

New Drugs Approved in FY 2021

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
1	May 27, 2021	1	Aloxi I.V. Injection 0.75 mg Aloxi I.V. Infusion Bag 0.75 mg (Taiho Pharmaceutical Co., Ltd.)	Change Change	Palonosetron hydrochloride	Drugs with a new additional pediatric dosage indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.).
1	Jun. 23, 2021	2	Upasita IV Injection 25 µg Syringe for Dialysis Upasita IV Injection 50 µg Syringe for Dialysis Upasita IV Injection 100 µg Syringe for Dialysis Upasita IV Injection 150 µg Syringe for Dialysis Upasita IV Injection 200 µg Syringe for Dialysis Upasita IV Injection 250 µg Syringe for Dialysis Upasita IV Injection 300 µg Syringe for Dialysis (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	<u>Upacicalcet sodium hydrate</u>	Drugs with a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on hemodialysis.
1	Jun. 23, 2021	3	Revestive 3.8 mg for S.C. Injection (Takeda Pharmaceutical Company Limited)	Approval	<u>Teduglutide (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of short bowel syndrome. [Orphan drug]
1	Jun. 25, 2021	4	(1) Cellcept Capsules 250 (2) Cellcept Powder for Oral Suspension 31.8% (3) Mycophenolate Mofetil Capsules 250 mg [Pfizer] ((1) (2) Chugai Pharmaceutical Co., Ltd. (3) Mylan Seiyaku Ltd.)	Change Change Change	Mycophenolate mofetil	Drugs with a new indication and a new dosage for the suppression of graft-versus-host disease in hematopoietic stem cell transplantation. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Aug. 25, 2021	5	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Orphan drug]
1	Aug. 25, 2021	6	Forxiga 5 mg Tablets Forxiga 10 mg Tablets (AstraZeneca K.K.)	Change Change	Dapagliflozin propylene glycolate hydrate	Drugs with a new indication for the treatment of chronic kidney disease. [Priority review]
1	Aug. 25, 2021	7	Darzquro Combination Subcutaneous Injection (Janssen Pharmaceutical K.K.)	Change	Daratumumab (genetical recombination)/ Vorhyaluronidase alfa (genetical recombination)	A drug with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Orphan drug]
1	Aug. 25, 2021	8	Decadron Tablets 0.5 mg Decadron Tablets 4 mg (Nichi-Iko Pharmaceutical Co., Ltd.)	Change Change	Dexamethasone	Drugs with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Expedited review]
1	Aug. 25, 2021	9	Endoxan for Injection 100 mg Endoxan for Injection 500 mg Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change Change Change	Cyclophosphamide hydrate	Drugs with a new indication and a new dosage for the treatment of systemic AL amyloidosis. [Expedited review]
1	Sep. 27, 2021	10	Moizerto Ointment 0.3% Moizerto Ointment 1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Difamilast</u>	Drugs with a new active ingredient indicated for the treatment of atopic dermatitis.
1	Sep. 27, 2021	11	Humira 40 mg for S.C. Injection Syringe 0.4 mL Humira 80 mg for S.C. Injection Syringe 0.8 mL Humira 40 mg for S.C. Injection in pre-filled pen 0.4 mL Humira 80 mg for S.C. Injection in pre-filled pen 0.8 mL Humira 20 mg for S.C. Injection Syringe 0.2 mL (AbbVie GK)	Change Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new indication and a new dosage, including a new additional pediatric dosage, for the treatment of moderate or severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Sep. 27, 2021	12	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new indication and a new dosage for the treatment of chronic graft-versus-host disease after hematopoietic stem cell transplantation (for use when steroid drugs are not sufficiently effective). [Orphan drug]
1	Sep. 27, 2021	13	Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Change	Sirolimus	A drug with a new indication and a new dosage for the treatment of refractory lymphatic disease (lymphangioma [lymphatic malformation], lymphangiomatosis, Gorham's disease, and lymphangiectasia). [Orphan drug]

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6-2	Sep. 27, 2021	25	Nexviazyme for I.V. Infusion 100 mg (Sanofi K.K.)	Approval	<u>Avalglucosidase alfa</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of Pompe disease. [Orphan drug]
6-2	Jan. 20, 2022	26	Mepsevii Intravenous Infusion 10 mg (Amicus Therapeutics, Inc.)	Approval	<u>Vestronidase alfa</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type VII. [Orphan drug]
6-2	Jan. 20, 2022	27	Ngenla Inj. 24 mg Pens Ngenla Inj. 60 mg Pens (Pfizer Japan Inc.)	Approval Approval	<u>Somatrogon</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of short stature due to growth hormone deficiency prior to epiphyseal closure.
