Kenketsu Venoglobulin IH 5% I.V. 2.5 g/50 mL (Benesis Corporation)	Change	Polyethylene glycol treated human normal immunoglobulin	A drug with a new additional indication and a new dosage for the improvement of muscular weakness in polymyositis/dermatomyositis (for use only when steroids are not sufficiently effective). [Orphan drug]
3-1	Oct. 27, 2010	33	Invega Tablets 3 mg Invega Tablets 6 mg Invega Tablets 9 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	Paliperidone	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Oct. 27, 2010	34	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Change Change Change	Pregabalin	Drugs with a new additional indication for the treatment of peripheral neuropathic pain.
3-1	Jan. 21, 2011	35	Nerbloc Intramuscular Injection 2500 Unit (Eisai Co., Ltd.)	Approval	Botulinum toxin type B	A drug with a new active ingredient indicated for the treatment of spasmodic torticollis (cervical dystonia).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
3-2	Apr. 16, 2010	36	DuoTrav Combination Ophthalmic Solution (Alcon Japan Ltd.)	Approval	Travoprost/timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Apr. 16, 2010	37	Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Approval Approval Approval Approval	Fentanyl citrate	Drugs with a new route of administration indicated for analgesia in various types of cancer associated with moderate to severe pain which cannot be managed by treatments with non-opioid analgesics or weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Apr. 16, 2010	38	Cosopt Ophthalmic Solution (Banyu Pharmaceutical Co., Ltd.)	Approval	Dorzolamide hydrochloride/timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other glaucoma drugs.
3-2	Jul. 23, 2010	39	Tramal Capsules 25 mg Tramal Capsules 50 mg (Nippon Shinyaku Co., Ltd.)	Approval Approval	Tramadol hydrochloride	Drugs with a new route of administration indicated for analgesia in various types of cancer with mild to moderate pain.
3-2	Aug. 20, 2010	40	Precedex Intravenous Solution 200 μg "Hospira" (Hospira Japan Co., Ltd.) Precedex Intravenous Solution 200 μg "Maruishi" (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Dexmedetomidine hydrochloride	Drugs with a new additional dosage indicated for sedation during artificial respiration and after weaning in patients in intensive care.
3-2	Oct. 27, 2010	41	Acref Oral Transmucosal Fentanyl Citrate 200μg Acref Oral Transmucosal Fentanyl Citrate 400μg Acref Oral Transmucosal Fentanyl Citrate 600μg Acref Oral Transmucosal Fentanyl Citrate 800μg (Mitsubishi Tanabe Pharma Corporation)	Approval Approval Approval Approval	Fentanyl citrate	Drugs with a new route of administration indicated for the analgesia of breakthrough pain in patients with cancer receiving a potent opioid analgesic at fixed time.
3-2	Oct. 27, 2010	42	OneDuro Patch 0.84 mg OneDuro Patch 1.7 mg OneDuro Patch 3.4 mg OneDuro Patch 5 mg OneDuro Patch 6.7 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval	Fentanyl	Drugs in new dosage forms indicated for the analgesia in various types of cancer with moderate to severe pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Oct. 27, 2010	43	MaQaid Intravitreal Injection 40 mg (Wakamoto Co., Ltd.)	Approval	Triamcinolone acetonide	A drug with a new route of administration indicated for the visualization of the vitreous body during vitreous surgery.
3-2	Feb. 23, 2011	44	Norspan Tape 5 mg Norspan Tape 10 mg Norspan Tape 20 mg (Mundipharma K.K.)	Approval Approval Approval	<u>Buprenorphine</u>	Drugs with a new active ingredient indicated for analgesia of chronic pain associated with osteoarthritis and lumbago which cannot be managed by treatments with non-opioid analgesics.
4	Jun. 18, 2010	45	(1) Takepron Capsules 15 Takepron Capsules 30 (2) Takepron OD Tablets 15 Takepron OD Tablets 30 (Takeda Pharmaceutical Company Limited) (3) Omepral Tablets 10 Omepral Tablets 20 (AstraZeneca K.K.) (4) Omeprazon Tablets 10 mg Omeprazon Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation) (5) Pariet Tablets 10 mg (Eisai Co., Ltd.) (6) Pasetocin Capsule 125 Pasetocin Capsule 250 (7) Pasetocin Tablets 250 (Kyowa Hakko Kirin Co., Ltd.) (8) Sawacillin Capsules 250 (9) Sawacillin Tablets 250 (Astellas Pharma Inc.) (10) Amolin Capsules 125 Amolin Capsules 250 (11) 10% Amolin Fine Granules (Takeda Pharmaceutical Company Limited) (12) Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) (13) Klaricid Tablets 200 mg (Abbott Japan Co., Ltd.) (14) Flagyl Oral Tablet 250 mg (Shionogi & Co., Ltd.) (15) Lansap 400 Lansap 800 (Takeda Pharmaceutical Company Limited)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	(1)(2) Lansoprazole (3)(4) Omeprazole (5) Sodium rabeprazole (6)(7)(8)(9)(10)(11) Amoxicillin hydrate (12)(13) Clarithromycin (14) Metronidazole (15) Lansoprazole/amoxicillin hydrate/clarithromycin	Drugs with a new additional indication for *helicobacter pylori (H. pylori)* eradication therapy for gastric MALT lymphoma, for the stomach after endoscopic treatment of early gastric cancer, and for idiopathic thrombocytopenic purpura, in *H. pylori* infection.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Jun. 18, 2010	46	Zovirax for I.V. Infusion 250	Change	Aciclovir	Drugs with new additional indications and a new additional dosage for herpes simplex, prevention of herpes simplex virus infection in hematopoietic stem cell transplantation, herpes zoster, and prevention of recurrence of genital herpes (oral dosage form), and neonatal herpes simplex virus infection (injectable dosage form) based on the discussion of the Investigational Committee on Pediatric Drug Therapies.
			Zovirax Tablets 200	Change		
			Zovirax Tablets 400	Change		
			Zovirax Granules 40%	Change		
			(GlaxoSmithKline K.K.)			
			Zobiclobill Tab. 200	Change		
			Zobiclobill Tab. 400	Change		
			(Nihon Pharmaceutical Industry Co.,Ltd.)			
			Natazil for I.V. Infusion 250 mg	Change		
			(Fujiyakuhin Co., Ltd.)			
			Tomill Kit for I.V. Infusion 250 mg	Change		
			(Mitsubishi Tanabe Pharma Corporation)			
			Viruhexal Tablets 200 mg	Change		
			Viruhexal Tablets 400 mg	Change		
			Viruhexal for I.V. Infusion 250 mg	Change		
			Viruhexal Granule 40%	Change		
			(Sandoz K.K.)			
			Astric Dry Syrup 80%	Change		
			(Nippon Kayaku Co., Ltd.)			
			Grosparl Syrup 8%	Change		
			Grosparl Granules 40%	Change		
			(Takata Seiyaku Co., Ltd.)			
			Vercusron Tablets 200	Change		
			Vercusron Tablets 400	Change		
			Vercusron Granules 40%	Change		
			Vercusron for Intravenous Infusion 250 mg	Change		
			Vercusron Injection 250	Change		
			(Towa Pharmaceutical Co., Ltd.)			
			Acirovec Tablets 200	Change		
			Acirovec Tablets 400	Change		
			Acirovec Granules 40%	Change		
			Acirovec DS 80%	Change		
			Acirovec for Intravenous Infusion 250 mg	Change		
			(Sawai Pharmaceutical Co., Ltd.)			
			Vizocross Tablets 200	Change		
			Vizocross Tablets 400	Change		
			Vizocross Granules 40%	Change		
			(Taisho Pharm. Ind., Ltd.)			
			Actidas for Intravenous Infusion 250 mg	Change		
			Actidas Tablets 400	Change		
			Actidas Tablets 200	Change		
			Actidas Kit	Change		
			(Shiono Chemical Co., Ltd.)			
			Aciclovir Tablets 200 mg "Mylan"	Change		
			Aciclovir Tablets 400 mg "Mylan"	Change		
			(Mylan Seiyaku Ltd.)			
			Pharrax Tablets 200	Change		
			Pharrax Tablets 400	Change		
			(Kyorin Rimedio Co., Ltd.)			
			Aciclovin Tablets 200	Change		
			Aciclovin Intravenous Infusion 250 mg	Change		
			Aciclovin Granules 40%	Change		
			Aciclovin Tablets 400	Change		
			(Nichi-Iko Pharmaceutical Co., Ltd.)			
			Acilomin Tablets 200	Change		
			Acilomin Tablets 400	Change		
			(Medisa Shinyaku Inc.)			
			Aciclovir Tablets 200 mg "Tanabe"	Change		
			Aciclovir Tablets 400 mg "Tanabe"	Change		
			Aciclovir Granules 40% "Tanabe"	Change		
			Zobistat Granules 40%	Change		
			(Choseido Pharmaceutical Co., Ltd.)			
			Aciclovir Injection 250 mg "Kayaku"	Change		
			Clovate Tab. 200	Change		
			Clovate Tab. 400	Change		
			(Pola Pharma Inc.)			
			Acycril Bag for I.V. Infusion 250 mg/100 mL	Change		
			Acycril for I.V. infusion 250 mg	Change		
			(I'rom Pharmaceutical Co.,Ltd.)			
			Vicclox I.V. Infusion 125 mg	Change		
			Vicclox I.V. Infusion 250 mg	Change		
			Vicclox Tablets 200	Change		
			Vicclox Tablets 400	Change		
			Vicclox Granules 40%	Change		
			Vicclox Syrup 8%	Change		
			(Kobayashi Kako Co., Ltd.)			
			Acivir Oral Jelly 200 mg	Change		
			Acivir Oral Jelly 800 mg	Change		
			(Nichi-Iko Pharmaceutical Co., Ltd.)			
			Ailax Tablets 200 mg	Change		
			Ailax Tablets 400 mg	Change		
			(Tatsumi Kagaku Co., Ltd.)			
			Actios Tablets 200	Change		
			Actios Tablets 400	Change		
			Actios for Intravenous Infusion 250 mg	Change		
			Actios for Intravenous Infusion 250 mg Kit	Change		
			Actios Granules 40%	Change		
			(Taiyo Pharmaceutical Industry Co., Ltd.)			

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Jul. 23, 2010	47	Pasil Intravenous Drip Infusion 300 mg Pasil Intravenous Drip Infusion 500 mg Pasil Intravenous Drip Infusion 1000 mg (Toyama Chemical Co., Ltd.) Pazucross Injection 300 Pazucross Injection 500 Pazucross Injection 1000 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change Approval Change Change Approval	Pazufloxacin mesilate	Drugs with new additional indications for the treatment of *Streptococcus pneumoniae* and sepsis and a new dosage in an additional dosage form.
4	Sep. 10, 2010	48	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Approval	Laninamivir octanoate hydrate	A drug with a new active ingredient indicated for the treatment of influenza A or B virus infections.
4	Oct. 27, 2010	49	Cravit Intravenous Drip Infusion 500 mg/100 mL Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Company, Limited)	Approval Approval	Levofloxacin hydrate	Drugs with a new route of administration indicated for the treatment of pneumonia, secondary infection of chronic respiratory disease, typhoid, paratyphoid, anthrax, brucellosis, plague, tularemia and Q fever.
4	Oct. 27, 2010	50	Rapiacta 300 mg Bag for Intravenous Drip Infusion Rapiacta 150 mg Vial for Intravenous Drip Infusion (Shionogi & Co., Ltd.)	Change Change	Peramivir hydrate	Drugs with new additional pediatric dosages for influenza A or B virus infection.
4	Dec. 21, 2010	51	Cravit Ophthalmic Solution 1.5% (Santen Pharmaceutical Co., Ltd.)	Approval	Levofloxacin hydrate	A drug with a new dosage of the 1.5% formulation for the treatment of blepharitis, dacryocystitis, hordeolum, conjunctivitis, meibomianitis, and keratitis (including corneal ulcer) and sterilization during the ophthalmic perioperative period.
4	Mar. 10, 2011	52	Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Meropenem hydrate	Drugs with a new dosage (the maximum daily dose has been changed) in patients with general infections that are severe and refractory.
5	Dec. 21, 2010	53	Sodium Phosphate Corrective Injection 0.5 mmol/mL (Otsuka Pharmaceutical Factory, Inc.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used for the correction of electrolyte levels of electrolyte fluids. [Expedited review]
5	Dec. 21, 2010	54	Lunabell Tablets (Nobelpharma Co., Ltd.)	Change	Norethisterone/ ethinylestradiol	Drugs with a new additional indication for the treatment of functional dysmenorrhoea.
5	Dec. 21, 2010	55	Kindaly 4E Kindaly 4D Kindaly AF-4P (Fuso Pharmaceutical Industries, Ltd.)	Approval Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations to be used as the perfusate of dialysis-based artificial kidneys in chronic renal failure (use in patients whose blood sugar level is not controlled well with sugarless dialysate and when other bicarbonate dialysate is not sufficiently effective to improve hyperkalemia and hypermagnesemia, or when hypercalcemia may occur).
5	Jul. 23, 2010	56	Yaz Combination Tablets (Bayer Yakuhin, Ltd.)	Approval	Drospirenone/ethinylestradiol betadex	A new combination drug with a new active ingredient indicated for the treatment of dysmenorrhea.
5	Feb. 23, 2011	57	Prostandin 20 for Injection (Ono Pharmaceutical Co., Ltd.)	Change	Alprostadil alfadex	A drug with a new route of administration and a new dosage for a new additional indication for the diagnosis of erectile disturbance.
5	Feb. 23, 2011	58	Norlevo Tablets 0.75 mg (Sosei Co., Ltd.)	Approval	Levonorgestrel	A drug with a new additional indication and a new dosage for emergency contraception.
6-1	Apr. 16, 2010	59	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Apr. 16, 2010	60	Diquas Ophthalmic Solution 3% (Santen Pharmaceutical Co., Ltd.)	Approval	Diquafosol sodium	A drug with a new active ingredient indicated for the treatment of dry eye.
6-1	Jul. 23, 2010	61	Orencia for I.V. Infusion 250 mg (Bristol-Myers K.K.)	Approval	Abatacept (genetical recombination)	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Jul. 23, 2010	62	Synvisc Intraarticular Injection 2 mL (Genzyme Japan K.K.)	Approval	Sodium hyaluronate crosslinked polymer and sodium hyaluronate crosslinked polymer crosslinked with vinylsulfone	A drug with a new active ingredient indicated for pain relief in patients with knee osteoarthritis who have not responded sufficiently to conservative non-drug treatment and oral drug treatment.
6-1	Jul. 23, 2010	63	Pulmicort 100 µg Turbuhaler 112 doses Pulmicort 200 µg Turbuhaler 56 doses Pulmicort 200 µg Turbuhaler 112 doses (AstraZeneca K.K.)	Change Change Change	Budesonide	Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma.
6-1	Jul. 23, 2010	64	Allelock Tablets 2.5 Allelock Tablets 5 Allelock OD Tablets 2.5 Allelock OD Tablets 5 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change	Olopatadine hydrochloride	Drugs with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin disease (eczema/dermatitis and pruritus cutaneous).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Oct. 27, 2010	65	Nevanac Ophthalmic Suspension 0.1% (Alcon Japan Ltd.)	Approval	Nepafenac	A drug with a new active ingredient indicated for the treatment of postoperative inflammation in intraocular surgery.
6-1	Oct. 27, 2010	66	Xyzal Tablets 5 mg (GlaxoSmithKline K.K.)	Approval	Levocetirizine hydrochloride	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, eczema/dermatitis, pruigo and cutaneous pruritus.
6-1	Oct. 27, 2010	67	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication of ankylosing spondylitis (for use only in patients who have not sufficiently responded to conventional treatment). [Priority review]
6-1	Nov. 16, 2010	68	Pulmicort Respules 0.25 mg Pulmicort Respules 0.5 mg (AstraZeneca K.K.)	Change Change	Budesonide	Drugs with new additional adult and pediatric (5 years of age and older) dosages for the treatment of bronchial asthma.
6-1	Jan. 21, 2011	69	Stelara Subcutaneous Injection 45 mg (Janssen Pharmaceutical K.K.)	Approval	Ustekinumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 21, 2011	70	Alvesco 50 μg Inhaler 112 puffs Alvesco 100 μg Inhaler 112 puffs Alvesco 100 μg Inhaler 56 puffs Alvesco 200 μg Inhaler 56 puffs (Teijin Pharma Limited)	Change Change Approval Change	Ciclesonide	Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma.
6-1	Jan. 21, 2011	71	Calonal Fine Gran. 20% Calonal Fine Gran. 50% Calonal Tab. 200 Calonal Tab. 300 Calonal Powder (Showa Yakuhin Kako Co., Ltd.) Cocarl Dry Syr. 40% Cocarl Tab. 200 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Calsil Fine Granules 20% Calsil Tablets 200 (Taiyo Pharmaceutical Industry Co., Ltd.) Anyrume Fine Granules 20% Anyrume Tablets 200 mg Anyrume Tablets 300 mg Pyrinazin Powder (Choseido Pharmaceutical Co., Ltd.) Napa (Mylan Seiyaku Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Acetaminophen	Drugs with a new additional indication for the treatment of osteoarthritis and with an expanded dosage of acetaminophen.
6-1	Feb. 23, 2011	72	Rheumatrex Capsules 2 mg (Pfizer Japan Inc.) Methotrexate Tablets 2 mg "Tanabe" (Mitsubishi Tanabe Pharma Corporation) Methotrexate Cap. 2 mg "Mylan" (Mylan Seiyaku Ltd.) Trexamette Capsules 2 mg (Shiono Chemical Co., Ltd.) Methotrexate Capsules 2 mg "Towa" (Towa Pharmaceutical Co., Ltd.) Metolate Tablets 2 mg (Santen Pharmaceutical Co., Ltd.) Methotrexate Cap. 2 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Methotrexate	Drugs with a revised indication and an expanded dosage for the treatment of rheumatoid arthritis (limitation of patients to be treated was abolished).
6-1	Feb. 23, 2011	73	Mohrus Tape 20 mg Mohrus Tape L 40 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change	Ketoprofen	Drugs with new additional indications for the treatment of myalgia and post-traumatic swelling/pain.
6-1	Feb. 23, 2011	74	Endoxan for Injection 100 mg Endoxan for Injection 500 mg Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change Change Change	Cyclophosphamide	Drugs with a new additional indication and new dosages for treatment-resistant rheumatic disease in adults and children. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Apr. 16, 2010	75	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Alogliptin benzoate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes (for use only in patients with inadequate glycemic control by following treatments: 1. Treatment by diet and exercise only 2. In addition to treatment by diet and exercise, treatment by alpha-glucosidase inhibitor).
6-2	Apr. 16, 2010	76	Metact Combination Tablets LD Metact Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Pioglitazone hydrochloride/metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes (only when a concomitant use of pioglitazone hydrochloride with metformin hydrochloride is deemed appropriate).
6-2	Jun. 18, 2010	77	Amaryl 0.5 mg Tablets Amaryl 1 mg Tablets Amaryl 3 mg Tablets (Sanofi-Aventis K.K.)	Change Change Change	Glimepiride	Drugs with a new dosage indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to diet and exercise therapies alone).
6-2	Jul. 23, 2010	78	Forteo S.C. Injection Kit 600 μg Forteo S.C. Injection Cart 600 μg (Eli Lilly Japan K.K.)	Approval Approval	Teriparatide (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Jul. 23, 2010	79	Viviant Tablets 20 mg (Pfizer Japan Inc.)	Approval	Bazedoxifene acetate	A drug with a new active ingredient indicated for the treatment of postmenopausal osteoporosis.
6-2	Aug. 20, 2010	80	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Alogliptin benzoate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to thiazolidinediones along with diet and exercise therapies.
6-2	Oct. 27, 2010	81	Byetta Subcutaneous Injection 5 μg Pen 300 Byetta Subcutaneous Injection 10 μg Pen 600 Byetta Subcutaneous Injection 10 μg Pen 300 (Eli Lilly Japan K.K.)	Approval Approval Approval	Exenatide	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to treatment with sulfinylurea [including concomitant treatment with biguanides or thiazolidines] along with diet and exercise therapies).
6-2	Jan. 21, 2011	82	Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval	Repaglinide	Drugs with a new active ingredient indicated for the improvement of postprandial changes of blood glucose in type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] alpha-glucosidase inhibitors along with diet and exercise therapies).
6-2	Jan. 21, 2011	83	Feburic Tablet 10 mg Feburic Tablet 20 mg Feburic Tablet 40 mg (Teijin Pharma Limited)	Approval Approval Approval	Febuxostat	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.
6-2	Jan. 21, 2011	84	Sonias Combination Tablets LD Sonias Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Pioglitazone hydrochloride/glimepiride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of pioglitazone hydrochloride with glimepiride is deemed appropriate).
6-2	Jan. 21, 2011	85	Edirol Capsule 0.5 μg Edirol Capsule 0.75 μg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Eldecalcitol	Drugs with a new active ingredient indicated for the treatment of osteoporosis.
6-2	Feb. 23, 2011	86	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Alogliptin benzoate	Drugs with new additional indications for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to sulfonylureas or biguanides along with diet and exercise therapies.
6-2	Mar. 10, 2011	87	L-Cartin Tablets 100 mg L-Cartin Tablets 300 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change	Levocarnitine chloride	Drugs with a new additional indication and new dosages for the treatment of carnitine deficiency. [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Mar. 23, 2011	88	Novolin R FlexPen Novolin R 100 IU/mL Novolin 30R FlexPen Novolin N FlexPen InnoLet 30R (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	Insulin human (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated. However, this application applies only to the change in manufacturing method of the drug substance, and thus formulation, manufacturing method, indications and dosage and administration of the product are the same as the approved product.
Oncology drugs	Apr. 16, 2010	89	Vectibix for Intravenous Infusion 100 mg (Takeda Pharmaceutical Company Limited) Vectibix for Intravenous Infusion 100 mg "Takeda Bio" (Takeda Bio Development Center Limited)	Approval Approval	Panitumumab (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable, advanced or recurrent colorectal cancer with wild-type KRAS.
Oncology drugs	Jun. 25, 2010	90	Revlimid Capsules 5 mg (Celgene K.K.)	Approval	Lenalidomide hydrate	A drug with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Jun. 18, 2010	91	LenaDex Tablets 4 mg (Celgene K.K.)	Approval	Dexamethasone	A drug with a new additional indication and a new dosage for the treatment of multiple myeloma. [Expedited review]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Jul. 23, 2010	92	Torisel Injection 25 mg (Pfizer Japan Inc.)	Approval	Temsirolimus	A drug with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Jul. 23, 2010	93	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Paclitaxel	A drug in a new dosage form and with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 20, 2010	94	Immucyst Intravesical 81 mg (Nippon Kayaku Co., Ltd.)	Change	Freeze-dried bacillus of Calmette and Guerin for intravesical use (Connaught strain)	A drug with a new additional dosage indicated for the treatment of superficial bladder cancer and carcinoma in situ of bladder.
Oncology drugs	Aug. 20, 2010	95	Revlimid Capsules 5 mg (Celgene K.K.)	Change	Lenalidomide hydrate	A drug with a new additional indication and a new dosage for the treatment of myelodysplastic syndrome associated with a deletion 5q cytogenetic abnormality. [Orphan drug]
Oncology drugs	Oct. 27, 2010	96	Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Approval	Bendamustine hydrochloride	A drug with a new active ingredient indicated for the treatment of relapsed or refractory indolent B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. [Orphan drug]
Oncology drugs	Nov. 16, 2010	97	Taxotere 20 mg for I.V. Infusion Taxotere 80 mg for I.V. Infusion (Sanofi-Aventis K.K.)	Change Change	Docetaxel hydrate	Drugs with new dosages for the treatment of breast cancer, non-small cell lung cancer, gastric cancer, head and neck cancer and ovarian cancer.
Oncology drugs	Dec. 21, 2010	98	Tasigna Capsules 150 mg Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Approval Change	Nilotinib hydrochloride hydrate	Drugs with new additional indications and a new dosage for the treatment of chronic- or accelerated-phase chronic myelocytic leukaemia.
Oncology drugs	Jan. 21, 2011	99	Vidaza for Injection 100 mg (Nippon Shinyaku Co., Ltd.)	Approval	Azacitidine	A drug with a new active ingredient indicated for the treatment of myelodysplastic syndrome. [Orphan drug]
Oncology drugs	Feb. 23, 2011	100	Hycamtin for Injection 1.1 mg (Nippon Kayaku Co., Ltd.)	Change	Nogitecan hydrochloride	A drug with a new additional indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 23, 2011	101	Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 23, 2011	102	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change Change	Gemcitabine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 10, 2011	103	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer with HER2 overexpression. [Priority review]
AIDS drugs	Dec. 8, 2010	104	Kaletra Combination Tablets (Abbott Japan Co., Ltd.)	Change	Lopinavir/ritonavir	A drug with new dosages for the treatment of HIV infection. [Orphan drug]
Biologicals	Oct. 27, 2010	105	Adsorbed Pandemic Influenza Vaccine (H5N1) "Kaketsuken" (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Inactivated influenza virus, H5N1 (whole virion)	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Biologicals	Jan. 14, 2011	106	Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine "Hokken" (The Kitasato Institute)	Approval	Freeze-dried live attenuated measles, rubella combined vaccine	A drug with a new active ingredient indicated for the prevention of measles and rubella.
Biologicals	Jan. 17, 2011	107	Encevac for Subcutaneous Injection (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Freeze-dried, cell culture-derived Japanese encephalitis vaccine (inactivated)	A drug with a new active ingredient indicated for the prevention of Japanese encephalitis. [Expedited review]
Blood products	May 13, 2010	108	Venoglobulin IH 5% I.V. 2.5 g/50 mL (Benesis Corporation)	Change	Polyethylene glycol treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	109	Kenketsu Venilon-I for Intravenous Injection 2500 mg (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Freeze-dried sulfonated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	110	Kenketu Glovenin-I for I.V. Injection 2500 mg (Nihon Pharmaceutical Co., Ltd.)	Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Blood products	May 13, 2010	111	Nisseki Polyglobin-N 5% I.V. 2.5 g/50 mL (Japanese Red Cross Society)	Change	pH4-treated acidic human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	112	Sanglopor I.V. Infusion 2.5 g (CSL Behring AG; designated marketing authorization holder, CSL Behring K.K.)	Change	Freeze-dried pH4 treated human immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	113	Gammagard for Intravenous Injection 2.5 g (Baxter Limited)	Change	Freeze-dried ion-exchange-resin treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	Jun. 18, 2010	114	Epogin Subcutaneous Injection Syringe 24000 (Chugai Pharmaceutical Co., Ltd.)	Approval	Epoetin beta (genetical recombination)	A drug with a new dosage in a new additional dosage form indicated for autologous blood storage.

