

New Drugs Approved in FY 2016

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	May 13, 2016	1	Cellcept Capsules 250 Cellcept Powder for Oral Suspension 31.8% (Chugai Pharmaceutical Co., Ltd.) Mycophenolate Mofetil Cap. 250 mg "Teva" (Teva Pharma Japan Inc.) Mycophenolate Mofetil Capsules 250 mg [Pfizer] (Mylan Seiyaku Ltd.)	Change Change Change	Mycophenolate mofetil	Drugs with a new additional indication and a new dosage for the treatment of lupus nephritis. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Jun. 20, 2016	2	Humira 40 mg for S.C. Injection Syringe 0.8 mL (AbbVie GK)	Change	Adalimumab (genetical recombination)	A drug with a new dosage indicated for the treatment of Crohn's disease.
1	Jul. 4, 2016	3	Epiduo Gel (Galderma S.A.)	Approval	Adapalene/Benzoyl peroxide	A new combination drug indicated for the treatment of acne vulgaris.
1	Jul. 4, 2016	4	Picoprep Combination Powder (Ferring Pharmaceuticals Co.,Ltd)	Approval	Sodium picosulfate hydrate/ Magnesium oxide/ Anhydrous citric acid	A new combination drug indicated for bowel cleansing preparation for colonoscopy or colorectal surgery.
1	Jul. 4, 2016	5	Hemangioli Syrup for Pediatric 0.375% (Maruho Co., Ltd.)	Approval	Propranolol hydrochloride	A drug with a new indication in a new dosage form indicated for the treatment of infantile hemangioma. [Orphan drug]
1	Sep. 28, 2016	6	Regroth Dental Kit 600 µg Regroth Dental Kit 1200 µg (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	Trafermin (genetical recombination)	Drugs with a new route of administration indicated for the treatment of alveolar bone loss due to periodontitis.
1	Sep. 28, 2016	7	Zentacort Capsules 3 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	Budesonide	A drug with a new route of administration indicated for the treatment of mild to moderately active Crohn's disease.
1	Sep. 28, 2016	8	Lialda Tab. 1200 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	Mesalazine	A drug in a new dosage form indicated for the treatment of ulcerative colitis (excluding severe cases).
1	Dec. 19, 2016	9	Parsabiv Intravenous Injection for Dialysis 2.5 mg Parsabiv Intravenous Injection for Dialysis 5 mg Parsabiv Intravenous Injection for Dialysis 10 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval	<u>Etelcalcetide</u> <u>hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on hemodialysis.
1	Dec. 19, 2016	10	Linress Tablets 0.25 mg (Astellas Pharma Inc.)	Approval	<u>Linacotide</u>	A drug with a new active ingredient indicated for the treatment of irritable bowel syndrome with constipation.
1	Mar. 24, 2017	11	Nobelzin Capsules 25 mg Nobelzin Capsules 50 mg Nobelzin Tablets 25 mg Nobelzin Tablets 50 mg (Nobelpharma Co., Ltd.)	Change Change Change Change	Zinc acetate dihydrate	Drugs with a new additional indication and a new dosage for the treatment of hypozincemia.
1	Mar. 30, 2017	12	Symproic Tablets 0.2 mg (Shionogi & Co., Ltd.)	Approval	<u>Naldemedine tosilate</u>	A drug with a new active ingredient indicated for the treatment of opioid-induced constipation.
1	Mar. 30, 2017	13	(1) Stelara Intravenous Infusion 130 mg (2) Stelara Subcutaneous Injection 45 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Change	Ustekinumab (genetical recombination)	(1) A drug with a new route of administration indicated for the induction therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). (2) A drug with a new indication and a new dosage for the maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).

