

New Drugs Approved in FY 2018

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
1	May 25, 2018	1	Xeljanz Tablets 5 mg (Pfizer Japan Inc.)	Change	Tofacitinib citrate	A drug with a new additional indication and a new dosage for the remission induction and maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jul. 2, 2018	2	Entyvio for I.V. Infusion 300 mg (Takeda Pharmaceutical Company Limited)	Approval	<u>Vedolizumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment and maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Aug. 21, 2018	3	Linzess Tablets 0.25 mg (Astellas Pharma Inc.)	Change	Linacotide	A drug with a new additional indication for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Sep. 21, 2018	4	Movicol Combination Oral Solution (EA Pharma Co., Ltd.)	Approval	Macrogol 4000/Sodium chloride/Sodium bicarbonate/Potassium chloride	A new combination drug indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Sep. 21, 2018	5	Lagnos NF Jelly for Oral Administration Divided Pack 12 g (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval	Lactulose crystal	A drug with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Feb. 21, 2019	6	Imuran Tablets 50 mg (Aspen Japan K.K.) Azanin Tablets 50 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Azathioprine	Drugs with a new additional indication for the treatment of autoimmune hepatitis. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Mar. 26, 2019	7	Ferinject Solution for Injection/Infusion 500 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	<u>Ferric carboxymaltose</u>	A drug with a new active ingredient indicated for the treatment of iron-deficiency anemia.
1	Mar. 26, 2019	8	Aselend Injection 100 µg (Fujimoto Pharmaceutical Corporation)	Approval	<u>Sodium selenite</u>	A drug with a new active ingredient indicated for the treatment of hyposelenemia.
2	Jul. 2, 2018	9	Trerief Tablets 25 mg Trerief OD Tablets 25 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Change Change	Zonisamide	Drugs with a new additional indication and a new dosage for the treatment of parkinsonism in patients with dementia with Lewy bodies (in the cases where parkinsonism persists after using levodopa-containing products).
2	Nov. 21, 2018	10	Praluent 75 mg solution for injection in pre-filled pen Praluent 150 mg solution for injection in pre-filled pen (Sanofi K.K.)	Change Change	Alirocumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular events, and in whom treatment with HMG-CoA reductase inhibitors is not suitable).
2	Jan. 8, 2019	11	Minnebro Tablets 1.25 mg Minnebro Tablets 2.5 mg Minnebro Tablets 5 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval	<u>Esaxerenone</u>	Drugs with a new active ingredient indicated for the treatment of hypertension.
2	Jan. 8, 2019	12	Demser Capsules 250 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Metirosine</u>	A drug with a new active ingredient indicated for the improvement of the status of excessive catecholamine secretion in patients with pheochromocytoma. [Orphan drug]
2	Jan. 8, 2019	13	(1) Bisono Tape 2 mg (2) Bisono Tape 4 mg (3) Bisono Tape 8 mg (Toa Eiyo Ltd.)	Approval Change Change	Bisoprolol	(1) A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of tachycardiac atrial fibrillation. (2)(3) Drugs with a new additional indication, a new dosage, and other characteristics indicated for the treatment of tachycardiac atrial fibrillation.
2	Mar. 26, 2019	14	Rosuzet Combination Tablets LD Rosuzet Combination Tablets HD (MSD K.K.)	Approval Approval	Ezetimibe/Rosuvastatin calcium	New combination drugs indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Mar. 26, 2019	15	Onoact for Intravenous Infusion 50 mg Onoact for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Landiolol hydrochloride	Drugs with new additional indications and a new dosage for the following life-threatening cardiac arrhythmia in refractory and urgent cases: ventricular fibrillation and hemodynamically unstable ventricular tachycardia. [Orphan drug]

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2	Mar. 26, 2019	16	Vyndaqel Capsules 20 mg (Pfizer Japan Inc.)	Change	Tafamidis meglumine	A drug with a new additional indication and a new dosage for the treatment of transthyretin cardiac amyloidosis (wild-type and hereditary). [SAKIGAKE designation, Orphan drug]
3-1	May 25, 2018	17	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of spasmodic dysphonia.
