

New Drugs Approved in May 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	May 17, 2024	1	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer.
4	May 17, 2024	2	Prevymis Tablets 240 mg Prevymis Intravenous Infusion 240 mg (MSD K.K.)	Change Change	Letermovir	Drugs with a new indication for the prophylaxis of cytomegalovirus disease in organ transplantation.
Oncology drugs	May 17, 2024	3	Braftovi Capsules 50 mg Braftovi Capsules 75 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Encorafenib	Drugs with new indications and a new dosage for the treatments of unresectable <i>BRAF</i> mutation-positive thyroid cancer that has progressed after cancer chemotherapy and unresectable <i>BRAF</i> mutation-positive anaplastic thyroid cancer.
Oncology drugs	May 17, 2024	4	Mektovi Tablets 15 mg (Ono Pharmaceutical Co., Ltd.)	Change	Binimetinib	A drug with new indications and a new dosage for the treatments of unresectable <i>BRAF</i> mutation-positive thyroid cancer that has progressed after cancer chemotherapy and unresectable <i>BRAF</i> mutation-positive anaplastic thyroid cancer.
Oncology drugs	May 17, 2024	5	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable biliary tract cancer.
Oncology drugs	May 17, 2024	6	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Kirin Co., Ltd.)	Change	Pegfilgrastim (genetical recombination)	A drug with a new indication for the mobilization of hematopoietic stem cells to the peripheral blood for autologous hematopoietic stem cell transplantation.

New Drugs Approved in June 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	Jun. 24, 2024	1	Nexium Capsules 10 mg Nexium Capsules 20 mg Nexium Granules for Suspension 10 mg Nexium Granules for Suspension 20 mg (AstraZeneca K.K.)	Change Change Change Change	Esomeprazole magnesium hydrate	Drugs with a new additional pediatric dosage indicated for the prevention of recurrent reflux esophagitis and gastric or duodenal ulcer after dosing non-steroid anti-inflammatory drugs, and prevention of recurrent gastric or duodenal ulcer after dosing low-dose aspirins.
1	Jun. 24, 2024	2	Fabhalta Capsules 200 mg (Novartis Pharma K.K.)	Approval	<u>Iptacopan</u> <u>hydrochloride hydrate</u>	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal haemoglobinuria.
1	Jun. 24, 2024	3	Vtama Cream 1% (Japan Tobacco Inc.)	Approval	<u>Tapinarof</u>	A drug with a new active ingredient indicated for the treatment of atopic dermatitis and plaque psoriasis.
6-2	Jun. 24, 2024	4	Awikli Injection FlexTouch 300 Units Awikli Injection FlexTouch 700 Units (Novo Nordisk Pharma Ltd.)	Approval Approval	<u>Insulin icodec</u> <u>(genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
3-1	Jun. 24, 2024	5	(1) Briviact Tablets 25 mg (2) Briviact Tablets 50 mg (3) Briviact for I.V. Injection 25 mg (UCB Japan Co., Ltd.)	Approval Approval Approval	<u>Brivaracetam</u>	(1) (2) Drugs with a new active ingredient indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. (3) A drug with a new active ingredient indicated for the following treatment; partial seizures (including secondary generalized seizures) in patients with epilepsy. It is used as an alternative therapy for blevaracetam oral formulation in patients who are temporarily unable to be administered orally.
Oncology drugs	Jun. 24, 2024	6	Jaypirca Tablets 50 mg Jaypirca Tablets 100 mg (Eli Lilly Japan K.K.)	Approval Approval	<u>Pirtobrutinib</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory mantle cell lymphoma with resistance or intolerance to other BTK inhibitors.