6-2	Mar. 28, 2022	28	Xenpozyme for I.V. Infusion 20 mg (Sanofi K.K.)	Approval	<u>Olipudase alfa</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of acid sphingomyelinase deficiency. [SAKIGAKE designation, orphan drug]
2	Jun. 23, 2021	29	Verquvo Tablets 2.5 mg Verquvo Tablets 5 mg Verquvo Tablets 10 mg (Bayer Yakuhin, Ltd.)	Approval Approval Approval	<u>Vericiguat</u>	Drugs with a new active ingredient indicated for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Jun. 23, 2021	30	Ajovy Syringes for S.C. Injection 225 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Fremanezumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the prevention of migraine attacks.
2	Jun. 23, 2021	31	Aimovig Subcutaneous Injection 70 mg Pens (Amgen K.K.)	Approval	<u>Erenumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the prevention of migraine attacks.
2	Aug. 25, 2021	32	Upravi Tablets 0.2 mg Upravi Tablets 0.4 mg (Nippon Shinyaku Co., Ltd.)	Change Change	Selexipag	Drugs with a new indication for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH. [Orphan drug]
2	Aug. 25, 2021	33	Lixiana Tablets 15 mg Lixiana OD Tablets 15 mg (Daiichi Sankyo Company, Limited)	Change Change	Edoxaban tosilate hydrate	Drugs with a new dosage indicated for the prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation.
2	Aug. 25, 2021	34	Nitropro Continuous Intravenous Solution 6 mg Nitropro Continuous Intravenous Solution 30 mg (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Sodium nitroprusside hydrate	Drugs with a new indication and a new dosage for the treatment of acute heart failure (including chronic heart failure in the exacerbation period) and hypertensive emergencies. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Sep. 27, 2021	35	Entresto Tablets 100 mg Entresto Tablets 200 mg (Novartis Pharma K.K.)	Change Change	Sacubitril valsartan sodium hydrate	Drugs with a new indication and a new dosage for the treatment of hypertension.
2	Sep. 27, 2021	36	Vynmac Capsules 61 mg (Pfizer Japan Inc.)	Approval	<u>Tafamidis</u>	A drug with a new active ingredient indicated for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary).
2	Sep. 27, 2021	37	Azilva Granules 1% Azilva Tablets 10 mg Azilva Tablets 20 mg Azilva Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval Change Change Change	Azilsartan	Drugs with a new additional pediatric dosage and a drug in an additional dosage form indicated for the treatment of hypertension.
2	Nov. 25, 2021	38	Jardiance Tablets 10 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Empagliflozin	A drug with a new indication and a new dosage for the treatment of chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
2	Dec. 24, 2021	39	Efient Tablets 2.5 mg Efient Tablets 3.75 mg (Daiichi Sankyo Company, Limited)	Change Change	Prasugrel hydrochloride	Drugs with a new indication and a new dosage for the prevention of recurrence after ischemic cerebrovascular disease (associated with large artery atherosclerosis or small vessel occlusion) (for use only in patients having a high risk of cerebral infarction).

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2	Jan. 20, 2022	40	Reyvow Tablets 50 mg Reyvow Tablets 100 mg (Eli Lilly Japan K.K.)	Approval Approval	<u>Lasmiditan succinate</u>	Drugs with a new active ingredient indicated for the treatment of migraine.
2	Jan. 20, 2022	41	Pivlaz I.V. Infusion liquid 150 mg (Idorsia Pharmaceuticals Japan Ltd.)	Approval	<u>Clazosentan sodium</u>	A drug with a new active ingredient indicated for the prevention of cerebrovascular spasm after surgery for subarachnoid hemorrhage caused by cerebral aneurysm, and cerebral infarctions and cerebral ischemic symptoms accompanying the cerebrovascular spasm.
