

New Drugs Approved in April 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
5	Apr. 28, 2023	1	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.

New Drugs Approved in May 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	May 25, 2023	1	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).
6-1	May 25, 2023	2	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.
Oncology drugs	May 25, 2023	3	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	4	Cylocide Injection 20 mg Cylocide Injection 40 mg Cylocide Injection 60 mg Cylocide Injection 100 mg Cylocide Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Change Change Change Change	Cytarabine	Drugs with a new dosage indicated for the treatment of acute leukemia. [Public knowledge-based application, Expedited review]
Oncology drugs	May 25, 2023	5	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]

New Drugs Approved in June 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).
6-2	Jun. 26, 2023	2	(1) Sogroya Subcutaneous Injection 5 mg (1) Sogroya Subcutaneous Injection 10 mg (2) Sogroya Subcutaneous Injection 15 mg (Novo Nordisk Pharma Ltd.)	Change Change Approval	Somapacitan (genetical recombination)	(1) Drugs with a new indication, a new dosage, and other characteristics for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure. (2) A drug with a new indication and a new dosage in an additional dosage form for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure.
6-2	Jun. 26, 2023	3	(1) Feburic Tablet 10 mg (2) Feburic Tablet 20 mg (2) Feburic Tablet 40 mg (Teijin Pharma Limited)	Change Change Change	Febuxostat	(1) A drug with a new additional pediatric dosage and other characteristics indicated for the treatment of gout and hyperuricemia. (2) Drugs with a new additional pediatric dosage indicated for the treatment of gout and hyperuricemia.
3-1	Jun. 26, 2023	4	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.
Oncology drugs	Jun. 26, 2023	5	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	6	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	7	Keytruda Injection 100 mg (MSD K.K.)	Change	<u>Pembrolizumab</u> (genetical recombination)	A drug with a new indication for the treatment of relapsed or refractory primary mediastinal large B-cell lymphoma. [Orphan drug]
Vaccines	Jun. 26, 2023	8	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.
6-1	Jun. 26, 2023	9	Dupixent 300 mg Syringe for S.C. Injection Dupixent 300 mg Pen for S.C. Injection (Sanofi K.K.)	Change Change	<u>Dupilumab</u> (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	10	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).
6-2	Jun. 26, 2023	11	Growject S.C. Injection 6 mg Growject S.C. Injection 12 mg (JCR Pharmaceuticals Co., Ltd.)	Change Change	Somatropin (genetical recombination)	Drugs with a new indication for the treatment of short stature in SHOX deficiency prior to epiphyseal closure.
1	Jun. 26, 2023	12	(1) Rinvoq Tablets 7.5 mg (2) Rinvoq Tablets 15 mg (3) Rinvoq Tablets 30 mg (4) Rinvoq Tablets 45 mg (AbbVie GK)	Change Change Change Change	<u>Upadacitinib hydrate</u>	(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).
2	Jun. 26, 2023	13	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).
Blood products	Jun. 26, 2023	14	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.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Jun. 26, 2023	15	Shingrix for I.M. Injection (Glaxo SmithKline K.K.)	Change	<u>Varicella zoster virus</u> gE antigen	A drug with a new dosage indicated for the prevention of herpes zoster.
Blood products	Jun. 26, 2023	16	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	<u>Ruriococog alfa</u> pegol (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.

New Drugs Approved in August 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
AIDS drugs	Aug. 1, 2023	1	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]
Vaccines	Aug. 2, 2023	2	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	3	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	4	(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]
1	Aug. 23, 2023	5	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]
3-1	Aug. 23, 2023	6	Soliris for Intravenous Infusion 300 mg (Alexion Pharma GK)	Change	Ecilizumab (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]
1	Aug. 23, 2023	7	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)]
Oncology drugs	Aug. 23, 2023	8	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]
Oncology drugs	Aug. 23, 2023	9	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.
6-1	Aug. 23, 2023	10	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.
Radio-pharmaceuticals	Aug. 23, 2023	11	FDGscan Injectible (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	12	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]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Radio-pharmaceuticals	Aug. 31, 2023	13	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]

New Drugs Approved in September 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Sep. 25, 2023	1	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> .
Blood products	Sep. 25, 2023	2	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</u> (<u>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]
Oncology drugs	Sep. 25, 2023	3	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.
1	Sep. 25, 2023	4	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.
3-2	Sep. 25, 2023	5	Korsuva IV Injection Syringe for Dialysis 17.5 µ g Korsuva IV Injection Syringe for Dialysis 25.0 µ g Korsuva IV Injection Syringe for Dialysis 35.0 µ g (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).
3-1	Sep. 25, 2023	6	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	7	Rystiggo for S.C. Injection 280 mg (UCB Japan Co., Ltd.)	Approval	<u>Rozanolixizumab</u> (<u>genetical recombination</u>)	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]
2	Sep. 25, 2023	8	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	9	Leqembi for Intravenous Infusion 200 mg Leqembi for Intravenous Infusion 500 mg (Eisai Co., Ltd.)	Approval Approval	<u>Lecanemab</u> (<u>genetical 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]
Blood products	Sep. 25, 2023	10	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</u> (<u>genetical recombination</u>)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Blood products	Sep. 25, 2023	11	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.
Vaccines	Sep. 25, 2023	12	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.
Oncology drugs	Sep. 25, 2023	13	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.
6-1	Sep. 25, 2023	14	(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.
Bio-CMC	Sep. 25, 2023	15	(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	16	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
1	Sep. 25, 2023	17	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.
<i>In vivo diagnostics</i>	Sep. 25, 2023	18	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)]
2	Sep. 25, 2023	19	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]
1	Sep. 25, 2023	20	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).

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	21	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).
Oncology drugs	Sep. 25, 2023	22	(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	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	23	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.

New Drugs Approved in October 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Oct. 24, 2023	1	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]

New Drugs Approved in November 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
2	Nov. 24, 2023	1	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.
Oncology drugs	Nov. 24, 2023	2	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	3	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	4	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	5	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	6	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.
Vaccines	Nov. 28, 2023	7	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]
Vaccines	Nov. 28, 2023	8	Daichirona for Intramuscular Injection (Daiichi Sankyo Company, Limited)	Change	<u>Ufrenmeran, 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).
4	Nov. 30, 2023	9	Fetroja for Intravenous Drip Infusion 1 g (Shionogi & Co., Ltd.)	Approval	<u>Cefiderocol tosilate 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]

New Drugs Approved in December 2023

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Dec. 22, 2023	1	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	Brexipiprazole	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).
1	Dec. 22, 2023	2	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	3	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]
6-1	Dec. 22, 2023	4	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.
Radio-pharmaceuticals	Dec. 22, 2023	5	MyoMIBG-1123 Injection (PDRadiopharma Inc.)	Change	<u>3-Iodobenzylguanidine</u> (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.
1	Dec. 22, 2023	6	Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Capsules 5 mg Prograf Granules 0.2 mg Prograf Granules 1 mg Gracaptor Capsules 0.5 mg Gracaptor Capsules 1 mg Gracaptor Capsules 5 mg (Astellas Pharma Inc.)	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]
6-2	Dec. 22, 2023	7	Genotropin TC Inj. 5.3 mg Genotropin TC Inj. 12 mg Genotropin GoQuick Inj. 5.3 mg Genotropin GoQuick Inj. 12 mg (Pfizer Japan Inc.)	Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new indication and a new dosage for the improvement of body composition in patients with Prader-Willi syndrome. [Orphan drug]

New Drugs Approved in January 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
3-1	Jan. 18, 2024	1	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	2	Vyvdura Combination Subcutaneous Injection (Argenx Japan K.K.)	Approval	Efgartigimod alfa (genetical recombination) and <u>Vorhyaluronidase alfa (genetical recombination)</u>	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).
3-2	Jan. 18, 2024	3	Eylea 8 mg Solution for IVT Inj. 114.3 mg/mL (Bayer Yakuhin, Ltd.)	Approval	Aflibercept (genetical recombination)	A drug in a new dosage form indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema.
1	Jan. 18, 2024	4	(1) Rapalimus Granules 0.2% (2) Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Approval Change	Sirolimus	(1) A drug with a new indication and a new dosage in an additional dosage form and (2) a drug with a new indication and a new dosage, for the treatment of the following refractory vascular tumors and refractory vascular malformations: lymphangioma (lymphatic malformation), lymphangiomatosis, Gorham disease, lymphangiectasia, hemangioendothelioma, tufted angioma, venous malformation, blue rubber bleb nevus syndrome, mixed vascular malformation and Klippel-Trenaunay-Weber syndrome. [Orphan drug]
1	Jan. 18, 2024	5	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]
6-2	Jan. 18, 2024	6	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 processing-deficient progeroid laminopathies. [Orphan drug]
2	Jan. 18, 2024	7	Evkeeza for intravenous infusion 345 mg (Ultragenyx Japan K.K.)	Approval	<u>Evinacumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of homozygous familial hypercholesterolemia. [Orphan drug]
6-1	Jan. 18, 2024	8	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.
Vaccines	Jan. 18, 2024	9	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.

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	10	(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	11	Reblozyl for S.C. Injection 25 mg Reblozyl for S.C. Injection 75 mg (Bristol-Myers Squibb K.K.)	Approval Approval	<u>Luspatercept</u> <u>(genetical</u> <u>recombination)</u>	Drugs with a new active ingredient indicated for the treatment of anemia associated with myelodysplastic syndrome. [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