

New Drugs Approved in FY 2019

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	May 22, 2019	1	Entyvio for I.V. Infusion 300 mg (Takeda Pharmaceutical Company Limited)	Change	<u> Vedolizumab</u> (genetical recombination)	A drug with a new additional indication for the treatment and maintenance therapy of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jun. 18, 2019	2	Ultomiris for intravenous Infusion 300 mg (Alexion Pharma G.K.)	Approval	<u> Ravulizumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of paroxysmal nocturnal hemoglobinuria. [Orphan drug]
1	Jun. 18, 2019	3	Romiplate for S.C. Injection 250 µg (Kyowa Hakko Kirin Co., Ltd.)	Change	<u> Romiplostim</u> (genetical recombination)	A drug with a new indication and a new dosage for the treatment of aplastic anemia in patients who have not responded sufficiently to conventional treatments.
1	Sep. 20, 2019	4	Evrenzo Tablets 20 mg Evrenzo Tablets 50 mg Evrenzo Tablets 100 mg (Astellas Pharma Inc.)	Approval Approval Approval	<u> Roxadustat</u>	Drugs with a new active ingredient indicated for the treatment of renal anaemia in patients who are undergoing dialysis.
1	Dec. 20, 2019	5	Venoglobulin IH 5% I.V. 0.5 g/10 mL Venoglobulin IH 5% I.V. 1 g/20 mL Venoglobulin IH 5% I.V. 2.5 g/50 mL Venoglobulin IH 5% I.V. 5 g/100 mL Venoglobulin IH 5% I.V. 10 g/200 mL 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 Change Change Change Change Change	<u> Polyethylene glycol treated human normal immunoglobulin</u>	Drugs with a new additional indication and a new dosage for the preoperative desensitization therapy for kidney transplantation in donor-specific antibodies (DSA) positive patients. [Orphan drug]
1	Dec. 20, 2019	6	Orkedia Tablets 1 mg Orkedia Tablets 2 mg (Kyowa Kirin Co., Ltd.)	Change Change	<u> Evocalcet</u>	Drugs with new additional indications and a new dosage for the treatment of hypercalcemia in patients with parathyroid carcinoma or patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy. [Orphan drug]
1	Jan. 23, 2020	7	Corectim Ointment 0.5% (Japan Tobacco Inc.)	Approval	<u> Delgocitinib</u>	A drug with a new active ingredient indicated for the treatment of atopic dermatitis.
1	Mar. 25, 2020	8	Lokelma 5 g Powder for Suspension (Single-dose package) Lokelma 10 g Powder for Suspension (Single-dose package) (AstraZeneca K.K.)	Approval Approval	<u> Sodium zirconium cyclosilicate hydrate</u>	Drugs with a new active ingredient indicated for the treatment of hyperkalemia.
1	Mar. 25, 2020	9	1) Stelara Intravenous Infusion 130 mg 2) Stelara Subcutaneous Injection 45 mg Syringe (Janssen Pharmaceutical K.K.)	Change Change	<u> Ustekinumab</u> (genetical recombination)	1) A drug with a new indication 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) A drug with a new indication for the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
6-2	May 22, 2019	10	Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.)	Change	<u> Liraglutide</u> (genetical recombination)	A drug with a new dosage and other characteristics indicated for the treatment of type 2 diabetes mellitus.
6-2	Jun. 18, 2019	11	Xultophy Combination Injection FlexTouch (Novo Nordisk Pharma Ltd.)	Approval	<u> Insulin degludec</u> (genetical recombination) / <u> Liraglutide</u> (genetical recombination)	A new combination drug indicated for the treatment of type 2 diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 20, 2019	12	Fiasp Injection FlexTouch Fiasp Injection Penfill Fiasp Injection 100 U/mL (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	<u> Insulin aspart</u> (genetical recombination)	Drugs in new dosage forms indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 20, 2019	13	Brineura Intracerebroventricular Injectable Solution 150 mg (BioMarin Pharmaceutical Japan K.K.)	Approval	<u> Cerliponase alfa</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2). [Orphan drug]

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6-2	Sep. 20, 2019	14	Crysvita Subcutaneous Injection 10 mg Crysvita Subcutaneous Injection 20 mg Crysvita Subcutaneous Injection 30 mg (Kyowa Kirin Co., Ltd.)	Approval Approval Approval	<u>Burosumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of FGF23-related hypophosphatemic rickets/osteomalacia. [Orphan drug]
6-2	Sep. 20, 2019	15	Teribone 28.2 µg Subcutaneous Autoinjector (Asahi Kasei Pharma Corporation)	Approval	Teriparatide acetate	A drug with a new dosage in an additional dosage form indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Jan. 23, 2020	16	Urece Tablets 0.5 mg Urece Tablets 1 mg Urece Tablets 2 mg (Fuji Yakuhin Co., Ltd.)	Approval Approval Approval	<u>Dotinurad</u>	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.