4	Jun. 24, 2024	7	Avigan Tablets 200 mg (Fujifilm Toyama Chemical Co., Ltd.)	Change	Favipiravir	A drug with a new indication and a new dosage for the treatment of severe fever with thrombocytopenia syndrome virus infection. [Orphan drug]
6-1	Jun. 24, 2024	8	(1) Relvar 50 Ellipta 14 dose for Pediatric (2) Relvar 50 Ellipta 30 dose for Pediatric (3) Relvar 100 Ellipta 14 dose (4) Relvar 100 Ellipta 30 dose (GlaxoSmithKline K.K.)	Approval Approval Change Change	Fluticasone furoate/Vilanterol trifenatate	(1) (2) New combination drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed). (3) (4) Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
Vaccines	Jun. 24, 2024	9	Covgoze Intramuscular Injection (Shionogi & Co., Ltd.)	Approval	<u>Recombinant coronavirus (SARS-CoV-2) spike protein antigen</u>	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Priority review]
4	Jun. 24, 2024	10	Zavicefta Combination for Intravenous Infusion (Pfizer Japan Inc.)	Approval	<u>Avibactam sodium</u> /Ceftazidime hydrate	A new combination drug with a new active ingredient indicated for the treatment of sepsis, pneumonia, cystitis, pyelonephritis, peritonitis, intra-abdominal abscess, cholecystitis, and liver abscess caused by Zavicefta-sensitive <i>Escherichia coli</i> , <i>Citrobacter</i> spp., <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>Serratia</i> spp., <i>Proteus</i> spp., <i>Morganella morganii</i> , <i>Haemophilus influenzae</i> , and <i>Pseudomonas aeruginosa</i> .
4	Jun. 24, 2024	11	Livtency Tablets 200 mg (Takeda Pharmaceutical Company Limited)	Approval	<u>Maribavir</u>	A drug with a new active ingredient indicated for the treatment of cytomegalovirus disease in organ transplantation (including hematopoietic stem cell transplantation) that is refractory to conventional anti-cytomegalovirus therapy. [Orphan drug]

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Vaccines	Jun. 24, 2024	12	Typhim Vi Syringe for Injection (Sanofi K.K.)	Approval	<u>Salmonella typhi</u> (TY2 strain) <u>purified</u> <u>Vi capsular</u> <u>polysaccharide</u>	A drug with a new active ingredient indicated for the prevention of typhoid fever.
Oncology drugs	Jun. 24, 2024	13	Targretin Capsules 75 mg (Minophagen Pharmaceutical Co., Ltd.)	Change	Bexarotene	A drug with a new indication for the treatment of adult T-cell leukemia/lymphoma with skin lesions.
Oncology drugs	Jun. 24, 2024	14	Omijara Tablets 100 mg Omijara Tablets 150 mg Omijara Tablets 200 mg (GlaxoSmithKline K.K.)	Approval Approval Approval	<u>Momelotinib</u> <u>hydrochloride hydrate</u>	Drugs with a new active ingredient indicated for the treatment of myelofibrosis.
Oncology drugs	Jun. 24, 2024	15	Haiyitan Tablets 50 mg (Haihe Biopharma K. K.)	Approval	<u>Gumarontinib hydrate</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent <i>MET</i> exon 14 (METex14) skipping mutation-positive non-small cell lung cancer.
Oncology drugs	Jun. 24, 2024	16	Retevmo Capsules 40 mg Retevmo Capsules 80 mg (Eli Lilly Japan K.K.)	Change Change	Selpercatinib	Drugs with a new indication and a new dosage for the treatment of <i>RET</i> fusion gene-positive advanced or recurrent solid tumor. [Orphan drug]
Oncology drugs	Jun. 24, 2024	17	Ezharmia Tablets 50 mg Ezharmia Tablets 100 mg (Daiichi Sankyo Company, Limited)	Change Change	Valemetostat tosilate	Drugs with a new indication for the treatment of relapsed or refractory peripheral T-cell lymphoma. [SAKIGAKE review]
Bio-CMC	Jun. 24, 2024	18	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL "GRP" (Global Regulatory Partners GK)	Approval	Aflibercept (genetical recombination) [aflibercept biosimilar 1]	A biosimilar indicated for the treatment of macular edema following retinal vein occlusion, choroidal neovascularization in patients with pathologic myopia, and diabetic macular edema.