Table 1. Products Approved in FY 2009: New Drugs

Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 22, 2009	1	Niflec (Ajinomoto Co., Inc.)	Change	N/A for this combination drug	A drug with a new additional indication and a new dosage for cleansing of gastrointestinal tract for pretreatment of barium enema X-ray examination.
			Gasmotin Tablets 2.5 mg Gasmotin Tablets 5 mg Gasmotin Powder (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Mosapride citrate hydrate	Drugs with a new additional indication and a new dosage for adjunctive treatment to pretreatment with orally gastrointestinal lavage solution for barium enema X-ray examination.
1	Jul. 7, 2009	2	Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Capsules 5 mg (Astellas Pharma Inc.)	Change Change Change	Tacrolimus hydrate	Drugs with a new additional indication and a new dosage for the treatment of refractory (steroid-resistant/steroid-dependent) active ulcerative colitis (limited to moderate-to-severe cases).
1	Oct. 16, 2009	3	Emend Capsules 80 mg Emend Capsules 125 mg Emend Capsules Set (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	Aprepitant	Drugs with a new active ingredient indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.).
1	Oct. 16, 2009	4	Feron for Injection 6 MIU Feron for Injection 3 MIU Feron for Injection 1 MIU (Toray Industries, Inc.)	Change	Interferon beta	Drugs with a new additional indication and a new dosage for the improvement of viraemia in chronic hepatitis C on concomitant administration with ribavirin.
			Rebetol Capsule 200 mg (Schering-Plough K.K.)	Change	Ribavirin	A drug with a new additional indication and a new dosage for the improvement of viraemia in chronic hepatitis C on concomitant administration with interferon beta.
1	Oct. 16, 2009	5	Asacol Tablets 400 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	Mesalazine	A drug in a new dosage form and with a new dosage indicated for the treatment of ulcerative colitis (excluding severe case).
1	Jan. 20, 2010	6	Aloxi I.V. Injection 0.75 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Palonosetron hydrochloride	A drug with a new active ingredient indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.).
1	Jan. 20, 2010	7	Epoetin Alfa BS Injection 750 syringe [JCR] Epoetin Alfa BS Injection 1500 syringe [JCR] Epoetin Alfa BS Injection 3000 syringe [JCR] Epoetin Alfa BS Injection 750 [JCR] Epoetin Alfa BS Injection 1500 [JCR] Epoetin Alfa BS Injection 3000 [JCR] (JCR Pharmaceuticals Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Epoetin kappa (genetical recombination) [epoetin alfa biosimilar 1]	Follow-on biologics indicated for the treatment of renal anemia in patients on dialysis and anemia of prematurity.
1	Mar. 12, 2010	8	Protecadin Tablet 5 Protecadin Tablet 10 (Taiho Pharmaceutical Co., Ltd.)	Change Change	Lafutidine	Drugs with a new additional indication for the treatment of reflux esophagitis.
2	Apr. 22, 2009	9	Micombi Combination Tablets AP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/ hydrochlorothiazide	New combination drugs indicated for the treatment of hypertension.
		10	Micombi Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval		
2	Jul. 7, 2009	11	Caduet Combination Tablets 1ban Caduet Combination Tablets 2ban Caduet Combination Tablets 3ban Caduet Combination Tablets 4ban (Pfizer Japan Inc.)	Approval Approval Approval Approval	Amlodipine besilate/atorvastatin calcium hydrate	New combination drugs indicated for the treatment of comorbidity of hypertension or angina pectoris and hypercholesterolemia or familial hypercholesterolemia.
2	Jul. 7, 2009	12	Rasilez Tablets 150 mg (Novartis Pharma K.K.)	Approval	Aliskiren fumarate	A drug with a new active ingredient indicated for the treatment of hypertension.
2	Oct. 16, 2009	13	Adcirca Tablets 20 mg (Eli Lilly Japan K.K.)	Approval	Tadalafil	A drug with a new indication and a new dosage for the treatment of pulmonary arterial hypertension.
2	Jan. 20, 2010	14	Exforge Combination Tablets (Novartis Pharma K.K.)	Approval	Valsartan/amlodipine besylate	A new combination drug indicated for the treatment of hypertension.
2	Jan. 20, 2010	15	Rezaltas Combination Tablets LD Rezaltas Combination Tablets HD (Daiichi Sankyo Co., Ltd.)	Approval Approval	Olmesartan medoxomil/ azelnidipine	New combination drugs indicated for the treatment of hypertension.

3-1	Apr. 22, 2009	16	Risperdal Consta Intramuscular Injection 25 mg Risperdal Consta Intramuscular Injection 37.5 mg Risperdal Consta Intramuscular Injection 50 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	Risperidone	Drugs with a new route of administration indicated for the treatment of schizophrenia.
3-1	Apr. 22, 2009	17	Strattera Capsules 5 mg Strattera Capsules 10 mg Strattera Capsules 25 mg (Eli Lilly Japan K.K.)	Approval Approval Approval	Atomoxetine hydrochloride	Drugs with a new active ingredient indicated for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in children. [Expedited review]
3-1	Apr. 22, 2009	18	Clozaril Tablets 25 mg Clozaril Tablets 100 mg (Novartis Pharma K.K.)	Approval Approval	Clozapine	Drugs with a new active ingredient indicated for the treatment of treatment-resistant schizophrenia.
3-1	Jul. 7, 2009	19	Remeron Tablets 15 mg (Schering-Plough K.K.) Reflex Tablets 15 mg (Meiji Seika Kaisha, Ltd.)	Approval Approval	Mirtazapine	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Oct. 16, 2009	20	Paxil Tablets 10 mg Paxil Tablets 20 mg (GlaxoSmithKline K.K.)	Change Change	Paroxetine hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of social anxiety disorder.
3-1	Oct. 16, 2009	21	Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Granules 0.2 mg Prograf Granules 1 mg (Astellas Pharma Inc.)	Change Change Change Change	Tacrolimus hydrate	Drugs with a revised indication for the treatment of myasthenia gravis (limitation of patients to be treated was abolished.) [Orphan drug]
3-1	Jan. 20, 2010	22	Bi•Sifrol Tablets 0.125 mg Bi•Sifrol Tablets 0.5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change Change	Pramipexole hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of moderate to severe idiopathic restless legs syndrome.
3-1	Jan. 20, 2010	23	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Approval Approval	Duloxetine hydrochloride	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Jan. 20, 2010	24	Kenketsu Venilon-I for Intravenous Injection 500 mg (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Freeze-dried sulfonated human normal immunoglobulin	A drug with a new additional indication and a new dosage for the improvement of neurological disorder in patients with Churg-Strauss syndrome or allergic granulomatous angiitis (for use only when steroids are not sufficiently effective). [Orphan drug]
3-2	Jul. 7, 2009	25	Lumigan Ophthalmic Solution 0.03% (Senju Pharmaceutical Co., Ltd.)	Approval	Bimatoprost	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3-2	Aug. 20, 2009	26	DisCoVisc 1.0 Ophthalmic Viscoelastic Substance (Alcon Japan Ltd.)	Approval	Sodium hyaluronate, chondroitin sulfate sodium	A drug in a new dosage form indicated for adjunctive treatment for crystalline lens reconstruction.
3-2	Jan. 20, 2010	27	Bridion Intravenous 200 mg Bridion Intravenous 500 mg (Schering-Plough K.K.)	Approval Approval	Sugammadex sodium	Drugs with a new active ingredient indicated for the recovery from neuromuscular blockade induced by rocuronium bromide or vecuronium bromide.
3-2	Jan. 20, 2010	28	Xalacom Combination Eye Drops (Pfizer Japan Inc.)	Approval	Latanoprost/timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Jan. 20, 2010	29	Durotep MT Patch 2.1 mg Durotep MT Patch 4.2 mg Durotep MT Patch 8.4 mg Durotep MT Patch 12.6 mg Durotep MT Patch 16.8 mg (Janssen Pharmaceutical K.K.)	Change Change Change Change Change	Fentanyl	Drugs with a new indication for analgesia of moderate to severe chronic pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Mar. 12, 2010	30	Dormicum Injection 10 mg (Astellas Pharma Inc.)	Change	Midazolam	A drug with a new additional pediatric dosage indicated for anesthetic premedication and for sedation during artificial respiration in patients under intensive care.
4	Apr. 22, 2009	31	Orapenem Fine Granules 10% for Pediatric (Meiji Seika Kaisha, Ltd.)	Approval	Tebipenem pivoxil	A drug with a new active ingredient indicated for the treatment of pneumonia, otitis media, and sinusitis.
4	Apr. 22, 2009	32	Cravit Tablets 250 mg Cravit Tablets 500 mg (Daiichi Sankyo Co., Ltd.)	Approval Approval	Levofloxacin hydrate	Drugs in an additional dosage form and with a revised dosage of once-daily administration for conventional indications.
		33	Cravit Fine Granules 10% (Daiichi Sankyo Co., Ltd.)	Approval		

4	May 20, 2009	34	Valixa Tablets 450 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Valganciclovir hydrochloride	A drug with a new additional indication for the treatment of cytomegalovirus infection in organ transplantation (including hematogenic stem cell transplantation), malignant tumor, etc.
4	Jun. 17, 2009	35	AmBisome 50 mg for Intravenous Drip Infusion (Dainippon Sumitomo Pharma Co., Ltd.)	Change	Amphotericin B	A drug with new additional indications and a new dosage for the treatment of fungal infections caused by Mucor species, Absidia species, Rhizopus species, Rhizomucor species, Cladosporium species, Cladophialophora species, Fonsecaea species, Phialophora species, Exophiala species, Coccidioides species, Histoplasma species, and Blastomyces species and visceral leishmaniasis.
4	Oct. 16, 2009	36	Vancomycin Ophthalmic Ointment 1% (Toa Pharmaceutical Co., Ltd.)	Approval	Vancomycin hydrochloride	A drug with a new route of administration indicated for the treatment of conjunctivitis, blepharitis, meibomianitis, and dacryocystitis caused by vancomycin-sensitive methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant Staphylococcus epidermidis (MRSE). [Orphan drug]
4	Oct. 16, 2009	37	Ozex Fine Granules 15% for Pediatric (Toyama Chemical Co., Ltd.)	Approval	Tosufloxacin tosilate hydrate	A drug with new additional indications and a new dosage and in a new dosage form for the treatment of pneumonia, cholera, otitis media, and anthrax in children.
4	Dec. 18, 2009	38	Tamiflu Dry Syrup 3% Tamiflu Capsule 75 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Oseltamivir phosphate	Drugs with a new additional indication and a new dosage for prophylaxis of influenza A or B virus infections.
4	Jan. 13, 2010	39	Rapiacta 300 mg Bag for Intravenous Drip Infusion Rapiacta 150 mg Vial for Intravenous Drip Infusion (Shionogi & Co., Ltd.)	Approval Approval	Peramivir hydrate	Drugs with a new active ingredient indicated for the treatment of influenza A or B virus infections.
4	Jan. 20, 2010	40	Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Meropenem hydrate	Drugs with a new additional indication and a new dosage for the treatment of febrile neutropenia.
5	Jul. 7, 2009	41	Avolve Capsules 0.5 mg (GlaxoSmithKline K.K.)	Approval	Dutasteride	A drug with a new active ingredient indicated for the treatment of benign prostatic hyperplasia.
5	Jul. 7, 2009	42	Gonalef 75 Gonalef Pen 300 Gonalef Pen 450 Gonalef Pen 900 (Merck Serono Co., Ltd.)	Change Change Change Change	Follitropin alfa (genetical recombination)	Drugs with a new additional indication and a new dosage for induction of ovulation in patients with anovulation and infrequent ovulation associated with hypothalamic-pituitary dysfunction or polycystic ovarian syndrome.
5	Nov. 6, 2009	43	Rinderon Injection 2 mg (0.4%) Rinderon Injection 4 mg (0.4%) (Shionogi & Co., Ltd.)	Change Change	Betamethasone sodium phosphate	Drugs with a new additional indication and a new dosage for prevention of neonatal respiratory distress syndrome by way of enhancing fetal lung maturation by maternal administration for use in cases where premature birth is expected.
5	Dec. 18, 2009	44	Uritos Tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.) Staybla Tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Imidafenacin	Drugs with a new dosage indicated for the treatment of urgency of urination, pollakiuria, and urge urinary incontinence associated with overactive bladder.
5	Dec. 18, 2009	45	Bup-4 Tablet 10 Bup-4 Tablet 20 Bup-4 Fine Granule 2% (Taiho Pharmaceutical Co., Ltd.)	Change Change Change	Propiverine hydrochloride	Drugs with a new additional indication for the treatment of urgency of urination, pollakiuria, and urge urinary incontinence associated with overactive bladder.
6-1	Apr. 22, 2009	46	Allermist 27.5 µg 56 metered Nasal Spray (GlaxoSmithKline K.K.)	Approval	Fluticasone furoate	A drug with a new active ingredient indicated for the treatment of allergic rhinitis.
6-1	Apr. 22, 2009	47	Zyrtec Dry Syrup 1.25% Zyrtec Tablet 5 (UCB Japan Co., Ltd.)	Change Change	Cetirizine hydrochloride	Drugs with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin disease (eczema/dermatitis and pruritus cutaneous).
6-1	Jun. 17, 2009	48	Celecox Tablets 100 mg Celecox Tablets 200 mg (Astellas Pharma Inc.)	Change Change	Celecoxib	Drugs with new additional indications for the treatment of lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tenosynovitis.

6-1	Jul. 7, 2009	49	Enbrel 25 mg for S.C. Injection (Wyeth K.K.)	Change	Etanercept (genetical recombination)	A drug with a new indication and a new dosage for the treatment of polyarticular-course juvenile idiopathic arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Jul. 7, 2009	50	Asmanex Twisthaler 100 µg 60 doses Asmanex Twisthaler 200 µg 60 doses (Schering-Plough K.K.)	Approval Approval	Mometasone furoate	Drugs with a new route of administration indicated for the treatment of bronchial asthma.
6-1	Jul. 7, 2009	51	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments. [Expedited review]
6-1	Oct. 16, 2009	52	Erizas Capsule for Nasal Spray 400 µg (Nippon Shinyaku Co., Ltd.)	Approval	Dexamethasone cipecilate	A drug with a new active ingredient indicated for the treatment of allergic rhinitis.
6-1	Oct. 16, 2009	53	Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.)	Approval Approval	Budesonide/formoterol fumarate hydrate	New combination drugs indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-$_2$ agonist is needed).
6-1	Nov. 6, 2009	54	Mohrus Tape 20 mg Mohrus Tape L 40 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change	Ketoprofen	Drugs with a new additional indication for relief of local pain associated with rheumatoid arthritis.
6-1	Jan. 20, 2010	55	Spiriva 2.5 µg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Tiotropium bromide hydrate	A drug in a new dosage form and with a new dosage as a kit product consisting of Respimat inhaler and a cartridge (solution).
6-1	Jan. 20, 2010	56	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 20, 2010	57	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.)	Change	Adalimumab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 5, 2010	58	Enbrel 10 mg for S.C. Injection Enbrel 25 mg Syringe 0.5 mL for S.C. Injection (Wyeth K.K.)	Change Change	Etanercept (genetical recombination)	Drugs with a new dosage indicated for the treatment of rheumatoid arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
		59	Enbrel 25 mg for S.C. Injection Enbrel 50 mg Syringe 1.0 mL for S.C. Injection (Wyeth K.K.)	Change Approval		
6-2	Apr. 22, 2009	60	Norditropin S Injection 5 mg Norditropin S Injection 10 mg Norditropin NordiFlex Injection 5 mg Norditropin NordiFlex Injection 10 mg Norditropin NordiFlex Injection 15 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of adult growth hormone deficiency (for use only in severe cases).
6-2	Apr. 22, 2009	61	Apidra Inj. Cart Apidra Inj. OptiClik Apidra Inj. SoloStar Apidra Inj. 100 U/mL （Sanofi-Aventis K.K.）	Approval Approval Approval Approval	Insulin glulisine (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	May 20, 2009	62	Melbin Tablets 250 mg (Dainippon Sumitomo Pharma Co., Ltd.) Glycoran Tablets 250 mg (Nippon Shinyaku Co., Ltd.)	Change Change	Metformin hydrochloride	Drugs with a new indication and a new dosage for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to either (1) diet and exercise therapies alone or (2) sulfonylurea along with diet and exercise therapies.
6-2	Jun. 17, 2009	63	Norditropin S Injection 5 mg Norditropin S Injection 10 mg Norditropin NordiFlex Injection 5 mg Norditropin NordiFlex Injection 10 mg Norditropin NordiFlex Injection 15 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of dwarfism with no epiphyseal closure in patients born small for gestational age (SGA).
6-2	Jul. 7, 2009	64	Growject for Injection 1.33 mg Growject for Injection 8 mg Growject BC for Injection 8 mg (JCR Pharmaceuticals Co., Ltd.)	Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of adult growth hormone deficiency (for use only in severe cases).