6-2	Jan. 23, 2020	17	Thyradin-S Intravenous Injection 200 µg (Aska Pharmaceutical Co., Ltd.)	Approval	Levothyroxine sodium hydrate	A drug with a new route of administration indicated for the treatment of myxedema coma and hypothyroidism (for hypothyroidism, only in patients ineligible for oral levothyroxine sodium therapy).
6-2	Mar. 25, 2020	18	Lyumjev Cart Lyumjev MirioPen Lyumjev MirioPen HD Lyumjev Injection 100 units/mL (Eli Lilly Japan K.K.)	Approval Approval Approval Approval	Insulin lispro (genetical recombination)	Drugs in new dosage forms indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Mar. 25, 2020	19	Baqsimi Nasal Powder 3 mg (Eli Lilly Japan K.K.)	Approval	Glucagon	A drug with a new route of administration indicated for the emergency treatment of hypoglycemia.
6-2	Mar. 25, 2020	20	Soliqua Injection Solostar (Sanofi K.K.)	Approval	Insulin glargine (genetical recombination)/ Lixisenatide	A new combination drug indicated for the treatment of type 2 diabetes mellitus in cases where insulin therapy is indicated.
2	May 22, 2019	21	Blipress Tablets 2 Blipress Tablets 4 Blipress Tablets 8 Blipress Tablets 12 (Teva Takeda Pharma Ltd.) Candesartan Tablets 2 mg "Aska" Candesartan Tablets 4 mg "Aska" Candesartan Tablets 8 mg "Aska" Candesartan Tablets 12 mg "Aska" (Aska Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change Change	Candesartan cilexetil	Drugs with a new additional pediatric dosage indicated for the treatment of hypertension. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Jun. 18, 2019	22	Defitelio Injection 200 mg (Nippon Shinyaku Co., Ltd.)	Approval	<u>Defibrotide sodium</u>	A drug with a new active ingredient indicated for the treatment of sinusoidal obstruction syndrome (SOS)/hepatic veno-occlusive disease (VOD). [Orphan drug]
2	Jun. 18, 2019	23	Repatha SC Injection 140 mg Syringe Repatha SC Injection 140 mg Pen Repatha SC Injection 420 mg Auto Mini-doser (Amgen Astellas BioPharma K.K.)	Change Change Change	Evolocumab (genetical recombination)	Drugs with a new additional indication 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	Sep. 20, 2019	24	Haruropi Tape 8 mg Haruropi Tape 16 mg Haruropi Tape 24 mg Haruropi Tape 32 mg Haruropi Tape 40 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Approval Approval Approval Approval	Ropinirole hydrochloride	Drugs with a new route of administration indicated for the treatment of Parkinson's disease.
2	Sep. 20, 2019	25	Equfina Tablets 50 mg (Meiji Seika Pharma Co., Ltd.)	Approval	<u>Safinamide mesilate</u>	A drug with a new active ingredient indicated for the improvement of wearing-off phenomenon in patients with Parkinson's disease under the treatment with levodopa-containing preparations.
2	Sep. 20, 2019	26	Coralan Tablets 2.5 mg Coralan Tablets 5 mg Coralan Tablets 7.5 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	<u>Ivabradine hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of chronic heart failure with sinus rhythm and a resting heart rate of 75 bpm or greater at baseline (for use only in patients receiving standard treatment of chronic heart failure, including β-blocker).
2	Feb. 21, 2020	27	Neoral Oral Solution 10% (Novartis Pharma K.K.)	Change	Ciclosporin	A drug with a new indication and a new dosage for the treatment of the acute phase of Kawasaki's disease (for patients with severe Kawasaki's disease who have the risk of developing coronary artery disorder).