3-1	Sep. 21, 2018	18	Lora-Pita Intravenous Injection 2 mg (Pfizer Japan Inc.)	Approval	Lorazepam	A drug with a new route of administration indicated for the treatment of status epilepticus.
3-1	Jan. 8, 2019	19	Selincro Tablets 10 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Nalmefene hydrochloride hydrate</u>	A drug with a new active ingredient indicated to reduce alcohol consumption in patients with alcohol dependence.
3-1	Jan. 8, 2019	20	(1) Vimpat Dry Syrup 10% (2) Vimpat Tablets 50 mg (3) Vimpat Tablets 100 mg (4) Vimpat for I.V. Infusion 200 mg (UCB Japan Co., Ltd.)	Approval Change Change Approval	Lacosamide	(1)-(3) A drug in an additional dosage form and drugs with a new additional pediatric dosage indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. (4) A drug with a new route of administration indicated for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy. It is used as an alternative therapy for lacosamide oral formulation in patients who are temporarily unable to be administered orally.
3-1	Jan. 8, 2019	21	Tarlige Tablets 2.5 mg Tarlige Tablets 5 mg Tarlige Tablets 10 mg Tarlige Tablets 15 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval Approval	<u>Mirogabalin besilate</u>	Drugs with a new active ingredient indicated for the treatment of peripheral neuropathic pain.
3-1	Feb. 21, 2019	22	Taurine powder 98% "Taisho" (Taisho Pharmaceutical Co., Ltd.)	Change	Taurine	A drug with a new additional indication and a new dosage for the inhibition of stroke-like episodes in patients with mitochondrial myopathy, encephalopathy, lactic acidosis and stroke-like episodes (MELAS). [Orphan drug]
3-1	Mar. 26, 2019	23	Vyvanse Capsules 20 mg Vyvanse Capsules 30 mg (Shionogi & Co., Ltd.)	Approval Approval	<u>Lisdexamfetamine mesilate</u>	Drugs with a new active ingredient indicated for the treatment of pediatric attention deficit/hyperactivity disorder (AD/HD).
3-1	Mar. 26, 2019	24	Privigen 10% I.V. Drip Infusion 5 g/50 mL Privigen 10% I.V. Drip Infusion 10 g/100 mL Privigen 10% I.V. Drip Infusion 20 g/200 mL (CSL Behring K.K.)	Approval Approval Approval	<u>pH4-treated acidic normal human immunoglobulin</u>	Drugs with a new active ingredient indicated for the improvement of muscle weakness in chronic inflammatory demyelinating polyneuropathy and for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (in the cases where patients show an improvement in their acute phase treatment).
3-1	Mar. 26, 2019	25	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	pH4-treated acidic normal human immunoglobulin (subcutaneous injection)	Drugs with a new additional indication and a new dosage for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (in the cases where patients show an improvement in their acute phase treatment).
3-2	Jul. 2, 2018	26	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.)	Approval Change Change Change Change Change	Fentanyl citrate	Drugs with a new dosage and in additional dosage form indicated for: (1) analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics or weak opioid analgesics (for use only in patients who switch from other opioid analgesics); or (2) analgesia in moderate to severe chronic pain (for use only in patients who switch from other opioid analgesics).
3-2	Sep. 21, 2018	27	Eybelis Ophthalmic Solution 0.002% (Santen Pharmaceutical Co., Ltd.)	Approval	<u>Omidenepag isopropyl</u>	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.

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3-2	Nov. 29, 2018	28	Precedex Intravenous Solution 200 µg "Pfizer" Precedex Intravenous Solution 200 µg/50 mL Syringe "Pfizer" (Pfizer Japan Inc.) Precedex Intravenous Solution 200 µg "Maruishi" Precedex Intravenous Solution 200 µg/50 mL Syringe "Maruishi" (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Dexmedetomidine hydrochloride	Drugs with a new additional pediatric dosage indicated for sedation during artificial respiration and after weaning in patients in intensive care.
