

New Drugs Approved in FY 2017

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
1	May 18, 2017	1	Asacol Tablets 400 mg (Zeria Pharmaceutical Co., Ltd.)	Change	Mesalazine	A drug with a new dosage indicated for the treatment of ulcerative colitis (excluding severe cases).
1	May 18, 2017	2	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new dosage indicated for the treatment of Crohn's disease. [Orphan drug]
1	Jun. 26, 2017	3	Oldamin for Injection 1 g (Fuji Chemical Industries Co., Ltd.)	Change	Monoethanolamine oleate	A drug with a new additional indication and a new dosage indicated for the regression of gastric varices.
1	Jul. 3, 2017	4	Jadenu Granules Sachet 90 mg Jadenu Granules Sachet 360 mg (Novartis Pharma K.K.)	Approval Approval	Deferasirox	Drugs in a new dosage form indicated for the treatment of chronic iron overload due to blood transfusions (in patients for whom injection of iron chelating agents is inappropriate).
1	Aug. 25, 2017	5	Kenketu Nonthron 500 for injection Kenketu Nonthron 1500 for injection (Nihon Pharmaceutical Co., Ltd.)	Change Change	Lyophilized human antithrombin III concentrate	Drugs with a new additional indication and a new dosage for the treatment of portal vein thrombosis associated with decreased antithrombin III.
1	Aug. 25, 2017	6	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (Novartis Pharma K.K.)	Change Change	Eltrombopag olamine	Drugs with a new additional indication and a new dosage for the treatment of aplastic anemia. [Orphan drug]
1	Aug. 25, 2017	7	Neoral Oral Solution 10% Neoral 10 mg Capsules Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Ciclosporin	Drugs with a revised indication and a new dosage for the treatment of aplastic anemia which is not severe. [Expedited review]
1	Sep. 22, 2017	8	Pariet Tablets 5 mg Pariet Tablets 10 mg (Eisai Co., Ltd.)	Change Change	Rabeprazole sodium	Drugs with a new dosage indicated for the treatment of reflux esophagitis.
1	Sep. 27, 2017	9	Rectabul 2 mg Rectal Foam 14 Doses (EA Pharma Co., Ltd.)	Approval	Budesonide	A drug with a new route of administration indicated for the treatment of ulcerative colitis which is not severe.

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1	Mar. 23, 2018	15	Rapalimus Gel 0.2% (Nobelpharma Co., Ltd.)	Approval	Sirolimus	A drug with a new route of administration indicated for the treatment of skin lesions associated with tuberous sclerosis complex. [Orphan drug, SAKIGAKE designation]
2	Jun. 26, 2017	16	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of chronic idiopathic thrombocytopenic purpura. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Jul. 3, 2017	17	Parmodia Tab. 0.1 mg (Kowa Company, Ltd.)	Approval	<u>Pemafibrate</u>	A drug with a new active ingredient indicated for the treatment of hyperlipidaemia (including familial hyperlipidaemia).
2	Sep. 27, 2017	18	Atozet Combination Tablets LD Atozet Combination Tablets HD (MSD K.K.)	Approval Approval	Ezetimibe/ Atorvastatin calcium hydrate	New combination drugs indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Sep. 27, 2017	19	Revatio Tablets 20 mg Revatio Dry Syrup for Suspension 900 mg Revatio OD Film 20 mg (Pfizer Japan Inc.)	Change Approval Approval	Sildenafil citrate	Drugs with a new additional pediatric dosage and in additional dosage forms indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Jan. 19, 2018	20	Ibulief I.V. Injection 20 mg (Senju Pharmaceutical Co., Ltd.)	Approval	<u>Ibuprofen L-lysine</u>	A drug with a new active ingredient indicated for the treatment of patent ductus arteriosus in premature infants when conservative treatment (fluid restriction, diuretic use, etc.) is not sufficiently effective.