6-2	Jun. 24, 2024	19	(1) Trulicity Subcutaneous Injection 0.75 mg Ateos (2) Trulicity Subcutaneous Injection 1.5 mg Ateos (Eli Lilly Japan K.K.)	Change Approval	Dulaglutide (genetical recombination)	(1) A drug with a new dosage for the treatment of type 2 diabetes mellitus. (2) A drug with a new dosage in an additional dosage form for the treatment of type 2 diabetes mellitus.
3-1	Jun. 24, 2024	20	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new indication and a new additional pediatric dosage for the treatment of upper and lower limb spasticity.
1	Jun. 24, 2024	21	(1) Skyrizi Intravenous Infusion 600 mg (2) Skyrizi for Subcutaneous Injection 360 mg Auto Dosers (3) Skyrizi for Subcutaneous Injection 180 mg Auto Dosers (AbbVie GK)	Change Change Approval	Risankizumab (genetical recombination)	1) A drug with a new indication and a new dosage for the remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments). (2) (3) Drugs with a new indication and a new dosage in an additional dosage form for the maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Jun. 24, 2024	22	Benlysta for S.C. Injection 200 mg Autoinjector (GlaxoSmithKline K.K.)	Change	Belimumab (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 24, 2024	23	Cellcept Capsules 250 Cellcept Powder for Oral Suspension 31.8% (Chugai Pharmaceutical Co., Ltd.)	Change Change	Mycophenolate mofetil	Drugs with a new indication and a new dosage for the treatment of systemic sclerosis-associated interstitial lung disease. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
Blood products	Jun. 24, 2024	24	Alhemo Subcutaneous Injection 15 mg Alhemo Subcutaneous Injection 60 mg Alhemo Subcutaneous Injection 150 mg Alhemo Subcutaneous Injection 300 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change	Concizumab (genetical recombination)	Drugs with a new indication for the control of bleeding tendency in patients with congenital haemophilia who do not have inhibitors against blood coagulation factor VIII or IX.

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Oncology drugs	Jun. 24, 2024	25	Paraplatin Injection 50 mg Paraplatin Injection 150 mg Paraplatin Injection 450 mg (Clinigen K.K.)	Change Change Change	Carboplatin	Drugs with a new indication and a new dosage for the treatment of endometrial cancer. [Public knowledge-based application after PAFSC's preliminary assessment]

New Drugs Approved in August 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Aug. 28, 2024	1	Nucala for s.c. Injection 100 mg Syringe Nucala for s.c. Injection 100 mg Pen (GlaxoSmithKline K.K.)	Change Change	Mepolizumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of chronic rhinosinusitis with nasal polyps (for use only in patients who have not responded sufficiently to conventional treatments).
Oncology drugs	Aug. 28, 2024	2	Alecensa Capsules 150mg (Chugai Pharmaceutical Co., Ltd.)	Change	Alectinib hydrochloride	A drug with a new indication, a new dosage, and other characteristics for the postoperative adjuvant treatment for anaplastic lymphoma kinase (<i>ALK</i>) fusion gene-positive non-small cell lung cancer. [Orphan drug]
2	Aug. 28, 2024	3	Azilva Tablets 10 mg Azilva Tablets 20 mg Azilva Granules 1% (Takeda Pharmaceutical Company Limited)	Change Change Change	Azilsartan	Drugs with a new additional pediatric dosage (aged 2 years to 5 years) indicated for the treatment of hypertension.
Oncology drugs	Aug. 28, 2024	4	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the preoperative and postoperative adjuvant treatment for non-small cell lung cancer.
Oncology drugs	Aug. 28, 2024	5	Alimta Injection 100 mg Alimta Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Pemetrexed sodium hydrate	Drugs with a new indication and a new dosage for the preoperative adjuvant treatment for non-squamous non-small cell lung cancer.