3-2	Mar. 26, 2019	29	Lafenta Tape 1.38 mg Lafenta Tape 2.75 mg Lafenta Tape 5.5 mg Lafenta Tape 8.25 mg Lafenta Tape 11 mg (Nippon Zoki Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Fentanyl	Drugs in a new dosage form indicated for analgesia in various types of cancer with moderate to severe pain that cannot be managed with non-opioid analgesics or weak opioid analgesics (for use only in patients who switch from other opioid analgesics).
4	Jul. 2, 2018	30	Dafclir Tablets 200 mg (Astellas Pharma Inc.)	Approval	<u>Fidaxomicin</u>	A drug with a new active ingredient indicated for the treatment of infectious enteritis (including pseudomembranous colitis) caused by <i>C. difficile</i> .
4	Jul. 2, 2018	31	Spiramycin Tablets 1.5M IU "Sanofi" (Sanofi K.K.)	Approval	<u>Spiramycin</u>	A drug with a new active ingredient indicated for the prophylaxis of congenital toxoplasmosis. [Orphan drug]
4	(1) Aug. 21, 2018 (2) Aug. 22, 2018	32	(1) Valixa Tablets 450 mg (2) Valixa Dry Syrup 5000 mg (Mitsubishi Tanabe Pharma Corporation)	(1) Change (2) Approval	Valganciclovir hydrochloride	Drugs with a new additional pediatric dosage and a drug in an additional dosage form of dry syrup, indicated for the prevention of cytomegalovirus disease in organ transplant patients (excluding hematopoietic stem cell transplantation). [Public knowledge-based application after PAFSC's preliminary assessment]
4	Sep. 21, 2018	33	Oravi Mucoadhesive Tablets 50 mg (Sosei Co., Ltd.)	Approval	Miconazole	A drug in a new dosage form indicated for the treatment of oropharyngeal candidiasis caused by <i>Candida</i> .
4	Jan. 8, 2019	34	Zerbaxa Combination for Intravenous Drip Infusion (MSD K.K.)	Approval	<u>Ceftolozane sulfate/Tazobactam sodium</u>	A new combination drug with new active ingredients indicated for the treatment of cystitis, pyelonephritis, peritonitis, intra-abdominal abscess, cholecystitis, and liver abscess caused by Zerbaxa-sensitive <i>Streptococcus</i> spp., <i>Escherichia coli</i> , <i>Citrobacter</i> spp., <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>Proteus</i> spp., or <i>Pseudomonas aeruginosa</i> .
4	Jan. 8, 2019	35	Epclusa Combination Tablets (Gilead Sciences K.K.)	Approval	Sofosbuvir/ <u>Velpatasvir</u>	A new combination drug with a new active ingredient indicated for: - Improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C who have previously been treated. - Improvement of viremia in patients with decompensated cirrhosis type C. [Priority review]
4	Jan. 8, 2019	36	Rebetol Capsules 200 mg (MSD K.K.)	Change	Ribavirin	A drug with a new additional indication and a new dosage, used in combination with sofosbuvir and velpatasvir, for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C who have previously been treated. [Expedited review]
4	Feb. 21, 2019	37	Famvir Tab. 250 mg (Asahi Kasei Pharma Corporation)	Change	Famciclovir	A drug with a new dosage indicated for the treatment of herpes simplex.
4	Mar. 26, 2019	38	Foscavir Infusion Solution 24 mg/mL (Clinigen K.K.)	Change	Foscarnet sodium hydrate	A drug with a new additional indication and a new dosage indicated for the treatment of human herpesvirus 6 encephalitis after hematopoietic stem cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 2, 2018	39	Jemina Tablets (Nobelpharma Co., Ltd.)	Approval	Levonorgestrel/ <u>Ethinylestradiol</u>	A new combination drug indicated for the treatment of dysmenorrhea.
5	Sep. 21, 2018	40	Beova Tablets 50 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	<u>Vibegron</u>	A drug with a new active ingredient indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.

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5	Jan. 8, 2019	41	Relumina Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval	<u>Relugolix</u>	A drug with a new active ingredient indicated for the alleviation of menorrhagia, lower abdominal pain, backache, and anemia that are associated with uterine fibroids.