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2	Feb. 21, 2020	28	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 acquired thrombotic thrombocytopenic purpura. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 25, 2020	29	Cabpirin Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Aspirin/Vonoprazan fumarate	A new combination drug indicated for inhibiting thrombus/embolization formation in the following diseases or post-operations (for use only in patients with a history of gastric ulcer or duodenal ulcer): • Angina pectoris (chronic stable angina, unstable angina), myocardial infarction, or ischemic cerebrovascular disease (transient ischemic attack [TIA], cerebral infarction) • Coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
5	Jun. 18, 2019	30	Minirinmelt OD Tablets 25 µg Minirinmelt OD Tablets 50 µg (Ferring Pharmaceuticals Co., Ltd.)	Approval Approval	Desmopressin acetate hydrate	Drugs with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of nocturia due to nocturnal polyuria in males.
5	Dec. 20, 2019	31	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new route of administration indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder or urinary incontinence due to neurogenic bladder, in patients who have not responded sufficiently to conventional therapies or in whom conventional therapies are not suitable.
5	Jan. 23, 2020	32	Propess Vaginal Inserts 10 mg (Ferring Pharmaceuticals Co., Ltd.)	Approval	Dinoprostone	A drug with a new route of administration indicated for the initiation of cervical ripening in patients with unfavourable cervix from 37 completed weeks of gestation.
5	Jan. 23, 2020	33	Dinagest Tablets 0.5 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Dienogest	A drug with a new indication and a new dosage in an additional dosage form for the treatment of dysmenorrhea.
3-1	Jun. 18, 2019	34	Lonasen Tape 20 mg Lonasen Tape 30 mg Lonasen Tape 40 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Approval Approval Approval	Blonanserin	Drugs with a new route of administration indicated for the treatment of schizophrenia.
3-1	Jun. 18, 2019	35	Onpattro for Intravenous Infusion 2 mg/mL (Alnylam Japan K.K.)	Approval	<u>Patisiran sodium</u>	A drug with a new active ingredient indicated for the treatment of transthyretin familial amyloid polyneuropathy. [Orphan drug]
3-1	Jun. 18, 2019	36	Intuniv Tablets 1 mg Intuniv Tablets 3 mg (Shionogi & Co., Ltd.)	Change Change	Guanfacine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Aug. 22, 2019	37	Afinitor Tablets 2.5 mg Afinitor Tablets 5 mg Afinitor Dispersible Tablets 2 mg Afinitor Dispersible Tablets 3 mg (Novartis Pharma K.K.)	Change Change Change Change	Everolimus	Drugs with a new indication and a new dosage for the treatment of tuberous sclerosis complex. [Orphan drug]
3-1	Aug. 22, 2019	38	Kenketsu Venilon-I for Intravenous Injection 500 mg Kenketsu Venilon-I for Intravenous Injection 1000 mg Kenketsu Venilon-I for Intravenous Injection 2500 mg Kenketsu Venilon-I for Intravenous Injection 5000 mg (KM Biologics Co., Ltd.)	Change Change Change Change	Freeze-dried sulfonated human normal immunoglobulin	Drugs with a new additional indication and a new dosage for the improvement of muscle weakness in patients with chronic inflammatory demyelinating polyneuropathy (including multifocal motor neuropathy).
3-1	Sep. 20, 2019	39	Trintellix Tablets 10 mg Trintellix Tablets 20 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Vortioxetine hydrobromide</u>	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Nov. 22, 2019	40	Soliris for Intravenous Infusion 300 mg (Alexion Pharma GK)	Change	Eculizumab (genetical recombination)	A drug with a new additional indication for the prevention of relapse of neuromyelitis optica spectrum disorder (including neuromyelitis optica). [Orphan drug]

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3-1	Dec. 20, 2019	41	Kenketsu Venilon-I for Intravenous Injection 500 mg Kenketsu Venilon-I for Intravenous Injection 1000 mg Kenketsu Venilon-I for Intravenous Injection 2500 mg Kenketsu Venilon-I for Intravenous Injection 5000 mg (KM Biologics Co., Ltd.)	Change Change Change Change	Freeze-dried sulfonated human normal immunoglobulin	Drugs with a new additional indication and a new dosage for the treatment of acute-phase optic neuritis (for use when steroid drugs are not sufficiently effective). [Orphan drug]
3-1	Dec. 20, 2019	42	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new dosage indicated for the treatment of upper limb spasticity.
3-1	Jan. 23, 2020	43	Fycempa Fine Granules 1% Fycempa Tablets 2 mg Fycempa Tablets 4 mg (Eisai Co., Ltd.)	Approval Change Change	Perampanel hydrate	A drug in an additional dosage form and drugs with a revised indication and a new additional pediatric dosage for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy.