Oncology drugs	Aug. 28, 2024	6	Pemetrexed for I.V. Infusion 100 mg “NK” Pemetrexed for I.V. Infusion 500 mg “NK” Pemetrexed for I.V. Infusion 800 mg “NK” Pemetrexed Solution for I.V. Infusion 100 mg “NK” Pemetrexed Solution for I.V. Infusion 500 mg “NK” Pemetrexed Solution for I.V. Infusion 800 mg “NK” (Nippon Kayaku Co., Ltd.)	Change Change Change Change Change Change	Pemetrexed sodium hemipentahydrate	Drugs with a new dosage for the preoperative adjuvant treatment for non-squamous non-small cell lung cancer.
AIDS drugs	Aug. 28, 2024	7	Truvada Combination Tab. (Gilead Sciences, Inc.)	Change	Emtricitabine/ Tenofovir disoproxil fumarate	A drug with a new indication and a new dosage for the pre-exposure prophylaxis against HIV-1 infection. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
Vaccines	Aug. 28, 2024	8	Prevenar20 Suspension Liquid for Injection (Pfizer Japan Inc.)	Change	Pneumococcal polysaccharide conjugated to CRM197 carrier protein	A drug with a new indication and a new dosage for the prophylaxis of pneumococcal disease in the elderly and in individuals who are considered to be at a high risk of pneumococcal disease.

New Drugs Approved in September 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Vaccines	Sep. 5, 2024	1	Nuvaxovid Intramuscular Injection 1 mL (Takeda Pharmaceutical Company Limited)	Approval	SARS-CoV-2 rS (Omicron JN.1 variant)	A drug with a new indication, a new dosage, and other characteristics in an additional dosage form for the prevention of disease caused by SARS-CoV-2 infection (COVID-19).
Vaccines	Sep. 13, 2024	2	Kostaive Intramuscular Injection (Meiji Seika Pharma Co., Ltd.)	Change	mRNA encoding the spike protein of SARS-CoV-2 (Omicron JN.1 variant)	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).
2	Sep. 24, 2024	3	Kisunla Intravenous Infusion 350 mg (Eli Lilly Japan K.K.)	Approval	<u>Donanemab</u> (<u>genetical recombination</u>)	A drug with a new active ingredient indicated for slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease.
3-2	Sep. 24, 2024	4	Septocaine Combination Injection Cartridge (GC Showayakuhin Corporation)	Approval	<u>Articaine hydrochloride</u> / Adrenaline bitartrate	A new combination drug with a new active ingredient indicated for infiltration anesthesia or nerve block in the fields of dentistry and oral surgery.
Oncology drugs	Sep. 24, 2024	5	Fruzaqla Capsules 1 mg Fruzaqla Capsules 5 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Fruquintinib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Sep. 24, 2024	6	Tasfygo Tablets 35 mg (Eisai Co., Ltd.)	Approval	<u>Tasurgratinib succinate</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. [Orphan drug]
Vaccines	Sep. 24, 2024	7	Mearubik II Subcutaneous Injection (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Live attenuated measles virus (Tanabe strain) and <u>live attenuated rubella virus</u> (<u>Matsuura/J16 strain</u>)	A new combination drug with a new active ingredient indicated for the prevention of measles and rubella.
1	Sep. 24, 2024	8	Veltassa 8.4 g Powder for Suspension (Single-dose package) (Zeria Pharmaceutical Co., Ltd.)	Approval	<u>Patiromer sorbitex calcium</u>	A drug with a new active ingredient indicated for the treatment of hyperkalaemia.
1	Sep. 24, 2024	9	Lupkynis Capsules 7.9 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Voclosporin</u>	A drug with a new active ingredient indicated for the treatment of lupus nephritis.