2	Mar. 28, 2022	42	Ondexxya for Intravenous Injection 200 mg (Alexion Pharma G.K.)	Approval	<u>Andexanet alfa</u> (<u>genetical</u> <u>recombination</u>)	A drug with a new active ingredient indicated for the reversal of anticoagulant effect in life-threatening or uncontrolled bleeding in patients treated with a direct-acting factor Xa inhibitor (apixaban, rivaroxaban, or edoxaban tosilate hydrate). [Orphan drug]
2	Mar. 28, 2022	43	Kerendia Tablets 10 mg Kerendia Tablets 20 mg (Bayer Yakuhin, Ltd.)	Approval Approval	<u>Finerenone</u>	Drugs with a new active ingredient indicated for the treatment of chronic kidney disease associated with type 2 diabetes mellitus (excluding patients who have end-stage renal failure or are undergoing dialysis).
2	Mar. 28, 2022	44	Samtasu for I.V. Infusion 8 mg Samtasu for I.V. Infusion 16 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Tolvaptan sodium</u> <u>phosphate</u>	Drugs with a new active ingredient indicated for the treatment of fluid retention in heart failure patients who have not responded sufficiently to other diuretics to such as loop diuretics.
5	Sep. 27, 2021	45	F-meno Capsules 100 mg (Fuji Pharma Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for the prevention of endometrial hyperplasia when estrogen preparations were administered for climacteric disturbance or ovarian deficiency symptoms.
5	Dec. 24, 2021	46	Relumina Tablets 40 mg (ASKA Pharmaceutical Co., Ltd.)	Change	Relugolix	A drug with a new indication for the alleviation of pain associated with endometriosis.
5	Feb. 25, 2022	47	Femara Tablets 2.5 mg (Novartis Pharma K.K.)	Change	Letrozole	A drug with a new indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Feb. 25, 2022	48	Suprecur Nasal Solution 0.15% (Sanofi K.K.)	Change	Buserelin acetate	A drug with a new indication and a new dosage for the induction of final follicular maturation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	49	Clomid Tablets 50 mg (Fuji Pharma Co., Ltd.)	Change	Clomiphene citrate	A drug with a new indication and a new dosage for the induction of spermatogenesis in oligozoospermia. [Public knowledge-based application]
5	Mar. 11, 2022	50	l'estrogeol 0.06% (Fuji Pharma Co., Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	51	Julina Tablets 0.5 mg (Bayer Yakuhin, Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	52	Divigel 1 mg (Sun Pharma Japan Ltd.)	Change	Estradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]

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5	Mar. 11, 2022	53	(1) Estrana Tape 0.72 mg (2) Estrana Tape 0.36 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change	Estradiol	(1) A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology and hormone replacement cycle in frozen-thawed embryo transfer. (2) A drug with a new indication and a new dosage for hormone replacement cycle in frozen-thawed embryo transfer. [Public knowledge-based application]
5	Mar. 11, 2022	54	Jemina Tablets (Nobelpharma Co., Ltd.)	Change	Levonorgestrel/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	55	Lunabell Tablets LD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	56	Lunabell Tablets ULD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ Ethinylestradiol	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	57	Yaz Flex Combination Tablets (Bayer Yakuhin, Ltd.)	Change	Drospirenone/ Ethinylestradiol betadex	A drug with a new indication and a new dosage for adjusting the start timing of controlled ovarian stimulation in assisted reproductive technology. [Public knowledge-based application]
5	Mar. 11, 2022	58	Hysron Tablets 5 (Kyowa Kirin Co., Ltd.)	Change	Medroxyprogesterone acetate	A drug with a new indication and a new dosage for the prevention of premature ovulation during controlled ovarian stimulation. [Public knowledge-based application]
5	Mar. 11, 2022	59	Duphaston Tablets 5mg (Mylan EPD G.K.)	Change	Dydrogesterone	A drug with a new indication and a new dosage for the prevention of premature ovulation during controlled ovarian stimulation. [Public knowledge-based application]
5	Mar. 28, 2022	60	Lympack TA5 (Nipro Corporation)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used as perfusion fluids for hemodialysis in patients with chronic renal failure (use in any of the following cases: ○ when bicarbonate dialysate with high bicarbonate concentration may cause excessive alkalosis; ○ when the patient's blood sugar level is difficult to control with sugarless dialysate; ○ when other bicarbonate dialysate is not sufficiently effective to improve hyperkalemia and hypermagnesemia or may cause hypercalcemia).