3-1	Jan. 23, 2020	44	Dayvigo Tablets 2.5 mg Dayvigo Tablets 5 mg Dayvigo Tablets 10 mg (Eisai Co., Ltd.)	Approval Approval Approval	<u>Lemborexant</u>	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Feb. 21, 2020	45	Modiodal Tablets 100 mg (Alfresa Pharma Corporation)	Change	Modafinil	A drug with a new indication for the treatment of excessive daytime sleepiness associated with idiopathic hypersomnia. [Orphan drug]
3-1	Mar. 25, 2020	46	Melatobel Granules 0.2% for Pediatric (Nobelpharma Co., Ltd.)	Approval	<u>Melatonin</u>	A drug with a new active ingredient indicated for the improvement of difficulty falling asleep associated with pediatric neurodevelopmental disorder.
3-1	Mar. 25, 2020	47	Latuda Tablets 20 mg Latuda Tablets 40 mg Latuda Tablets 60 mg Latuda Tablets 80 mg (Sumitomo Dainippon Pharma Co., Ltd.)	Approval Approval Approval Approval	<u>Lurasidone hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of schizophrenia and the improvement of depressive symptoms in patients with bipolar disorder.
3-1	Mar. 25, 2020	48	Viltepso Intravenous Infusion 250 mg (Nippon Shinyaku Co., Ltd.)	Approval	<u>Viltolarsen</u>	A drug with a new active ingredient indicated for the treatment of Duchenne muscular dystrophy (DMD) with a confirmed deficiency of the dystrophin gene amenable to exon 53 skipping therapy. [SAKIGAKE designation] [Conditional early approval] [Orphan drug]
3-2	Sep. 20, 2019	49	Retympha 250 µg Set for Otology (Nobelpharma Co., Ltd.)	Approval	Trafermin (genetical recombination)	A drug with a new route of administration indicated for the treatment of tympanic membrane perforation.
3-2	Sep. 20, 2019	50	Aibeta Combination Ophthalmic Solution (Senju Pharmaceutical Co., Ltd.)	Approval	Brimonidine tartrate/Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs.
3-2	Nov. 22, 2019	51	Lucentis Solution for Intravitreal Injection 10 mg/mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of retinopathy of prematurity. [Orphan drug]
3-2	Jan. 23, 2020	52	Anerem 50 mg for I.V. Injection (Mundipharma K.K.)	Approval	<u>Remimazolam besilate</u>	A drug with a new active ingredient indicated for the induction and maintenance of general anesthesia.
3-2	Mar. 25, 2020	53	Beovu Kit for Intravitreal Injection 120 mg/mL (Novartis Pharma K.K.)	Approval	<u>Brolucizumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization.
3-2	Mar. 25, 2020	54	Ailamide Combination Ophthalmic Suspension (Senju Pharmaceutical Co., Ltd.)	Approval	Brimonidine tartrate/ Brinzolamide	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs.
3-2	Mar. 25, 2020	55	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of neovascular glaucoma. [Orphan drug]
4	Jun. 18, 2019	56	Inavir for Inhalation Suspension 160 mg Set (Daiichi Sankyo Company, Limited)	Approval	Laninamivir octanoate hydrate	A drug in a new dosage form indicated for the treatment of influenza A or B virus infection.

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4	Jun. 18, 2019	57	Azimycin Ophthalmic Solution 1% (Senju Pharmaceutical Co., Ltd.)	Approval	Azithromycin hydrate	A drug with a new route of administration indicated for the treatment of conjunctivitis, blepharitis, hordeolum and dacryocystitis caused by azithromycin-sensitive <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., <i>Streptococcus pneumoniae</i> , <i>Corynebacterium</i> spp., <i>Haemophilus influenzae</i> or <i>Propionibacterium acnes</i> .
4	Aug. 22, 2019	58	Maviret Combination Tablets (AbbVie GK)	Change	Glecaprevir hydrate/Pibrentasvir	A drug with a new additional pediatric dosage indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C. [Priority review]
4	Sep. 20, 2019	59	Lasvic Tablets 75 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval	<u>Lasclufloxacin hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, otitis media, and sinusitis caused by Lasvic-sensitive <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., <i>Streptococcus pneumoniae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , <i>Prevotella</i> spp., and <i>Mycoplasma pneumoniae</i> .