5	Feb. 21, 2019	42	Gonalef for Subcutaneous Injection 75 Gonalef for Subcutaneous Injection 150 Gonalef for Subcutaneous Injection Pen 300 Gonalef for Subcutaneous Injection Pen 450 Gonalef for Subcutaneous Injection Pen 900 (Merck Serono Co., Ltd.)	Change Change Change Change	Follitropin alfa (genetical recombination)	Drugs with changes in dosage regimen indicated for the induction of spermatogenesis in male hypogonadotropic hypogonadism (MH) and with a new additional indication and a new dosage for controlled ovarian stimulation in assisted reproductive technology.
5	Mar. 26, 2019	43	Enoras Liquid 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.
6-1	May 25, 2018	44	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Change	Mepolizumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of eosinophilic granulomatosis with polyangiitis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Jul. 2, 2018	45	Ilaris for S.C. Injection 150 mg Ilaris Solution for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change Change	Canakinumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of systemic juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Aug. 21, 2018	46	Taltz 80 mg Syringe for SC Injection Taltz 80 mg Auto-Injector for SC Injection (Eli Lilly Japan K.K.)	Change Change	Ixekizumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Sep. 21, 2018	47	Firazyr Subcutaneous Injection 30 mg Syringe (Shire Japan KK)	Approval	<u>Icatibant acetate</u>	A drug with a new active ingredient indicated for the treatment of acute attacks of hereditary angioedema. [Orphan drug]
6-1	Nov. 21, 2018	48	Tremfya Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Change	Guselkumab (genetical recombination)	A drug with a new additional indication for the treatment of palmoplantar pustulosis in patients who have not responded sufficiently to conventional therapies.
6-1	Dec. 21, 2018	49	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg Pen (Novartis Pharma K.K.)	Change Change	Secukinumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 21, 2019	50	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 (AbbVie GK)	Change Change Change Change	Adalimumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of hidradenitis suppurativa. [Orphan drug]
6-1	Mar. 26, 2019	51	Skyrizi 75 mg for S.C. Injection Syringe 0.83 mL (AbbVie GK)	Approval	<u>Risankizumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 26, 2019	52	Trelegy 100 Ellipta 14 doses Trelegy 100 Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval	Fluticasone furoate/Umeclidinium bromide/Vilanterol trifenate	New combination drugs indicated for the relief of symptoms in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with an inhaled corticosteroid, a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist).
6-1	Mar. 26, 2019	53	Smyraf Tablets 50 mg Smyraf Tablets 100 mg (Astellas Pharma Inc.)	Approval Approval	<u>Peficitinib hydrobromide</u>	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.

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6-1	Mar. 26, 2019	54	Dupixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Change	Dupilumab (genetical recombination)	A drug with a new additional indication, a new dosage and other characteristics for the treatment of bronchial asthma (for use only in patients with severe or intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Mar. 26, 2019	55	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 additional indication and a new dosage for the treatment of cytokine release syndrome induced by tumor-specific T-cell infusion therapy. [Expedited review]
6-1	Mar. 26, 2019	56	Rheumatrex Capsules 2 mg (Pfizer Japan Inc.)	Change	Methotrexate	A drug with new additional indications and a new dosage for the treatment of plaque psoriasis in patients who have not responded sufficiently to topical therapy, or psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis . [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Sep. 21, 2018	57	Tradiance Combination Tablets AP Tradiance Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Empagliflozin/Linagliptin	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of empagliflozin with linagliptin is deemed appropriate).
6-2	Sep. 21, 2018	58	Metoana Combination Tablets LD Metoana Combination Tablets HD (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval	Anagliptin/Metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of anagliptin with metformin hydrochloride is deemed appropriate).
6-2	Dec. 21, 2018	59	Suglat Tablets 25 mg Suglat Tablets 50 mg (Astellas Pharma Inc.)	Change Change	Ipragliflozin L-proline	Drugs with a new additional indication and a new dosage for the treatment of type 1 diabetes mellitus.