6-2	Aug. 20, 2009	65	NovoRapid 70 Mix Penfill NovoRapid 70 Mix FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin aspart (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Aug. 20, 2009	66	Humalog Mix 50 Cart Humalog Mix 50 Kit Humalog Mix 50 MirioPen (Eli Lilly Japan K.K.)	Change Change Change	Insulin lispro (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Sep. 18, 2009	67	NovoRapid 50 Mix Penfill NovoRapid 50 Mix FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin aspart (genetical recombination)	Drugs with a new dosage and in an additional dosage form indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Oct. 16, 2009	68	Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (Banyu Pharmaceutical Co., Ltd.) Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Sitagliptin phosphate hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who do not sufficiently respond to any one of the following treatments): 1. Dietary therapy and/or exercise therapy only 2. Use of sulfonylureas in addition to dietary therapy and/or exercise therapy 3. Use of thiazolidinediones in addition to dietary therapy and/or exercise therapy 4. Use of biguanides in addition to dietary therapy and/or exercise therapy
6-2	Oct. 16, 2009	69	Basen Tablets 0.2 Basen OD Tablets 0.2 (Takeda Pharmaceutical Company Limited)	Change Change	Voglibose	Drugs with a new additional indication and a new dosage for prevention of type 2 diabetes mellitus in patients with impaired glucose tolerance (only for whom glycemic control is not sufficient by diet and/or exercise).
6-2	Nov. 6, 2009	70	Seibule Tablets 25 mg Seibule Tablets 50 mg Seibule Tablets 75 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change Change Change	Miglitol	Drugs with a new additional indication for improvement of postprandial hyperglycemia in patients with diabetes mellitus (for use only in patients who have not responded sufficiently to treatment with biguanides in conjunction with dietary and exercise regimens).
6-2	Jan. 20, 2010	71	Equa Tablets 50 mg (Novartis Pharma K.K.)	Approval	Vildagliptin	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies).
6-2	Jan. 20, 2010	72	Metgluco Tablets 250 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Metformin hydrochloride	A drug with a new dosage exceeding the maximum dosage (750 mg/day) of the conventional formulation indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies).
6-2	Jan. 20, 2010	73	Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.)	Approval	Liraglutide (genetical recombination)	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies).
AIDS drugs	Aug. 20, 2009	74	Prezistanaive Tablets 400 mg (Janssen Pharmaceutical K.K.)	Approval	Darunavir ethanolate	A drug with a new dosage indicated for the treatment of HIV infection. [Orphan drug]
Blood products	Oct. 16, 2009	75	BeneFIX Intravenous 250 BeneFIX Intravenous 500 BeneFIX Intravenous 1000 BeneFIX Intravenous 2000 (Wyeth K.K.)	Approval Approval Approval Approval	Nonacog alfa (genetical recombination)	Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with hemophilia B (congenital blood coagulation factor IX deficiency). [Orphan drug]
Blood products	Mar. 12, 2010	76	NovoSeven for Injection 1.2 mg NovoSeven for Injection 4.8 mg (Novo Nordisk Pharma Ltd.)	Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new additional indication and a new dosage for inhibition of bleeding tendency in patients with congenital factor VII deficiency.
		77	NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change		
Oncology drugs	Apr. 22, 2009	78	Doxil Injection 20 mg (Janssen Pharmaceutical K.K.)	Change	Doxorubicin hydrochloride	A drug with a new indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy. [Expedited review]
Oncology drugs	Apr. 22, 2009	79	Tykerb Tablets 250 mg (GlaxoSmithKline K.K.)	Approval	Lapatinib tosilate hydrate	A drug with a new active ingredient indicated for the treatment of inoperable or recurrent breast cancer with HER2 overexpression. [Priority review]

Oncology drugs	May 20, 2009	80	Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.)	Change	Sorafenib tosilate	A drug with a new additional indication for the treatment of unresectable hepatocellular carcinoma. [Priority review]
Oncology drugs	May 20, 2009	81	Alimta Injection 100 mg Alimta Injection 500 mg (Eli Lilly Japan K.K.)	Approval Change	Pemetrexed sodium hydrate	Drugs with a new additional indication and a new dosage in an additional dosage form (Alimta Injection 100 mg) indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
Oncology drugs	Aug. 20, 2009	82	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat for Injection 50 mg Elplat for Injection 100 mg (Yakult Honsha Co., Ltd.)	Approval Approval Change Change	Oxaliplatin	Drugs with a new additional indication and a new dosage in an additional dosage form (Elplat I.V. Infusion Solution 50 mg and Elplat I.V. Infusion Solution 100 mg) for post-operative adjuvant chemotherapy for colon cancer. [Priority review]
Oncology drugs	Aug. 20, 2009	83	Miripla Suspension Vehicle 4 mL (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Iodine addition products of the ethyl esters of the fatty acids obtained from poppyseed oil	A drug with a new indication for suspending Miripla for intra-arterial injection 70 mg.
Oncology drugs	Sep. 18, 2009	84	Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection.
Oncology drugs	Sep. 18, 2009	85	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection.
Oncology drugs	Sep. 18, 2009	86	Elplat for Injection 100 mg Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg (Yakult Honsha Co., Ltd.)	Change Change Change	Oxaliplatin	Drugs with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection.
		87	Elplat for Injection 50 mg (Yakult Honsha Co., Ltd.)	Change		
Oncology drugs	Oct. 16, 2009	88	Miripla for Intra-arterial Injection 70 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Miriplatin hydrate	A drug with a new active ingredient indicated for lipiodolization in hepatocellular carcinoma.
Oncology drugs	Oct. 16, 2009	89	Rasuritek 1.5 mg for I.V. Infusion Rasuritek 7.5 mg for I.V. Infusion (Sanofi-Aventis K.K.)	Approval Approval	Rasburicase (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of hyperuricemia in patients receiving cancer chemotherapy.
Oncology drugs	Nov. 6, 2009	90	Fludara Tab. 10 mg (Bayer Yakuhin, Ltd.)	Change	Fludarabine phosphate	A drug with a new additional indication for the treatment of chronic lymphocytic leukemia with anemia or thrombocytopenia.
Oncology drugs	Nov. 6, 2009	91	Fludara for IV Inj. 50 mg (Bayer Yakuhin, Ltd.)	Change	Fludarabine phosphate	A drug with new additional indications and a new dosage for the treatment of recurrent or refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.
Oncology drugs	Nov. 6, 2009	92	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent non-squamous non-small cell lung cancer. [Priority review]
Oncology drugs	Jan. 20, 2010	93	Temodal Injection 100 mg (Schering-Plough K.K.)	Approval	Temozolomide	A drug with a new route of administration indicated for the treatment of malignant glioma.
Oncology drugs	Jan. 20, 2010	94	Afinitor Tablets 5 mg (Novartis Pharma K.K.)	Approval	Everolimus	A drug with a new additional indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Feb. 5, 2010	95	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change Change	Gemcitabine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of inoperable or recurrent breast cancer.
Biologicals	Oct. 16, 2009	96	Cervarix (GlaxoSmithKline K.K.)	Approval	HPV-16 L1 VLP and HPV-18 L1 VLP	A drug with a new active ingredient indicated for prevention of cervical cancer (squamous-cell carcinoma and adenocarcinoma) and its precursor lesions (cervical intraepithelial neoplasia [CIN] 2 and 3) associated with human papillomavirus (HPV) types 16 and 18 infection. [Priority review]

Biologicals	Oct. 16, 2009	97	Prevenar Suspension Liquid for S.C. Injection (Wyeth K.K.)	Approval	Pneumococcal polysaccharide (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F)-CRM_{197} conjugate	A drug with a new active ingredient indicated for prophylaxis of pneumococcal invasive disease (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F). [Priority review]
Biologicals	Jan. 20, 2010	98	Arepanrix (H1N1) Intramuscular Injection (GlaxoSmithKline K.K.)	Emergency approval	Inactivated split-virus influenza A (A/California/7/2009 [H1N1])	A drug with a new active ingredient indicated for prophylaxis of pandemic (H1N1) influenza. [Emergency approval]
Biologicals	Jan. 20, 2010	99	Cell-culture Derived Influenza A (H1N1) Emulsion HA Vaccine "Novartis" for Intramuscular Injection (Novartis Pharma K.K.)	Emergency approval	Pandemic influenza virus surface antigens of A/California/7/2009 (H1N1) like strain	A drug with a new active ingredient indicated for prophylaxis of pandemic (H1N1) influenza. [Emergency approval]
In vivo Diagnostics	Sep. 18, 2009	100	Indigocarmine Injection 20 mg "Daiichi Sankyo" (Daiichi Sankyo Co., Ltd.)	Change	Indigocarmine	A drug with a new route of administration, a new indication, and a new dosage for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review]
In vivo Diagnostics	Sep. 18, 2009	101	Diagnogreen for Injection 25 mg (Daiichi Sankyo Co., Ltd.)	Change	Indocyanine green	A drug with a new route of administration, a new indication, and a new dosage for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review]
In vivo Diagnostics	Mar. 12, 2010	102	FerriSeltz Powder 20% (Otsuka Pharmaceutical Co., Ltd.)	Change	Ferric ammonium citrate	A drug with a new additional indication and a new dosage for negative contrast of digestive tract in cholangiopancreatography.
Bio-CMC	Jun. 22, 2009	103	Somatropin BS S.C. Injection 5 mg [Sandoz] Somatropin BS S.C. Injection 10 mg [Sandoz] (Sandoz K.K.)	Approval Approval	Somatropin (genetical recombination)	Follow-on biologics indicated for the treatment of growth disturbance due to growth hormone deficiency before epiphyseal closure and growth disturbance associated with Turner syndrome or chronic renal insufficiency before epiphyseal closure.
Radio-pharmaceuticals	Sep. 18, 2009	104	Tin Colloid Tc-99m Kit (Nihon Medi-Physics Co., Ltd.)	Change	Technetium (^{99m}Tc) stannous colloid	A drug with a new route of administration and a new indication for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review]
Radio-pharmaceuticals	Sep. 18, 2009	105	Techne Phytate Kit (Fujifilm RI Pharma Co., Ltd.)	Change	Technetium (^{99m}Tc) phytate	A drug with a new route of administration and a new indication for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review]
Radio-pharmaceuticals	Nov. 6, 2009	106	MyoMIBG-I^{123} Injection (Fujifilm RI Pharma Co., Ltd.)	Change	3-iodobenzylguanidine (^{123}I) injection	A drug with a new additional indication and a new dosage for diagnosis of neuroblastoma in tumor scintigraphy.
Radio-pharmaceuticals	Feb. 5, 2010	107	Cardiolite Injection Daiichi Cardiolite Daiichi (Fujifilm RI Pharma Co., Ltd.)	Change Change	Technetium (^{99m}Tc) hexakis (2-methoxy-isobutyl isonitrile) Tetrakis (2-methoxy-isobutyl isonitrile) copper (I) tetrafluoroborate	Drugs with a new additional indication for diagnostic localization of hyperparathyroidism in parathyroid scintigraphy.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Table 1. Products Approved in FY 2008: New Drugs

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 16, 2008	1	Exjade Dispersible Tablets 125 mg Exjade Dispersible Tablets 500 mg (Novartis Pharma K.K.)	Approval Approval	Deferasirox	Drugs with a new active ingredient indicated for the treatment of chronic iron overload due to blood transfusions (in patients for whom injection of iron chelating agents is inappropriate). [Priority review]
1	Jun. 6, 2008	2	Simulect I.V. Injection 10 mg for Pediatric (Novartis Pharma K.K.)	Change	Basiliximab (genetical recombination)	A drug with a new dosage and in a new dosage form indicated for supression of acute organ rejection after renal transplantation. [Orphan drug]
1	Jul. 16, 2008	3	Irribow Tablets 2.5 μg Irribow Tablets 5 μg (Astellas Pharma Inc.)	Approval Approval	Ramosetron hydrochloride	Drugs with a new indication and new dosages for the treatment of diarrhea-predominant irritable bowel syndrome in men.
1	Jul. 16, 2008	4	Graceptor Capsules 0.5 mg Graceptor Capsules 1 mg Graceptor Capsules 5 mg (Astellas Pharma Inc.)	Approval Approval Approval	Tacrolimus hydrate	Drugs in a new dosage form indicated for suppression of organ rejection in renal, liver, heart, lung, and pancreatic transplantation, as well as for suppression of graft rejection and graft versus host disease (GVHD) in bone marrow transplantation.
1	Jul. 16, 2008	5	Differin Gel 0.1% (Galderma S.A.)	Approval	Adapalene	A drug containing a new active ingredient indicated for the treatment of acne vulgaris.
1	Oct. 16, 2008	6	Sumiferon 300 Sumiferon 600 Sumiferon DS 300 Sumiferon DS 600 (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change Change	Interferon alfa (NAMALWA)	Drugs with a new indication and a new dosage for the treatment of viremia in patients with compensated cirrhosis type C (excluding patients with high blood levels of serogroup 1 HCV-RNA).
1	Oct. 16, 2008	7	Fosrenol Chewable Tablets 250 mg Fosrenol Chewable Tablets 500 mg (Bayer Yakuhin Ltd.)	Approval Approval	lanthanum carbonate hydrate	Drugs containing a new active ingredient indicated for the treatment of hyperphosphatemia in dialysis patients with chronic renal failure.
1	Oct. 16, 2008	8	Kenketu Glovenin-I-Nichiyaku (Nihon Pharmaceutical Co., Ltd.)	Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	A drug with a new indication and a new dosage for the treatment of pemphigus (for use when steroid drugs are not sufficiently effective).
1	Nov. 25, 2008	9	Oxarol Ointment 25 μg/g Oxarol Lotion 25 μg/g (Chugai Pharmaceutical Co., Ltd.)	Change Change	Maxacalcitol	Drugs with a new indication for the treatment of palmoplantar pustulosis.
1	Dec. 22, 2008	10	Pentasa Tablets 250 Pentasa Tablets 500 (Nisshin Kyorin Pharmaceutical Co., Ltd. (currently Kyorin Pharmaceutical Co., Ltd.))	Change Change	Mesalazine	Drugs with a new dosage indicated for the treatment of ulcerative colitis (excluding severe cases).
2	Apr. 16, 2008	11	Irbetan Tablets 50 mg Irbetan Tablets 100 mg (Shionogi & Co., Ltd.) Avapro Tablets 50 mg Avapro Tablets 100 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval Approval Approval	Irbesartan	Drugs containing a new active ingredient indicated for the treatment of hypertension.
2	May 20, 2008	12	Arixtra Injection 1.5 mg Arixtra Injection 2.5 mg (GlaxoSmithKline K.K.)	Change Change	Fondaparinux sodium	Drugs with a new indication for prophylaxis of venous thromboembolism in patients undergoing abdominal surgery who are at a high risk of developing venous thromboembolism. [Priority review]
2	Jul. 16, 2008	13	INOflo for Inhalation 800 ppm (INO therapeutics LLC)	Approval	Nitric oxide	A drug containing a new active ingredient indicated for the treatment of hypoxic respiratory failure (HRF) with concurrent pulmonary hypertension in neonates. [Orphan drug]
2	Jul. 16, 2008	14	Novastan HI Inj. 10 mg/2mL (Mitsubishi Tanabe Pharma Corporation) Slonnon HI Injection 10 mg/2mL (Daiichi Sankyo Co., Ltd.)	Change Change	Argatroban hydrate	Drugs with a new indication and a new dosage for prophylaxis of thrombosis in patients with heparin-induced thrombocytopenia (HIT) type II. [Orphan drug]
2	Oct. 16, 2008	15	Bepricor Tablets 50 mg Bepricor Tablets 100 mg (Schering-plough K.K.)	Change Change	Bepridil hydrochloride hydrate	Drugs with a new indication for the treatment of persistent atrial fibrillation in patients in whom other antiarrhythmic drugs are contraindicated or who have not responded to other antiarrhythmic drugs. [Priority review]
2	Jan. 21, 2009	16	Trerief Tablets 25 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Zonisamide	A drug with a new indication and a new dosage for the treatment of Parkinson's disease (in patients who have been treated with other anti-Parkinson drugs in combination with a levodopa-containing agent, but sufficient therapeutic effect was not obtained).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Jan. 21, 2009	17	Co-Dio Combination Tablets MD Co-Dio Combination Tablets EX (Novartis Pharma K.K.)	Approval Approval	Valsartan/ hydrochlorothiazide	New combination drugs indicated for the treatment of hypertension.
2	Jan. 21, 2009	18	Ecard Combination Tablets LD Ecard Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Candesartan cilexetil/hydrochlorothiazide	New combination drugs indicated for the treatment of hypertension.
2	Feb. 23, 2009	19	Clexane Subcutaneous Injection Kit 2000 IU (Sanofi-Aventis K.K.)	Change	Enoxaparin sodium	A drug with a new additional indication for prophylaxis of venous thromboembolism in patients undergoing abdominal surgery who are at a high risk of developing venous thromboembolism.
2	Feb. 23, 2009	20	Norvasc Tablets 2.5 mg Norvasc Tablets 5 mg Norvasc OD Tablets 2.5 mg Norvasc OD Tablets 5 mg (Pfizer Japan Inc.) Amlodin Tablets 2.5 mg Amlodin Tablets 5 mg Amlodin OD Tablets 2.5 mg Amlodin OD Tablets 5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change Change Change Change Change Change	Amlodipine besilate	Drugs with a new dosage indicated for the treatment of hypertension and angina pectoris.
3	Apr. 16, 2008	21	Popscaine 0.75% Inj. 75 mg/10 mL Popscaine 0.75% Inj. 150 mg/20 mL Popscaine 0.25% Inj. 25 mg/10 mL Popscaine 0.25% Inj. Bag 250 mg/100 mL Popscaine 0.75% Inj. Syringe 75 mg/10 mL Popscaine 0.25% Inj. Syringe 25 mg/10 mL (Maruishi Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Levobupivacaine hydrochloride	Drugs containing a new active ingredient. The 0.25% formulation is indicated for postoperative analgesia, and the 0.75% formulation is indicated for epidural anaesthesia.
3	Jul. 16, 2008	22	AtvagoReverse Intravenous Injection Syringe 3 mL AtvagoReverse Intravenous Injection Syringe 6 mL (Terumo Corporation)	Approval Approval	Neostigmine methylsulfate/ atropine sulfate hydrate	New combination drugs indicated for reversal of nondepolarizing muscle relaxants.
3	Jul. 16, 2008	23	Macugen Ivt Inj. Kit 0.3 mg (Pfizer Japan Inc.)	Approval	Pegaptanib sodium	A drug containing a new active ingredient indicated for treatment of age-related macular degeneration with concurrent choroidal neovascularization. [Orphan drug]
3	Oct. 16, 2008	24	Lamictal Tablets 2 mg for Children Lamictal Tablets 5 mg for Children Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Lamotrigine	Drugs containing a new active ingredient indicated for use as adjunctive treatment with other antiepileptic drugs for partial seizures (including secondary generalized seizures), tonic-clonic seizures, and generalized seizures associated with Lennox-Gastaut syndrome in patients with epilepsy for whom other antiepileptic drugs are not sufficiently effective.
3	Oct. 16, 2008	25	Tapros Ophthalmic Solution 0.0015% (Santen Pharmaceutical Co., Ltd.)	Approval	Tafluprost	A drug containing a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3	Oct. 16, 2008	26	Noberbar 250 mg for Injection (Nobelpharma Co., Ltd.)	Approval	Phenobarbital sodium	A drug with a new route of administration indicated for the treatment of 1) neonatal seizures and 2) status epilepticus. [Orphan drug: 1]
3	Jan. 21, 2009	27	Remitch Capsules 2.5 μg (Toray Industries, Inc.)	Approval	Nalfurafine hydrochloride	A drug containing a new active ingredient indicated for the treatment of pruritus in hemodialysis patients (for use only when conventional therapies are not sufficiently effective).
3	Jan. 21, 2009	28	Lucentis Solution for Intravitreal Injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Approval	Ranibizumab (genetical recombination)	A drug containing a new active ingredient indicated for treatment of age-related macular degeneration with concurrent choroidal neovascularization. [Orphan drug]
3	Jan. 21, 2009	29	Botox Vista Injection 50 Units (GlaxoSmithKline K.K.)	Approval	Botulinum toxin type A	A drug with a new indication and a new dosage for the temporary improvement in the appearance of glabellar lines between the brows in adults aged under 65 years.
3	Feb. 23, 2009	30	Botox Injection 50 Botox Injection 100 (GlaxoSmithKline K.K.)	Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of equinus deformity associated with lower limb spasticities in juvenile cerebral palsy in patients 2 years or older.
4	Apr. 16, 2008	31	Famvir Tab. 250 mg Famciclovir (Asahi Kasei Pharma Corporation)	Approval Approval	Famciclovir	A drug containing a new active ingredient indicated for the treatment of herpes zoster.
4	Jul. 16, 2008	32	Zosyn 2.25 g for Intravenous Injection Zosyn 4.5 g for Intravenous Injection (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	Tazobactam/ piperacillin hydrate	New combination drugs indicated for the treatment of septicemia, pneumonia, pyelonephritis, and complicated cystitis.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
4	Jul. 16, 2008	33	Mycobutin Capsules 150 mg (Pfizer Japan Inc.)	Approval	Rifabutin	A drug containing a new active ingredient indicated for the treatment of 1) tuberculosis, 2) non-tuberculous mycobacteriosis including mycobacterium avium complex (MAC) infections, and 3) prophylaxis of disseminated MAC infections in patients with HIV disease.
4	Aug. 29, 2008	34	Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200 mg (Abbott Japan Co., Ltd.)	Change Change	Clarithromycin	Drugs with a new indication and a new dosage for non-tuberculous mycobacteriosis including mycobacterium avium complex (MAC) infections.
4	Sep. 24, 2008	35	Hepsera Tablets 10 (GlaxoSmithKline K.K.)	Change	Adefovir dipivoxil	A drug with a new indication for inhibition of hepatitis B virus replication in patients with type B chronic liver disease in whom abnormal hepatic function was observed in association with proliferation of hepatitis B virus.
4	Jan. 21, 2009	36	Zithromac SR Dry Syrup 2 g for Adults (Pfizer Japan Inc.)	Approval	Azithromycin hydrate	A drug with a new additional indication for Neisseria gonorrhoeae infections, with a new dosage in a new dosage form. Conversion from an immediate release formulation of azithromycin to a sustained release formulation.
5	Apr. 16, 2008	37	Julina Tablets 0.5 mg (Bayer Yakuhin, Ltd.)	Approval	Estradiol	A drug with a new route of administration indicated for the treatment of vasomotor symptoms (hot flushes and sweating) and vaginal atrophy symptoms associated with climacteric disturbance and ovarian deficiency symptoms.
5	Apr. 16, 2008	38	Lunabell Tablets (Nobelpharma Co., Ltd.)	Approval	Norethisterone/ ethinylestradiol	A new combination drug indicated for the treatment of dysmenorrhea associated with endometriosis.
5	Jul. 16, 2008	39	Ganirest Subcutaneous 0.25 mg Syringe (Nippon Organon K.K.)	Approval	Ganirelix acetate	A drug containing a new active ingredient indicated for prevention of premature ovulation during controlled ovarian stimulation.
5	Sep. 1, 2008	40	Gonatropin 5000 (ASKA Pharmaceutical. Co., Ltd.)	Change	[JP] Human chorionic gonadotrophin (extract from human urine)	A drug with a new route of administration and a new indication for induction of spermatogenesis in male hypogonadotropic hypogonadism. [Expedited review]
5	Oct. 16, 2008	41	Menoaid Combipatch (ASKA Pharmaceutical. Co., Ltd.)	Approval	Estradiol/norethisterone acetate	A new combination drug indicated for the treatment of vasomotor symptoms (hot flushes and sweating) associated with climacteric disturbance and ovarian deficiency symptoms.
5	Mar. 31, 2009	42	Elneopa No. 1 Injection Elneopa No. 2 Injection (Otsuka Pharmaceutical Factory, Inc.)	Approval Approval	N/A for this combination drug	A combination drug similar to other products indicated for the supplementation of water, electrolytes, calories (a calorie source), amino acids, vitamins, Zn, Fe, Mn, and I in patients in whom peroral or enteral nutrition is impossible or insufficient, and who have to rely on parenteral nutrition.
6-1	Apr. 16, 2008	43	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Approval Change Approval	Tocilizumab (genetical recombination)	Drugs with a new indication and a new dosage in a new dosage form for the treatment of rheumatoid arthritis (including prevention of structural damage of joint) that cannot be treated sufficiently with conventional therapies, active juvenile idiopathic arthritis in multiple joints, and systemic juvenile idiopathic arthritis. [Priority review] [Expedited review]
6-1	Apr. 16, 2008	44	Humira 40mg for S.C. Injection (Abbott Japan Co., Ltd.)	Approval	Adalimumab (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of rheumatoid arthritis (for use only when conventional therapies are not sufficiently effective).
6-1	Jul. 16, 2008	45	Nasonex Nasal Suspension 50 μg 56 spray Nasonex Nasal Suspension 50 μg 112 spray (Schering-Plough K.K.)	Approval Approval	Mometasone furoate hydrate	Drugs containing a new active ingredient indicated for the treatment of allergic rhinitis.
6-1	Sep. 24, 2008	46	Rheumatrex Capsules 2 mg (Wyeth K.K.) Trexamette Capsules 2 mg (Shiono Chemical Co., Ltd.) Methotrexate Cap. 2 mg “Sawai” (Sawai Pharmaceutical Co., Ltd.) Methotrexate Capsules 2 mg “Towa” (Towa Pharmaceutical Co., Ltd.) Methotrexate Cap. 2 mg “Mylan” (Mylan Seiyaku Ltd.) Metolate Tablets 2 mg (Santen Pharmaceutical Co., Ltd.) Methotrexate Tablets 2 mg "Tanabe" (Mitsubishi Tanabe Pharma Corporation)	Change Change Change Change Change Change Change	Methotrexate	Drugs with a new indication and a new dosage for the treatment of juvenile idiopathic arthritis accompanied by articular symptoms. [Expedited review]
6-1	Oct. 16, 2008	47	Neoral solution Neoral 10 mg Capsules Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Cyclosporine	Drugs with a new indication and a new dosage for the treatment of atopic dermatitis (in patients in whom conventional therapies are not sufficiently effective).
6-1	Oct. 16, 2008	48	Pirespa Tablets 200 mg (Shionogi & Co., Ltd.)	Approval	Pirfenidone	A drug containing a new active ingredient indicated for the treatment of idiopathic pulmonary fibrosis. [Orphan drug]