<i>In vivo</i> diagnostics	Aug. 25, 2021	61	Inulead Injection (Fuji yakuhin Co., Ltd.)	Change	Inulin	A drug with a new dosage indicated for renal function tests based on measurement of glomerular filtration rate.
3-1	Jun. 23, 2021	62	Evrysdi Dry Syrup 60 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Risdiplam</u>	A drug with a new active ingredient indicated for the treatment of spinal muscular atrophy. [Orphan drug]
3-1	Jun. 23, 2021	63	Xeomin 50 Units for Intramuscular Injection Xeomin 100 Units for Intramuscular Injection Xeomin 200 Units for Intramuscular Injection (Teijin Pharma Limited)	Change Change Change	Incobotulinumtoxin A	Drugs with a new indication and a new dosage for the treatment of lower limb spasticity.
3-1	Sep. 27, 2021	64	Midafresa Injection 0.1% (Alfresa Pharma Corporation)	Change	Midazolam	A drug with a new dosage indicated for the treatment of status epilepticus.
3-1	Jan. 20, 2022	65	Vyvgart for Intravenous Infusion 400 mg (Argenx Japan K.K.)	Approval	<u>Efgartigimod alfa</u> (<u>genetical</u> <u>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]

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3-1	Mar. 28, 2022	66	Dysval Capsules 40 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	<u>Valbenazine tosilate</u>	A drug with a new active ingredient indicated for the treatment of tardive dyskinesia.
3-1	Mar. 28, 2022	67	Tarlige Tablets 2.5 mg Tarlige Tablets 5 mg Tarlige Tablets 10 mg Tarlige Tablets 15 mg (Daiichi Sankyo Company, Limited)	Change Change Change Change	Mirogabalin besilate	Drugs with a new indication for the treatment of neuropathic pain.
3-1	Mar. 28, 2022	68	Spinraza Intrathecal Injection 12 mg (Biogen Japan Ltd.)	Change	Nusinersen sodium	A drug with a new indication for the treatment of spinal muscular atrophy without any clinical manifestations that is predicted to develop with genetic test. [Orphan drug]
3-2	Aug. 25, 2021	69	Fentos Tape 0.5 mg Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change Change Change Change	Fentanyl citrate	Drugs with a new indication and a new additional pediatric dosage for the analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics (for use only in patients who switch from other opioid analgesics).
3-2	Mar. 28, 2022	70	Vabysmo Solution for Intravitreal Injection 120 mg/mL (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Faricimab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema.
4	Jun. 23, 2021	71	Recarbrio Combination for Intravenous Drip Infusion (MSD K.K.)	Approval	<u>Relebactam hydrate/Imipenem hydrate/Cilastatin sodium</u>	A new combination drug with a new active ingredient indicated for the treatment of infections caused by Recarbrio-sensitive <i>Escherichia coli</i> , <i>Citrobacter</i> spp., <i>Klebsiella</i> spp., <i>Enterococcus</i> spp., <i>Serratia</i> spp., <i>Pseudomonas aeruginosa</i> , and <i>Acinetobacter</i> spp. (limited to the bacterial strains resistant to carbapenem antimicrobial drugs) [Orphan drug]
4	Jul. 19, 2021	72	Ronapreve for Intravenous Infusion Set 300 Ronapreve for Intravenous Infusion Set 1332 (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Casirivimab (genetical recombination)</u> , <u>Imdevimab (genetical recombination)</u>	Drugs with new active ingredients indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Sep. 27, 2021	73	Stelues Suspension Liquid for Intramuscular Injection 600,000 Units Stelues Suspension Liquid for Intramuscular Injection 2,400,000 Units (Pfizer Japan Inc.)	Approval Approval	Benzylpenicillin benzathine hydrate	Drugs with a new route of administration indicated for the treatment of syphilis (excluding neurosyphilis) caused by <i>Treponema pallidum</i> .