1	Sep. 24, 2024	10	Venoglobulin IH 10% I.V. 0.5 g/5 mL Venoglobulin IH 10% I.V. 2.5 g/25 mL Venoglobulin IH 10% I.V. 5 g/50 mL Venoglobulin IH 10% I.V. 10 g/100 mL Venoglobulin IH 10% I.V. 20 g/200 mL (Japan Blood Products Organization)	Change Change Change Change Change	Polyethylene glycol treated human normal immunoglobulin	Drugs with new indications and a new dosage for 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]
6-2	Sep. 24, 2024	11	Tepezza for Intravenous Infusion 500 mg (Amgen K.K.)	Approval	<u>Teprotumumab</u> (<u>genetical recombination</u>)	A drug with a new active ingredient indicated for the treatment of active thyroid eye disease. [Orphan drug]
5	Sep. 24, 2024	12	Alyssa Combination Tablets (Fuji Pharma Co., Ltd.)	Approval	<u>Estetrol</u> <u>hydrate</u> /Drospirenone	A new combination drug with a new active ingredient indicated for the treatment of dysmenorrhea.
2	Sep. 24, 2024	13	Yuvanci Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Macitentan/Tadalafil	A new combination drug indicated for the treatment of pulmonary arterial hypertension.

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2	Sep. 24, 2024	14	Treprost Inhalation Solution 1.74 mg (Mochida Pharmaceutical Co., Ltd.)	Change	Treprostinil	A drug with a new indication and a new dosage for the treatment of pulmonary hypertension associated with interstitial lung disease. [Orphan drug]
3-1	Sep. 24, 2024	15	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 Change	Brexiprazole	Drugs with new indications and a new dosage for the treatment of excessive motor activity or verbal/physical aggression attributable to rapid changes in mood and/or irritability, outburst associated with Alzheimer's dementia.
3-1	Sep. 24, 2024	16	Quviviq Tablets 25 mg Quviviq Tablets 50 mg (Nexera Pharma Co., Ltd.)	Approval Approval	<u>Daridorexant hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Sep. 24, 2024	17	Firdapse Tablets 10 mg (DyDo Pharma, Inc.)	Approval	<u>Amifampridine phosphate</u>	A drug with a new active ingredient indicated for the improvement of muscle weakness in patients with Lambert-Eaton myasthenic syndrome. [Orphan drug]
3-1	Sep. 24, 2024	18	Rozebalaamin for Injection 25 mg (Eisai Co., Ltd.)	Approval	Mecobalamin	A drug with a new indication and a new dosage in an additional dosage form for slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis (ALS). [Orphan drug]
Oncology drugs	Sep. 24, 2024	19	Augtyro Capsules 40 mg (Bristol-Myers Squibb K.K.)	Approval	<u>Repotrectinib</u>	A drug with a new active ingredient indicated for the treatment of <i>ROS1</i> fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Sep. 24, 2024	20	Rybrevant Intravenous Infusion 350 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Amivantamab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent epidermal growth factor receptor (EGFR) gene exon 20 insertion mutation-positive non-small cell lung cancer.
6-1	Sep. 24, 2024	21	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 hidradenitis suppurativa.
Oncology drugs	Sep. 24, 2024	22	Trodelyv for Injection 200 mg (Gilead Sciences, Inc.)	Approval	<u>Sacituzumab govitecan (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of hormone receptor-negative and human epidermal growth factor receptor 2 (HER2)-negative unresectable or recurrent breast cancer in patients who have previously been treated with chemotherapy. [Priority review]
5	Sep. 24, 2024	23	Kidparen Injection (Otsuka Pharmaceutical Factory, Inc.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for the supplementation of water, electrolytes, calories, amino acids, and vitamins in patients with chronic renal failure (for use only in patients with or at a risk of hyperkalemia or hyperphosphatemia) for whom receiving oral or enteral nutrition is impossible or insufficient and the total parenteral nutrition is the only choice.
