

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	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	<u>Tenapanor hydrochloride</u>	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]

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1	Jan. 18, 2024	11	(1) Rapalimus Granules 0.2% (2) Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Approval Change	<u>Sirolimus</u>	(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	<u>Danicopan</u>	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	<u>Empagliflozin</u>	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	<u>Cyclophosphamide hydrate</u>	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	<u>Zinc histidine hydrate</u>	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	<u>Crovalimab (genetical recombination)</u>	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	<u>Belumosudil mesilate</u>	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	<u>Somapacitan (genetical recombination)</u>	(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	<u>Febuxostat</u>	(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	<u>Somatropin (genetical recombination)</u>	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	<u>Somatropin (genetical recombination)</u>	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	<u>Lonafarnib</u>	Drugs with a new active ingredient indicated for the treatment of Hutchinson-Gilford Progeria syndrome and 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	<u>Pemafibrate</u>	Drugs in a new dosage form indicated for the treatment of hyperlipidaemia (including familial hyperlipidaemia).

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2	Sep. 25, 2023	24	Leqvio for S.C. Injection Syringe 300 mg (Novartis Pharma K.K.)	Approval	<u>Inclisiran sodium</u>	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	<u>Lecanemab</u> <u>(genetical</u> <u>recombination)</u>	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	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	<u>Evinacumab</u> <u>(genetical</u> <u>recombination)</u>	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	<u>Efgartigimod alfa</u> <u>(genetical</u> <u>recombination)</u>	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	<u>Apadamtase alfa</u> <u>(genetical</u> <u>recombination)/</u> <u>Cinaxadamtase alfa</u> <u>(genetical</u> <u>recombination)</u>	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	<u>Mifepristone</u> 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.

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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.
<i>In vivo diagnostics</i>	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	<u>Zilucoplan sodium</u>	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	<u>Rozanolixizumab</u> (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]

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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	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	Vyvatura Combination Subcutaneous Injection (Argenx Japan K.K.)	Approval	Efgartigimod alfa (genetical recombination) and <u>Vorhyaluronidase alfa</u> (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	<u>Aceneuramic acid</u>	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	<u>Difelikefalin acetate</u>	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	<u>Aflibercept</u> (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% (Viartis Pharmaceuticals Japan Inc.)	Approval	<u>Cysteamine</u> <u>hydrochloride</u>	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	<u>Faricimab</u> (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	<u>Cefiderocol tosilate</u> <u>sulfate hydrate</u>	A drug with a new active ingredient indicated for the treatment of infections caused by Cefiderocol-sensitive <i>Escherichia coli</i> , <i>Citrobacter</i> spp, <i>Klebsiella pneumoniae</i> , <i>Klebsiella</i> spp, <i>Enterobacter</i> spp, <i>Serratia marcescens</i> , <i>Proteus</i> spp, <i>Morganella morganii</i> , <i>Pseudomonas aeruginosa</i> , <i>Burkholderia</i> spp, <i>Stenotrophomonas maltophilia</i> , and <i>Acinetobacter</i> 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	<u>Ensitrelvir fumaric</u> <u>acid</u>	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19).

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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	Rifaxima 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	<u>Ritlecitinib tosilate</u>	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	<u>Lebrikizumab (genetical recombination)</u>	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.

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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) Fasenera Subcutaneous Injection 30 mg Syringe (2) Fasenera 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	<u>Sargramostim</u> (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	<u>Lenacapavir sodium</u>	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	<u>Pegaspargase</u>	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	<u>Futibatinib</u>	A drug with a new active ingredient indicated for the treatment of unresectable <i>FGFR2</i> 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 <i>HER2</i> (<i>ERBB2</i>) mutation-positive non-small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]

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 <i>BRCA</i> 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 <u>Vorhyaluronidase alfa (genetical recombination)</u>	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	<u>Epcoritamab (genetical recombination)</u>	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 <i>BRAF</i> mutation-positive solid tumor (excluding colon/rectal cancer) that is refractory or intolerant to standard therapies and relapsed or refractory <i>BRAF</i> 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 <i>BRAF</i> mutation-positive solid tumor (excluding colon/rectal cancer) that is refractory or intolerant to standard therapies and relapsed or refractory <i>BRAF</i> 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 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	<u>Talazoparib tosilate</u>	(1) A drug with a new active ingredient indicated for the treatment of <i>BRCA</i> mutation-positive, metastatic castration-resistant prostate cancer. (2) A drug with a new active ingredient indicated for the treatment of <i>BRCA</i> mutation-positive, metastatic castration-resistant prostate cancer and unresectable or recurrent <i>BRCA</i> 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 <i>BRCA</i> 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	<u>Luspatercept</u> (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	<u>Capivasertib</u>	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 <i>PIK3CA</i> , <i>AKT1</i> , or <i>PTEN</i> mutation that has progressed after endocrine therapy.
Oncology drugs	Mar. 26, 2024	95	Vyloy for I.V. Infusion 100 mg (Astellas Pharma Inc.)	Approval	<u>Zolbetuximab</u> (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	<u>Elranatamab</u> (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 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	<u>Ufrenmeran</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, 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	(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) <u>Haemophilus influenzae type b polysaccharide-tetanus toxoid 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> .
Vaccines	Sep. 25, 2023	109	Arexvy Intramuscular Injection (GlaxoSmithKline K.K.)	Approval	<u>Recombinant respiratory syncytial virus PreF3 antigen</u>	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	<u>Zapomeran</u>	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]

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, <u>MAFB-7256a</u>	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	<u>Respiratory syncytial virus-A prefusion F protein</u> <u>Respiratory syncytial virus-B prefusion F protein</u>	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	<u>Inactivated tick-borne encephalitis virus</u>	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	<u>Pneumococcal polysaccharide conjugated to CRM197 carrier protein</u>	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	<u>Concizumab (genetical recombination)</u>	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	Altuviiiio Intravenous 250 Altuviiiio Intravenous 500 Altuviiiio Intravenous 1000 Altuviiiio Intravenous 2000 Altuviiiio Intravenous 3000 Altuviiiio Intravenous 4000 (Sanofi K.K.)	Approval Approval Approval Approval Approval Approval	<u>Efanesoctocog alfa (genetical recombination)</u>	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	<u>Human normal immunoglobulin G (pH4-treated acidic normal human immunoglobulin [subcutaneous injection])</u>	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Mar. 26, 2024	122	Ceprotrin for Intravenous Injection 1000 IU (Takeda Pharmaceutical Company Limited)	Approval	<u>Human protein C</u>	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 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	<u>Susoctocog alfa</u> (<u>genetical</u> <u>recombination</u>)	A drug with a new active ingredient indicated for the control of bleeding episodes in patients with acquired hemophilia A. [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