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Jan. 21, 2009	49	Xolair for S.C. Injection (Novartis Pharma K.K.)	Approval	Omalizumab (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Jan. 21, 2009	50	Adoair 250 Diskus (GlaxoSmithKline K.K.)	Change	Salmeterol xinafoate/fluticasone propionate	A drug with a new additional indication and a new dosage for the alleviation of various symptoms associated with chronic obstructive pulmonary disease (chronic bronchitis and emphysema) (for use when concomitant use of inhaled corticosteroid and long-acting β2-agonist is required).
6-1	Jan. 21, 2009	51	Adoair 100 Diskus Adoair 50 Air 120 puffs (GlaxoSmithKline K.K.)	Change Approval	Salmeterol xinafoate/fluticasone propionate	A drug with a new additional pediatric dosage in a new dosage form indicated for the treatment of bronchial asthma (for use when concomitant use of inhaled corticosteroid and long-acting β2-agonist is required). [Expedited review]
6-2	Apr. 16, 2008	52	Aroglycem Capsules 25 mg (Schering-plough K.K.)	Approval	Diazoxide	A drug containing a new active ingredient indicated for the treatment of hyperinsulinemic hypoglycemia. [Priority review]
6-2	Jul. 16, 2008	53	Biopten Granules 2.5% (Asubio Pharma Co., Ltd.)	Change	Sapropterin hydrochloride	A drug with a new indication and a new dosage for reduction of serum phenylalanine levels in patients with hyperphenylalaninemia (tetrahydrobiopterin-responsive hyperphenylalaninemia) caused by tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency. [Orphan drug]
6-2	Jul. 16, 2008	54	Actonel Tab. 17.5 mg (Ajinomoto Co., Inc.) Benet Tablets 17.5 mg. (Takeda Pharmacdeutical Co., Ltd.)	Change Change	Risedronate sodium hydrate	Drugs with a new indication and a new dosage for the treatment of Paget's disease of bone. [Orphan drug]
6-2	Oct. 16, 2008	55	1) Wellnara Combination Tablets (Bayer Yakuhin, Ltd.) 2) Julina 0.5 mg (Bayer Yakuhin, Ltd.)	Approval Change	1) Estradiol/levonorgestrel 2) Estradiol	1) A new combination drug and 2) a drug with a new indication and a new dosage for the treatment of postmenopausal osteoporosis.
6-2	Oct. 16, 2008	56	Genotropin 5.3 mg Genotropin MiniQuick S.C. Inj. 0.4 mg Genotropin MiniQuick S.C. Inj. 0.6 mg Genotropin MiniQuick S.C. Inj. 0.8 mg Genotropin MiniQuick S.C. Inj. 1.0 mg Genotropin MiniQuick S.C. Inj. 1.4 mg Genotropin Inj. 12 mg (Pfizer Japan Inc.)	Change Change Change Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of dwarfism with no epiphyseal closure in patients born small-for-gestational age (SGA).
6-2	Dec. 22, 2008	57	Seibule Tablets 25 mg Seibule Tablets 50 mg Seibule Tablets 75 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change Change Change	Miglitol	Drugs with a new indication for the treatment of postprandial hyperglycemia in Type 2 diabetes mellitus (for use only in patients who have not benefitted sufficiently from taking insulin preparations in conjunction with dietary and exercise regimens) and the treatment of postprandial hyperglycemia in Type 1 diabetes mellitus (for use only in patients who have not benefited sufficiently from dietary and exercise regimens or from taking sulfonylurea or insulin preparations in conjunction with dietary and exercise regimens).
6-2	Dec. 22, 2008	58	Fastic Tablets 30 Fastic Tablets 90 (Ajinomoto Co., Inc.) Starsis Tablets 30 mg Starsis Tablets 90 mg (Astellas Pharma Inc.)	Change Change Change Change	Nateglinide	Drugs with a new additional indication for the treatment of postprandial glucose excursions in Type 2 diabetes mellitus (for use only when treatment with thiazolidines in conjunction with dietary and exercise regimens is not sufficiently effective).
6-2	Dec. 22, 2008	59	Actos Tablets 15 Actos Tablets 30 (Takeda Pharmaceutical Company Limited)	Change Change	Pioglitazone hydrochloride	Drugs with a new additional indication for the treatment of Type 2 diabetes mellitus (for use only in patients in whom treatment with biguanides in conjunction with dietary and exercise regimens is not sufficiently effective, and insulin resistance is suspected).
6-2	Jan. 21, 2009	60	Recalbon Tablets 1 mg (Ono Pharmaceutical Co., Ltd.) Bonoteo Tablets 1 mg (Astellas Pharma Inc.)	Approval Approval	Minodronic acid hydrate,	Drugs containing a new active ingredient indicated for the treatment of osteoporosis.
6-2	Feb. 23, 2009	61	Glufast Tab. 5 mg Glufast Tab. 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change Change	Mitiglinide calcium hydrate	Drugs with a new additional indication for the treatment of postprandial glucose excursions in Type 2 diabetes mellitus in patients who have not benefited sufficiently from taking thiazolidines in conjunction with dietary and exercise regimens.
6-2	Mar. 24, 2009	62	Actos Tablets 15 Actos Tablets 30 (Takeda Pharmaceutical Company Limited)	Change Change	Pioglitazone hydrochloride	Drugs with a new indication and a new dosage for the treatment of Type 2 diabetes mellitus in patients who have not benefitted sufficiently from taking insulin preparations in conjunction with dietary and exercise regimens in whom insulin resistance is suspected.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Apr. 16, 2008	63	Sutent Capsule 12.5 mg (Pfizer Japan Inc.)	Approval	Sunitinib malate	A drug containing a new active ingredient indicated for the treatment of imatinib-resistant gastrointestinal stromal tumors, and unresectable or metastatic renal cell carcinomas. [Priority review]
Oncology drugs	May 20, 2008	64	Fludara for IV Inj.50 mg (Bayer Yakuhin, Ltd.)	Change	Fludarabine phosphate	A drug with a new indication and a new dosage for use as a conditioning prior to allogeneic hematopoietic stem cell transplantation in the following diseases: acute myeloid leukemia, myelodysplastic syndrome, chronic myeloid leukemia, chronic lymphocytic leukemia, malignant lymphoma, and multiple myeloma.
Oncology drugs	Jul. 16, 2008	65	Erbitux Injection 100 mg (Merck KGaA)	Approval	Cetuximab (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of EGFR-expressing, unresectable and advanced/recurrent colorectal carcinomas. [Priority review]
Oncology drugs	Aug. 29, 2008	66	Taxotere Injection (Sanofi-Aventis K.K.)	Change	Docetaxel hydrate	A drug with a new indication and a new dosage for the treatment of prostate cancer. [Priority review]
Oncology drugs	Oct. 16, 2008	67	Thaled Capsule 100 (Fujimoto Pharmaceutical Corporation)	Approval	Thalidomide	A drug containing a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Nov. 25, 2008	68	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change	Gemcitabine hydrochloride	Drugs with a new additional indication for the treatment of urothelial carcinoma.
Oncology drugs	Jan. 21, 2009	69	Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Approval	Nilotinib hydrochloride hydrate	A drug containing a new active ingredient indicated for the treatment of imatinib-resistant, chronic phase and accelerated phase chronic myelogenous leukemia. [Orphan drug]
Oncology drugs	Jan. 21, 2009	70	Sprycel Tablets 20 mg Sprycel Tablets 50 mg (Bristol-Myers K.K.)	Approval Approval	Dasatinib hydrate	Drugs containing a new active ingredient indicated for the treatment of 1) imatinib-resistant chronic myelogenous leukemia and 2) recurrent or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Mar. 24, 2009	71	Leustatin Injection 8 mg (Janssen Pharmaceutical K.K.)	Change	Cladribine	A drug with a new additional dosage indicated for the treatment of recurrent, relapsing, or refractory indolent B-cell non-Hodgkin's lymphoma including follicular lymphoma, and mantle cell lymphoma.
AIDS drugs	Jun. 24, 2008	72	Isentress Tablets 400 mg (Banyu Pharmaceutical Co., Ltd.)	Approval	Raltegravir potassium	A drug containing a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Dec. 25, 2008	73	Intelence Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval	Etravirine	A drug containing a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Dec. 25, 2008	74	Celsentri Tablets 150 mg (Pfizer Japan Inc.)	Approval	Maraviroc	A drug containing a new active ingredient indicated for the treatment of CCR5-tropic HIV-1 infection. [Orphan drug]
In vivo Diagnostics	Oct. 16, 2008	75	Thyrogen IM Injection 0.9 mg (Sato Pharmaceutical Co., Ltd.)	Approval	Thyrotropin human alfa (genetical recombination)	A drug containing a new active ingredient indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine scintigraphy in patients with differentiated thyroid cancer who have undergone near total or total thyroidectomy. [Orphan drug]
In vivo Diagnostics	May 20, 2008	76	Iomeron 350 Iomeron 350 Syringe (Bracco-Eisai Co., Ltd.)	Change Change	Iomeprol	A drug with a new dosage (Iomeron 350) and a drug with a new dosage in a new dosage form (Iomeron 350 Syringe) indicated for use in angiocardiography, thoracic angiography, abdominal angiography, angiography of the extremities, intravenous digital angiography, arterial digital angiography, computed tomography, and intravenous urography.
In vivo Diagnostics	Feb. 23, 2009	77	Patch test tapes “Nickel sulfate” 160 μg “Potassium dichromate” 19 μg “Cobalt chloride” 16 μg “Mercaptobenzothiazole” 61 μg “Formaldehyde” 150 μg “Thimerosal” 6.5 μg (Sato Pharmaceutical Co., Ltd.)	 Approval Approval Approval Approval Approval Approval	 Nickel sulfate Potassium dichromate Cobalt chloride Mercaptobenzothiazole N-hydroxymethyl succinimide Thimerosal	Drugs indicated for use in patch tests to identify allergens in patients with allergic dermatitis.
Biologicals	Feb. 23, 2009	78	Jebik V (Research Foundation for Microbial Diseases of Osaka University)	Approval	Inactivated Japanese encephalitis virus (Beijing strain)	A drug containing a new active ingredient indicated for prophylaxis against Japanese encephalitis.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Review Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Blood products	Jul. 16, 2008	79	Thymoglobuline for Intravenous Infusion 25 mg (Sanofi-Aventis K.K.)	Approval	Anti-human thymocyte immunoglobulin, Rabbit	A drug containing a new active ingredient indicated for the treatment of moderate to very severe aplastic anemia, for use as pretreatment prior to hematopoietic stem cell transplantation, and for the treatment of acute graft-versus-host disease after hematopoietic stem cell transplantation. [Orphan drug]

Table 1. FY2007 List of Approved Products: New Drugs

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
1	Apr. 18, 2007	1	Visiclear Tablets (Zeria Pharmaceutical Co., Ltd.)	Approval	Monobasic sodium phosphate monohydrate/dibasic sodium phosphate anhydrous	A new combination drug indicated for bowel cleansing as a preparation for colonoscopy.
1	Apr. 18, 2007	2	Nesp Injection Syringe 10 µg Nesp Injection Syringe 15 µg Nesp Injection Syringe 20 µg Nesp Injection Syringe 30 µg Nesp Injection Syringe 40 µg Nesp Injection Syringe 60 µg Nesp Injection Syringe 120 µg (Kirin Brewery Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of renal anemia in dialysis patients.
1	May 24, 2007	3	Omepral Tablets 10 (AstraZeneca K.K.) Omeprazon Tablets 10 mg (Mitsubishi Pharma Corporation)	Change Change	Omeprazole	Drugs with a new indication and dosage for the treatment of non-erosive reflux disease.
1	Sep. 28, 2007	4	Cyanokit Injection Set (Merck Ltd., Japan)	Approval	Hydroxocobalamin	Drugs with a new indication and dosage for the treatment of cyanogen and cyanide poisoning.
1	Oct. 19, 2007	5	Regpara Tablets 25 mg Regpara Tablets 75 mg (Kirin Pharma Co., Ltd.)	Approval Approval	Cinacalcet hydrochloride	A drug containing a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis.
1	Nov. 13, 2007	6	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetically engineered)	A drug with a new indication and dosage for use as maintenance therapy in Crohn's disease. [Orphan drug]
1	Feb. 29, 2008	7	Pentasa Tablets 250 (Nisshin Kyorin Pharmaceutical Co., Ltd.)	Change	Mesalazine	A drug with a new dosage for use in pediatric patients for the treatment of ulcerative colitis (excluding severe patients) and Crohn's disease.
1	Feb. 29, 2008	8	Hebsbulin-IH for Intravenous (Benesis Corporation)	Change	Polyethylene glycol-treated human anti-HBs immunoglobulin	A drug with a new indication and dosage for the prevention of hepatitis B recurrence in HBs antigen-positive recipients after liver transplantation and of hepatitis B occurrence in recipients after liver transplantation from HBc antigen-positive donors.
2	Apr. 18, 2007	9	Arixtra Injection for Subcutaneous 1.5 mg Arixtra Injection for Subcutaneous 2.5 mg (GlaxoSmithKline K.K.)	Approval Approval	Fondaparinux sodium	Drugs containing a new active ingredient indicated for the prevention of venous thromboembolism in high-risk patients who have undergone lower-extremity orthopedic surgery. [Priority review]
2	Apr. 18, 2007	10	Zetia Tablets 10 mg (Schering-plough K.K.)	Approval	Ezetimibe	A drug containing a new active ingredient indicated for the inhibition of cholesterol absorption.
2	Jul. 31, 2007	11	Selara Tablets 25 mg Selara Tablets 50 mg Selara Tablets 100 mg (Pfizer Japan Inc.)	Approval Approval Approval	Eplerenone	Drugs containing a new active ingredient indicated for the treatment of hypertension.
2	Jun. 21, 2007	12	Tambocor Tablets 50 mg Tambocor Tablets 100 mg (Eisai Co., Ltd.)	Change Change	Flecainide acetate	Drugs with a new indication for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation and flutter).
2	Jun. 21, 2007	13	Ephedrine Hydrochloride Injection Fuso (Fuso Pharmaceutical Industries, Ltd.) Ephedrine Nagai Injection 40 mg (Dainippon Sumitomo Pharma Co., Ltd.) Ephedrine Hydrochloride Injection Sanken (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change Change Change	Ephedrine hydrochloride	Drugs with a new indication and route of administration, or the intravenous route for the treatment of hypotension occurring during anesthesia,G20 and without intramuscular injection administered for their approved indications.
2	Aug. 23, 2007	14	Aricept Tablets 3 mg Aricept Tablets 5 mg Aricept Tablets 10 mg Aricept D Tablets 3 mg Aricept D Tablets 5 mg Aricept D Tablets 10 mg Aricept Fine Granules 0.5% (Eisai Co., Ltd.)	Change Change Approval Change Change Approval Change	Donepezil hydrochloride	Drugs with a new indication and dosage for patients with severe dementia of the Alzheimer's type.
2	Oct. 19, 2007	15	Careload LA Tablets 60 µg (Toray Industries, Inc.) Berasus LA Tablets 60 µg (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	Beraprost sodium	Drugs with a new indication and dosage and in a new dosage form for the treatment of pulmonary arterial hypertension. [Priority review]