5	Sep. 24, 2024	24	Enosolid Semi Solid for Enteral Use (EN Otsuka Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding, especially for patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
1	Sep. 24, 2024	25	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 refractory nephrotic syndrome (for use steroid-resistant nephrotic syndrome). [Orphan drug]

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3-1	Sep. 24, 2024	26	Evrysdi Dry Syrup 60 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Risdiplam	A drug with a new indication and a new additional pediatric dosage (under 2 months of age) for the treatment of spinal muscular atrophy. [Orphan drug]
1	Sep. 24, 2024	27	Jakavi Tablets 5 mg Jakavi Tablets 10 mg Jakavi Oral Solution for Pediatric 0.5% (Novartis Pharma K.K.)	Change Change Approval	Ruxolitinib phosphate	Drugs with a new indication and a new additional pediatric dosage and a drug with a new indication and a new additional pediatric dosage in an additional dosage form for the treatment of graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
Blood products	Sep. 24, 2024	28	NovoSeven HI Syringe for I.V. Injection 1 mg NovoSeven HI Syringe for I.V. Injection 2 mg NovoSeven HI Syringe for I.V. Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new indication and a new dosage for the control of bleeding tendency in patients with Glanzmann thrombasthenia. [Public knowledge-based application]
6-1	Sep. 24, 2024	29	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg Rinvoq Tablets 30 mg (AbbVie GK)	Change Change Change	Upadacitinib hydrate	Drugs with a new additional pediatric dosage indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
<i>In vivo diagnostics</i>	Sep. 24, 2024	30	Alaglio Divided Granules 1.5 g Alaglio Oral 1.5 g (SBI Pharmaceuticals Co., Ltd.)	Change Change	Aminolevulinic acid hydrochloride	Drugs with a new dosage and other characteristics indicated for the visualization of tumor tissues of the non-muscle invasive bladder cancer in transurethral resection of bladder tumor. [Orphan drug]
Oncology drugs	Sep. 24, 2024	31	Padcev for I.V. infusion 20 mg Padcev for I.V. infusion 30 mg (Astellas Pharma Inc.)	Change Change	Enfortumab vedotin (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable urothelial carcinoma. [Priority review]
Oncology drugs	Sep. 24, 2024	32	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of unresectable urothelial carcinoma. [Priority review]
Oncology drugs	Sep. 24, 2024	33	(1) Tafenlar Dispersible Tablets for Pediatric 10 mg (2) Tafenlar Capsules 50 mg (3) Tafenlar Capsules 75 mg (Novartis Pharma K.K.)	Approval Change Change	Dabrafenib mesilate	(1) A drug with a new indication and a new dosage in an additional dosage form for the treatment of <i>BRAF</i> mutation-positive low-grade glioma. (2) (3) Drugs with a new indication for the treatment of <i>BRAF</i> mutation-positive low-grade glioma. [Orphan drug]
Oncology drugs	Sep. 24, 2024	34	(1) Mekinist Dry Syrup for Pediatric 4.7 mg (2) Mekinist Tablets 0.5 mg (3) Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Approval Change Change	Trametinib dimethyl sulfoxide	(1) A drug with a new indication and a new dosage in an additional dosage form for the treatment of <i>BRAF</i> mutation-positive low-grade glioma. (2) (3) Drugs with a new indication for the treatment of <i>BRAF</i> mutation-positive low-grade glioma. [Orphan drug]

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Oncology drugs	Nov. 22, 2024	1	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of locally advanced cervical cancer. [Orphan drug]
Oncology drugs	Nov. 22, 2024	2	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Change Change	Durvalumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of advanced or recurrent endometrial cancer.
Oncology drugs	Nov. 22, 2024	3	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication and a new dosage for the maintenance therapy of advanced or recurrent endometrial cancer with proficient mismatch repair (pMMR) in patients who have received chemotherapy including treatment with durvalumab (genetical recombination).
Vaccines	Nov. 22, 2024	4	Arexvy Intramuscular Injection (GlaxoSmithKline K.K.)	Change	Recombinant respiratory syncytial virus PreF3 antigen	A drug with a new dosage indicated for the prevention of disease caused by RS virus infection in individuals aged 50 years or older who are considered to be at a high risk of developing severe RS virus infection.