4	Sep. 27, 2021	74	Xevudy for Intravenous Injection 500 mg (GlaxoSmithKline K.K.)	Approval	<u>Sotrovimab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Sep. 27, 2021	75	Noxafil Tablets 100 mg Noxafil for Intravenous Infusion 300 mg (MSD K.K.)	Change Change	Posaconazole	Drugs with a new indication for the treatment of invasive aspergillosis.
4	Nov. 5, 2021	76	Ronapreve for Intravenous Infusion Set 300 Ronapreve for Intravenous Infusion Set 1332 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Casirivimab (genetical recombination), Imdevimab (genetical recombination)	Drugs with a new route of administration and a new indication for the treatment and suppression of development of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
4	Dec. 24, 2021	77	Lagevrio Capsules 200 mg (MSD K.K.)	Approval	<u>Molnupiravir</u>	A drug with a new active ingredient indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]

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4	Feb. 10, 2022	78	Paxlovidpack (Pfizer Japan Inc.)	Approval	<u>Nirmatrelvir/Ritonavir</u>	A drug with new active ingredients indicated for the treatment of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
6-1	Apr 23, 2021	79	Olumiant Tablets 2 mg Olumiant Tablets 4 mg (Eli Lilly Japan K.K.)	Change Change	Baricitinib	Drugs with a new indication and a new dosage for the treatment of pneumonia caused by SARS-CoV-2 (only for the patients requiring supplemental oxygen). [Priority review]
6-1	May 27, 2021	80	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of psoriatic arthritis in patients who have not responded sufficiently to conventional therapies.
6-1	Aug. 25, 2021	81	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Change Change	Upadacitinib hydrate	Drugs with a new indication and a new dosage for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	82	Rinvoq Tablets 30 mg (AbbVie GK)	Approval	Upadacitinib hydrate	A drug in an additional dosage form indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	83	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg Pen Cosentyx for S.C. Injection 75 mg Syringe (Novartis Pharma K.K.)	Change Change Approval	Secukinumab (genetical recombination)	Drugs with a new additional pediatric dosage and a drug in an additional dosage form indicated for the treatment of plaque psoriasis, psoriatic arthritis, and pustular psoriasis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	84	Cibinqo Tablets 50 mg Cibinqo Tablets 100 mg Cibinqo Tablets 200 mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Abrocitinib</u>	Drugs with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	85	Saphnelo for I.V. Infusion 300 mg (AstraZeneca K.K.)	Approval	<u>Anifrolumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of systemic lupus erythematosus in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2021	86	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 systemic sclerosis. [Orphan drug]
6-1	Sep. 27, 2021	87	Tavneos Capsules 10 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	<u>Avacopan</u>	A drug with a new active ingredient indicated for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis. [Orphan drug]
6-1	Dec. 24, 2021	88	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 pemphigus vulgaris and pemphigus foliaceus. [Orphan drug]
6-1	Jan. 20, 2022	89	Lyfnua Tablets 45 mg (MSD K.K.)	Approval	<u>Gefapixant citrate</u>	A drug with a new active ingredient indicated for the treatment of refractory chronic cough.
6-1	Jan. 20, 2022	90	Bimzelx Syringe for S.C Injection 160 mg Bimzelx Autoinjector for S.C Injection 160 mg (UCB Japan Co., Ltd.)	Approval Approval	<u>Bimekizumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Jan. 21, 2022	91	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 and a new dosage for the treatment of pneumonia caused by SARS-CoV-2 (only for the patients requiring supplemental oxygen). [Priority review]

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6-1	Mar. 28, 2022	92	Mitchga Syringes 60 mg (Maruho Co., Ltd.)	Approval	<u>Nemolizumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of pruritus associated with atopic dermatitis (for use only in patients who have not responded sufficiently to conventional treatments).