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
2	Oct. 19, 2007	16	Sigmart Injection 2 mg Sigmart Injection 12 mg Sigmart Injection 48 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Nicorandil	Drugs with a new indication and dosage for the treatment of acute cardiac failure including the acute exacerbation period of chronic cardiac failure.
2	Oct. 19, 2007	17	Plavix Tablets 25 mg Plavix Tablets 75 mg (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with a new indication and dosage for the treatment of acute coronary syndrome (unstable angina and non-ST-elevation myocardial infarction) in patients in whom percutaneous coronary intervention (PCI) is considered. [Priority review]
2	Jan. 25, 2008	18	Clexane Subcutaneous Injection Kit 2000 IU (Sanofi-Aventis K.K.)	Approval	Enoxaparin sodium	A drug containing a new active ingredient indicated for the prevention of venous thromboembolism in patients who have undergone total hip replacement, total knee replacement and hip fracture surgery. [Priority review]
2	Jan. 25, 2008	19	Amerge Tablets 2.5 mg (GlaxoSmithKline K.K.)	Approval	Naratriptan hydrochloride	A drug containing a new active ingredient indicated for the treatment of migraine.
2	Jan. 25, 2008	20	Recomodulin Injection 12800 (Asahi Kasei Pharma Corporation)	Approval	Thrombomodulin alfa (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of disseminated intravascular coagulation (DIC).
2	Jan. 25, 2008	21	Revatio Tablets 20 mg (Pfizer Japan Inc.)	Approval	Sildenafil citrate	A drug with a new indication and dosage for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Feb. 29, 2008	22	Vasolan Tablets 40 mg (Eizai Co., Ltd.)	Change	Verapamil hydrochloride	A drug with a new indication for the treatment of tachyarrhythmia (atrial fibrillation and flutter, and paroxysmal supraventricular tachycardia).
2	Mar. 19, 2008	23	Brevibloc Injection 100 mg (Maruishi Pharmaceutical Co., Ltd.)	Change	Esmolol hydrochloride	A drug with a new dosage indicated for the emergency treatment of supraventricular tachyarrhythmia occurring during surgery.
3	Apr. 18, 2007	24	Mikelan LA Ophthalmic Solution 1% Mikelan LA Ophthalmic Solution 2% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Carteolol hydrochloride	Drugs in a new dosage form indicated for the treatment of glaucoma and ocular hypertension.
3	Jul. 31, 2007	25	Topina Topina Tablets 50 mg TopinaTablets 100 mg (Kyowa Hakko Kogyo Co., Ltd.)	Approval Approval Approval	Topiramate	Drugs containing a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy not fully responding to other antiepileptic therapies.
3	Jul. 31, 2007	26	Eslax Intravenous 1% (Organon Japan)	Approval	Rocuronium bromide	A drug containing a new active ingredient indicated for inducing muscular relaxation during anesthesia and tracheal intubation.
3	Jul. 31, 2007	27	Travatanz Ophthalmic Solution 0.004% (Alcon Japan Ltd.)	Approval	Travoprost	A drug containing a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3	Aug. 23, 2007	28	Fentanyl Injection 0.1 mg Sankyo Fentanyl Injection 0.25 mg Sankyo (Daiichi Sankyo Propharma Co., Ltd.)	Change	Fentanyl citrate	Drugs with a new dosage for use in pediatric patients for inducing general anesthesia and for inducing analgesia during general anesthesia. Expedited review.
3	Oct. 19, 2007	29	Salagen Tablets 5 mg (Kissei Pharmaceutical Co., Ltd.)	Change	Pilocarpine hydrochloride	A drug with a new indication for the treatment of oral dryness in patients with Sjögren's syndrome.
3	Oct. 26, 2007	30	Concerta Tablets 18 mg Concerta Tablets 27 mg (Janssen Pharmaceutical K.K.)	Approval Approval	Methylphenidate hydrochloride	Drugs with a new indication for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in children. Expedited review.
3	Jan. 25, 2008	31	Lonasen Tablets 2 mg Lonasen Tablets 4 mg Lonasen Powder 2% (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval Approval	Blonanserin	Drugs containing a new active ingredient indicated for the treatment of schizophrenia.
3	Jan. 25, 2008	32	Champix Tablets 0.5 mg Champix Tablets 1 mg (Pfizer Japan Inc.)	Approval Approval	Varenicline tartrate	Drugs containing a new active ingredient indicated as a smoking-cessation aid for nicotine-dependent smokers. Expedited review.
3	Mar. 19, 2008	33	Durotep MT Patch 2.1 mg Durotep MT Patch 4.2 mg Durotep MT Patch 8.4 mg Durotep MT Patch 12.6 mg Durotep MT Patch 16.8 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval	Fentanyl	Drugs with a new dosage form indicated for pain relief in cancer patients with moderate to severe pain.

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
4	Apr. 18, 2007	34	Valtrex Granules 50% (GlaxoSmithKline K.K.)	Change	Valaciclovir hydrochloride	A drug with a new indication and dosage for the treatment of varicella in children.
4	Jul. 31, 2007	35	Geninax Tablets 200 mg (Toyama Chemical Co., Ltd.)	Approval	Garenoxacin mesilate	A drug containing a new active ingredient indicated for the treatment of laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, infections secondary to chronic respiratory disease, otitis media, and sinusitis.
4	Jul. 31, 2007	36	Beselna Cream 5% (Mochida Pharmaceutical Co., Ltd.)	Approval	Imiquimod	A drug containing a new active ingredient indicated for the treatment of condyloma acuminatum (limited to the external genitals or perianal region).
4	Aug. 23, 2007	37	Takepron Capsules 15 Takepron Capsules 30 Takepron OD Tablets 15 Takepron OD Tablets 30 (Takeda Pharmaceutical Co., Ltd.) Omepral Tablets 10 mg Omepral Tablets 20 mg (AstraZeneca K.K.) Omeprazon Tablets 10 mg Omeprazon Tablets 20 mg (Mitsubishi Pharma Corporation) Pariet Tablets 10 mg (Eisai Co., Ltd.) Pasetocin Capsules Pasetocin Tablets 250 (Kyowa Hakko Kogyo Co., Ltd.) Sawacillin Capsules Sawacillin Tablets 250 (Takeda Pharmaceutical Co., Ltd.) Amolin Capsules 125 Amolin Capsules 250 10% Amolin Fine Granules (Astellas Pharma Inc.) Amopenixin Capsules 250 (Nipro Pharma Corporation) Flagyl (Shionogi & Co., Ltd.) Asuzol tablets (Fuji Pharma Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	Lansoprazole Omeprazole Rabeprazole sodium Amoxicillin Metronidazole	Drugs with a new indication and dosage for use as a secondary eradication therapy for infection with *Helicobacter pylori* (3-drug combination therapy consisting of one-week dosing of a proton pump inhibitor (PPI), amoxicillin (AMPC), and metronidazole to patients in whom primary eradication therapy with PPI, AMPC, and clarithromycin was unsuccessful).
4	Sep. 28, 2007	38	Clavamox Dry Syrup for Pediatric Use (GlaxoSmithKline K.K)	Change	Clavulanate potassium/Amoxicillin hydrate	A drug with a new indication for the treatment of superficial skin infections, deep skin infections, lymphangitis and lymphadenitis, chronic pyoderma, laryngopharyngitis, tonsillitis, acute bronchitis, cystitis, and pyelonephritis.
4	Sep. 28, 2007	39	Valtrex Tablets 500 Valtrex Granules 50% (GlaxoSmithKline K.K)	Change Change	Valaciclovir hydrochloride	Valtrex Tablets 500: A drug with a new indication and dosage for the treatment of varicella in adults and children.
4	Jan. 25, 2008	40	Gracevit Tablets 50 mg Gracevit Fine Granules 10% (Daiichi Sankyo Co., Ltd.)	Approval Approval	Sitafloxacin hydrate	A drug containing a new active ingredient indicated for the treatment of laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, infections secondary to chronic respiratory disease, cystitis, pyelonephritis, urethritis, cervicitis, otitis media, sinusitis, periodontal inflammation, pericoronitis and jaw inflammation.
4	Nov. 13, 2007	41	Rocephin Intravenous 0.5 g Rocephin Intravenous 1 g Rocephin Intravenous Drip 1 g Bag (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Ceftriaxone sodium	Drugs with a new dosage for use in children, premature infants, and neonates.
4	Feb. 29, 2008	42	Habekacin Injection 25 mg Habekacin Injection 75 mg Habekacin Injection 100 mg Habekacin Injection 200 mg (Meiji Seika Kaisha, Ltd.)	Change Change Change Approval	Arbekacin sulfate	Drugs with a new dosage and in a new dosage form indicated for the treatment of septicemia and pneumonia caused by arbekacin-sensitive methicillin-resistant *staphylococcus aureus* (MRSA).
5	Apr. 18, 2007	43	Imidafenacin Uritos Tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.) Staybla Tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	Imidafenacin	Drugs containing a new active ingredient indicated for the treatment of micturition urgency, pollakiuria, and urge incontinence associated with overactive bladder.

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
5	Jul. 31, 2007	44	Divigel 1 mg (Pola Pharma Inc.)	Approval	Estradiol	A drug in a new dosage form, or gel, indicated for the treatment of vasomotor symptoms (hot flushes and sweating) associated with menopausal disorders and ovarian deficiency symptoms.
5	Jul. 31, 2007	45	Cialis Tablets 5 mg Cialis Tablets 10 mg Cialis Tablets 20 mg (Eli Lilly Japan K.K.)	Approval Approval Approval	Tadalafil	Drugs containing a new active ingredient indicated for the treatment of erectile dysfunction (patients unable to obtain or maintain erections sufficient for satisfactory sexual activity).
5	May 24, 2007	46	Levitra Tablets 5 mg Levitra Tablets 10 mg Levitra Tablets 20 mg (Bayer Yakuhin Ltd.)	Change Change Approval	Vardenafil hydrochloride hydrate	Drugs with a new dosage indicated for the treatment of erectile dysfunction (patients unable to obtain or maintain erections sufficient for satisfactory sexual activity).
5	Oct. 19, 2007	47	Dinagest Tablets 1 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Dienogest	A drug containing a new active ingredient indicated for the treatment of endometriosis.
5	Oct. 19, 2007	48	Artcereb Irrigation and Perfusion Solution for Cerebrospinal Surgery (Ostuka Pharmaceutical Factory, Inc.)	Approval	N/A because of a new combination drug	A new combination drug indicated for irrigation during craniotomy/trepanation and spinal surgery, and perfusion during endoscopic neurosurgery.
5	Mar. 19, 2008	49	Bicanate Infusion (Ostuka Pharmaceutical Factory, Inc.)	Approval	N/A because of a combination drug	A combination drug similar to other products indicated for the supply/correction of extracellular fluid in the cases where circulating blood and interstitial fluid decrease, and for the correction of metabolic acidosis.
6-1	Apr. 18, 2007	50	Alvesco 50 µg Inhaler 112 puffs Alvesco 100 µg Inhaler 112 puffs Alvesco 200 µg Inhaler 112 puffs Alvesco 200 µg Inhaler 56 puffs (Teijin Pharma Ltd.)	Approval Approval Approval Approval	Ciclesonide	Drugs containing a new active ingredient indicated for the treatment of asthma.
6-1	Apr. 18, 2007	51	Adoair 100 Diskus Adoair 250 Diskus Adoair 500 Diskus (GlaxoSmithKline K.K)	Approval Approval Approval	Salmeterol xinafoate/Fluticasone propionate	A new combination drug indicated for the treatment of asthma (in the case where a combination of inhaled corticosteroids and inhaled long-acting β_2 agonists is necessary).
6-1	Jul. 31, 2007	52	Singulair Fine Granules 4 mg (Banyu Pharmaceutical Co., Ltd.) Kipres Fine Granules 4 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval Approval	Montelukast sodium	Drugs with a new dosage and in a new dosage form, or fine granules, indicated for the treatment of asthma in children aged 1 or more and less than 6 years.
6-1	Sep. 28, 2007	53	Calonal Fine Granules 20%	Change	Acetaminophen	Drugs with a new indication and dosage for use as an antipyretic/analgesic in pediatric patients. Expedited review.
			Calonal Fine Granules 50%	Change		
			Calonal Tablets 200	Change		
			Calonal Tablets 300	Change		
			Calonal Syrup 2%	Change		
			Calonal Suppositories 100	Change		
			Calonal Suppositories 200	Change		
			(Showa Yakuhin Kako Co., Ltd.)			
			Pyrinazin Powder	Change		
			(Astellas Pharma Inc.)			
			Anhiba Suppositories 50 mg for Pediatric Use	Change		
			Anhiba Suppositories 100 mg for Pediatric Use	Change		
			Anhiba Suppositories 200 mg for Pediatric Use	Change		
			(Abbott Japan Co., Ltd.)			
			Pyretinol	Change		
			(Iwaki Seiyaku Co.,Ltd.)			
			Acetaminophen Tablets 200 mg "Isei"	Change		
			(Isei Co., Inc.)			
			Cocarl Dry Syrup 20% for Pediatric	Change		
			Cocarl Dry Syrup 40%	Change		
			Cocarl Tablets 200 mg	Change		
			(Sanwa Kagaku Kenkyusho Co., Ltd.)			
			Paraceta Suppositories 100	Change		
			Paraceta Suppositories 200	Change		
			(Sioe Pharmaceutical Co., Ltd.)			
			Acetaminophen Tablets 200 mg (TYK)	Change		
			Acetaminophen Suppositories 100	Change		
			Acetaminophen Suppositories 200	Change		
			Acetaminophen Fine Granules 20% (TYK)	Change		
			(Taisho Pharmaceutical Co., Ltd.)			
			Calsil Fine Granules 20%	Change		
			Calsil Tablets 200	Change		
			Calsil Syrup 2% for Pediatric Use	Change		
			Calsil Suppositories 200 for Pediatric Use	Change		

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
			Calsil Suppositories 100 for Pediatric Use	Change		
			(Taiyo Yakuhin Co., Ltd.)			
			Atmiphen Tablets 200	Change		
			Atmiphen Dry Syrup 20%	Change		
			(Takata Seiyaku Co., Ltd.)			
			Acetaminophen Tablets 200 "Tatsumi"	Change		
			Acetaminophen Fine Granules 20% "Tatsumi"	Change		
			(Tatsumi Kagaku Co., Ltd.)			
			Anyrume Tablets 200 mg	Change		
			Anyrume Tablets 300 mg	Change		
			Anyrume S	Change		
			Anyrume S Suppositories 200	Change		
			Anyrume Fine Granules	Change		
			(Choseido Pharmaceutical Co., Ltd.)			
			Atenemen 20% Fine Granules	Change		
			Atenemen Tablets 200 mg	Change		
			Atenemen Suppositories 100 mg	Change		
			Atenemen Suppositories 200 mg	Change		
			(Tsuruhara Pharmaceutical Co., Ltd.)			
			Acetaminophen "Hachi"	Change		
			(Oriental Pharmaceutical and Synthetic Chemical Co., Ltd.)			
			Sarutu Fine Granules 20%	Change		
			Sarutu Tablets 200 mg	Change		
			Sarutu Syrup for Pediatric 2%	Change		
			Sarutu Dry Syrup for Pediatric 20%	Change		
			(Towa Pharmaceutical Co., Ltd.)			
			Aphlogis Suppositories 100	Change		
			Aphlogis Suppositories 200	Change		
			(Nissin Pharmaceutical Co., Ltd.)			
			Acetaminophen Tablets 200 mg "NP"	Change		
			Acetaminophen Fine Granules 20%	Change		
			(Nipro Pharma Corporation)			
			Alpiny Suppositories 50	Change		
			Alpiny Suppositories 100	Change		
			Alpiny Suppositories 200	Change		
			(Hisamitsu Pharmaceutical Co., Inc.)			
			Aspain	Change		
			(Maruishi Pharmaceutical Co., Ltd.)			
			Napa	Change		
			Napa Dry Syrup 20%	Change		
			(Merck Seiyaku Ltd.)			
			Acetaminophen "Yoshida"	Change		
			(Yoshida Pharmaceutical Co., Ltd.)			
6-1	Oct. 19, 2007	54	Claritin Tablets 10 mg Claritin RediTabs 10 mg Claritin Dry Syrup 1% (Schering-plough K.K.)	Change Change Approval	Loratadine	Drugs with a new dosage and in a new dosage form, or dry syrup, for use in pediatric patients.
6-1	Jan. 25, 2008	55	Singulair Tablets 5 mg Singulair Tablets 10 (Banyu Pharmaceutical Co., Ltd.) Kipres Tablets 5 mg Kipres Tablets 10 (Kyorin Pharmaceutical Co., Ltd.)	Approval Change Approval Change	Montelukast sodium	Drugs with a new indication and dosage and in a new dosge form for the treatment of allergic rhinitis.
6-1	Jan. 25, 2008	56	Talymus Ophthalmic Suspension 0.1% (Senju Pharmaceutical Co., Ltd.)	Approval	Tacrolimus hydrate	A drug with a new route of administration indicated for the treatment of vernal conjunctivitis (in the case where anti-allergic drugs are not sufficiently effective). [Orphan drug]
6-2	Apr. 18, 2007	57	Myozyme 50 mg for Intravenous Infusion (Genzyme Japan K.K.)	Approval	Alglucosidase alfa (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of type 2 glycogenosis. [Orphan drug]
6-2	Apr. 18, 2007	58	Actonel Tablets 17.5 mg (Takeda Pharmacdeutical Co., Ltd.) Benet Tablets 17.5 mg (Ajinomoto Co., Inc.)	Change Change	Risedronate sodium hydrate	Drugs with a new dosage and in a new dosage form indicated for the treatment of osteoporosis (once-weekly dosing).
6-2	May 24, 2007	59	Glufast Tablets 5 mg Glufast Tablets 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change	Mitiglinide calcium hydrate	Drugs with a new indication for use in combination with α-glucosidase inhibitors to reduce glycemic excursions in patients with type 2 diabetes mellitus in whom diet and exercise therapy is not sufficiently effective.

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
6-2	Aug. 23, 2007	60	NovoRapid 300 NovoRapid 300 FlexPen NovoRapid 100 U/mL Vial NovoRapid 30 Mix NovoRapid 30 Mix FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	Insulin aspart (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated. A change has been made to the manufacturing process of the drug substance. Pharmaceutical formulations, manufacturing processes, indications, and dosage are the same as those in the approved formulations.
6-2	Oct. 04, 2007	61	Elaprase 6 mg for Intravenous Infusion (Genzyme Japan K.K.)	Approval	Idursulfase (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of mucopolysaccharidosis II. [Orphan drug]
6-2	Oct. 19, 2007	62	Levemir 300 Levemir 300 FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin detemir (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Nov. 13, 2007	63	Fastic Tablets 30 Fastic Tablets 90 (Ajinomoto Co., Inc.) Starsis Tablets 30 mg Starsis Tablets 90 mg (Astellas Pharma Inc.)	Change Change Change Change	Nateglinide	Drugs with a new indication for reducing glycemic excursions in patients with type 2 diabetes mellitus (in the case where therapy with biguanides in addition to diet and exercise therapy is not sufficiently effective).
6-2	Jan. 25, 2008	64	Nobelzin Capsules 25 mg Nobelzin Capsules 50 mg (Nobelpharma Co., Ltd.)	Approval Approval	Zinc acetate dihydrate	Drugs containing a new active ingredient indicated for the treatment of Wilson's disease (hepatolenticular degeneration). [Orphan drug]
6-2	Mar. 28, 2008	65	Naglazyme 5 mg for Intravenous Infusion (AnGes MG, Inc.)	Approval	Galsulfase (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of mucopolysaccharidosis VI. [Orphan drug]
In vivo Diagnostics	May 24, 2007	66	Magnevist Magnevist Syringe (Nihon Schering K.K.)	Change	Meglumine gadopentetate	A drug with a new dosage for use in magnetic resonance computerized tomography imaging of the brain/spinal cord and body/extremities.
In vivo Diagnostics	Oct. 19, 2007	67	EOB・Primovist Injection Syringe (Bayer Yakuhin Ltd.)	Approval	Gadoxetate sodium	A drug containing a new active ingredient indicated for use in magnetic resonance computerized tomography imaging of liver tumors.
Oncology drugs	Apr. 18, 2007	68	Avastin 100 mg/4 mL for Intravenous Infusion Avastin 400 mg/16 mL for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Bevacizumab (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of unresectable advanced/relapsed colorectal cancer. [Priority review]
Oncology drugs	Jul. 31, 2007	69	Metastron Injectable (GE Healthcare Ltd.)	Approval	Strontium (^{89}Sr) chloride	A drug containing a new active ingredient indicated for pain relief in bone scintigraphy-positive metastatic lesions in patients with solid cancers.
Oncology drugs	Aug. 23, 2007	70	TS-1 Capsule 20 TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Change Change	A combination drug of Tegafur, Gimeracil, and Oteracil potassium	Drugs with a new indication for the treatment of biliary cancer in addition to gastric cancer, colorectal cancer, head and neck cancer, non-small cell lung cancer, inoperable or relapsed breast cancer, and pancreatic cancer.
Oncology drugs	Oct. 19, 2007	71	Tarceva Tablets 25 mg Tarceva Tablets 100 mg Tarceva Tablets 150 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval Approval	Erlotinib	Drugs containing a new active ingredient indicated for the treatment of unresectable, relapsed/advanced non-small cell lung cancer exacerbated after cancer chemotherapy. [Priority review]
Oncology drugs	Oct. 19, 2007	72	Arranon G Injection 250 mg (GlaxoSmithKline K.K.)	Approval	Nelarabine	A drug containing a new active ingredient indicated for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma. [Orphan drug]
Oncology drugs	Dec. 12, 2007	73	Xeloda Tablets 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new indication and dosage for use as a postoperative adjuvant chemotherapy of colon cancer. A drug with a new dosage for the treatment of inoperable or relapsed breast cancer.
Oncology drugs	Dec. 12, 2007	74	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.)	Change Change	Paclitaxel	Drugs with a new dosage indicated for the treatment of breast cancer, with once-weekly dosing continuously for 6 weeks followed by a 2-week withdrawal period.