Oncology drugs	Nov. 22, 2024	5	Randa Injection 10 mg/20 mL Randa Injection 25 mg/50 mL Randa Injection 50 mg/100 mL (Nippon Kayaku Co., Ltd.)	Change Change Change	Cisplatin	Drugs with a new dosage indicated for the treatment of cervical cancer. [Expedited review]
2	Nov. 22, 2024	6	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 chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Nov. 22, 2024	7	Romiplate for S.C. Injection 250 µg (Kyowa Kirin Co., Ltd.)	Change	Romiplostim (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Nov. 22, 2024	8	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]

New Drugs Approved in December 2024

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 27, 2024	1	Brukinsa Capsules 80 mg (BeiGene Japan GK.)	Approval	<u>Zanubrutinib</u>	A drug with a new active ingredient indicated for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma), Waldenström's macroglobulinemia, and lymphoplasmacytic lymphoma.
Oncology drugs	Dec. 27, 2024	2	Balversa Tablets 3 mg Balversa Tablets 4 mg Balversa Tablets 5 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	<u>Erdafitinib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable urothelial carcinoma with <i>FGFR3</i> gene mutation or fusion gene that has progressed after cancer chemotherapy.
Oncology drugs	Dec. 27, 2024	3	Calquence Tablets 100 mg (AstraZeneca K.K.)	Approval	<u>Acalabrutinib maleate hydrate</u>	A drug with a new active ingredient indicated for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma).
3-2	Dec. 27, 2024	4	Ryjusea Mini ophthalmic solution 0.025% (Santen Pharmaceutical Co., Ltd.)	Approval	Atropine sulfate hydrate	A drug with a new indication in a new dosage form for slowing the progression of myopia.
3-1	Dec. 27, 2024	5	Vyvadura Combination Subcutaneous Injection (Argenx Japan K.K.)	Change	Efgartigimod alfa (genetical recombination) and Vorhyaluronidase alfa (genetical recombination)	A drug with a new indication and a new dosage for the treatment of chronic inflammatory demyelinating polyneuropathy. [Orphan drug]
3-1	Dec. 27, 2024	6	Qalsody Intrathecal Injection 100 mg (Biogen Japan Ltd.)	Approval	<u>Tofersen</u>	A drug with a new active ingredient indicated for slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis with <i>SOD1</i> mutation. [Orphan drug]
6-2	Dec. 27, 2024	7	Zepbound Subcutaneous Injection 2.5 mg Ateos Zepbound Subcutaneous Injection 5 mg Ateos Zepbound Subcutaneous Injection 7.5 mg Ateos Zepbound Subcutaneous Injection 10 mg Ateos Zepbound Subcutaneous Injection 12.5 mg Ateos Zepbound Subcutaneous Injection 15 mg Ateos (Eli Lilly Japan K.K.)	Approval Approval Approval Approval Approval	Tirzepatide	Drugs with a new indication, a new dosage, and other characteristics for the treatment of obesity. For use only in patients with any of hypertension, hyperlipidemia or type 2 diabetes mellitus who have not responded sufficiently to diet therapy and exercise therapy, and meet the following conditions: <ul style="list-style-type: none">• BMI of 27 kg/m² or greater in the presence of at least two obesity-related comorbidities or• BMI of 35 kg/m² or greater
1	Dec. 27, 2024	8	Zeposia Capsules 0.92 mg Zeposia Capsules Starter Pack (Bristol-Myers Squibb K.K.)	Approval Approval	<u>Ozanimod hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
Radio-pharmaceuticals	Dec. 27, 2024	9	Tauvid Injection (PDRadiopharma Inc.)	Approval	<u>Flortaucipir (¹⁸F)</u>	A drug with a new active ingredient indicated for the support of selection of patients with mild cognitive impairment and mild dementia due to Alzheimer's disease, for whom donanemab (genetical recombination) is indicated. [Expedited review]
2	Dec. 27, 2024	10	(1) Uptravi Tablets 0.2 mg (2) Uptravi Tablets 0.4 mg (3) Uptravi Tablets for Pediatric 0.05 mg (Nippon Shinyaku Co., Ltd.)	Change Change Approval	Selexipag	(1), (2) Drugs with a new additional pediatric dosage and other characteristics and (3) a drug with a new additional pediatric dosage in an additional dosage form, indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
1	Dec. 27, 2024	11	Oldamin for Injection 1 g (Fuji Chemical Industries Co., Ltd.)	Change	Monoethanolamine oleate	A drug with a new indication and a new dosage for the use in sclerotherapy of venous malformation.