4	Dec. 20, 2019	60	Zerbaxa Combination for Intravenous Drip Infusion (MSD K.K.)	Change	Ceftolozane sulfate/Tazobactam sodium	A drug with new additional indications and a new dosage for the treatment of sepsis and pneumonia caused by <i>Serratia</i> and <i>Haemophilus influenzae</i> .
4	Jan. 23, 2020	61	Noxafil Tablets 100 mg Noxafil for Intravenous Infusion 300 mg (MSD K.K.)	Approval Approval	<u>Posaconazole</u>	Drugs with a new active ingredient indicated for the •prophylaxis of deep mycosis in hematopoietic stem cell transplantation recipients or patients with hematologic malignancy who are predicated to decrease neutrophil. •treatment of the following mycoses: Fusariosis, mucormycosis, coccidioidomycosis, chromoblastomycosis, and mycetoma.
AIDS drugs	May 22, 2019	62	Genvoya Combination Tablets (Japan Tobacco Inc.)	Change	Elvitegravir/Cobicistat /Emtricitabine/Tenofovir alafenamide fumarate	A drug with a new additional pediatric dosage indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Jun. 18, 2019	63	Symtuza Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Darunavir ethanolate/Cobicistat /Emtricitabine/Tenofovir alafenamide fumarate	A new combination drug indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Jan. 14, 2020	64	Dovato Combination Tablets (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium/Lamivudine	A new combination drug indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Jan. 14, 2020	65	Pifeltro Tablets 100 mg (MSD K.K.)	Approval	<u>Doravirine</u>	A drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
6-1	May 22, 2019	66	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 adult Still's disease in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 18, 2019	67	Breztri Aerosphere 56 Inhalations Breztri Aerosphere 120 Inhalations (AstraZeneca K.K.)	Approval Approval	Budesonide / <u>Glycopyrronium bromide</u> /Formoterol fumarate hydrate	New combination drugs with a new active ingredient 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	Jun. 18, 2019	68	Bevespi Aerosphere 28 Inhalations Bevespi Aerosphere 120 Inhalations (AstraZeneca K.K.)	Approval Approval	<u>Glycopyrronium bromide</u> /Formoterol fumarate hydrate	New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with a long-acting inhaled anticholinergic agent and a long-acting beta-2 agonist).
6-1	Sep. 20, 2019	69	Otezla Tablets 10 mg Otezla Tablets 20 mg Otezla Tablets 30 mg (Celgene K.K.)	Change Change Change	Apremilast	Drugs with a new indication for the treatment of oral ulcer associated with Behcet's disease in patients who have not responded sufficiently to local treatment.

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6-1	Sep. 20, 2019	70	Alesion LX Ophthalmic Solution 0.1% (Santen Pharmaceutical Co., Ltd.)	Approval	Epinastine hydrochloride	A drug with a new dosage in an additional dosage form indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 20, 2019	71	Benlysta for I.V. Infusion 120 mg Benlysta for I.V. Infusion 400 mg (GlaxoSmithKline K.K.)	Change Change	Belimumab (genetical recombination)	Drugs 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	Nov. 22, 2019	72	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 additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments.
6-1	Dec. 11, 2019	73	Xolair for S.C. Injection 75 mg Xolair for S.C. Injection 150 mg Xolair for S.C. Injection 75 mg Syringe Xolair for S.C. Injection 150 mg Syringe (Novartis Pharma K.K.)	Change Change Change Change	Omalizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of seasonal allergic rhinitis (for use only in severe or the most severe patients who have not responded sufficiently to conventional therapies).
6-1	Dec. 20, 2019	74	Cimzia 200 mg Syringe for S.C. Injection Cimzia 200 mg AutoClicks for S.C. Injection (UCB Japan Co., Ltd.)	Change Change	Certolizumab pegol (genetical recombination)	Drugs with new additional indications and a new dosage 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	Dec. 20, 2019	75	Ofev Capsules 100 mg Ofev Capsules 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change Change	Nintedanib ethanesulfonate	Drugs with a new additional indication for the treatment of systemic sclerosis associated interstitial lung disease. [Orphan drug]
6-1	Jan. 23, 2020	76	Rinvoq Tablets 7.5 mg Rinvoq Tablets 15 mg (AbbVie GK)	Approval Approval	<u>Upadacitinib hydrate</u>	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Feb. 21, 2020	77	Orencia for I.V. Infusion 250 mg Orencia SC 125 mg Syringe 1 mL Orencia SC 125 mg Autoinjector 1 mL (Bristol-Myers Squibb K.K.)	Change Change Change	Abatacept (genetical recombination)	Drugs with a new additional indication for the treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Mar. 25, 2020	78	Dupilixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Change	Dupilumab (genetical recombination)	A drug with a new additional 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).
