

New Drugs Approved in May 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
4	May 7, 2020	1	Veklury for Intravenous Injection 100 mg (Solution) Veklury for Intravenous Injection 100 mg (Lyophilized powder) (Gilead Sciences K.K.)	Approval	<u>Remdesivir</u>	Drugs with a new active ingredient indicated for the treatment of infection caused by SARS-CoV-2. [Drug pertaining to Special Approval for Emergency]
6-1	May 29, 2020	2	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]
Oncology drugs	May 29, 2020	3	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	4	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.
Vaccines	May 29, 2020	5	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.
6-1	May 29, 2020	6	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]

New Drugs Approved in June 2020

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	1	Mayzent Tablets 0.25 mg Mayzent Tablets 2 mg (Novartis Pharma K.K.)	Approval Approval	<u>Siponimod fumaric acid</u>	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]
2	Jun. 29, 2020	2	Entresto Tablets 50 mg Entresto Tablets 100 mg Entresto Tablets 200 mg (Novartis Pharma K.K.)	Approval Approval Approval	<u>Sacubitril valsartan sodium hydrate</u>	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	3	Ongentys Tablets 25 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Opicapone</u>	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	4	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	5	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]
1	Jun. 29, 2020	6	Vafseo Tablets 150 mg Vafseo Tablets 300 mg (Mitsubishi Tanabe Pharma Corporation)	Approval Approval	<u>Vadadustat</u>	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Jun. 29, 2020	7	Duvroq Tablets 1 mg Duvroq Tablets 2 mg Duvroq Tablets 4 mg Duvroq Tablets 6 mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	<u>Daprodustat</u>	Drugs with a new active ingredient indicated for the treatment of renal anemia.
6-2	Jun. 29, 2020	8	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.
3-1	Jun. 29, 2020	9	Xeomin 50 Units for Intramuscular Injection Xeomin 100 Units for Intramuscular Injection Xeomin 200 Units for Intramuscular Injection (Teijin Pharma Limited)	Approval Approval Approval	<u>Incobotulinumtoxin A</u>	Drugs with a new active ingredient indicated for the treatment of upper limb spasticity.
3-1	Jun. 29, 2020	10	Enspryng Syringes for Subcutaneous Injection 120 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Satralizumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]
6-1	Jun. 29, 2020	11	Ilumya Subcutaneous Injection 100 mg Syringe (Sun Pharma Japan Ltd.)	Approval	<u>Tildrakizumab (genetical recombination)</u>	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	12	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).

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6-1	Jun. 29, 2020	13	Ateectura Inhalation Capsules Low Dose Ateectura Inhalation Capsules Medium Dose Ateectura Inhalation Capsules High Dose (Novartis Pharma K.K.)	Approval Approval Approval	<u>Indacaterol</u> <u>acetate</u> /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	14	Energair Inhalation Capsules Medium Dose Energair Inhalation Capsules High Dose (Novartis Pharma K.K.)	Approval Approval	<u>Indacaterol</u> <u>acetate</u> /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).
Oncology drugs	Jun. 29, 2020	15	Sarclisa 100 mg I.V. Infusion Sarclisa 500 mg I.V. Infusion (Sanofi K.K.)	Approval Approval	<u>Isatuximab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma.
Oncology drugs	Jun. 29, 2020	16	Tabrecta Tablets 150 mg Tabrecta Tablets 200 mg (Novartis Pharma K.K.)	Approval Approval	<u>Capmatinib hydrochloride hydrate</u>	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent <i>MET</i> exon 14 (<i>MET</i> ex14) skipping mutation-positive non-small-cell lung cancer. [Orphan drug]
5	Jun. 29, 2020	17	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).
3-2	Jun. 29, 2020	18	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.
Oncology drugs	Jun. 29, 2020	19	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.
Bio-CMC	Jun. 29, 2020	20	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).

New Drugs Approved in July 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Jul. 21, 2020	1	Silgard9 Aqueous Suspension for Intramuscular Injection Syringes (MSD K.K.)	Approval	<u>Recombinant adsorbed 9-valent human papillomavirus virus-like particle vaccine (yeast origin)</u>	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: <ul style="list-style-type: none"> • 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 neoplasia (VaIN) 1, 2, and 3 • Condyloma acuminatum

New Drugs Approved in August 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-2	Aug. 21, 2020	1	[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	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)]
Blood products	Aug. 21, 2020	2	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	Albtrepenonacog alfa (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with blood coagulation factor IX deficiency.
Oncology drugs	Aug. 21, 2020	3	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	4	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	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	5	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	6	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.
6-1	Aug. 21, 2020	7	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]
Oncology drugs	Aug. 21, 2020	8	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]

New Drugs Approved in September 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: New active ingredient)	Notes
5	Sep. 25, 2020	1	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
1	Sep. 25, 2020	2	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	3	Ecclock Gel 5% (Kaken Pharmaceutical Co., Ltd.)	Approval	<u>Sofpironium bromide</u>	A drug with a new active ingredient indicated for the treatment of primary axillary hyperhidrosis.
1	Sep. 25, 2020	4	Enaroy Tablets 2 mg Enaroy Tablets 4 mg (Japan Tobacco Inc.)	Approval Approval	<u>Enarodustat</u>	Drugs with a new active ingredient indicated for the treatment of renal anemia.
3-1	Sep. 25, 2020	5	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	6	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	7	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]
3-2	Sep. 25, 2020	8	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.
6-1	Sep. 25, 2020	9	Jyseleca Tablets 100 mg Jyseleca Tablets 200 mg (Gilead Sciences K.K.)	Approval Approval	<u>Filgotinib maleate</u>	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.