Vaccines	Dec. 27, 2024	12	Efluelda intramuscular injection (Sanofi K.K.)	Approval	<u>Influenza virus (type A and type B) HA fraction</u>	A drug with a new active ingredient indicated for the prevention of influenza.
Blood products	Dec. 27, 2024	13	HyQvia 10% S.C. Injection Set 5 g/50 mL HyQvia 10% S.C. Injection Set 10 g/100 mL HyQvia 10% S.C. Injection Set 20 g/200 mL (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Human normal immunoglobulin G (pH4-treated acidic normal human immunoglobulin [subcutaneous injection]) <u>and Vorhyaluronidase alfa (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Dec. 27, 2024	14	Hympavzi S.C. Injection 150 mg Pen (Pfizer Japan Inc.)	Approval	<u>Marstacimab (genetical recombination)</u>	A drug with a new active ingredient indicated for the control of bleeding tendency in patients with congenital haemophilia who do not have inhibitors against blood coagulation factor VIII or IX.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
6-1	Dec. 27, 2024	15	(1) Fasenra Subcutaneous Injection 30 mg Syringe (2) Fasenra Subcutaneous Injection 30 mg Pen (AstraZeneca K.K.)	Change Approval	Benralizumab (genetical recombination)	(1) A drug with a new indication and a new dosage and (2) a drug with a new indication and a new dosage in an additional dosage form, indicated for the treatment of eosinophilic granulomatosis with polyangiitis in patients who have not responded sufficiently to conventional therapies.
4	Dec. 27, 2024	16	Tepoxx Capsules 200 mg (Japan Biotechno Pharma Co., Ltd.)	Approval	<u>Tecovirimat hydrate</u>	A drug with a new active ingredient indicated for the treatment of smallpox, mpox, cowpox, as well as complications due to replication of vaccinia virus following vaccination against smallpox . [Expedited review]
4	Dec. 27, 2024	17	Kavigale Injection Solution 300 mg (AstraZeneca K.K.)	Approval	<u>Sipavibart (genetical recombination)</u>	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Expedited review]
Oncology drugs	Dec. 27, 2024	18	Datroway for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Approval	<u>Datopotamab deruxtecan (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative unresectable or recurrent breast cancer in patients who have previously been treated with chemotherapy.
Oncology drugs	Dec. 27, 2024	19	Lunsumio for Intravenous Infusion 1 mg Lunsumio for Intravenous Infusion 30 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Mosunetuzumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory follicular lymphoma.
Oncology drugs	Dec. 27, 2024	20	Imdelltra for I.V. Infusion 1 mg Imdelltra for I.V. Infusion 10 mg (Amgen K.K.)	Approval Approval	<u>Tarlatamab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 27, 2024	21	Tecvayli Subcutaneous Injection 153 mg Tecvayli Subcutaneous Injection 30 mg (Janssen Pharmaceutical K.K.)	Approval Approval	<u>Teclistamab (genetical recombination)</u>	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	Dec. 27, 2024	22	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 urothelial carcinoma.
Oncology drugs	Dec. 27, 2024	23	Randa Injection 10 mg/20 mL Randa Injection 25 mg/50 mL Randa Injection 50 mg/100 mL (Nippon Kayaku Co., Ltd.)	Change Change Change	Cisplatin	Drugs with a new indication and a new dosage for the treatment of urothelial carcinoma.
Bio-CMC	Dec. 27, 2024	24	Ustekinumab BS 45 mg Syringe for S.C. Injection "YD" (Yoshindo Inc.)	Approval	Ustekinumab (genetical recombination) [ustekinumab biosimilar 2]	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
Oncology drugs	Dec. 27, 2024	25	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of advanced or recurrent endometrial cancer. [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
n vivo diagnostics	Contrast agents, reagents for function tests (excluding in-vitro diagnostics)
Bio-CMC	Quality of biologics, biosimilars