6-1	Mar. 25, 2020	79	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Change	Mepolizumab (genetical recombination)	A drug with a new additional pediatric dosage indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
Oncology drugs	May 22, 2019	80	Pomalyst Capsules 1 mg Pomalyst Capsules 2 mg Pomalyst Capsules 3 mg Pomalyst Capsules 4 mg (Celgene K.K.)	Change Change Change Change	Pomalidomide	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Jun. 18, 2019	81	Portrazza Injection 800 mg (Eli Lilly Japan K.K.)	Approval	<u>Necitumumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent squamous non-small cell lung cancer.
Oncology drugs	Jun. 18, 2019	82	Vanflyta Tablets 17.7 mg Vanflyta Tablets 26.5 mg (Daiichi Sankyo Company, Limited)	Approval Approval	<u>Quizartinib hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory FLT3-ITD mutation-positive acute myeloid leukemia. [Orphan drug]
Oncology drugs	Jun. 18, 2019	83	Rozlytrek Capsules 100 mg Rozlytrek Capsules 200 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Entrectinib</u>	Drugs with a new active ingredient indicated for the treatment of <i>NTRK</i> fusion gene positive advanced or recurrent solid tumors. [SAKIGAKE designation, Orphan drug]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 18, 2019	84	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change Change	Gemcitabine hydrochloride	Drugs with a new dosage indicated for the treatment of non-small cell lung cancer.
Oncology drugs	Jun. 18, 2019	85	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new indication for the treatment of patients with unresectable hepatocellular carcinoma whose serum AFP level is greater than 400 ng/mL and conditions have progressed after cancer chemotherapy.
Oncology drugs	Jun. 18, 2019	86	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Change Change	Olaparib	Drugs with a new indication for maintenance treatment of BRCA mutation-positive ovarian cancer in patients who have received first chemotherapy. [Orphan drug]
Oncology drugs	Aug. 22, 2019	87	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of extensive-stage small-cell lung cancer. [Orphan drug]
Oncology drugs	Aug. 22, 2019	88	Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.)	Change Change	Trifluridine/Tipiracil hydrochloride	Drugs with a new indication for the treatment of unresectable advanced or recurrent gastric cancer that have progressed after chemotherapy.
Oncology drugs	Aug. 22, 2019	89	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Change Change	Daratumumab (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Aug. 22, 2019	90	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new dosage indicated for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 20, 2019	91	Venclexta Tablets 10 mg Venclexta Tablets 50 mg Venclexta Tablets 100 mg (AbbVie GK)	Approval Approval Approval	<u>Venetoclax</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.
Oncology drugs	Sep. 20, 2019	92	Tecentriq Intravenous Infusion 840 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Atezolizumab (genetical recombination)	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer.
Oncology drugs	Sep. 20, 2019	93	Eribitux Injection 100 mg (Merck Biopharma Co., Ltd.)	Change	Cetuximab (genetical recombination)	A drug with a new indication for the treatment of unresectable, advanced or recurrent colon or rectal cancer with wild-type RAS.
Oncology drugs	Sep. 20, 2019	94	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Nov. 22, 2019	95	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.
Oncology drugs	Nov. 22, 2019	96	Empliciti for I.V. Infusion 300 mg Empliciti for I.V. Infusion 400 mg (Bristol-Myers Squibb K.K.)	Change Change	Elotuzumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Nov. 22, 2019	97	Kyprolis for Intravenous Injection 10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Carfilzomib	Drugs with a new dosage indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Dec. 20, 2019	98	Bavencio Injection 200 mg (Merck Biopharma Co., Ltd.)	Change	Avelumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Dec. 20, 2019	99	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	1) Drugs with a new indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma. 2) Drugs with a new indication for the treatment of recurrent or metastatic head and neck cancer.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 20, 2019	100	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Change	Brentuximab vedotin (genetical recombination)	1) A drug with a new indication and a new dosage for the treatment of CD30-positive peripheral T-cell lymphoma. 2) A drug with a new additional pediatric dosage indicated for the treatment of relapsed or refractory CD30-positive Hodgkin's lymphoma and peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Dec. 20, 2019	101	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Change Change	Daratumumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of multiple myeloma. [Orphan drug]
Oncology drugs	Jan. 23, 2020	102	Nubeqa Tablets 300 mg (Bayer Yakuhin, Ltd.)	Approval	<u>Darolutamide</u>	A drug with a new active ingredient indicated for the treatment of non-metastatic, castration-resistant prostate cancer.