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
Oncology drugs	Jan. 25, 2008	75	Nexavar Tablets 200 mg (Bayer Yakuhin Ltd.)	Approval	Sorafenib tosilate	A drug containing a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Jan. 25, 2008	76	1. Zevalin Yttrium (^{90}Y) Injection Set 2. Zevalin Indium (^{111}In) Injection Set (Bayer Yakuhin Ltd.)	Approval Approval	1: Ibritumomab tiuxetan (genetical recombination) Yttrium chloride (90Y) 2: Ibritumomab tiuxetan (genetical recombination) Indium chloride (111In)	1: A drug containing a new active ingredient indicated for the treatment of relapsed or refractory, CD20-positive lyphomas of the following: low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. 2: A drug containing a new active ingredient indicated for determining the site of ibritumomab tiuxetan (genetical recombination) accumulation. [Orphan drug]
			Rituxan Injection 10 mg/mL (Zenyaku Kogyo K.K.)	Change	Rituximab (genetical recombination)	Pretreatment for indium (111In) ibritumomab tiuxetan (genetical recombination) injection and yttrium (90Y) ibritumomab tiuxetan (genetical recombination) injection. Expedited review.
Oncology drugs	Feb. 29, 2008	77	Herceptin Injection 60 Herceptin Injection 150 (Chugai Pharmaceutical Co., Ltd.)	Change	Trastuzumab (genetical recombination)	Drugs with a new indication and dosage for use as a postoperative adjuvant chemotherapy in patients with HER2-overexpressing breast cancer. [Priority review]
Blood products	Oct. 19, 2007	78	rHSA Bulk Solution Medway Injection 25% Medway Injection 5% (Mitsubishi Tanabe Pharma Corporation) rHSA Bulk Solution—Bipha Stem Injection 25% Stem Injection 5% (Bipha Corporation)	Approval Approval Approval Approval Approval Approval	Human serum albumin (genetical recombination)	Drugs containing a new active ingredient indicated for the treatment of hypoalbuminemia caused by loss of albumin (due to thermal burn, nephrotic syndrome, etc.) and reduced albumin synthesis (cirrhosis, etc.), and hemorrhagic shock.
Biologicals	Oct. 19, 2007	79	Adsorbed Pandemic Influenza Vaccine (H5N1) "Hokken" (The Kitasato Institute)	Approval	Inactivated influenza virus, H5N1 (whole virion)	A drug containing a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Biologicals	Oct. 19, 2007	80	Adsorbed Pandemic Influenza Vaccine (H5N1) "Biken" (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Inactivated influenza virus, H5N1 (whole virion)	A drug containing a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
AIDS drugs	Nov. 22, 2007	81	Prezista Tablets 300 mg (Janssen Pharmaceutical K.K.)	Approval	Darunavir ethanolate	A drug containing a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]

FY2006 List of Approved Products: New Drugs

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
1	20-Apr-06	1 Feron (Toray Industries, inc.)	Partial	Interferon-beta	Drug with a new indication and dosage for treatment of viremia in compensated cirrhosis type C (excluding the patients with a high viral load of HCV serogroup 1). [Priority Review]
1	15-Jun-06	2 Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company, Ltd)	Partial Partial	Lansoprazole	Drugs with a new indication and dosage for treatment of non-erosive reflux disease.
1	15-Jun-06	3 Imuran Tablets (GlaxoSmithKline K.K.)	Partial	Azathioprine	Drug with a new indication and dosage indicated for induction and maintenance of remission in steroid-dependent Crohn's disease and maintenance of remission in steroid-dependent ulcerative colitis. [Notification of off-label use]
1	20-Oct-06	4 Aldurazyme for I.V. Infusion 2.9mg (Genzyme Japan KK)	Approval	Laronidase (genetical recombination)	Drug containing a new active ingredient indicated for treatment of mucopolysaccharidosis I. [Orphan Drug]
1	20-Oct-06	5 Takepron Intravenous 30mg (Takeda Pharmaceutical Company, Ltd)	Approval	Lansoprazole	Drug with a new route of administration indicated for patients with gastric ulcer, duodenal ulcer, acute stress ulcer and acute gastric mucosal lesion with bleeding who are unable to take the oral formulations.
1	20-Dec-06	6 Bonalfa High Ointment 20μg/g (Teijin Pharma Limited)	Partial	Tacalcitol	Drug with a revised indication that eliminates a limitation to use in intractable cases, and now indicated for treatment of psoriasis vulgaris regardless of the severity.
1	26-Jan-07	7 Copegus Tablets 200mg (Chugai Pharmaceutical Co., Ltd.) Pegasys Subcutaneous Injection 90μg Pegasys Subcutaneous Injection 180μg (Chugai Pharmaceutical Co., Ltd.)	Approval Partial Partial	Ribavirin Peginterferon alfa-2a (genetical recombination)	New drug application for Copegus to treat the following conditions, and additional indications and dosages for Pegasys. a) Ribavirin In combination with peginterferon alfa-2a (genetical recombination), Ribavirin is indicated for the treatment of either of the following viremia in chronic hepatitis C. 1. Patients with a high viral RNA load of HCV serogroup 1 (genotype I (1a) or II (1b)). 2. Patients who are not responding to or relapsing after interferon monotherapy. b) PEG-IFNα-2a In combination with Ribavirin, peginterferon alfa-2a is indicated for the treatment of either of the following viremia in chronic hepatitis C. 1. Patients with a high viral RNA load of HCV serogroup 1 (genotype I (1a) or II (1b)). 2. Patients who are not responding to or relapsing after interferon monotherapy. (the above is the added part of labeling)
1	26-Jan-07	8 Certican Tablets 0.25mg Certican Tablets 0.5mg Certican Tablets 0.75mg (Novartis Pharma K.K.)	Approval Approval Approval	Everolimus	Drugs containing a new active ingredient indicated for the prophylaxis of organ rejection in cardiac transplant. [Priority Review]
1	2-Mar-07	9 Urso Tablets 50mg Urso Tablets 100mg (Mitsubishi Pharma Corporation)	Partial Partial	Ursodeoxycholic acid	Drugs with a new indication and dosage indicated for the improvement of liver enzyme elevations in chronic hepatitis C.
2	20-Apr-06	10 Nu-Lotan Tablets 25 Nu-Lotan Tablets 50 (Banyu Pharmaceutical Co., LTD.)	Partial Partial	Losartan potassium	Addition of a new indication for diabetic nephropathy in patients with type2 diabetes, hypertension, and proteinuria.
2	26-Jul-06	11 Mozavaptan Hydrochloride Physulime Tablets 30mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	Mozavaptan hydrochloride	Drugs with a new active ingredient indicated for improvement of hyponatremia in syndrome of inappropriate secretion of antidiuretic hormone due to paraneoplastic syndrome of inappropriate antidiuretic hormone secretion (used only when conventional therapies are not sufficiently effective). [Orphan Drug]

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
2	26-Jul-06	12 Polidocasklerol 0.5% Inj. 2mL Polidocasklerol 1% Inj. 2mL Polidocasklerol 3% Inj. 2mL (Sakai Chemical Industry Co.,Ltd.)	Approval Approval Approval	Polidocanol	Drugs with a new route of administration, used as a sclerosant to treat primary varicose veins of the lower extremity (excluding the varicosity of the main stem of the saphenous vein).
2	20-Oct-06	13 Ropinirole Hydrochloride ReQuip Tablets 0.25mg ReQiuip Tablets 1mg ReQuip Tablets 2mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Ropinirole hydrochloride	Drugs with a new active ingredient, indicated for Parkinson's Disease.
2	20-Oct-06	14 Preminent Tablets (Banyu Pharmaceutical Co., LTD.)	Approval	Losartan potassium / Hydrochlorothiazide	A new combination drug indicated for hypertension.
2	20-Oct-06	15 Onoact 50 for Injection (Ono Pharmaceutical Co., Ltd.)	Partial	Landiolol hydrochloride	Additional indication for emergency treatment of postoperative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) under hemodynamic monitoring.
2	26-Jan-07	16 Ancaron Injection 150 (sanofi-aventis K.K.)	Approval	Amiodarone hydrochloride	Drug with a new route of administration, used for emergency treatment of refractory arrhythmias (ventricular fibrillation and hemodynamically unstable ventricular tachycardia). [Orphan Drug]
2	26-Jan-07	17 Comtan Tablets (Novartis Pharma K.K..)	Approval	Entacapone	Drug containing a new active ingredient used in combination with levodopa/carbidopa or levodopa/benserazide hydrochloride to improve daily fluctuation, or 'wearing-off' phenomena, in Parkinson's disease.
3	20-Apr-06	18 Sertraline Hydrochloride Pfizer J Zoloft Tablets 25mg J Zoloft Tablets 50mg (Pfizer Japan Inc.)	Approval Approval Approval	Sertraline hydrochloride	Drugs containing a new active ingredient, indicated for depression and panic disorder.
3	15-Jun-06	19 Neoral Oral Solution Neoral 10mg Capsules Neoral 25mg Capsules Neoral 50mg Capsules (Novartis Pharma K.K.)	Partial Partial Partial Partial	Ciclosporine	Addition of a new indication for systemic myasthenia gravis (in cases where post-thymectomy steroid therapy is not sufficiently effective or not well tolerated due to adverse drug reactions). [Notification of off-label use]
3	26-Jul-06	20 Gabapentin Pfizer Gabapen Tablets 200mg Gabapen Tablets 300mg Gabapen Tablets 400mg (Pfizer Japan Inc.)	Approval Approval Approval Approval	Gabapentin	Drugs containing a new active ingredient indicated for use as adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondarily generalized seizure) in patients with epilepsy, to whom other antiepileptic therapies are not sufficiently effective.
3	26-Jul-06	21 Avonex IM Injection Syringe 30μg (Genzyme Japan K.K)	Approval	Interferon beta-1a (genetical recombination)	Drug containing a new active ingredient, indicated for relapse prevention of multiple sclerosis. [Orphan Drug]
3	20-Oct-06	22 Ultiva Intravenous 2mg Ultiva Intravenous 5mg (Janssen Pharmaceutical K.K.)	Approval Approval	Remifentanil hydrochloride	Drugs with a new active ingredient, used for analgesia during induction and maintenance of general anesthesia. [Expedited Review]
3	20-Oct-06	23 OxiNorm Powder 0.5% (Shionogi & Co., Ltd.)	Approval	Oxycodone hydrochloride hydrate	Drug with a new dosage form used as an analgesic agent for moderate to severe pain associated with various types of cancer.
3	26-Jan-07	24 Gabalon for Intrathecal Infusion 0.005% Gabalon for Intrathecal Infusion 0.05% Gabalon for Intrathecal Infusion 0.2% (Daiichi Pharmaceutical Co., Ltd.)	Partial Partial Partial	Baclofen	Addition of pediatric dosage for treatment of severe spastic paralysis resulting from cerebrospinal disorders (used only when conventional therapies are not sufficiently effective). [Orphan Drug]
3	26-Jan-07	25 Modiodal Modiodal Tablets 100mg (Alfresa Pharma Corporation)	Approval Approval	Modafinil	Drugs containing a new active ingredient indicated for treatment of excessive daytime sleepiness associated with narcolepsy. [Orphan Drug]

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
4	20-Apr-06	26 AmBisome 50mg for Intravenous Drip Infusion (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Amphotericin B	Various infections caused by Aspergillus species, Candida species or Cryptococcus species (drug with a new dosage and dosage form).
4	20-Apr-06	27 Zyvox Injection 600mg Zyvox Tablets 600mg (Pfizer Japan Inc.)	Partial Partial	Linezolid	Addition of a new indication for methicillin-resistant Staphylococcus aureus (MRSA).
4	20-Apr-06	28 Funguard for Infusion 25mg Funguard for Infusion 50mg Funguard for Infusion 75mg (Astellas Pharma Inc.)	Approval Partial Partial	Micafungin sodium	Addition of a new pediatric dosage and a dosage form of 25 mg.
4	26-Jul-06	29 Vegamox Ophthalmic Solution 0.5% (Alcon Japan Ltd.)	Approval	Moxifloxacin hydrochloride	Drug with a new route of administration, indicated for blepharitis, dacryocystitis, hordeolum, conjunctivitis, meibomianitis, keratitis (including corneal ulcer), and perioperative sterilization in ophthalmological surgery.
4	26-Jul-06	30 Itrizole Oral Solution 1% (Janssen Pharmaceutical K.K.)	Approval	Itraconazole	Addition of a new dosage form and dosage for treatment of oropharyngeal candidiasis and oesophageal candidiasis.
4	26-Jul-06	31 Baraclude Tablets 0.5mg (Bristol Pharmaceuticals Y.K.)	Approval	Entecavir hydrate	Drug containing a new active ingredient indicated for use to improve levels of viral marker, liver function, and the histology of the liver affected by chronic hepatitis B in patients with evidence of hepatitis B virus replication and associated abnormal liver function. [Priority Review]
4	21-Aug-06	32 Stromectol Tablets 3mg (Banyu Pharmaceutical Co., LTD.)	Partial	Ivermectin	Addition of a new indication and dosage for treatment of scabies. [Notification of off-label use]
4	13-Sep-06	33 Valtrex Tablets 500 Valtrex Tablets Granules 50% (GlaxoSmithKline K.K.)	Partial Partial	Valaciclovir hydrochloride	Addition of a new indication and dosage indicated for the suppression of recurrent genital herpes. [Notification of off-label use]
4	20-Oct-06	34 Itrizole Injection 1% (Janssen Pharmaceutical K.K.)	Approval	Itraconazole	Drug with a new route of administration indicated for treatment of fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, esophageal candidiasis, blastomycosis, and histoplasmosis, caused by *Aspergillus* species, *Candida* species, *Cryptococcus* species, *Blastomyces* species or *Histoplasma* species and febrile neutropenia suspected of having fungal infections.
4	26-Jan-07	35 Pariet Tablets 10mg (Eisai Co., Ltd.) Pasetocin Capsules Pasetocin Fine Granules Pasetocin Tablets 250 (Kyowa Hakko Kogyo Co., Ltd.) Amopenixin Capsules 250 (Nipro Pharma Corporation) Sawacillin Capsules Sawacillin Fine Granules Sawacillin Tablets 250 (Astellas Pharma Inc.) Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200mg (Abbott Japan Co., Ltd.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Sodium rabeprazole Amoxicillin Clarithromycin	Addition of a new dosage indicated for a combination therapy with sodium rabeprazole, amoxicillin, and clarithromycin to eradicate *Helicobacter pylori* in patients with gastric or duodenal ulcer.
4	26-Jan-07	36 Relenza (GlaxoSmithKline K.K.)	Partial	Zanamivir hydrate	Addition of a new indication for prophylaxis of influenza typeA or typeB infections. [Expedited Review]

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
4	26-Jan-07	37 Funguard for Infusion 50mg	Partial	Micafungin sodium	Drugs with a new indication and dosage for prophylaxis of aspergillosis and candidiasis in hematopoietic stem cell transplant patients.
		Funguard for Infusion 75mg	Partial		
		Funguard for Infusion 25mg	Partial		
		(Astellas Pharma Inc.)			
4	31-Jan-07	38 Omepral Tablets 10	Partial	Omeprazole	Revision of the dosage for a combination therapy of amoxicillin, clarithromycin, and omeprazole indicated for treatment of *Helicobacter pylori* infections in patients with gastric ulcer or duodenal ulcer.
		Omepral Tablets 20	Partial		
		(AstraZeneca K.K.)			
		Omeprazon Tablets 10mg	Partial		
		Omeprazon Tablets 20mg	Partial		
		(Mitsubishi Pharma Corporation)			
		Pasetocin Capsules	Partial	Amoxicillin	
		Pasetocin Tablets 250	Partial		
		(Kyowa Hakko Kogyo Co., Ltd.)			
		Sawacillin Capsules	Partial		
		Sawacillin Tablets 250	Partial		
		(Astellas Pharma Inc.)			
		Amoxicillin Capsules "TOWA"	Partial		
		(Towa Pharmaceutical Co., Ltd.)			
		Clarith Tab. 200	Partial	Clarithromycin	
		(Taisho Pharmaceutical Co., Ltd.)			
		Klaricid Tablets 200mg	Partial		
		(Abbott Japan Co., Ltd.)			
5	20-Apr-06	39 Vesicare Powder	Approval	Solifenacin succinate	Drugs with a new active ingredient indicated for treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
		Vesicare Tablets 2.5mg	Approval		
		Vesicare Tablets 5mg	Approval		
		(Astellas Pharma Inc.)			
5	20-Apr-06	40 Detrusitol Capsules 2mg	Approval	Tolterodine tartrate	Drugs with a new active ingredient indicated for treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
		Detrusitol Capsules 4mg	Approval		
		(Pfizer Japan Inc.)			
5	20-Apr-06	41 Cetrorelix Acetate for Injection 0.25mg "Shionogi"	Approval	Cetrorelix acetate	Drugs containing a new active ingredient, indicated for prevention of premature ovulation during controlled ovarian stimulation.
		Cetrorelix Acetate for Injection 3mg "Shionogi"	Approval		
		(Shionogi & Co., Ltd.)			
		Cetrotide for Injection 0.25mg	Approval		
		Cetrotide for Injection 3mg	Approval		
		(Nippon Kayaku Co., Ltd.)			
5	20-Oct-06	42 L'estrogel 0.06%	Approval	Estradiol	Drug with a new dosage form indicated for vasomotor symptoms (hot flush and sweating) associated with menopausal disorders and ovarian deficiency symptoms.
		(Shiseido Co., Ltd.)			
5	26-Jan-07	43 Mirena 52mg	Approval	Levonorgestrel	Drug with a new route of administration, indicated for use in contraception. (intrauterine contraceptive system)
		(Nihon Schering K.K.)			
5	26-Jan-07	44 Follistim Injection 50	Approval	Follitropin beta (genetical recombination)	Drugs with a new indication and dosage indicated for the induction of ovulation in patients with anovulation and oligoovulation associated to hypothalamo-pituitary dysfunction.
		Follistim Injection 75	Partial		
		(Organon Japan)			
5	2-Mar-07	45 Carbostar Dialysate L	Approval	(combination drug)	A combination drug similar to other products. (Dialysate)
		Carbostar Dialysate M	Approval		
		Carbostar Dialysate P	Approval		
		(Ajinomoto Co., Inc.)			
6-1	26-Jul-06	46 Pulmicort Respules 0.25mg	Approval	Budesonide	Drugs with new dosages and dosage forms indicated for use in children from 6 months and under 5 years of age to treat asthma. [Expedited Review]
		Pulmicort Respules 0.5mg	Approval		
		(AstraZeneca K.K.)			
6-1	26-Jul-06	47 Patanol Ophthalmic Solution 0.1%	Approval	Olopatadine hydrochloride	Drug with a new route of administration indicated for allergic conjunctivitis.
		(Alcon Japan Ltd.)			

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
6-1	20-Oct-06	48 Allegra Tablets 60mg Allegra Tablets 30mg (sanofi-aventis K.K.)	Partial Approval	Fexofenadine hydrochloride	Addition of new dosages and dosage form indicated for use in small children.
6-1	26-Jan-07	49 Celecoxib (Pfizer Japan Inc.) Celecox Tablets 100mg Celecox Tablets 200mg (Astellas Pharma Inc.)	Approval Approval Approval	Celecoxib	Drugs with a new active ingredient indicated for relief of inflammation and pain associated with rheumatoid arthritis and osteoarthritis.
6-1	26-Jan-07	50 Remicade for I.V. Infusion 100 (Tanabe Seiyaku Co.,Ltd.)	Partial	Infliximab (genetical recombination)	Addition of an indication for refractory uveoretinitis associated with Behcet's disease (used only when conventional therapies are not sufficiently effective). [Orphan Drug]
6-2	20-Apr-06	51 Humatrope C6mg Humatrope C12mg (Eli Lilly Japan K.K.)	Partial Partial	Somatropin (genetical recombination)	Addition of an indication and dosage for treatment of adult growth hormone deficiency (used only in severe cases).
6-2	26-Jul-06	52 Fosamac Tablets 35mg (Banyu Pharmaceutical Co., LTD.) Bonalon Tablets 35mg (Teijin Pharma Limited)	Approval Approval	Alendronate sodium hydrate	Addition of once-a-week dosage and dosage forms indicated for treatment of osteoporosis.
6-2	26-Jul-06	53 Genotropin 5.3mg Genotropin MiniQuick S.C. Inj. 0.4mg Genotropin MiniQuick S.C. Inj. 0.6mg Genotropin MiniQuick S.C. Inj. 0.8mg Genotropin MiniQuick S.C. Inj. 1.0mg Genotropin MiniQuick S.C. Inj. 1.2mg Genotropin MiniQuick S.C. Inj. 1.4mg Genotropin MiniQuick S.C. Inj. 1.6mg Genotropin MiniQuick S.C. Inj. 1.8mg Genotropin MiniQuick S.C. Inj. 2.0mg Genotropin Inj. 12mg (Pfizer Japan Inc.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Somatropin (genetical recombination)	Addition of an indication for treatment of adult growth hormone deficiency (used only in severe cases).
6-2	26-Jan-07	54 Somavert for S.C. Injection 10mg Somavert for S.C. Injection 15mg Somavert for S.C. Injection 20mg (Pfizer Japan Inc.)	Approval Approval Approval	Pegvisomant (genetical recombination)	Drugs with a new active ingredient used to treat excessive secretion of IGF-I (somatomedin C) and other related symptoms in patients with acromegaly (used in cases where other surgical and pharmaceutical therapies are not sufficiently effective or practicable.) [Orphan Drug]
6-2	26-Jan-07	55 Prograf Capsules 0.5mg Prograf Capsules 1mg (Astellas Pharma Inc.)	Partial Partial	Tacrolimus hydrate	Drugs with a new indication for lupus nephritis (in cases where steroid therapy is not sufficiently effective or well tolerated due to side effects). [Orphan Drug]
6-2	6-Feb-07	56 Replagal for Intravenous Infusion 3.5mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Agalsidase alfa (genetical recombination)	Drug with a new active ingredient indicated for treatment of Fabry disease. [Orphan Drug]
In vivo Diagnostics	20-Apr-06	57 Bothdel Oral Solution 10 (Meiji Dairies Corporation) Bothdel Oral Solution 10 (Kyowa Hakko Kogyo Co., Ltd.)	Approval Approval	Manganese chloride tetrahydrate	Drugs with a new indication and dosage for use as a negative gastrointestinal contrast medium in Magnetic Resonance Cholangio-Pancreatography.
In vivo Diagnostics	20-Oct-06	58 Sonazoid for Injection (Daiichi Pharmaceutical Co., Ltd.)	Approval	Perflubutane	Drug with a new active ingredient used as a contrast agent for ultrasound imaging of lesions associated with hepatic tumors.
Oncology drugs	20-Apr-06	59 Zometa Injection Solution 4mg (Novartis Pharma K.K..)	Partial	Zoledronic acid hydrate	Drug with a new indication and revised dosage indicated for bone lesions of multiple myeloma or bone metastasis from solid cancers.