6-1	Mar. 28, 2022	93	Takhzyro Subcutaneous Injection 300 mg Syringes (Takeda Pharmaceutical Company Limited)	Approval	<u>Lanadelumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the prophylaxis of acute attacks of hereditary angioedema. [Orphan drug]
6-1	Mar. 28, 2022	94	Unitalc Intrapleural 4 g (Nobelpharma Co., Ltd.)	Change	Talc	A drug with a new indication for the treatment of inoperable secondary intractable pneumothorax. [Orphan drug]
Oncology drugs	May 27, 2021	95	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma. [Orphan drug]
Oncology drugs	May 27, 2021	96	Ninlaro Capsules 2.3 mg Ninlaro Capsules 3 mg Ninlaro Capsules 4 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Ixazomib citrate	Drugs with a new indication for the maintenance therapy of multiple myeloma.
Oncology drugs	May 27, 2021	97	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	Nivolumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma. [Orphan drug]
Oncology drugs	Jun. 23, 2021	98	Tazverik Tablets 200 mg (Eisai Co., Ltd.)	Approval	<u>Tazemetostat</u> hydrobromide	A drug with a new active ingredient indicated for the treatment of relapsed or refractory <i>EZH2</i> gene mutation-positive follicular lymphoma (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Jun. 23, 2021	99	Lutathera Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	<u>Lutetium (¹⁷⁷Lu)</u> oxodotreotide	A drug with a new active ingredient indicated for the treatment of somatostatin receptor-positive neuroendocrine tumor.
Oncology drugs	Jun. 23, 2021	100	Lysakare Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	L-Lysine hydrochloride, L-Arginine hydrochloride	A new combination drug indicated for the reduction of renal radiation exposure from Lutetium (¹⁷⁷ Lu) oxodotreotide.
Oncology drugs	Jun. 23, 2021	101	Unituxin I.V. Injection 17.5 mg/5 mL (Ohara Pharmaceutical Co., Ltd.)	Approval	<u>Dinutuximab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of neuroblastoma following high-dose chemotherapy. [Orphan drug]
Oncology drugs	Jun. 23, 2021	102	Hiyasta Tablets 10 mg (Huya Japan G.K.)	Approval	<u>Tucidinostat</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory adult T-cell leukemia-lymphoma. [Orphan drug]
Oncology drugs	Jun. 23, 2021	103	Gran Injection 75 Gran Injection 150 Gran Injection M300 Gran Syringe 75 Gran Syringe 150 Gran Syringe M300 (Kyowa Kirin Co., Ltd.)	Change Change Change Change Change Change	Filgrastim (genetical recombination)	Drugs with a new indication and a new dosage for the enhancement of an antitumor effect of dinutuximab (genetical recombination) for neuroblastoma. [Expedited review]
Oncology drugs	Jun. 23, 2021	104	Imunace 35 for Injection (Shionogi & Co., Ltd.)	Change	Teceleukin (genetical recombination)	A drug with a new indication and a new dosage for the enhancement of an antitumor effect of dinutuximab (genetical recombination) for neuroblastoma. [Expedited review]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Aug. 25, 2021	105	Keytruda Injection 100 mg (MSD K.K.)	Change	<u>Pembrolizumab</u> (genetical recombination)	(1) A drug with a new indication for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer. (2) A drug with a new indication and a new dosage for the treatment of PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer.