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Oncology drugs	Sep. 25, 2020	10	Zejula Capsules 100 mg (Takeda Pharmaceutical Company Limited)	Approval	<u>Niraparib tosilate hydrate</u>	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	11	Akalux IV Infusion 250 mg (Rakuten Medical Japan K.K.)	Approval	<u>Cetuximab sarotalocan sodium (genetical recombination)</u>	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	12	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	13	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	14	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	15	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	16	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]
6-1	Sep. 25, 2020	17	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.

New Drugs Approved in October 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: New active ingredient)	Notes
3-2	Oct. 29, 2020	1	Oxycontin TR Tablets 5 mg Oxycontin TR Tablets 10 mg Oxycontin TR Tablets 20 mg Oxycontin TR Tablets 40 mg (Shionogi Pharma Co., Ltd)	Change Change Change Change	Oxycodone <u>hydrochloride hydrate</u>	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.

New Drugs Approved in November 2020

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Nov. 27, 2020	1	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).
1	Nov. 27, 2020	2	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.
4	Nov. 27, 2020	3	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	4	Lasvic Intravenous Drip Infusion Kit 150 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	Lascafloracin 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 <i>Staphylococcus</i> spp, <i>Streptococcus</i> spp, <i>Streptococcus pneumoniae</i> , <i>Enterococcus</i> spp, <i>Moraxella (Branhamella) catarrhalis</i> , <i>Escherichia coli</i> , <i>Klebsiella</i> spp, <i>Enterobacter</i> spp, <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , <i>Peptostreptococcus</i> spp, <i>Veillonella</i> spp, <i>Bacteroides</i> spp, <i>Prevotella</i> spp, <i>Porphyromonas</i> spp, <i>Fusobacterium</i> spp, and <i>Mycoplasma pneumoniae</i> .
6-1	Nov. 27, 2020	5	(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 trifenate	(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	6	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	7	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]
Oncology drugs	Nov. 27, 2020	8	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	9	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]
Oncology drugs	Nov. 27, 2020	10	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]

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Oncology drugs	Nov. 27, 2020	11	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	12	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	13	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	14	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	15	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.

New Drugs Approved in December 2020

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	1	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	2	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	3	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]
6-1	Dec. 25, 2020	4	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.
Vaccines	Dec. 25, 2020	5	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: <ul style="list-style-type: none"> • Cervical cancer (squamous cell carcinoma and adenocarcinoma) 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 neoplasia (VaIN) 1, 2, and 3 • Anal cancer (squamous cell carcinoma) and its precursor lesions (anal intraepithelial neoplasia [AIN] 1, 2, and 3) • Condyloma acuminatum
3-1	Dec. 25, 2020	6	(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.
6-2	Dec. 25, 2020	7	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]
Oncology drugs	Dec. 25, 2020	8	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]
Oncology drugs	Dec. 25, 2020	9	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]

New Drugs Approved in January 2021

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jan. 22, 2021	1	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	2	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	<u>Molidustat sodium</u>	Drugs with a new active ingredient indicated for the treatment of renal anemia.
6-2	Jan. 22, 2021	3	Sogroya Subcutaneous Injection 5 mg Sogroya Subcutaneous Injection 10 mg (Novo Nordisk Pharma Ltd.)	Approval Approval	<u>Somapacitan</u> (<u>genetical</u> <u>recombination</u>)	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	4	Hunterase ICV Injection 15 mg (Clinigen K.K.)	Approval	<u>Idursulfase beta</u> (<u>genetical</u> <u>recombination</u>)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type II. [Orphan drug]
2	Jan. 22, 2021	5	Emgality Subcutaneous Injection 120 mg Autoinjectors Emgality Subcutaneous Injection 120 mg Syringe (Eli Lilly Japan K.K.)	Approval Approval	<u>Galcanezumab</u> (<u>genetical</u> <u>recombination</u>)	Drugs with a new active ingredient indicated for the prevention of migraine attacks.
2	Jan. 22, 2021	6	(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.
5	Jan. 22, 2021	7	Zymso Intravesical Solution 50% (Kyorin Pharmaceutical Co., Ltd.)	Approval	<u>Dimethyl sulfoxide</u>	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]
1	Jan. 22, 2021	8	(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	9	Adlumiz Tablets 50 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Anamorelin</u> <u>hydrochloride</u>	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.
6-1	Jan. 22, 2021	10	Orladeyo Capsules 150 mg (OrphanPacific, Inc.)	Approval	<u>Berotrastat</u> <u>hydrochloride</u>	A drug with a new active ingredient indicated for the prophylaxis of acute attacks of hereditary angioedema. [SAKIGAKE review, orphan drug]
Oncology drugs	Jan. 22, 2021	11	Calquence Capsules 100 mg (AstraZeneca K.K.)	Approval	<u>Acalabrutinib</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Blood products	Jan. 22, 2021	12	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	<u>Simoctocog alfa</u> (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	13	Lynspad for Intravenous Infusion 1000 mg (Grifols Therapeutics LLC)	Approval	<u>Lyophilized human alpha1-proteinase inhibitor concentrate</u>	A drug with a new active ingredient indicated for the augmentation and maintenance therapy of severe alpha 1-antitrypsin deficiency. [Orphan drug]
Oncology drugs	Jan. 22, 2021	14	Alunbrig Tablets 30 mg Alunbrig Tablets 90 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Brigatinib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable advanced/recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer.
Bio-CMC	Jan. 22, 2021	15	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.

***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