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
Oncology drugs	15-Jun-06	60 Gemzar Injection 200mg Gemzar Injection 1g (Eli Lilly Japan K.K.)	Partial Partial	Gemcitabine hydrochloride	Addition of an indication for biliary tract cancer.
Oncology drugs	26-Jul-06	61 Busulfex Injection 60mg (Kirin Brewery Company, Limited)	Approval	Busulfan	Drug with a new route of administration used for conditioning regimen prior to allogeneic hematopoietic stem cell transplantation. [Orphan Drug]
Oncology drugs	26-Jul-06	62 Temodal Capsules 20mg Temodal Capsules 100mg (Schering-plough K.K.)	Approval Approval	Temozolomide	Drugs containing a new active ingredient indicated for treatment of malignant glioma. [Priority Review]
Oncology drugs	10-Aug-06	63 TS-1 Capsule 20 TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Partial Partial	Combination drug containing Tegafur, Gimeracil, and Oteracil potassium.	Addition of an indication for pancreatic cancer.
Oncology drugs	20-Oct-06	64 Velcade Injection 3mg (Janssen Pharmaceutical K.K.)	Approval	Bortezomib	Drug containing a new active ingredient indicated for treatment of relapsed or refractory multiple myeloma. [Orphan Drug]
Oncology drugs	20-Oct-06	65 Busulfex Injection 60mg (Kirin Brewery Company, Limited)	Partial	Busulfan	Addition of pediatric dosage for conditioning regimen prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem cell transplantation in Ewing sarcoma family tumors and neuroblastoma. [Orphan Drug]
Oncology drugs	4-Jan-07	66 Alimta Injection 500mg (Eli Lilly Japan K.K.) Randa Inj. (Nippon Kayaku Co., Ltd.) Briplatin Injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) Cisplatin Inj. 'Maruko' (Maruko Pharmaceutical Co., Ltd.) Cisplamerck Injection Solution 0.05% (Merck Seiyaku Ltd.) Cisplatin Injection 10mg 'Nichi iko' Cisplatin Injection 25mg 'Nichi iko' Cisplatin Injection 50mg 'Nichi iko' (Nichi-Iko Pharmaceutical Co., Ltd.)	Approval Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Pemetrexed sodium hydrate Cisplatin	Combination therapy with a drug containing a new active ingredient and a drug with a new indication and dosage, for use to treat malignant pleural mesothelioma. [Priority Review] [Expedited Review]
Oncology drugs	26-Jan-07	67 Fludara Tab. 10mg (Nihon Schering K.K.)	Approval	Fludarabine phosphate	Drug with a new route of administration and indications for treatment of low-grade B cell non-Hodgkin lymphoma and mantle-cell lymphoma
Oncology drugs	31-Jan-07	68 Glivec Tablets 100mg (Novartis Pharma K.K..)	Partial	Imatinib mesilate	Drug with a new indication and dosage for treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan Drug]
AIDS drugs	1-Sep-06	69 Invirase Capsules 200mg Invirase Tablets 500mg (Chugai Pharmaceutical Co., Ltd.)	Partial Approval	Saquinavir mesilate	Addition of a new dosage and dosage form of 500mg tablets, indicated for treatment of HIV infection. [Orphan Drug]
AIDS drugs	1-Sep-06	70 Kaletra Tablets (Abbott Japan Co., Ltd.)	Approval	Lopinavir/Ritonavir	Drug with a new dosage indicated for treatment of HIV infection. [Orphan Drug]
AIDS drugs	4-Jan-07	71 Doxil Injection 20mg (Janssen Pharmaceutical K.K.)	Approval	Doxorubicin hydrochloride	Drug with a new indication and dosage for treatment of AIDS-related Kaposi's sarcoma. [Orphan Drug]

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
Blood products	20-Apr-06	72 Epogin Injection Ampoule 750 Epogin Injection Ampoule 1500 Epogin Injection Ampoule 3000 Epogin Injection Syringe 750 Epogin Injection Syringe 1500 Epogin Injection Syringe 3000 (Chugai Pharmaceutical Co.,Ltd.)	Partial Partial Partial Partial Partial Partial	Epoetin beta (genetical recombination)	Addition of a new indication for anemia in premature infants.
Blood products	22-May-06	73 Feiba (Baxter Limited)	Partial	Anti-inhibitor coagulant complex	Drug with a revised indication for "the control of bleeding by promoting blood coagulation in plasma in patients with inhibitors to blood coagulation factor VIII or factor IX." [Notification of off-label use]
Blood products	20-Oct-06	74 Anact C for Injection 2500 Units (Kaketsuken)	Partial	Freeze-dried human activated protein C concentrated	Addition of an indication and dosage for treatment of purpura fulminans caused by congenital protein C deficiency. [Orphan Drug]
Blood products	20-Oct-06	75 Advate for Injection 250 Advate for Injection 500 Advate for Injection 1000 (Baxter Limited)	Approval Approval Approval	Rurioctocog alfa (genetical recombination)	Drugs containing a new active ingredient, indicated for the control of bleeding tendency by supplementing blood coagulation factor VIII in patients with blood coagulation factor VIII deficiency (new product that eliminates the addition of human- and animal-derived components).
Biologicals	20-Oct-06	76 Pneumovax NP (Banyu Pharmaceutical Co., Ltd.)	Approval	Pneumococcal vaccine	Revision to the test procedures and acceptance criteria as well as to the manufacturing process for drug substance and formulation of pneumococcal capsular serotype polysaccharide.
Biologicals	26-Jan-07	77 ActHIB (Sanofi Pasteur-Daiichi Vaccines Co., Ltd.)	Approval	Haemophilus influenzae type b polysaccharide-tetanus toxoid conjugate vaccine	Drug containing a new active ingredient indicated for vaccination against *Haemophilus influenzae* type b infections.

Table-18. A List of Approved Articles in 2005 (New Drugs)

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
1	11-Apr-05	1 Actemra Liquid Concentrate Actemra for Intravenous Infusion 200 (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Tocilizumab (genetical recombination	Drugs containing a new active ingredient indicated for improving various symptoms and laboratory findings associated with Castleman's disease for which lymphadenectomy is not indicated. **[Orphan drug]**
1	16-Sep-05	2 Zefix Tablets 100 (GlaxoSmithKline K.K.)	Partial	Lamivudine	A new indication for "improving viral markers in patients with hepatitis B cirrhosis complicated by proliferation of hepatitis B virus and with abnormal hepatic function to be confirmed" in monotherapy **[Priority review]**
1	11-Oct-05	3 Propecia Tablets-1mg Propecia Tablets-0.2mg (Banyu Pharmaceutical Co., Ltd.)	Approval	Finasteride	Drugs containing a new active ingredient used for delaying progression of male pattern alopecia in men.
1	11-Oct-05	4 Seibule Tablets 25mg Seibule Tablets 50mg Seibule Tablets 75mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval	Miglitol	Drugs containing a new active ingredient, an α-glucosidase inhibitor, indicated for improving postprandial hyperglycemia in patients with type 2 diabetes.
1	22-Dec-05	5 PegIntron Sterile Powder for Injection (50μg/0.5 mL) PegIntron Sterile Powder for Injection (100μg/0.5 mL) PegIntron Sterile Powder for Injection (150μg/0.5 mL) (Schering-plough K.K.)	Partial	Peginterferon alfa-2b (genetical recombination)	A new indication for either case of chronic hepatitis C mentioned below in combined therapy (1) Patients with high blood levels of HCV-RNA except serogroup 1
		Rebetol Capsule 200 (Schering-plough K.K.)	Partial	Ribavirin	(2) Patients with no response to monotherapy with interferon preparation, or patients relapsing after monotherapy with interferon preparation **[Priority review]**
2	11-Apr-05	6 Tracleer Tablets 62.5 mg (Actelion Japan)	Approval	Bosentan hydrate	A drug containing a new active ingredient, the endothelin-receptor antagonist, indicated for pulmonary arterial hypertension **[Orphan drug]**
2	25-Jul-05	7 Cleactor Injection 400,000 Cleactor Injection 800,000 Cleactor Injection 1,600,000 (Eisai Co., Ltd.)	Partial Partial Partial	Monteplase (genetical recombination)	A new indication for "lysis of pulmonary artery thrombosis caused by acute pulmonary embolism in the presence of hemodynamic instability" **[Orphan drug]**
2	11-Oct-05	8 Activacin for Injection 6,000,000 Activacin for Injection 12,000,000 Activacin for Injection 24,000,000 (Kyowa Hakko Kogyo Co., Ltd.) Grutopa for Injection 6,000,000 Grutopa for Injection 12,000,000 Grutopa for Injection 24,000,00 (Mitsubishi Pharma Corporation)	Partial Partial Partial Partial Partial Partial	Alteplase (genetical recombination)	A new indication for improving dysfunction caused by acute ischemic cerebrovascular diseases **[Priority review]**
2	11-Oct-05	9 Blopress Tablets 2 Blopress Tablets 4 Blopress Tablets 8 (Takeda Pharmaceutical Company Limited)	Partial Partial Partial	candesartan cilexetil	A new indication for chronic heart failure, extended from use as an angiotensin-converting enzyme inhibitor
2	31-Oct-05	10 Bayaspirin 100mg Aspirin "Bayer" (Bayer Yakuhin, Ltd.)	Partial Approval	Aspirin	A new indication for "Kawasaki disease" **[Notification of off label use]**
2	31-Oct-05	11 Bufferin 81 mg Tablets (Lion Corporation)	Partial	Aspirin dialminate	A new indication for "Kawasaki disease" **[Notification of off label use]**
		Nitogis Tablets 81 mg (Shiono Chemical Co.,Ltd.)	Partial		
		Bassamin Tablets 81 mg (Taiyo Yakuhin Co., Ltd.)	Partial		
		Famoter 81mg Tablets (Tsuruhara Pharmaceutical Co., Ltd.)	Partial		
		Asphanate Tablets 81 mg (Nakakita Yakuhin Co., Ltd.)	Partial		
		Aspirin "Metal" (Nakakita Yakuhin Co., Ltd.)	Partial	Aspirin	
		aspirin "Yoshida" (Yoshida Pharmaceutical Co., Ltd.)	Partial		
		Aspirin "Hoei" (Merck Hoei Ltd.)	Partial		
2	23-Jan-06	12 Clopidogrel sulfate (Sanofi-Synthelabo Daiichi K.K..)	Approval	Clopidogrel sulfate	Drugs containing a new active ingredient indicated for preventing recurrences of ischemic cerebrovascular diseases (except cardiogenic cerebral infarction) **[Prompt review]**
		Plavix Tablets 25 mg Plavix Tablets 75 mg （Daiichi Pharmaceutical Co.,Ltd.）	Approval Approval		
3	11-Apr-05	13 Gabalon 0.005% 1 mL Gabalon 0.05% 20 mL Gabalon 0.2% 5 mL (Daiichi Pharmaceutical Co.,Ltd.)	Approval Approval Approval	Baclofen	Drugs with a new route of intrathecal infusion indicated for the treatment of severe spasticity resulting from cerebrospinal diseases **[Orphan drug]**

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
3	25-Jul-05	14 Salagen Tablets 5 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	Pilocarpine hydrochloride	Drug with a new route of oral administration indicated for the treatment of symptoms of dry mouth caused by radiotherapy for head and neck cancer
3	30-Sep-05	15 Pacif Capsules 30 mg Pacif Capsules 60 mg Pacif Capsules120 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Morphine hydrochloride	Drugs with a new formulation, a sustained-release preparation containing morphine hydrochloride given once a day
3	11-Oct-05	16 Luvox Tablets 25 Luvox Tablets 50 (Solvay Seiyaku K.K.) Depromel Tablets 25 Depromel Tablets 50 (Meiji Seika Kaisha, Ltd.)	Partial Partial Partial Partial	Fluvoxamine maleate	A new indication for the treatment of "social anxiety disorder"
3	23-Jan-06	17 Aripiprazole Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Powder 1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Aripiprazole	Drugs containing a new active ingredient indicated for schizophrenia, with partial agonist activity at D2 receptor
3	23-Jan-06	18 Paxil Tablets 10 mg Paxil Tablets 20 mg （GlaxoSmithKline K.K.）	Partial Partial	Paroxetine hydrochloride hydrate	A new indication for the treatment of "obsessive compulsive disorder"
4	11-Apr-05	19 Luliconazole (Nihon Nohyaku Co., Ltd.) Lulicon Cream 1% Lulicon Solution1% (Pola Kasei Kogyo KK)	Approval Approval Approval	Luliconazole	Drugs containing a new active ingredient, an imidazole anti-fungal agent
4	11-Apr-05	20 Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg (Pfizer Japan Inc.)	Approval Approval Approval	Voriconazole	Drugs containing a new active ingredient, a triazole anti-fungal agent
4	25-Jul-05	21 Finibax for Intravenous Infusion 0.25 g Finbax for Intradermal Test (Shionogi & Co., Ltd.)	Approval Approval	Doripenem hydrate	Drugs containing a new active ingredient, a carbapenem antimicrobial agent
4	11-Oct-05	22 Augmentin ES Dry Syrups for Children (GlaxoSmithKline K.K.)	Approval	Clavulante potasium · amoxicillin	A combination prescription drug with a new composition ratio
4	11-Oct-05	23 Avelox Tablets 400 mg (Bayer Yakuhin, Ltd.)	Approval	Moxifloxacin Hydrochloride	A drug containing a new active ingredient, a new quinolone antimicrobial agent
4	14-Oct-05	24 Synagis Intramuscular 50 mg Synagis Intramuscular 100 mg (Abbott Japan Co., Ltd.)	Partial Partial	Palivizumab (genetical recombination)	Drugs with a new indication for preventing serious lower respiratory tract disease caused by RS virus infections in newborns, infants and children under 24 months of age with haemodynamically significant congenital heart disease **[Priority review drug]**
4	23-Jan-06	25 Ozex Ophthalmic Solution 0.3% （Toyama Chemical Co., Ltd.） Tosuflo Ophthalmic Solution 0.3% （Nidek Co., Ltd.）	Approval Approval	Tosufloxacin tosilate	Drugs with a new route of administration (eye drops) indicated for the treatment of blepharitis, dacryoadenitis, hordeolum, conjunctivitis, inflammation of the tarsal glands, inflammation of the cornea (including corneal ulcer), and aseptic treatment during ophthalmic surgery.
4	17-Feb-06	26 Relenza （GlaxoSmithKline K.K.）	Partial	Zanamivir hydrate	A new pediatric dosage regimen indicated for the treatment of influenza virus infection
4	23-Feb-06	27 Gatiflo Tablets 100 mg （Kyorin Pharmaceutical Co., Ltd.）	Partial	Gatifloxacin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	28 Clarith Tablets 200 Clarith Tablets 50 for Pediatric Clarith Dry Syrup for Pediatric (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200 mg Klaricid Tablets 50 mg for Pediatric Klaricid Dry Syrups for Pediatric （Abbott Japan Co., Ltd.）	Partial Partial Partial Partial Partial Partial	Clarithromycin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	29 Ciproxan-I.V.200 Ciproxan-I.V.300 Ciproxan 100 Ciproxan 200 （Bayer Yakuhin, Ltd.）	Partial Partial Partial Partial	Ciprofloxacin Ciprofloxacin hydrochloride	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	30 Cravit Tablets Cravit Fine Granules （Daiichi Pharmaceutical Co., Ltd）	Partial Partial	Levofloxacin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
5	11-Apr-05	31 Follistim Injection 75 Follistim Injection 150 (Organon-Japan)	Approval Approval	Follitropin beta (genetical recombination)	Drugs containing a new active ingredient, a human follicle-stimulating hormone (genetical recombination), indicated for "regularly stimulating the ovary to develop multiple follicles in
5	23-Jan-06	32 Gonalef 75 (Subcutaneous) Gonalef 150 (Subcutaneous) (Serono Japan Co., Ltd.)	Approval Approval	follitropin alfa （genetical recombination）	Drugs containing a new active ingredient indicated for induction of spermatogenesis in male hypogonadotrophic hypogonadism in combination with human chorionic gonadotropin **[Orphan drug]**
5	23-Jan-06	33 Profasi 5000 (Injection) (Serono Japan Co., Ltd.)	Partial	Chorionic Gonadotrophin	A new indication and a new route of subcutaneous administration for induction of spermatogenesis in male hypogonadotrophic hypogonadism in combination with follitropin alpha **[Prompt review drug]**

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
5	23-Jan-06	34 Magsent Injection 100mL （Toa Pharmaceuticals Co., Ltd.）	Approval	magnesium sulfate /glucose	A new indication and new dosage for relaxing the uterus muscles and suppressing preterm labour **[Notification of off label]**
5	23-Jan-06	35 Silodosin "SFL" （Shiono Finesse, Ltd.） Urief Capsules 2mg Urief Capsules 4mg （Kissei Pharmaceutical Co., Ltd.）	Approval Approval Approval	Silodoshin	Drugs containing a new active ingredient indicated for the treatment of urination disorder associated with prostatic hypertrophy
5	3-Mar-06	36 Amigrand Intravenous Infusion （Terumo Corporation） Paresafe for IV. Infusion （Ajinomoto Medica Co., Ltd.）	Approval Approval		A combination prescription drugs containing thiamine hydrochloride combined with peripheral parenteral nutrition
5	3-Mar-06	37 Bfluid for I.V. Infusion （Otsuka Pharmaceutical Factory, Inc.）	Approval		A combination prescription drug containing thiamine hydrochloride combined with peripheral parenteral nutrition
6	11-Apr-05	38 Prograf Capsules 0.5 mg Prograf Capsules 1 mg (Astellas Pharma Inc.)	Partial Partial	Tacrolimus hydrate	A new indication for the treatment of articular rheumatism (only where conventional treatments are inadequate)
6	11-Oct-05	39 Papilock Mini Ophthalmic Solution 0.1% (Santen Pharmaceutical Co., Ltd.)	Approval	Ciclosporin	Eye drops indicated for the treatment of spring catarrh (where treatment with anti-allergic agents is inadequate) **[Orphan drug]**
6	22-Dec-05	40 Voltaren (Novartis Pharma K.K.) Sorelmon Tablets. (Towa Pharmaceutical Co., Ltd.) Volmagen Tablets (Taisho Pharm. Ind. Ltd.) Adefuronic (Taiyo Yakuhin Co., Ltd.) Blesin Tablets (Sawai Pharmaceutical Co., Ltd.)	Partial Partial Partial Partial Partial	Diclofenac Sodium	A new indication for the treatment of “toothache”, the format of the indication for "rheumatoid arthritis" was coordinated. **[Notification of off label use]**
6	22-Dec-05	41 Loxonin Tablets, Loxonin Fine Granules (Sankyo Co., Ltd.) Ollox Oral Solution 60 mg (Teikoku Medix Co., Ltd.) Lobu Tablets (Ohara Pharmaceutical Co., Ltd.) LoxipainTablets 60 mg (Kyowa Pharmaceutical) Threenofen Tablets (Asuka Pharmaceutical Co., Ltd.) Loxoprofen Sodium Tablets "Kunihiro" 60 mg (Kokando Pharmaceutical Co., Ltds) Cobalokinin Tablets (Kobayashi Kako Co., Ltd.) Letrac Tablets 60 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Loxomarin Tablets (Taisho Pharm. Ind. Ltd.) Roseol Tablets, Roseol Fine Granules (Tatsumi Kagaku Co., Ltd.) Lokiflan Tablets, Lokiflan Fine Granuales (Choseido Pharmaceutical Co., Ltd.) Tsurumerin Tablets (Tsuruhara Pharmaceutical Co., Ltd.) Confatanin Tablets (Towa Pharmaceutical Co., Ltd.) Lorfenamin Tablets, Lorfenamin Fine Granules (Nichi-Iko Pharmaceutical Co., Ltd.) Loxot Tablets (Nissin Pharmaceutical Co., Ltd.) Kentan Tablets, Kentan Fine Granules (Medisa Shinyaku Inc.) Unastin Tablets (Merck Hoei Ltd.) Ringereaze Tablets (Yoshindo Inc.) Rokifen Tablets 60 mg (Ryukakusan Co., Ltd.) Syllable Tablets (Taiyo Yakuhin Co., Ltd.) Loxipronal Tablets (Kotobuki Pharmaceutical Co., Ltd.)	Partial Partial Partial Partial