Oncology drugs	Aug. 25, 2021	106	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	<u>Nivolumab</u> (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 25, 2021	107	Cabometyx Tablets 20 mg (Takeda Pharmaceutical Company Limited)	Change	<u>Cabozantinib malate</u>	A drug with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 25, 2021	108	Carboplatin Injection 50 mg "NK" Carboplatin Injection 150 mg "NK" Carboplatin Injection 450 mg "NK" (Mylan Seiyaku Ltd.)	Change Change Change	<u>Carboplatin</u>	Drugs with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 25, 2021	109	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	<u>Paclitaxel</u>	A drug with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 25, 2021	110	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	<u>Busulfan</u>	A drug with a new dosage indicated for the conditioning treatments prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem-cell transplantation for Ewing's sarcoma family of tumors and neuroblastoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 27, 2021	111	Retevmo Capsules 40 mg Retevmo Capsules 80 mg (Eli Lilly Japan K.K.)	Approval Approval	<u>Selpercatinib</u>	Drugs with a new active ingredient indicated for the treatment of <i>RET</i> fusion gene-positive unresectable advanced or recurrent non-small cell lung cancer. [Orphan drug]
Oncology drugs	Sep. 27, 2021	112	Raiatt MIBG-I 131 Injection (Fujifilm Toyama Chemical Co., Ltd.)	Approval	<u>3-Iodobenzylguanidine</u> (¹³¹ I)	A drug with a new active ingredient indicated for the treatment of unresectable MIBG-positive pheochromocytoma/paraganglioma. [Orphan drug]
Oncology drugs	Sep. 27, 2021	113	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 120 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change	<u>Nivolumab</u> (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of relapsed or refractory classical Hodgkin lymphoma. [Orphan drug]
Oncology drugs	Sep. 27, 2021	114	Padcev for I.V. infusion 30 mg (Astellas Pharma Inc.)	Approval	<u>Enfortumab vedotin</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable urothelial carcinoma that has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Sep. 27, 2021	115	Megludase for Intravenous Use 1000 (Ohara Pharmaceutical Co., Ltd.)	Approval	<u>Glucarpidase</u> (genetical recombination)	A drug with a new active ingredient indicated to reduce toxic plasma methotrexate concentration in patients with delayed clearance of methotrexate due to methotrexate/leucovorin salvage therapy. [Orphan drug]
Oncology drugs	Nov. 25, 2021	116	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	<u>Trastuzumab</u> (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive salivary gland tumors. [Orphan drug]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Nov. 25, 2021	117	Hiyasta Tablets 10 mg (Huya Japan G.K.)	Change	Tucidinostat	A drug with a new indication for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Nov. 25, 2021	118	Leucovorin Tablets 5 mg (Pfizer Japan Inc.)	Change	Calcium folinate	A drug with a new dosage indicated for the alleviation of toxicity of antitoxates.
Oncology drugs	Nov. 25, 2021	119	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 esophageal cancer.
Oncology drugs	Nov. 25, 2021	120	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)	1) Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer. 2) Drugs with a new indication and a new dosage for postoperative adjuvant therapy for esophageal cancer.
Oncology drugs	Nov. 25, 2021	121	Lorbrena Tablets 25 mg Lorbrena Tablets 100 mg (Pfizer Japan Inc.)	Change Change	Lorlatinib	Drugs with a new indication for the treatment of unresectable or advanced/recurrent anaplastic lymphoma kinase (ALK) fusion gene-positive non-small cell lung cancer.
Oncology drugs	Nov. 25, 2021	122	Sarclisa 100 mg I.V. Infusion Sarclisa 500 mg I.V. Infusion (Sanofi K.K.)	Change Change	Isatuximab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma.
Oncology drugs	Nov. 25, 2021	123	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of esophageal cancer. [Public knowledge-based application]
Oncology drugs	Dec. 24, 2021	124	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 carcinoma of unknown primary. [Orphan drug]
Oncology drugs	Dec. 24, 2021	125	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 endometrial carcinoma that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 24, 2021	126	Lenvima Capsules 4 mg Lenvima Capsules 10 mg (Eisai Co., Ltd.)	Change Change	Lenvatinib mesilate	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent endometrial carcinoma that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Dec. 24, 2021	127	Verzenio Tablets 50 mg Verzenio Tablets 100 mg Verzenio Tablets 150 mg (Eli Lilly Japan K.K.)	Change Change Change	Abemaciclib	Drugs with a new indication and a new dosage for the postoperative adjuvant treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer with a high risk of recurrence.