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1	Mar. 30, 2017	14	(1) Simponi Subcutaneous Injection 50 mg Syringe (2) Simponi Subcutaneous Injection 100 mg Syringe (Janssen Pharmaceutical K.K.)	Change Approval	Golimumab (genetical recombination)	Drugs with a new additional indication and a new dosage, in a new additional dosage form for improvement and maintenance of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Mar. 30, 2017	15	Comclo Shampoo 0.05% (Maruho Co., Ltd.)	Approval	Clobetasol propionate	A drug in a new dosage form indicated for the treatment of psoriasis vulgaris of the scalp.
2	Jul. 4, 2016	16	Praluent 75 mg solution for injection in pre-filled pen Praluent 150 mg solution for injection in pre-filled pen Praluent 75 mg solution for injection in pre-filled syringe Praluent 150 mg solution for injection in pre-filled syringe (Sanofi K.K.)	Approval Approval Approval Approval	<u>Alirocumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of familial hypercholesterolemia and hypercholesterolemia (for use only in patients who are at higher risk of developing cardiovascular event and have not responded sufficiently to HMG-CoA reductase inhibitors).
2	Jul. 4, 2016	17	Duodopa Enteral Combination Solution (AbbVie GK)	Approval	Levodopa/ Carbidopa hydrate	A new combination drug indicated for the improvement of wearing-off phenomenon in the symptoms of Parkinson's disease in patients who have not responded sufficiently to conventional levodopa-containing drug therapies. [Orphan drug]
2	Sep. 28, 2016	18	Micatio Combination Tablets (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/ Amlodipine besilate/ Hydrochlorothiazide	A new combination drug indicated for the treatment of hypertension.
2	Sep. 28, 2016	19	(1) Brilinta Tablets 60 mg (2) Brilinta Tablets 90 mg (AstraZeneca K.K.)	Approval Approval	<u>Ticagrelor</u>	Drugs with a new active ingredient indicated for the treatment of: (1) Old myocardial infarction at especially high risk of developing atherothrombosis with at least one of the following risk factors: age of 65 years or older, with diabetes mellitus requiring drug therapy, history of two or more episodes of myocardial infarction, angiography-confirmed multivessel coronary artery disease, or non-end-stage chronic renal dysfunction. (2) Acute coronary syndrome (unstable angina, non-ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction) for which percutaneous coronary intervention (PCI) is indicated. (provided that dual antiplatelet therapy including aspirin is appropriate but the administration of other antiplatelet drugs in combination with aspirin is not suitable for the patient.)
2	Sep. 28, 2016	20	Upravi Tablets 0.2 mg Upravi Tablets 0.4 mg (Nippon Shinyaku Co., Ltd.)	Approval Approval	<u>Selexipag</u>	Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Sep. 28, 2016	21	Juxtapid Capsules 5 mg Juxtapid Capsules 10 mg Juxtapid Capsules 20 mg (Aegerion Pharmaceuticals K.K.)	Approval Approval Approval	<u>Lomitapide mesilate</u>	Drugs with a new active ingredient indicated for the treatment of homozygous familial hypercholesterolemia. [Orphan drug]
2	Sep. 28, 2016	22	Prizbind Intravenous Solution 2.5 g (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	<u>Idarucizumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the reversal of anticoagulant effect of dabigatran under the following situations: • In life-threatening or uncontrolled bleeding • When performing emergency surgery or procedures in which serious bleeding is expected. [Priority review]
2	Sep. 28, 2016	23	Polidocasklerol 1% Inj. 2 mL Polidocasklerol 3% Inj. 2 mL (Kaigen Pharma Co., Ltd.)	Change Change	Polidocanol	Drugs with a new indication and a new dosage for the use in sclerotherapy of primary varicose veins of lower extremity.

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2	Dec. 19, 2016	24	Selara Tablets 25 mg Selara Tablets 50 mg (Pfizer Japan Inc.)	Change Change	Eplerenone	Drugs with a new additional indication and a new dosage for the treatment of chronic heart failure in patients receiving basic treatment with angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists, β -blockers, diuretics, etc.
2	Mar. 2, 2017	25	Epoprostenol ACT 0.5 mg Epoprostenol ACT 1.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change Change	Epoprostenol sodium	Drugs with a new additional pediatric dosage indicated for the treatment of pulmonary arterial hypertension.
3-1	May. 23, 2016	26	Botox Vista Injection 50 Units (Allergan Japan K.K.)	Change	Botulinum toxin type A	A drug with a new additional indication and a new dosage for the temporary improvement in the appearance of lateral canthal lines (crow's feet lines) in adults aged under 65 years.
3-1	Jul. 4, 2016	27	Ocnobel Tablets 150 mg Ocnobel Tablets 300 mg Ocnobel Oral Suspension 6% (Nobelpharma Co., Ltd.)	Approval Approval Approval	<u>Oxcarbazepine</u>	Drugs with a new active ingredient indicated for the use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Jul. 4, 2016	28	Vimpat Tablets 50 mg Vimpat Tablets 100 mg (UCB Japan Co., Ltd.)	Approval Approval	<u>Lacosamide</u>	Drugs with a new active ingredient indicated for the use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Sep. 28, 2016	29	Abilify Tablets 1 mg Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Tablets 12 mg Abilify OD Tablets 3 mg Abilify OD Tablets 6 mg Abilify OD Tablets 12 mg Abilify Powder 1% Abilify Oral Solution 0.1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Change Change Change Change Change Change Change Change	Aripiprazole	Drugs with a new additional indication, dosage, and dosage form for the treatment of irritability associated with autism spectrum disorder in children and adolescents.
3-1	Sep. 28, 2016	30	Kenketu Glovenin-I for I.V. Injection 500 mg Kenketu Glovenin-I for I.V. Injection 2500 mg Kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication for the treatment of Guillain-Barré syndrome (severe cases in an acute exacerbation phase with difficulty in walking).
3-1	Dec. 19, 2016	31	Tecfidera Capsules 120 mg Tecfidera Capsules 240 mg (Biogen Japan Ltd.)	Approval Approval	<u>Dimethyl fumarate</u>	Drugs with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis. [Orphan drug]
3-1	Dec. 19, 2016	32	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication for the treatment of pain associated with osteoarthritis.
3-1	Dec. 19, 2016	33	Kenketu Glovenin-I for I.V. Injection 2500 mg Kenketu Glovenin-I for I.V. Injection 500 mg Kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.)	Change Change Change	Polyethylene glycol treated human normal immunoglobulin G	Drugs with a new additional indication and a new dosage for inhibiting progression of motor disability due to chronic inflammatory demyelinating polyneuropathy (including multifocal motor neuropathy) (in the cases where patients show an improvement in their acute phase treatment) [Orphan drug]
3-1	Mar. 30, 2017	34	Intuniv Tablets 1 mg Intuniv Tablets 3 mg (Shionogi & Co., Ltd.)	Approval Approval	<u>Guanfacine hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of pediatric attention deficit/hyperactivity disorder (AD/HD).
3-2	Aug. 26, 2016	35	Ultiva Intravenous 2 mg Ultiva Intravenous 5 mg (Janssen Pharmaceutical K.K.)	Change Change	Remifentanyl hydrochloride	Drugs with a new additional indication and a new dosage for use in pediatric patients for analgesia during maintenance of general anesthesia.