2	Mar. 23, 2018	21	Azilect Tablets 0.5 mg Azilect Tablets 1 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Rasagiline mesilate</u>	Drugs with a new active ingredient indicated for the treatment of Parkinson's disease.
3-1	Jul. 3, 2017	22	Bipresso Extended Release Tablets 50 mg Bipresso Extended Release Tablets 150 mg (Astellas Pharma Inc.)	Approval Approval	Quetiapine fumarate	Drugs with a new indication in new dosage form indicated for the improvement of depressive symptoms in patients with bipolar disorder.
3-1	Jul. 3, 2017	23	Spinraza Intrathecal injection 12 mg (Biogen Japan Ltd.)	Approval	<u>Nusinersen sodium</u>	A drug with a new active ingredient indicated for the treatment of infantile spinal muscular atrophy. [Orphan drug]
3-1	Jul. 3, 2017	24	Depromel Tablets 25 Depromel Tablets 50 Depromel Tablets 75 (Meiji Seika Pharma Co., Ltd.) Luvox Tablets 25 Luvox Tablets 50 Luvox Tablets 75 (AbbVie GK)	Change Change Change Change Change Change	Fluvoxamine maleate	Drugs with a new additional pediatric dosage indicated for the treatment of obsessive-compulsive disorder.

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3-1	Aug. 25, 2017	25	Leuplin SR for Injection Kit 11.25 mg (Takeda Pharmaceutical Company Limited)	Change	Leuprorelin acetate	A drug with a new additional indication for inhibiting progression of spinal and bulbar muscular atrophy. [Orphan drug]
3-1	Aug. 25, 2017	26	Vimpat Tablets 50 mg Vimpat Tablets 100 mg (UCB Japan Co., Ltd.)	Change Change	Lacosamide	Drugs with a revised indication for the treatment of partial seizures (including secondary generalized seizures) in patients with epilepsy.
3-1	Sep. 22, 2017	27	Spinraza Intrathecal injection 12 mg (Biogen Japan Ltd.)	Change	Nusinersen sodium	A drug with a revised indication and a new dosage for the treatment of spinal muscular atrophy. [Orphan drug]
3-1	Dec. 25, 2017	28	Soliris for Intravenous Infusion 300 mg (Alexion Pharma G.K.)	Change	Eculizumab (genetical recombination)	A drug with a new additional indication and a new dosage indicated for the treatment of generalized myasthenia gravis (for use only in patients whose symptoms cannot be sufficiently controlled with high-dose intravenous immunoglobulin or plasmapheresis). [Orphan drug]
3-1	Jan. 19, 2018	29	Rexulti Tablets 1 mg Rexulti Tablets 2 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Brexpiprazole</u>	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Mar. 23, 2018	30	Hernicore 1.25 Units for Intradiscal Inj. (Seikagaku Corporation)	Approval	<u>Condoliase</u>	A drug with a new active ingredient indicated for the treatment of lumbar disc herniation with subligamentous extrusion that has not adequately responded to conservative treatment.
3-2	Sep. 22, 2017	31	Remitch Capsules 2.5 µg Remitch OD Tablets 2.5 µg (Toray Industries, Inc.) Nopicor Capsules 2.5 µg (Toray Medical Co., Ltd.)	Change Change Change	Nalfurafine hydrochloride	Drugs with a revised indication for the improvement of pruritus in patients on peritoneal dialysis (for use only in patients who have not responded sufficiently to conventional treatments).
3-2	Jan. 19, 2018	32	Naruvein Injection 2 mg Naruvein Injection 20 mg (Daiichi Sankyo Propharma Co., Ltd.)	Approval Approval	Hydromorphone hydrochloride	Drugs with a new route of administration indicated for management of moderate to severe pain in various types of cancer.
4	May 18, 2017	33	Zosyn for Intravenous Injection 2.25 Zosyn for Intravenous Injection 4.5 Zosyn for I.V. Infusion bag 4.5 (Taiho Pharmaceutical Co., Ltd.)	Change Change Change	Tazobactam/Piperacillin hydrate	Drugs with additional indications and new dosages for the treatment of "bacterial skin infections mainly involving the dermis and/or subcutaneous tissues" and "secondary bacterial infections of pre-existing skin ulcers and/or erosion".
4	Jul. 3, 2017	34	Amenalief Tab. 200 mg (Maruho Co., Ltd.)	Approval	<u>Amenamevir</u>	A drug with a new active ingredient indicated for the treatment of herpes zoster.
4	Sep. 27, 2017	35	Zinplava for Intravenous Infusion 625 mg (MSD K.K.)	Approval	<u>Bezlotoxumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the prevention of recurrent <i>Clostridium difficile</i> infection.

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4	Sep. 27, 2017	36	Maviret Combination Tablets (AbbVie GK)	Approval	<u>Glecaprevir hydrate/ Pibrentasvir</u>	A new combination drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C. [Priority review]
4	Jan. 19, 2018	37	Nailin Capsules 100 mg (Sato Pharmaceutical Co., Ltd.)	Approval	<u>Fosravuconazole L-lysine ethanolate</u>	A drug with a new active ingredient indicated for the treatment of onychomycosis due to <i>Trichophyton</i> species.
4	Jan. 19, 2018	38	Sirturo Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Bedaquiline fumarate</u>	A drug with a new active ingredient indicated for the treatment of pulmonary multidrug-resistant tuberculosis. [Orphan drug]
4	Feb. 16, 2018	39	Harvoni Combination Tablets (Gilead Sciences, Inc.)	Change	<u>Ledipasvir acetate/Sofosbuvir</u>	A drug with a new additional indication for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2).
4	Feb. 23, 2018	40	Xofluza Tablets 10 mg Xofluza Tablets 20 mg (Shionogi & Co., Ltd.)	Approval Approval	<u>Baloxavir marboxil</u>	Drugs with a new active ingredient indicated for the treatment of influenza A or B virus infections. [SAKIGAKE designation]
4	Mar. 23, 2018	41	Sivextro Tablets 200 mg Sivextro Intravenous Infusion 200 mg (Bayer Yakuhin, Ltd.)	Approval Approval	<u>Tedizolid phosphate</u>	Drugs with a new active ingredient indicated for the treatment of bacterial skin infections mainly involving the dermis and/or subcutaneous tissues, secondary bacterial infections of pre-existing skin ulcers and/or erosion, and secondary bacterial infections of trauma, burn, and surgical wounds.
4	Mar. 23, 2018	42	Prevymis Tablets 240 mg Prevymis Intravenous Infusion 240 mg (MSD K.K.)	Approval Approval	<u>Letermovir</u>	Drugs with a new active ingredient indicated for the prophylaxis of cytomegalovirus disease in allogeneic hematopoietic stem cell transplant recipients. [Orphan drug]
5	Mar. 23, 2018	43	Onepal No. 1 Injection Onepal No. 2 Injection (AY Pharmaceuticals Co., Ltd.)	Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the supplementation of water, electrolytes, amino acids, calories, vitamins, zinc, iron, copper, manganese, and iodine in patients for whom receiving oral or enteral nutrition is impossible or insufficient and the total parenteral nutrition is the only choice.
6-1	Jun. 26, 2017	44	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Change Change	<u>Tocilizumab (genetical recombination)</u>	Drugs with a new dosage indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not responded sufficiently to conventional treatments.
6-1	Jul. 3, 2017	45	Olumiant Tablets 4 mg Olumiant Tablets 2 mg (Eli Lilly Japan K.K.)	Approval Approval	<u>Baricitinib</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	Jul. 3, 2017	46	Prolia Subcutaneous Injection 60 mg Syringe (Daiichi Sankyo Company, Limited)	Change	Denosumab (genetical recombination)	A drug with a new additional indication and a new dosage indicated for inhibiting progression of bone erosion associated with rheumatoid arthritis.
6-1	Aug. 25, 2017	47	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Change Change	Tocilizumab (genetical recombination)	Drugs with new additional indications and a new dosage for the treatment of Takayasu arteritis and giant cell arteritis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Sep. 27, 2017	48	Cedarcure Japanese Cedar Pollen Sublingual Tablets 2,000 JAU Cedarcure Japanese Cedar Pollen Sublingual Tablets 5,000 JAU (Torii Pharmaceutical Co., Ltd.)	Approval Approval	<u>Japanese cedar pollen extract bulk powder</u>	Drugs with a new active ingredient indicated for the treatment of Japanese cedar pollinosis (desensitization therapy).
6-1	Sep. 27, 2017	49	Kevzara 150 mg Syringe for SC Injection Kevzara 200 mg Syringe for SC Injection Kevzara 150 mg Auto-injector for SC Injection Kevzara 200 mg Auto-injector for SC Injection (Sanofi K.K.)	Approval Approval Approval Approval	<u>Sarilumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Sep. 27, 2017	50	Rupafin Tablets 10 mg (Teikoku Seiyaku Co., Ltd.)	Approval	<u>Rupatadine fumarate</u>	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	Sep. 27, 2017	51	Benlysta for I.V. Infusion 120 mg Benlysta for I.V. Infusion 400 mg Benlysta for S.C. Injection 200 mg Autoinjector Benlysta for S.C. Injection 200 mg Syringe (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	<u>Belimumab</u> (genetical recombination)	Drugs 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	Jan. 19, 2018	52	Allesaga Tape 4 mg Allesaga Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval Approval	Emedastine fumarate	Drugs with a new route of administration indicated for the treatment of allergic rhinitis.
6-1	Jan. 19, 2018	53	Dupixent 300 mg Syringe for S.C. Injection (Sanofi K.K.)	Approval	<u>Dupilumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of atopic dermatitis in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 19, 2018	54	Fasenra Subcutaneous Injection 30 mg Syringe (AstraZeneca K.K.)	Approval	<u>Benralizumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Feb. 16, 2018	55	Miticure House Dust Mite Sublingual Tablets 3,300 JAU Miticure House Dust Mite Sublingual Tablets 10,000 JAU (Torii Pharmaceutical Co., Ltd.)	Change Change	<i>Dermatophagoides farinae</i> extract, <i>Dermatophagoides pteronyssinus</i> extract	Drugs with a new additional pediatric dosage for children aged under 12 years. These drugs comprise allergen immunotherapy for the treatment of house dust mite antigen-induced allergic rhinitis.

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6-1	Feb. 16, 2018	56	Actair 100 IR Sublingual Tablets-HDM Actair 300 IR Sublingual Tablets-HDM (Shionogi & Co., Ltd.)	Change Change	<i>Dermatophagoides farinae</i> extract bulk powder, <i>Dermatophagoides pteronysinus</i> extract bulk powder	Drugs with a new additional pediatric dosage for children aged under 12 years. These drugs comprise allergen immunotherapy for the treatment of house dust mite antigen-induced allergic rhinitis.
6-1	Feb. 23, 2018	57	Orencia for I.V. Infusion 250 mg (Bristol-Myers Squibb K.K.)	Change	Abatacept (genetical recombination)	A drug with a new additional indication and a new dosage indicated for the treatment of polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 23, 2018	58	Tremfya Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Approval	<u>Guselkumab (genetical recombination)</u>	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. 23, 2018	59	Humira 40 mg for S.C. Injection Syringe 0.8 mL 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 indicated for the treatment of pustular psoriasis in patients who have not responded sufficiently to conventional therapies.
6-2	May 18, 2017	60	Teribone Inj. 56.5 µg (Asahi Kasei Pharma Corporation)	Change	Teriparatide acetate	A drug with a new dosage indicated for the treatment of osteoporosis with high risk of fracture.
6-2	Jul. 3, 2017	61	Canalia Combination Tablets (Mitsubishi Tanabe Pharma Corporation)	Approval	Teneligliptin hydrobromide hydrate/Canagliflozin hydrate	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of teneligliptin hydrobromide hydrate with canagliflozin hydrate is deemed appropriate).
6-2	Nov. 30, 2017	62	Norditropin FlexPro Injection 5 mg Norditropin FlexPro Injection 10 mg Norditropin FlexPro Injection 15 mg Norditropin S Injection 10 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication for the treatment of short stature associated with Noonan syndrome with no epiphyseal closure.
6-2	Mar. 23, 2018	63	Ozempic Subcutaneous Injection 2 mg (Novo Nordisk Pharma Ltd.)	Approval	<u>Semaglutide (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 23, 2018	64	Sujanu Combination Tablets (MSD K.K.)	Approval	Sitagliptin phosphate hydrate/Pragliflozin L- proline	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of sitagliptin phosphate hydrate with ipragliflozin L-proline is deemed appropriate).

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6-2	Mar. 23, 2018	65	Galafold Capsules 123 mg (Amicus Therapeutics, Inc.)	Approval	<u>Migalastat hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of Fabry disease in patients with <i>GLA</i> mutations categorized as amenable to treatment with migalastat. [Orphan drug]
6-2	Mar. 23, 2018	66	Signifor LAR Kit for i.m. injection 10 mg Signifor LAR Kit for i.m. injection 30 mg Signifor LAR Kit for i.m. injection 20 mg Signifor LAR Kit for i.m. injection 40 mg (Novartis Pharma K.K.)	Approval Approval Change Change	Pasireotide pamoate	Drugs with a new additional indication and a new dosage and in additional dosage forms indicated for the treatment of Cushing's disease (when surgical therapies are not sufficiently effective or are difficult to perform). [Orphan drug]
<i>In vivo</i> diagnostics	Aug. 25, 2017	67	Ovisot for Injection 0.1 g (Daiichi Sankyo Company, Limited)	Change	Acetylcholine chloride	A drug with a new route of administration indicated for the induction of coronary spasm in a drug-induced coronary spasm provocation test during coronary angiography. [Public knowledge-based application after PAFSC's preliminary assessment]
<i>In vivo</i> diagnostics	Sep. 27, 2017	68	Alaglio Granules sachets 1.5 g (SBI Pharmaceuticals Co., Ltd.)	Approval	Aminolevulinic acid hydrochloride	A drug with a new additional indication and a new dosage in an additional dosage form for the visualization of tumor tissues of the non-muscle invasive bladder cancer in transurethral resection of bladder tumor. [Orphan drug]
Radio- pharmaceut icals	Sep. 27, 2017	69	Vizamyl Intravenous Injectable (Nihon Medi-Physics Co., Ltd.)	Approval	<u>Flutemetamol (18F)</u>	A drug with a new active ingredient indicated for visualization of beta-amyloid plaques in the brains of patients with cognitive impairment suspected to be Alzheimer's disease.
Radiophar maceuticals	Feb. 16, 2018	70	FDGscan Injectable (Nihon Medi-Physics Co., Ltd.)	Change	Fludeoxyglucose (¹⁸ F)	A drug with a new additional indication for visualization of inflammatory sites in the diagnosis of large-vessel vasculitis. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	May 18, 2017	71	Xalkori Capsules 200 mg Xalkori Capsules 250 mg (Pfizer Japan Inc.)	Change Change	Crizotinib	Drugs with a new additional indication for the treatment of unresectable advanced/relapsed ROS1 fusion gene-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	May 18, 2017	72	Kyprolis for Intravenous Injection 10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Carfilzomib	Drugs with a new dosage and other characteristics indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]

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Oncology drugs	Jun. 26, 2017	73	Stivarga Tablets 40 mg (Bayer Yakuhin, Ltd.)	Change	Regorafenib hydrate	A drug with a new additional indication for the treatment of unresectable hepatocellular carcinoma which has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Jul. 3, 2017	74	Difolta Injection 20 mg (Mundipharma K.K.)	Approval	<u>Pralatrexate</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Jul. 3, 2017	75	Istodax Injection 10 mg (Celgene K.K.)	Approval	<u>Romidepsin</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Jul. 3, 2017	76	Somatuline 120 mg for s.c. Injection (Teijin Pharma Limited)	Change	Lanreotide acetate	A drug with a new additional indication and a new dosage indicated for the treatment of neuroendocrine tumors of the pancreas and gastrointestinal tract.
Oncology drugs	Aug. 25, 2017	77	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with a new dosage indicated for the treatment of gastric cancer.
Oncology drugs	Sep. 22, 2017	78	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Change	Ceritinib	A drug with a revised indication for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer.
Oncology drugs	Sep. 22, 2017	79	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	<u>Nivolumab</u> (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable advanced or recurrent gastric cancer which has progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Sep. 27, 2017	80	Ibrance Capsules 25 mg Ibrance Capsules 125 mg (Pfizer Japan Inc.)	Approval Approval	<u>Palbociclib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Sep. 27, 2017	81	Darzalex Intravenous Infusion 100 mg Darzalex Intravenous Infusion 400 mg (Janssen Pharmaceutical K.K.)	Approval Approval	<u>Daratumumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 27, 2017	82	Bavencio Injection 200 mg (Merck Serono Co., Ltd.)	Approval	<u>Avelumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable Merkel cell carcinoma. [Orphan drug]

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Oncology drugs	Sep. 27, 2017	83	Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)	Change	Fulvestrant	A drug with a revised indication and a new dosage for the treatment of breast cancer. [Expedited review]
Oncology drugs	Nov. 30, 2017	84	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with a new additional indication for the treatment of relapsed or refractory classical Hodgkin's lymphoma.
Oncology drugs	Dec. 25, 2017	85	Tasigna Capsules 50 mg Tasigna Capsules 150 mg Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Change Change Change	Nilotinib hydrochloride hydrate	Drugs with a new pediatric dosage indicated for the treatment of chronic- or accelerated-phase chronic myeloid leukemia. [Expedited review (only Tasigna Capsules 50 mg)]
Oncology drugs	Dec. 25, 2017	86	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Change Change	Pembrolizumab (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable urothelial cancer which progressed after cancer chemotherapy. [Priority review]
Oncology drugs	Jan. 19, 2018	87	Tecentriq Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Atezolizumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent non-small-cell lung cancer.
Oncology drugs	Jan. 19, 2018	88	Besponsa Injection 1 mg (Pfizer Japan Inc.)	Approval	<u>Inotuzumab ozogamicin (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory CD22-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Jan. 19, 2018	89	Lynparza Tablets 100 mg Lynparza Tablets 150 mg (AstraZeneca K.K.)	Approval Approval	<u>Olaparib</u>	Drugs with a new active ingredient indicated for the maintenance treatment of recurrent ovarian cancer in patients who are in a complete or partial response to platinum-based chemotherapy.
Oncology drugs	Feb. 16, 2018	90	Zytiga Tablets 250 mg (Janssen Pharmaceutical K.K.)	Change	Abiraterone acetate	A drug with a new additional indication for the treatment of prostate cancer in patients with high-risk prognostic factors who have not received previous endocrine therapy. [Priority review]
Oncology drugs	Mar. 23, 2018	91	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 unresectable advanced or recurrent BRAF mutation-positive non-small-cell lung cancer. [Orphan drug]
Oncology drugs	Mar. 23, 2018	92	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Change Change	Trametinib dimethyl sulfoxide	Drugs with a new additional indication for the treatment of unresectable advanced or recurrent BRAF mutation-positive non-small-cell lung cancer. [Orphan drug]

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Oncology drugs	Mar. 23, 2018	93	Lenvima Capsule 4 mg (Eisai Co., Ltd.)	Change	Lenvatinib mesilate	A drug with a new additional indication and a new dosage indicated for the treatment of unresectable hepatic cell carcinoma.
Oncology drugs	Mar. 23, 2018	94	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new additional indication and a new dosage indicated for the treatment of Waldenström's macroglobulinemia and lymphoplasmacytic lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Vaccines	Mar. 23, 2018	95	Shingrix for Intramuscular Injection (Japan Vaccine Co., Ltd.)	Approval	<u>Freeze-dried recombinant herpes zoster vaccine (prepared from Chinese hamster ovary cells)</u>	A drug with a new active ingredient indicated for the prevention of herpes zoster.
Vaccines	Mar. 23, 2018	96	Emulsion-adjuvanted Cell-culture Derived Influenza HA Vaccine H5N1 for Intramuscular Injection "Kaketsuken" (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Emulsion-adjuvanted cell-culture derived influenza HA vaccine (H5N1)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 23, 2018	97	Emulsion-adjuvanted Cell-culture Derived Influenza HA Vaccine (prototype) for Intramuscular Injection "Kaketsuken" (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Emulsion-adjuvanted cell-culture derived influenza HA vaccine (prototype)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza. [Orphan drug]
Blood products	Mar. 23, 2018	98	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.)	Approval Approval Approval Approval	<u>Emicizumab (genetical recombination)</u>	Drugs with a new active ingredient 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	Sep. 27, 2017	99	Afstyla I.V. Injection 250 Afstyla I.V. Injection 500 Afstyla I.V. Injection 1000 Afstyla I.V. Injection 1500 Afstyla I.V. Injection 2000 Afstyla I.V. Injection 2500 Afstyla I.V. Injection 3000 (CSL Behring K.K.)	Approval Approval Approval Approval Approval Approval	<u>Lonococog alfa (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	Nov. 30, 2017	100	Adynovate Intravenous 250 Adynovate Intravenous 500 Adynovate Intravenous 1000 Adynovate Intravenous 2000 (Baxalta Japan Limited)	Change Change Change Change	<u>Rurioctocog alfa pegol (genetical recombination)</u>	Drugs with a new additional pediatric dosage indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient (underlined: new active ingredient)	Notes
Bio-CMC	Sep. 27, 2017	101	Infliximab BS for I.V. Infusion 100 mg "Nichiiko" (Nichi-Iko Pharmaceutical Co., Ltd.) Infliximab BS for I.V. Infusion 100 mg "AYUMI" (Yakuhon Pharmaceutical Co., Ltd.)	Approval Approval	Infliximab (genetical recombination) [Infliximab biosimilar 2]	Follow-on biologics indicated for the treatment of rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis.
Bio-CMC	Sep. 27, 2017	102	Rituximab BS Intravenous Infusion 100 mg [KHK] Rituximab BS Intravenous Infusion 500 mg [KHK] (Sandoz K.K.)	Approval Approval	Rituximab (genetical recombination) [Rituximab biosimilar 1]	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, Wegener's granulomatosis, and microscopic polyangiitis.
Bio-CMC	Jan. 19, 2018	103	Etanercept BS 10 mg for S.C. Inj. "MA" Etanercept BS 25 mg for S.C. Inj. "MA" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "MA" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "MA" Etanercept BS 50 mg PEN 1.0 mL for S.C. Inj. "MA" (Mochida Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Etanercept (genetical recombination) [etanercept biosimilar 1]	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.
Bio-CMC	Mar. 23, 2018	104	Trastuzumab BS for I.V. Infusion 60 mg "NK" Trastuzumab BS for I.V. Infusion 150 mg "NK" (Nippon Kayaku Co., Ltd.) Trastuzumab BS for I.V. Infusion 60 mg "CTH" Trastuzumab BS for I.V. Infusion 150 mg "CTH" (Celltrion Inc.)	Approval Approval Approval Approval	Trastuzumab (genetical recombination) [trastuzumab biosimilar 1]	Follow-on biologics indicated for the treatment of unresectable advanced or recurrent gastric cancer with HER2 overexpression.

***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