

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	<u>Sutimlimab (genetical recombination)</u>	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	<u>Purified pineapple stem juice</u>	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 Injection 1080 mg (Swedish Orphan Biovitrum Japan Co., Ltd.)	Approval	<u>Pegcetacoplan</u>	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	<u>Mirikizumab (genetical recombination)</u>	(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	<u>Vosoritide (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of achondroplasia prior to epiphyseal closure. [Orphan drug]

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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	<u>Tirzepatide</u>	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	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	Palyzqi Subcutaneous Injection 2.5 mg Palyzqi Subcutaneous Injection 10 mg Palyzqi Subcutaneous Injection 20 mg (BioMarin Pharmaceutical Japan K.K.)	Approval Approval Approval	<u>Pegvaliase (genetical recombination)</u>	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	<u>Cholic acid</u>	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	<u>Caplacizumab (genetical recombination)</u>	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	<u>Donepezil</u>	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	Treprostnil	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	<u>Foslevodopa, Foscarbidopa hydrate</u>	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	<u>Fostamatinib sodium hydrate</u>	Drugs with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]

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2	Mar. 27, 2023	27	Doptelet Tablets 20 mg (Swedish Orphan Biovitrum Japan Co., Ltd.)	Approval	<u>Avatrombopag maleate</u>	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	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]

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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	<u>Selumetinib sulfate</u>	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	<u>Vutrisiran sodium</u>	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	<u>Fenfluramine hydrochloride</u>	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).

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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 <i>Staphylococcus aureus</i> (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	<u>Tixagevimab (genetical recombination)</u> , <u>Cilgavimab (genetical recombination)</u>	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	<u>Ensitrelvir fumaric acid</u>	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]

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4	Dec. 23, 2022	61	Cresemba Capsules 100 mg Cresemba for I.V. Infusion 200 mg (Asahi Kasei Pharma Corporation)	Approval Approval	<u>Isavuconazonium sulfate</u>	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-sensitive <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., <i>Streptococcus pneumoniae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Klebsiella pneumoniae</i> , <i>Enterobacter</i> spp., <i>Serratia</i> spp., <i>Haemophilus influenzae</i> , <i>Pseudomonas aeruginosa</i> , and <i>Acinetobacter</i> 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	<u>Ozoralizumab (genetical recombination)</u>	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	<u>Spesolimab (genetical recombination)</u>	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	<u>Tezepelumab (genetical recombination)</u>	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	<u>Deucravacitinib</u>	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.

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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	<u>Tralokinumab (genetical recombination)</u>	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	<u>1) 2) Cabotegravir</u> <u>3) Cabotegravir sodium</u> <u>4) 5) Rilpivirine</u>	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	<u>Darinaparsin</u>	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	<u>Pimipespib</u>	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 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 <i>BRCA</i> 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	<u>Valemetostat tosilate</u>	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	Erbix 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 <i>RAS</i> 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 the treatment 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 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 Capsules T20 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	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	<u>Tremelimumab</u> (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	<u>Cemiplimab</u> (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	<u>Ropeginterferon alfa-2b</u> (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 <i>FGFR1</i> 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 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	<u>Recombinant coronavirus (SARS- CoV-2) vaccine</u>	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	<u>COVID-19 (SARS-CoV- 2) vaccine (recombinant adenovirus vector)</u>	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	<u>Neisseria meningitidis polysaccharides conjugated to tetanus toxoid (serogroups A, C, W, and Y)</u>	A drug with a new active ingredient indicated for the prophylaxis of invasive meningococcal disease caused by <i>Neisseria meningitidis</i> (serogroups A, C, W and Y).

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	<u>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</u>	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 neoplasia (VaIN) 1, 2, and 3 • Condyloma acuminatum [Expedited review]
Vaccines	Mar. 27, 2023	131	Fulmist Intranasal Spray (Daiichi Sankyo Company, Limited)	Approval	<u>Live attenuated influenza virus (type A and type B)</u>	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 <i>Bordetella pertussis</i> Diphtheria toxoid Tetanus toxoid Inactivated poliovirus types 1-3 (Sabin strain) <u>Haemophilus influenzae type b oligosaccharide - diphtheria CRM₁₉₇ conjugate</u>	A new combination drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, acute poliomyelitis, and infections caused by <i>Haemophilus influenzae type b</i> .
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	Beriner 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	<u>Anti-human thymocyte immunoglobulin, equine</u>	A drug with a new active ingredient indicated for the treatment of moderate to severe aplastic anemia. [Orphan drug]

***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