Oncology drugs	Jan. 23, 2020	103	Ibrance 25 mg Tablets Ibrance 125 mg Tablets (Pfizer Japan Inc.)	Approval Approval	Palbociclib	Drugs with a new indication in a new dosage form for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative inoperable or recurrent breast cancer.
Oncology drugs	Feb. 21, 2020	104	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	Lenalidomide hydrate	Drugs with new indications and a new dosage for the treatment of relapsed or refractory follicular lymphoma and marginal zone lymphoma.
Oncology drugs	Feb. 21, 2020	105	Alecensa Capsule 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Alectinib hydrochloride	A drug with a new indication and a new dosage for the treatment of relapsed or refractory ALK fusion gene-positive anaplastic large cell lymphoma. [Orphan drug]
Oncology drugs	Feb. 21, 2020	106	Rozlytrek Capsules 100 mg Rozlytrek Capsules 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Entrectinib	Drugs with a new indication and a new dosage for the treatment of ROS1 fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Feb. 21, 2020	107	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg Opdivo Intravenous Infusion 240 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change	Nivolumab (genetical recombination)	1) Drugs with a new indication for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy. 2) Drugs with a new indication for the treatment of unresectable advanced or recurrent oesophageal cancer that has progressed after cancer chemotherapy. 2) [Priority review]
Oncology drugs	Mar. 25, 2020	108	Onivyde I.V. Infusion 43 mg (Nihon Servier Co., Ltd.)	Approval	Irinotecan hydrochloride hydrate	A drug with a new indication in a new dosage form for the treatment of unresectable pancreatic cancer that has progressed after cancer chemotherapy.
Oncology drugs	Mar. 25, 2020	109	Cabometyx Tablets 20 mg Cabometyx Tablets 60 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Cabozantinib malate</u>	Drugs with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Mar. 25, 2020	110	Velexbru Tablets 80 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Tirabrutinib hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory primary central nervous system (CNS) lymphoma. [Orphan drug]
Oncology drugs	Mar. 25, 2020	111	Enhertu for Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Approval	<u>Trastuzumab deruxtecan</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer in patients who have previously been treated with chemotherapy (for use only if refractory or intolerant to standard therapies). [Conditional early approval]
Oncology drugs	Mar. 25, 2020	112	Steboronine 9000 mg/300 mL for infusion (Stella Pharma Corporation)	Approval	<u>Borofalan (¹⁰B)</u>	A drug with a new active ingredient indicated for the treatment of locally unresectable recurrent or unresectable advanced head and neck cancer. [SAKIGAKE designation]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 25, 2020	113	Tepmetko Tablets 250 mg (Merck Biopharma Co., Ltd.)	Approval	<u>Tepotinib hydrochloride hydrate</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent <i>MET</i> exon 14 (<i>MET</i> ex14) skipping mutation-positive non-small cell lung cancer. [SAKIGAKE designation] [Orphan drug]
Oncology drugs	Mar. 25, 2020	114	Rethio 100 mg for Intravenous Infusion (Sumitomo Dainippon Pharma Co., Ltd.)	Change	Thiotepa	A drug with a new indication and a new dosage for the conditioning treatment of malignant lymphoma in patients prior to autologous hematopoietic stem-cell transplantation.
Oncology drugs	Mar. 25, 2020	115	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 and a new dosage for the maintenance treatment of multiple myeloma in patients after autologous hematopoietic stem-cell transplantation.
Oncology drugs	Mar. 25, 2020	116	Busulfex Injection 60 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Busulfan	A drug with a new indication and a new dosage for the conditioning treatment of malignant lymphoma in patients prior to autologous hematopoietic stem-cell transplantation. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 20, 2019	117	Esperoct for I.V. Injection 500 Esperoct for I.V. Injection 1000 Esperoct for I.V. Injection 1500 Esperoct for I.V. Injection 2000 Esperoct for I.V. Injection 3000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	<u>Turoctocog alfa pegol (genetical recombination)</u>	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Blood products	Feb. 21, 2020	118	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.)	Change Change Change	pH4-treated acidic normal human immunoglobulin	Drugs with new indications and a new dosage for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Mar. 25, 2020	119	Vonvendi Intravenous 1300 (Shire Japan K.K.)	Approval	<u>Vonicog alfa (genetical recombination)</u>	A drug with a new active ingredient indicated for the control of bleeding tendency in patients with von Willebrand disease (VWD). [Orphan drug]
Bio-CMC	Jun. 18, 2019	120	Bevacizumab BS Intravenous Infusion 100 mg [Pfizer] Bevacizumab BS Intravenous Infusion 400 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Bevacizumab (genetical recombination) [bevacizumab biosimilar 1]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colorectal cancer.