6-2	Jan. 8, 2019	60	Evenity Subcutaneous Injection 105 mg Syringe (Amgen Astellas BioPharma K.K.)	Approval	<u>Romosozumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Mar. 26, 2019	61	Revcovi 2.4 mg for Intramuscular Injection (Teijin Pharma Limited)	Approval	<u>Elaeopadomase</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of adenosine deaminase deficiency. [Orphan drug]
6-2	Mar. 26, 2019	62	Forxiga 5 mg Tablets Forxiga 10 mg Tablets (AstraZeneca K.K.)	Change Change	Dapagliflozin propylene glycolate hydrate	Drugs with a new additional indication and a new dosage for the treatment of type 1 diabetes mellitus.
<i>In vivo</i> diagnostics	Jul. 2, 2018	63	Diagnogreen for Injection 25 mg (Daiichi Sankyo Company, Limited)	Change	Indocyanine green	A drug with a new additional indication and a new dosage for the evaluation of vascular and tissue blood flow. [Public knowledge-based application after PAFSC's preliminary assessment]
<i>In vivo</i> diagnostics	Sep. 21, 2018	64	Dobutrex Injection 100 mg Dobutrex Kit for Intravenous Infusion 200 mg Dobutrex Kit for Intravenous Infusion 600 mg (Kyowa Pharmaceutical Industry Co., Ltd.) Dobutamine Injection 100 mg [Pfizer] Dobutamine Injection 200 mg Kit [Pfizer] Dobutamine Injection 600 mg Kit [Pfizer] (Mylan Seiyaku Ltd.)	Change Change Change Change Change Change	Dobutamine hydrochloride	Drugs with a new additional indication and a new dosage for stress echocardiography. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	May 25, 2018	65	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	May 25, 2018	66	Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)	Change	Ipilimumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Jul. 2, 2018	67	Imfinzi Injection 120 mg Imfinzi Injection 500 mg (AstraZeneca K.K.)	Approval Approval	<u>Durvalumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the maintenance treatment of locally-advanced, unresectable non-small cell lung cancer following definitive chemoradiation therapy.
Oncology drugs	Jul. 2, 2018	68	Gazyva Intravenous Infusion 1000 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Obinutuzumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of CD20-positive follicular lymphoma.

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Oncology drugs	Jul. 2, 2018	69	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	<u>Olaparib</u>	Drugs with a new additional indication for the treatment of unresectable or recurrent BRCA mutation-positive and HER2-negative breast cancer in patients who have previously been treated with chemotherapy. [Orphan drug]
Oncology drugs	Jul. 2, 2018	70	Treakisym Injection 25 mg Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change Change	Bendamustine hydrochloride	Drugs with a new dosage indicated for the treatment of low-grade B-cell non-Hodgkin's lymphoma.
Oncology drugs	Jul. 2, 2018	71	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Change Change	Dabrafenib mesilate	Drugs with a new additional indication and a new dosage indicated for the treatment of BRAF mutation-positive melanoma. [Orphan drug]
Oncology drugs	Jul. 2, 2018	72	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Change Change	Trametinib dimethyl sulfoxide	Drugs with a new additional indication and a new dosage indicated for the treatment of BRAF mutation-positive melanoma. [Orphan drug]
Oncology drugs	Jul. 2, 2018	73	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new additional indication for the treatment of chronic lymphocytic leukemia (including small lymphocytic lymphoma). [Orphan drug]
Oncology drugs	Aug. 21, 2018	74	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	(1) Drugs with new indications and a new dosage for the treatment of unresectable or recurrent malignant pleural mesothelioma and melanoma that have progressed after chemotherapy. [Orphan drug] (2) Drugs with a new dosage indicated for the treatment of melanoma, unresectable or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable or recurrent gastric cancer that has progressed after chemotherapy, and (3) unresectable or metastatic renal cell carcinoma. [(3) Priority review]
Oncology drugs	Aug. 21, 2018	75	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 or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Aug. 21, 2018	76	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Change Change	Osimertinib mesilate	Drugs with a new indication for the treatment of inoperable or recurrent epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer. [Priority review]
Oncology drugs	Aug. 21, 2018	77	Poteligeo Injection 20 mg (Kyowa Hakkō Kirin Co., Ltd.)	Change	Mogamulizumab (genetical recombination)	A drug with new indications and a new dosage for the treatment of relapsed or refractory cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Sep. 21, 2018	78	Verzenio Tablets 50 mg Verzenio Tablets 100 mg Verzenio Tablets 150 mg (Eli Lilly Japan K.K.)	Approval Approval Approval	<u>Abemaciclib</u>	Drugs with a new active ingredient indicated for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer.
Oncology drugs	Sep. 21, 2018	79	Blinicyto for Drip Infusion 35 µg (Amgen Astellas BioPharma K.K.)	Approval	<u>Blinatumomab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Sep. 21, 2018	80	Lorbrena Tablets 25 mg Lorbrena Tablets 100 mg (Pfizer Japan Inc.)	Approval Approval	<u>Lorlatinib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer with resistance or intolerance to ALK tyrosine kinase inhibitors. [Conditional early approval]
Oncology drugs	Sep. 21, 2018	81	Xospata Tablets 40 mg (Astellas Pharma Inc.)	Approval	<u>Gilteritinib fumarate</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory FLT3 mutation-positive acute myeloid leukemia. [Orphan drug, SAKIGAKE designation]

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Oncology drugs	Sep. 21, 2018	82	Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Nivolumab (genetical recombination)	(1) A drug with new indications and a new dosage in an additional dosage form for the treatment of unresectable or recurrent malignant pleural mesothelioma and melanoma that have progressed after chemotherapy. [Orphan drug] (2) A drug with a new dosage in an additional dosage form indicated for the treatment of melanoma, unresectable or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable or recurrent gastric cancer that has progressed after chemotherapy, and (3) unresectable or metastatic renal cell carcinoma. [(3) Priority review]
Oncology drugs	Sep. 21, 2018	83	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	A drug with a new indication and a new dosage for the treatment of CD30-positive Hodgkin's lymphoma [Orphan drug]
Oncology drugs	Sep. 21, 2018	84	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.) Oxaliplatin i.v. Infusion 50 mg "Sawai" Oxaliplatin i.v. Infusion 100 mg "Sawai" Oxaliplatin i.v. Infusion 200 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Oxaliplatin I.V. Infusion Solution 50 mg "NK" Oxaliplatin I.V. Infusion Solution 100 mg "NK" Oxaliplatin I.V. Infusion Solution 200 mg "NK" (Nippon Kayaku Co., Ltd.) Oxaliplatin I.V. Infusion 50 mg "Nipro" Oxaliplatin I.V. Infusion 100 mg "Nipro" Oxaliplatin I.V. Infusion 200 mg "Nipro" (Nipro Corporation) Oxaliplatin I.V. Drip Infusion 50 mg "DSEP" Oxaliplatin I.V. Drip Infusion 100 mg "DSEP" Oxaliplatin I.V. Drip Infusion 200 mg "DSEP" (Daiichi Sankyo Espha Co., Ltd.)	Change Change Change Change Change Change Change Change Change Change Change Change	Oxaliplatin	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	85	(1) Isovorin Injection 25 mg Isovorin Injection 100 mg (Pfizer Japan Inc.) (2) Levofolinate for I.V. Drip Infusion 25 "Ohara" Levofolinate for I.V. Drip Infusion 100 "Ohara" (Ohara Pharmaceutical Co., Ltd.) (3) Levofolinate for I.V. Infusion 25 mg "Yakult" Levofolinate for I.V. Infusion 100 mg "Yakult" (Yakult Honsha Co., Ltd.) (4) Levofolinate for I.V. Infusion 25 mg "NK" Levofolinate for I.V. Infusion 100 mg "NK" (Takata Pharmaceutical Co., Ltd.) (5) Levofolinate for I.V. Infusion 25 mg "NP" Levofolinate for I.V. Infusion 100 mg "NP" (Nipro Corporation)	Change Change Change Change Change Change Change Change	Except (2): Levofolinate calcium (2): Calcium levofolinate hydrate	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	86	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new indication and a new dosage for the treatment of small intestine cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 21, 2018	87	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Busulfan	A drug with a new additional once-daily dosage indicated for a conditioning regimen prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem cell transplantation for Ewing's sarcoma (ES) family tumors and neuroblastoma. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Oct. 10, 2018	88	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Change	Pertuzumab (genetical recombination)	A drug with a new indication for the treatment of HER2-positive breast cancer.
Oncology drugs	Dec. 21, 2018	89	Keytruda Injection 100 mg Keytruda Injection 20 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with new indications and a new dosage for the treatment of: (1) advanced or recurrent microsatellite instability-high (MSI-High) solid tumors that have progressed after cancer chemotherapy (for use only if refractory or intolerant to standard therapies), (2) melanoma, and (3) unresectable advanced or recurrent non-small cell lung cancer. [(1) Conditional early approval, (2) Orphan drug, (3) Priority review]
Oncology drugs	Dec. 21, 2018	90	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new dosage indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer. [Priority review]
Oncology drugs	Jan. 8, 2019	91	Braftovi Capsules 50 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Encorafenib</u>	A drug with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF gene mutation. [Orphan drug]
Oncology drugs	Jan. 8, 2019	92	Mektovi Tablets 15 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Binimetinib</u>	A drug with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF gene mutation. [Orphan drug]
Oncology drugs	Jan. 8, 2019	93	Vizimpro Tablets 15 mg Vizimpro Tablets 45 mg (Pfizer Japan Inc.)	Approval Approval	<u>Dacomitinib hydrate</u>	Drugs with a new active ingredient indicated for the treatment of inoperable or recurrent non-small cell lung cancer with EGFR gene mutation. [Priority review]
Oncology drugs	Jan. 8, 2019	94	Gonax 80 mg for Subcutaneous Injection Gonax 120 mg for Subcutaneous Injection Gonax 240 mg for Subcutaneous Injection (Astellas Pharma Inc.)	Change Change Approval	Degarelix acetate	Drugs with a new dosage and a drug in an additional dosage form indicated for the treatment of prostate cancer.
Oncology drugs	Feb. 21, 2019	95	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Change	Ceritinib	A drug with a new dosage indicated for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer.
Oncology drugs	Feb. 21, 2019	96	Temodal Capsules 20 mg Temodal Capsules 100 mg Temodal Infusion 100 mg (MSD K.K.) Temozolomide Tab. 20 mg "NK" Temozolomide Tab. 100 mg "NK" (Nippon Kayaku Co., Ltd.)	Change Change Change Change Change	Temozolomide	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory Ewing's sarcoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 26, 2019	97	Erlveda Tablets 60 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Apalutamide</u>	A drug with a new active ingredient indicated for the treatment of non-metastatic, castration-resistant prostate cancer.
Oncology drugs	Mar. 26, 2019	98	Rethio 100 mg for Intravenous Infusion (Sumitomo Dainippon Pharma Co., Ltd.)	Approval	<u>Thiotepa</u>	A drug with a new active ingredient indicated for the treatment of solid tumors in pediatric patients prior to autologous hematopoietic stem-cell transplantation. [Expedited review]
Oncology drugs	Mar. 26, 2019	99	Rituxan Intravenous Infusion 100 mg Rituxan Intravenous Infusion 500 mg (Zenyaku Kogyo Co., Ltd.)	Change Change	Rituximab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of CD20-positive chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Mar. 26, 2019	100	Vepesid Injection 100 mg (Bristol-Myers Squibb K.K.) Lastet Inj. 100 mg/5 mL (Nippon Kayaku Co., Ltd.) Etoposide Intravenous Infusion 100 mg "Sandoz" (Sandoz K.K.) Etoposide Intravenous Infusion 100 mg "Taiyo" (Teva Takeda Pharma Ltd.) Etoposide Intravenous Infusion 100 mg "SN" (Shiono Chemical Co., Ltd.)	Change Change Change Change Change	Etoposide	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 26, 2019	101	Fludara 50 mg for Intravenous Infusion (Sanofi K.K.)	Change	Fludarabine phosphate	A drug with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	102	Cylocide N Injection 400 mg Cylocide N Injection 1 g (Nippon Shinyaku Co., Ltd.) Cytarabine for I.V. Infusion 400 mg "Teva" Cytarabine for I.V. Infusion 1 g "Teva" (Teva Takeda Pharma Ltd.)	Change Change Change Change	Cytarabine	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	103	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
Oncology drugs	Mar. 26, 2019	104	Treakisym Injection 25 mg Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change Change	Bendamustine hydrochloride	Drugs with other characteristics indicated for the treatment prior to tumor-specific T-cell infusion therapy. [Expedited review]
AIDS drugs	May 14, 2018	105	Isentress Tablets 600 mg (MSD K.K.)	Approval	Raltegravir potassium	A drug with a new dosage and in an additional dosage form indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Aug. 21, 2018	106	Odefsey Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Rilpivirine hydrochloride /Emtricitabine/ <u>Tenofovir alafenamide fumarate</u>	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Nov. 26, 2018	107	Juluca Combination Tablets (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium/ <u>Rilpivirine hydrochloride</u>	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Mar. 26, 2019	108	Biktary Combination Tablets (Gilead Sciences K.K.)	Approval	<u>Bictegravir sodium</u> / Emtricitabine/Tenofovir alafenamide fumarate	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
Vaccines	Mar. 26, 2019	109	Rabipur Intramuscular Injection (GlaxoSmithKline K.K.)	Approval	<u>Freeze-dried inactivated tissue culture rabies vaccine</u>	A drug with a new active ingredient indicated for the pre-exposure and post-exposure prophylaxis against rabies.
Blood products	Jul. 2, 2018	110	Refixia I.V. Injection 500 Refixia I.V. Injection 1000 Refixia I.V. Injection 2000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	<u>Nonacog beta pegol</u> (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with coagulation factor IX deficiency.
Blood products	Sep. 21, 2018	111	Jivi for iv injection 250 Jivi for iv injection 500 Jivi for iv injection 1000 Jivi for iv injection 2000 Jivi for iv injection 3000 (Bayer Yakuhin, Ltd.)	Approval Approval Approval Approval	<u>Damoctocog alfa pegol</u> (genetical recombination)	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Dec. 21, 2018	112	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change	Emicizumab (genetical recombination)	Drugs with a new dosage indicated for the control of bleeding tendency in patients with congenital blood coagulation factor VIII deficiency with blood coagulation factor VIII inhibitors. [Orphan drug]
Blood products	Dec. 21, 2018	113	Hemlibra s.c. 30 mg Hemlibra s.c. 60 mg Hemlibra s.c. 90 mg Hemlibra s.c. 105 mg Hemlibra s.c. 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change	Emicizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency without blood coagulation factor VIII inhibitors.
Bio-CMC	Jul. 2, 2018	114	Infliximab BS for I.V. Infusion 100 mg [Pfizer] (Pfizer Japan Inc.)	Approval	Infliximab (genetical recombination) [Infliximab biosimilar 3]	Follow-on biologics indicated for the treatment of rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial	Active Ingredient (underlined: new active ingredient)	Notes
Bio-CMC	Sep. 21, 2018	115	Agalsidase Beta BS I.V. Infusion 5 mg [JCR] Agalsidase Beta BS I.V. Infusion 35 mg [JCR] (JCR Pharmaceuticals Co., Ltd.)	Approval Approval	Agalsidase beta (genetical recombination) [agalsidase beta biosimilar 1]	Follow-on biologics indicated for the treatment of Fabry disease.
Bio-CMC	Sep. 21, 2018	116	Trastuzumab BS for Intravenous Drip Infusions 60 mg "Daiichi Sankyo" Trastuzumab BS for Intravenous Drip Infusions 150 mg "Daiichi Sankyo" (Daiichi Sankyo Company, Limited)	Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 2]	Follow-on biologics indicated for the treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2.
Bio-CMC	Sep. 21, 2018	117	Trastuzumab BS for Intravenous Infusion 60 mg [Pfizer] Trastuzumab BS for Intravenous Infusion 150 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 3]	Follow-on biologics indicated for the treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2.
Bio-CMC	Mar. 26, 2019	118	Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. "TY" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "TY" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "TY" Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. "TY" (YL Biologics Limited) Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. "Nichiiko" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "Nichiiko" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "Nichiiko" Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. "Nichiiko" (Kyowa Pharmaceutical Industry Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval	Etanercept (genetical recombination) [etanercept biosimilar 2]	Follow-on biologics indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) and polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies.

***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