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
6	23-Jan-06	42 Loxonin Pap 100mg (Lead Chemical Co., Ltd.)	Approval	Loxoprofen Sodium	A drug with a new route of administration indicated for the treatment of osteoarthritis, myalgia, post-traumatic swelling/pain and anti-inflammatory/analgesic effects on these symptoms
Radiopharma-ceuticals	25-Jul-05	43 FDGscan Injectable (Nihon Mediphysics Co., Ltd.) FDGscan-MP Injectable (The Medical & Pharmacological Research Center Foundation)	Approval Approval	fludeoxyglucose (F18)	Drugs containing a new active ingredient used for making a diagnosis of malignant tumors accompanied by accelerated glucose metabolism, ischemic heart diseases or epilepsy
In vivo diagnostics	11-Apr-05	44 Adenoscan Injection 60mg Adenoscan Injection 90mg (Daiichi Suntory Pharma Co., Ltd.)	Approval Approval	adenosine	Drugs containing a new active ingredient used for load induction to make a diagnosis of heart disease based on myocardial perfusion scintigraphy in patients unable to tolerate sufficient exercise load
In vivo diagnostics	11-Oct-05	45 Inulin (Kanto Kagaku) Inulead Injection (Fujiyakuhin Co., Ltd.)	Approval Approval	Inulin	Drugs containing a new active ingredient used for renal function tests based on measurement of glomerular filtration rate
Oncology drugs	11-Apr-05	46 Tamibarotene "Toko" Amnolake Tablet 2 mg (Toko Pharmaceutical Industrial Co., Ltd.)	Approval Approval	tamibarotene	Drugs containing a new active ingredient indicated for the treatment of acute promyelocytic leukemia **[Orphan drug]**
Oncology drugs	31-May-05	47 Navelbine Injection 10 Navelbine Injection 40 (Kyowahakko Co., Ltd.)	Partial Partial	Vinorelbine ditartrate	A new indication for the treatment of inoperable or recurrent breast cancer, in addition to the current indication for lung cancer
Oncology drugs	31-May-05	48 Taxol Injection (Bristol Seiyaku KK)	Partial	Paclitaxel	A new indication for the treatment of cancer of the uterus body, in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer and stomach cancer
Oncology drugs	25-Jul-05	49 Mylotarg Injection 5 mg (Wyeth K.K.)	Approval	Gemtuzumab Ozogamicin (Genetical Recombination)	A drug containing a new active ingredient indicated for the treatment of relapsing or intractable CD33 positive acute myeloid **[Orphan drug]**
Oncology drugs	18-Aug-05	50 Taxotere Injection (Aventis Pharma Ltd.)	Partial	Docetaxel hydrate	A new indication for the treatment of "cancer of the uterus body", in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer, stomach cancer, head and neck carcinoma, and esophageal carcinoma
Oncology drugs	18-Aug-05	51 Leuplin SR For Injection Kit 11.25 (Takeda Pharmaceutical Company Limited)	Partial	leuprorelin acetate	A new indication for the treatment of "premenopausal breast cancer", in addition to the current indication for prostatic cancer
Oncology drugs	15-Sep-05	52 Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer **[Combination chemotherapy with anti-cancer drgs]**
Oncology drugs	15-Sep-05	53 Farmorubicin Injection Farmorubicin RTU Inj (Pfizer Japan Inc.) Epirubicin Hydrochloride Injection 10 mg "Merck" Epirubicin Hydrochloride Injection 50 mg "Merck" (Merck Hoei Ltd.)	Partial Partial Partial Partial	Epirubicin hydrochloride	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer **[Combination chemotherapy with anti-cancer drgs]**
		Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	
Oncology drugs	15-Sep-05	54 Randa Injection (Nippon Kayaku Co., Ltd.) Briplatin Injection (Bristol Seiyaku KK) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.) Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial Partial Partial Partial Partial Partial Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant lymphoma **[Combination chemotherapy with anti-cancer drgs]**
		Solu-Medrol 40 Solu-Medrol 125 Solu-Medrol 500 (Pfizer Japan Inc.) Decacort 125 Decacort 500 (Sawai Pharmaceutical Co., Ltd.) Sol-melcort Injection 40 Sol-melcort Injection 125 Sol-melcort Injection 500 (Fuji Pharma Co., Ltd.) Pridol for Injection 40 Pridol for Injection 125 Pridol for Injection 500 (Sankyo Yell Yakuhin Co., Ltd.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Methylprednisolone sodium succinate	

Category	Date of Approval		Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	15-Sep-05	55	Randa Injection (Nippon Kayaku Co., Ltd.)	Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant solid tumors of childhood **[Combination chemotherapy with anti-cancer drgs]**
			Briplatin Injection (Bristol Seiyaku KK)	Partial		
			Platosin Injection 10	Partial		
			Platosin Injection 25	Partial		
			Platosin Injection 50 (Pfizer Japan Inc.)	Partial		
			Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.)	Partial		
			Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial		
			Paraplatin For Injection 150 mg	Partial	Carboplatin	
			Paraplatin Injection (Bristol Seiyaku KK)	Partial		
			Carbomerck for Injection 1% (Merck Hoei Ltd.)	Partial		
			Carboplatin Injection 1% (Nippon Hexal Corporation)	Partial		
			Cosmegen (Banyu Pharmaceutical Co., Ltd.)	Partial	Actinomycin D	
Oncology drugs	15-Sep-05	56	Decadron Tablets (Banyu Pharmaceutical Co., Ltd.)	Partial	Dexamethasone	A new indication and a new dosage regimen for the treatment of gastrointestinal (nausea, vomiting) symptoms associated with administration of antitumor agents **[Combination chemotherapy with anti-cancer drgs]**
			Dexamethasone Tablets 0.5 mg "Taiyo" (Taiyo Yakuhin Co., Ltd)	Partial		
			Decadron Phosphate Injection	Partial	Dexamethasone Sodium Phosphate	
			Orgadrone Injection (Banyu Pharmaceutical Co., Ltd.)	Partial		
			Dexart Injection (Fuji Pharma Co., Ltd.)	Partial		
Oncology drugs	14-Nov-05	57	TS-1 Capsule 20	Partial	Tegafur/Gimeracil/Oteracil potassium	A new indication for the treatment of “inoperable or recurrent breast cancer”
			TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Partial		
Oncology drugs	23-Jan-06	58	Femara	Approval	Letrozole	Drugs containing a new active ingredient indicated for the treatment of post-menopausal breast cancer
			Femara 2.5 mg Tablet （Nihon Ciba-Geigy K.K.. ）	Approval		
Biological products	25-Jul-05	59	Mearubik (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella
Biological products	14-Oct-05	60	Freeze-Dried Live Attenuated Measles and Rubella Combined Vaccine "Takeda" (Takeda Pharmaceutical Company Limited)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Table 18 A list of approved items in 2004 (new drugs)

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
1	23-Apr-04	1 Sandostatin LAR for intramuscular injection 10mg Sandostatin LAR for intramuscular injection 20mg Sandostatin LAR for intramuscular injection 30mg (Nihon Chiba-Geigy K.K.)	Approval Approval Approval	Octreotide Acetate	New form drug with a new administration route administered once every four weeks and which has the following indications: alleviation of various symptoms associated with gastrointestinal hormone-producing tumors and alleviation of excessive secretions of growth hormone and somatomedin-C and other various symptoms in acromegaly and pituitary gigantism
1	9-Jul-04	2 Zione Injection / Lidocaine Zione Injection (Mitsubishi Pharmaceutical Co., Ltd.)	Approval Approval	Aluminum potassium sulfate, tannic acid	A new compound agent for local injection with indications for internal hemorrhoids associated with prolapse and is used for internal hemorrhoid sclerotherapy.
1	22-Oct-04	3 Hepsera Tablet 10 (Glaxo SmithKline K.K.)	Approval	Adefovir pivoxil	A nucleotide analogue of adenosine monophosphate which selectively inhibits HBV DNA polymerase, a new drug containing a new active ingredient with indications for improving hepatic function and levels of viral markers through combined use with lamivudine in chronic hepatitis B and hepatitis B cirrhosis in which abnormality of hepatic function with persistent regrowth of hepatitis B viruses has been confirmed during administration of lamivudine <Priority assessment>
		Zefix Tablets 100 (Glaxo SmithKline K.K.)	Supplemental Change	Lamivudine	Addition to indications for improving the levels of viral markers and hepatic function in chronic hepatitis B and hepatitis B cirrhosis in which an abnormality of the hepatic function with persistent regrowth of type B hepatitis viruses has been confirmed during administration of this drug combined with adefovir pivoxil. <Priority assessment>
1	22-Oct-04	4 Intron A for injection 300 Intron A for injection 600 Intron A for injection 1000 (Schering Plough K.K.)	Supplemental Change Supplemental Change Supplemental Change	Interferon alfa-2b (Genetical Recombination)	When this drug is combined with ribavirin, the directions and dosage of ribavirin must be changed. <Priority assessment>
		Rebetol capsule 200mg (Schering Plough K.K.)	Supplemental Change	Ribavirin	Addition to indications of combined use with Peginterferon alfa-2b (Genetical recombination) to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA in serogroup 1. <Priority assessment>
		PegIntron Sterile Powder for Injection 50μg/0.5mL PegIntron Sterile Powder for Injection 100μg/0.5mL PegIntron Sterile Powder for Injection 150μg/0.5mL (Schering Plough K.K.)	Approval Approval Approval	Peginterferon alfa-2b (Genetical recombination)	A drug containing a new active ingredient which enables weekly administration through chemical modification of interferon alfa-2b by polyethylene glycol (PEG) to prolong the drug elimination time in blood and has indications combined with ribavirin to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA levels for serogroup 1. <Priority assessment>
2	22-Jun-04	5 Flolan for injection 0.5mg Flolan for injection 1.5mg (Glaxo SmithKline K.K.)	Supplemental Change Supplemental Change	Epoprostenol sodium	Addition to indications of pulmonary hypertension associated with specific diseases and a change of the description from "primary pulmonary hypertension" to "pulmonary arterial hypertension" <Orphan drug>

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
2	22-Oct-04	6 Fenofibrate fine powder Lipidil capsule 67 Lipidil capsule 100 (Grelan Pharmaceutical. Co., Ltd.) Tricor capsule 67mg Tricor capsule 100mg (Taisho Pharmaceutical Co., Ltd.)	 Approval Approval Approval Approval Approval	Fenofibrate	Pulverization enables a reduction in the dosage to two thirds of the current dosage for hyperlipidemia (including familial hyperlipidemia).
2	19-Jan-05	7 Crestor 2.5mg Crestor 5mg Crestor 10mg (AstraZeneca K.K.)	 Approval Approval Approval	Rosuvastatin calcium	A drug containing a new active ingredient with indications for HMG-CoA reductase inhibition for hypercholestelemia and familial hypercholestelemia.
3	22-Oct-04	8 Tiotropium Bromide Hydrate Spiriva Inhalation Capsules 18μg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Tiotropium Bromide Hydrate	A drug containing a new active ingredient with indications for anticholinergic bronchodilation to alleviate various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
3	22-Oct-04	9 P Guard Tablets 20mg P Guard Tablets 30mg P Guard Tablets 60mg P Guard Tablets 120mg (Tanabe Seiyaku Co., Ltd.)	 Approval Approval Approval Approval	Morphine sulfate	A new formulation of opioid drug for daily administration with indications as analgesia for moderate to severe pain in various cancers.
3	22-Oct-04	10 Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Takeda Pharmaceutical Co., Ltd.) Morphine hydrochloride (Sankyo Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Shionogi & Co., Ltd.) Anpec (Dainippon Pharmaceutical. Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Tanabe Seiyaku Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Morphine hydrochloride	Addition of new routes of administration (epidural and intrathecal administration), besides previous subcutaneous or intravenous administration.
3	19-Jan-05	11 Enbrel 25mg for S.C. Injection (Wyeth K.K..)	Approval	Etanercept (genetic recombination)	A drug containing a new active ingredient, humanized fusion protein having an inhibitory action on the binding of the tumor necrosis factor (TNF) to a TNF receptor that has indications for rheumatoid arthritis

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
3	19-Jan-05	12 Qval 50 Qval 100 (Dainippon Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change	Beclometasone dipropionate	Addition of a pediatric dosage for bronchial asthma
3	19-Jan-05	13 Alesion Dry Syrup 1% (Nippon Boehringe Ingerheim Co., Ltd.)	Approval	Epinastine hydrochloride	A pediatric preparation with indications for allergic rhinitis, urticaria, skin diseases (eczema, dermatitis, skin pruritus)
3	4-Mar-05	14 Epipen injection 0.15mg Epipen injection 0.3mg (Merck Ltd.)	Approval Supplemental Change	Epinephrine	Addition of its pediatric application and indications for adjunctive therapy for anaphylactic reaction induced by food, drug and others.
Anti-infective	23-Apr-04	15 Meropen for intravenous drip infusion 0.25g Meropen for intravenous drip infusion 0.5g (Sumitomo Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change	Meropenem trihydrate	A carbapenem antibacterial agent. Addition of indications for purulent meningitis and dosage for pediatric patients.
Anti-infective	21-May-04	16 Zithromac Tablets 250mg (Pfizer Japan Inc.)	Supplemental Change	Azithromycin hydrate	Addition of indications for Chlamydia trachomatis, urethritis and uterine cervicitis and to dosage regimen.
Anti-infective	22-Jun-04	17 Rocephin 0.5g Rocephin 1g Rocephin 1g Bag (Chugai Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Ceftriaxone Sodium	Addition of indications for gonococcus and gonococcal pharyngitis, gonococcal urethritis, gonococcal uterine cervicitis, gonococcal pelvic inflammatory diseases, gonococcal epididymitis, gonococcal proctitis, and to dosage regimen.
Anti-infective	9-Jul-04	18 Gatiflo 0.3% ophthalmic solution (Senju Pharmaceutical. Co., Ltd.)	Approval	Gatifloxacin hydrate	New quinolone antibacterial agent. An ophthalomic solution with indications for blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, aseptic therapy for ophthalmologic perioperative period.
Anti-infective	9-Jul-04	19 Tamiflu capsule 75 (Chugai Pharmaceutical. Co., Ltd.)	Supplemental Change	Oseltamivir Phosphate	Addition of indications to prevent influenza A or B viral infections and dosage regimen.
Anti-infective	16-Sep-04	20 Maxipime for injection 0.5g Maxipime for injection 1g (Bristol Myers K.K.)	Supplemental Change Supplemental Change	Cefepime dihydrochloride	Addition of indications on febrile neutropenia
Anti-infective	22-Oct-04	21 Vancomycin for I.V.Infusion (Eli Lilly Japan K.K.)	Supplemental Change	Vancomycin hydrochloride	Additions of indications for sepsis, pneumonia, and purulent meningitis caused by penicillin-resistant-*Streptococcus* . <orphan drug>
Anti-infective	22-Feb-05	22 Pasil 300mg Pasil 500mg (Toyama Chemical Co., Ltd.) Pazucross injection 300 Pazucross injection 500 (Mitsubishi Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Pazufloxacin mesilate	Addition of indications for legionella infection.
5	23-Apr-04	23 Levitra 5mg Levitra 10mg (Bayer Yakuhin, Ltd.)	Approval Approval	Vardenafil hydrochloride	A drugs containing a new active ingredient with indications for phosphodiesterase-5 inhibitor in erectile dysfunction.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Radioacitve	23-Apr-04	24 Benzodine Injectable (Nihon Medi-Physics Co., Ltd.)	Approval	Iomazenil (^{123}I)	A drug containing a new active ingredient with indications for detection of epileptic focus in epilepsy by the central benzodiazepine-receptor scintigraphy.
In vivo diagnostic	22-Oct-04	25 Pralmorelin hydrochloride GHRP Kaken 100 (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	Pralmorelin hydrochloride	A diagnostic agent used for examination of secretory functions of growth hormones.
Oncology drug	31-May-04	26 Bleo (Nippon Kayaku Co., Ltd.)	Supplemental Change	Bleomycin hydrochloride	Addition of indications for germ cell tumors and dosage regimen
		Lastet Inj. (Nippon Kayaku Co., Ltd) VePesid Injection (Bristol Pharmaceuticals Y.K.)	Supplemental Change	Etoposide	
		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	22-Oct-04	27 Zometa (Nihon Ciba-Geigy K.K.)	Approval	Zoledronic Acid Hydrate	A drug containing a new active ingredient which has a bone-absorption-inhibitory action and has indications for hypercalcemia caused by malignant tumors.
Oncology drug	22-Oct-04	28 Sandostatin 50μg Sandostatin 100μg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Octreotide Acetate	Addition of indications to alleviate digestive symptoms associated with digestive obstruction in patients with advanced or recurrent cancer.
Oncology drug	22-Oct-04	29 Anhydrous ethanol (Fuso) (Fuso Pharmaceutical Industries, Ltd.) Anhydrous ethanol (Shimizu) (Shimizu Pharmaceutical Co., Ltd.) Anhydrous ethanol (Merck) (Merck Hoei Ltd)	Approval Approval Approval	Anhydrous ethanol	A drug with a new administration route with indications for percutaneous ethanol injection therapy in hepatocellular carcinoma.
Oncology drug	22-Oct-04	30 Trisenox Injection 10mg (Nippon Shinyaku Co., Ltd.)	Approval	Arsenic Trioxide	A drug with a new administration route with indications for relapsed or refractory acute promyelocytic leukemia. <Priority review>
Oncology drug	14-Dec-04	31 TS-1 capsule 20 TS-1 capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Supplemental Change Supplemental Change	Tegafur, Gimeracil, Oteracil potassium	An addition to indications of non-small cell lung cancer to current indications of gastric cancer, rectal and colonic cancers and head and neck cancers.
Oncology drug	14-Dec-04	32 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of relapsed or refractory germ cell tumors (testicular tumor, ovarian tumor, extragonadal tumors) and to dosage regimen.
		Exal for Inj. 10mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vinblastine sulfate	

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Oncology drug	19-Jan-05	33 Aredia 15mg Aredia 30mg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Pamidronate Disodium	Addition to indications of combined use with chemotherapy, endocrine therapy, or radiotherapy for osteolytic bone metastases of <Combined therapy with anticancer agents>
Oncology drug	14-Feb-05	34 Adriacin injection (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in pre- or postoperative chemotherapy for operable cases of breast cancer and to dosage regimen.
Oncology drug	14-Feb-05	35 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in postoperative chemotherapy or chemotherapy for metastasis or recurrence of endometrial cancer <Combined therapy with anti-cancer agents>
		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	14-Feb-05	36 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents for malignant bone tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	14-Feb-05	37 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents for malignant bone and soft tissue tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifosfamide for malignant bone and soft tissue tumors, an addition to dosage for inhibiting the development of urological impairment associated with administration of said ifosfamide. <Combined therapy with anticancer agents>

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Oncology drug	14-Feb-05	38 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents on pediatric malignant solid tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		VePesid Injection (Bristol Pharmaceuticals Y.K.) Lastet Inj. (Nippon Kayaku Co., Ltd)	Supplemental Change Supplemental Change	Etoposide	
		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifofamide for pediatric malignant solid tumors, an addition to dosage for inhibiting the development of urological impairment associated with the administration of said ifosfamide. <Combined therapy with anticancer agents>
Oncology drug	14-Feb-05	39 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with anticancer agents for colonic and rectal cancers and to dosage regimen. <Combined therapy with anticancer agents>
		Isovolin injection 25mg (Wyeth K.K.)	Supplemental Change	Levofolinate Calcium	
Oncology drug	14-Feb-05	40 Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	Addition to indications of combined therapy with anticancer agents for multiple myeloma and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Decadron Phosphate Injection (Banyu Phamaceutical Co., Ltd.) Orgadrone Injection (Nippon Organon K.K.) Dexart (Fuji Pharma Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Dexamethasone sodium phosphate	
Oncology drug	14-Feb-05	41 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with other anticancer agents for head and neck cancers and to dosage regimen. <Combined therapy with anticancer agents>
Oncology drug	14-Feb-05	42 Natulan (Chugai Pharmaceutical Co., Ltd.)	Supplemental Change	Procarbazine hydrochloride	Addition to indications of combined therapy with other anticancer agents for glioma which possesses components of malignant astrocytoma and oligodendroglioma and to dosage regimen. <Combined therapy with anticancer agents>
		Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	
Oncology drug	18-Mar-05	43 Elplat for Injection 100mg (Yakult Honsha Co., Ltd)	Approval	Oxaliplatin	A drug containing a new active ingredient with indications for colonic and rectal cancers. <Priority review>
AIDS	5-Nov-04	44 VALIXA Tablets 450mg (Tanabe Seiyaku Co., Ltd.)	Approval	Valganciclovir hydrochloride	A drug containing a new active ingredient, L-valine ester of ganciclovir, with indications for treatment of retinitis caused by cytomegalovirus in patients with acquired immune deficiency syndrome (AIDS) and dosage regimen. <Orphan drug>
AIDS	24-Dec-04	45 Lexiva Tablets 700 (Glaxo Smith Kline K.K.)	Approval	Fosamprenavir Calcium Hydrate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	24-Dec-04	46 Epzicom Tablets (Glaxo Smith Kline K.K.)	Approval	Lamivudine, Abacavir Sulfate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	24-Dec-04	47 Ziagen Tablets (Glaxo Smith Kline K.K.)	Supplemental Change	Abacavir Sulfate	Addition to dosage regimen of ”daily 600mg, once a day“ to the current ones of ”300mg per dose, twice a day.” < Orphan drug >

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
AIDS	23-Mar-05	48 Emtriva Capsules 200mg (Japan Tobacco Inc.)	Approval	Emtricitabine	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >
AIDS	23-Mar-05	49 Truvada Tablets (Japan Tobacco Inc.)	Approval	Emtricitabine, Tenofovir disoproxil fumarate	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >