

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 (Daichi 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 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	Pembrolizumab (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	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	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	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).
2	Jun. 26, 2023	13	Parmodia XR Tablets 0.2 mg Parmodia XR Tablets 0.4 mg (Kowa Company, Ltd.)	Approval Approval	Pemafibrate	Drugs in a new dosage form indicated for the treatment of hyperlipidaemia (including familial hyperlipidaemia).
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.

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Vaccines	Jun. 26, 2023	15	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.
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 Change	Ruriotocog alfa 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, Elasomelan and Imelasomelan, Elasomelan 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 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	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]
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 Injectable (Nihon Medi-Physics Co., Ltd.)	Change	Fludeoxyglucose ( <sup>18</sup> 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 ( <sup>18</sup> 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]

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Radio-pharmaceuticals	Aug. 31, 2023	13	Amyvid Injection (PDRadiopharma Inc.)	Change	florbetapir ( <sup>18</sup> 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 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