Bio-CMC	Sep. 20, 2019	121	Teriparatide BS Subcutaneous Injection Kit 600 µg "MOCHIDA" (Mochida Pharmaceutical Co., Ltd.)	Approval	Teriparatide (genetical recombination) [teriparatide biosimilar 1]	A follow-on biologic indicated for the treatment of osteoporosis with a high risk of fracture.
Bio-CMC	Sep. 20, 2019	122	Darbepoetin Alfa BS Injection 5 µg Syringe [JCR] Darbepoetin Alfa BS Injection 10 µg Syringe [JCR] Darbepoetin Alfa BS Injection 15 µg Syringe [JCR] Darbepoetin Alfa BS Injection 20 µg Syringe [JCR] Darbepoetin Alfa BS Injection 30 µg Syringe [JCR] Darbepoetin Alfa BS Injection 40 µg Syringe [JCR] Darbepoetin Alfa BS Injection 60 µg Syringe [JCR] Darbepoetin Alfa BS Injection 120 µg Syringe [JCR] Darbepoetin Alfa BS Injection 180 µg Syringe [JCR] (JCR Pharmaceuticals Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [darbepoetin alfa biosimilar 1]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.
Bio-CMC	Sep. 20, 2019	123	Darbepoetin Alfa BS 5 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 10 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 15 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 20 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 30 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 40 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 60 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 120 µg Syringe for Injection "Sanwa" Darbepoetin Alfa BS 180 µg Syringe for Injection "Sanwa" (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [darbepoetin alfa biosimilar 2]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (<u>underlined</u> : new active ingredient)	Notes
Bio-CMC	Sep. 20, 2019	124	Darbepoetin Alfa BS Injection 5 µg Syringe "MYL" Darbepoetin Alfa BS Injection 10 µg Syringe "MYL" Darbepoetin Alfa BS Injection 15 µg Syringe "MYL" Darbepoetin Alfa BS Injection 20 µg Syringe "MYL" Darbepoetin Alfa BS Injection 30 µg Syringe "MYL" Darbepoetin Alfa BS Injection 40 µg Syringe "MYL" Darbepoetin Alfa BS Injection 60 µg Syringe "MYL" Darbepoetin Alfa BS Injection 120 µg Syringe "MYL" Darbepoetin Alfa BS Injection 180 µg Syringe "MYL" (Mylan EPD G.K.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination) [<u>darbepoetin alfa biosimilar 3</u>]	Follow-on biologics indicated for the treatment of nephrogenic anaemia.
Bio-CMC	Sep. 20, 2019	125	Bevacizumab BS Intravenous Drip Infusions 100 mg "Daiichi Sankyo" Bevacizumab BS Intravenous Drip Infusions 400 mg "Daiichi Sankyo" (Daiichi Sankyo Company, Limited)	Approval Approval	Bevacizumab (genetical recombination) [<u>bevacizumab biosimilar 2</u>]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent colon or rectal cancer.
Bio-CMC	Sep. 20, 2019	126	Rituximab BS Intravenous Infusion 100 mg [Pfizer] Rituximab BS Intravenous Infusion 500 mg [Pfizer] (Pfizer Japan Inc.)	Approval Approval	Rituximab (genetical recombination) [<u>rituximab biosimilar 2</u>]	Follow-on biologics indicated for the treatment of CD20-positive B-cell non-Hodgkin's lymphoma, CD20-positive B-cell lymphoproliferative disorder associated with immunosuppression, granulomatosis with polyangiitis, and microscopic polyangiitis.
Bio-CMC	Mar. 25, 2020	127	Insulin Lispro BS Injection HU Solostar "Sanofi" Insulin Lispro BS Injection HU Cart "Sanofi" Insulin Lispro BS Injection HU 100 U/mL "Sanofi" (Sanofi K.K.)	Approval Approval Approval	Insulin lispro (genetical recombination) [<u>Insulin lispro biosimilar 1</u>]	Follow-on biologics indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.

***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