Oncology drugs	Jan. 20, 2022	128	Lumakras Tablets 120 mg (Amgen K.K.)	Approval	<u>Sotorasib</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent KRAS G12C mutation-positive non-small cell lung cancer that has progressed after cancer chemotherapy. [Orphan drug]
Oncology drugs	Feb. 25, 2022	129	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Kirin Co., Ltd.)	Change	Pegfilgrastim (genetical recombination)	A drug with a new indication and a new dosage for the mobilization of hematopoietic stem cell to the peripheral blood for allogeneic peripheral blood stem cell transplantation.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Oncology drugs	Feb. 25, 2022	130	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new indication for the treatment of advanced or recurrent solid tumors with tumor mutation burden-high (TMB-high) that have progressed after cancer chemotherapy (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Feb. 25, 2022	131	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 unresectable thyroid cancer and <i>RET</i> gene mutation-positive unresectable medullary thyroid cancer. [Orphan drug]
Oncology drugs	Feb. 25, 2022	132	Lenvima Capsules 4 mg Lenvima Capsules 10 mg (Eisai Co., Ltd.)	Change Change	Lenvatinib mesilate	Drugs with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Feb. 25, 2022	133	Keytruda Injection 100 mg (MSD K.K.)	Change	Pembrolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Feb. 25, 2022	134	Treakisym Injection Solution 100 mg/4 mL (SymBio Pharmaceuticals Limited)	Change	Bendamustine hydrochloride hydrate	A drug with a new dosage indicated for the treatment of low-grade B-cell non-Hodgkin's lymphoma, mantle cell lymphoma, chronic lymphocytic leukemia, and relapsed or refractory diffuse large B-cell lymphoma.
Oncology drugs	Mar. 28, 2022	135	Scemblix Tablets 20 mg Scemblix Tablets 40 mg (Novartis Pharma K.K.)	Approval Approval	<u>Asciminib hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies. [Orphan drug]
Oncology drugs	Mar. 28, 2022	136	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 postoperative adjuvant therapy for urothelial carcinoma.
Oncology drugs	Mar. 28, 2022	137	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Change	Pertuzumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive colon or rectal cancer that has progressed after cancer chemotherapy.
Oncology drugs	Mar. 28, 2022	138	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of unresectable advanced or recurrent HER2-positive colon or rectal cancer that has progressed after cancer chemotherapy.
Bio-CMC	Sep. 27, 2021	139	Ranibizumab BS Intravitreal Injection kit 10 mg/mL "Senju" (Senju Pharmaceutical Co., Ltd.)	Approval	Ranibizumab (genetical recombination) [ranibizumab biosimilar 1]	Follow-on biologics indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization or choroidal neovascularization in patients with pathologic myopia.
Bio-CMC	Jan. 20, 2022	140	Bevacizumab BS Intravenous Infusion 100 mg "Nichi-Iko" Bevacizumab BS Intravenous Infusion 400 mg "Nichi-Iko" (Nichi-Iko Pharmaceutical Co., Ltd.)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 3]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer and unresectable advanced or recurrent non-squamous non-small cell lung cancer.
Vaccines	May 21, 2021	141	COVID-19 Vaccine Moderna Intramuscular Injection (Takeda Pharmaceutical Company Limited)	Approval	<u>CX-024414</u>	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Indications
Vaccines	May 21, 2021	142	Vaxzevria Intramuscular Injection (AstraZeneca K.K.)	Approval	<u>COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)</u>	A drug with a new active ingredient indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Nov.11, 2021	143	Comirnaty Intramuscular Injection (Pfizer Japan Inc.)	Change	Tozinameran	A drug with a new dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Dec. 16, 2021	144	Spikevax Intramuscular Injection (previously COVID-19 Vaccine Moderna Intramuscular Injection) (Takeda Pharmaceutical Company Limited)	Change	Elasomeran (former ingredient name: CX-024414)	A drug with a new dosage indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Vaccines	Jan. 21, 2022	145	Comirnaty Intramuscular Injection for 5 to 11 Years Old (Pfizer Japan Inc.)	Approval	Tozinameran	A drug with a new pediatric dosage and a drug in an additional dosage form indicated for the prevention of disease caused by SARS-CoV-2 infection (COVID-19). [Drug pertaining to Special Approval for Emergency]
Blood products	Mar. 28, 2022	146	Fibrinogen HT I.V. 1 g "JB" (Japan Blood Products Organization)	Change	Freeze-dried human fibrinogen	A drug with a new indication and a new dosage for the replacement of fibrinogen in patients with acquired hypofibrinogenemia associated with critical obstetrical hemorrhage. [Public knowledge-based application after PAFSC's preliminary assessment]

***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