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3-2	Sep. 28, 2016	36	Mikeluna Combination Ophthalmic Solution (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Carteolol hydrochloride/</u> <u>Latanoprost</u>	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Mar. 2, 2017	37	MaQaid Intravitreal Injection 40 mg (Wakamoto Co., Ltd.)	Change	<u>Triamcinolone acetonide</u>	A drug with a new route of administration indicated for alleviation of diabetic macular edema and macular edema associated with retinal vein occlusion or non-infectious uveitis.
3-2	Mar. 30, 2017	38	Narusus Tablets 2 mg Narusus Tablets 6 mg Narusus Tablets 12 mg Narusus Tablets 24 mg Narurapid Tablets 1 mg Narurapid Tablets 2 mg Narurapid Tablets 4 mg (Daiichi Sankyo Propharma Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	<u>Hydromorphone hydrochloride</u>	Drugs with a new active ingredient indicated for management of moderate to severe pain in various types of cancer.
4	Aug. 26, 2016	39	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Change	<u>Laninamivir octanoate hydrate</u>	A drug with a new additional dosage and administration for the prophylaxis of influenza A or B virus infections in single inhalation doses for adults and children aged 10 years and older, and children aged under 10 years.
4	Aug. 26, 2016	40	Valixa Tablets 450 mg (Mitsubishi Tanabe Pharma Corporation)	Change	<u>Valganciclovir hydrochloride</u>	A drug with a new additional indication and a new dosage 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. 28, 2016	41	Rifaxima Tablets 200 mg (Aska Pharmaceutical Co., Ltd.)	Approval	<u>Rifaximin</u>	A drug with a new active ingredient indicated for the improvement of hyperammonemia in patients with hepatic encephalopathy. [Orphan drug]
4	Sep. 28, 2016	42	Grazyna Tablets 50 mg (MSD K.K.)	Approval	<u>Grazoprevir hydrate</u>	A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Sep. 28, 2016	43	Erelisa Tablets 50 mg (MSD K.K.)	Approval	<u>Elbasvir</u>	A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review]
4	Sep. 28, 2016	44	Viekirax Combination Tablets (AbbVie GK)	Change	<u>Ombitasvir hydrate/</u> <u>Paritaprevir hydrate/</u> <u>Ritonavir</u>	A drug with a new additional indication and a new dosage for the improvement of viremia in patients with chronic hepatitis C in serogroup 2 (genotype 2).
4	Sep. 28, 2016	45	Rebetol Capsules 200 mg (MSD K.K.)	Change	<u>Ribavirin</u>	A drug with a new additional indication and a new dosage for the improvement of viremia in patients with chronic hepatitis C in serogroup 2 (genotype 2), for a combination use of ombitasvir hydrate, paritaprevir hydrate, and ritonavir.
4	Dec. 19, 2016	46	Ximency Combination Tablets (Bristol-Myers Squibb K.K.)	Approval	<u>Daclatasvir hydrochloride/</u> <u>Asunaprevir/</u> <u>Beclabuvir hydrochloride</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 in serogroup 1 (genotype 1).
4	Dec. 19, 2016	47	Riamet Combination Tablets (Novartis Pharma K.K.)	Approval	<u>Artemether/</u> <u>Lumefantrine</u>	A new combination drug with new active ingredients indicated for the treatment of malaria.

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4	Dec. 19, 2016	48	Vemlidy Tablets 25 mg (Gilead Sciences, Inc.)	Approval	<u>Tenofovir alafenamide fumarate</u>	A drug with a new active ingredient indicated for the suppression of proliferation of hepatitis B virus in patients with chronic liver disease with hepatitis B virus infection in whom abnormal liver function is confirmed along with hepatitis B virus proliferation. [Priority review]
4	Mar. 2, 2017	49	Ozex Fine Granules 15% for Pediatric (Toyama Chemical Co., Ltd.)	Change	Tosufloxacin tosilate hydrate	A drug with a new additional indication for the treatment of mycoplasma pneumoniae caused by <i>Mycoplasma pneumoniae</i> .
4	Mar. 24, 2017	50	Sovaldi Tablets 400 mg (Gilead Sciences, Inc.)	Change	Sofosbuvir	A drug with a new additional indication and a new dosage for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]
4	Mar. 24, 2017	51	Rebetol Capsules 200 mg (MSD K.K.)	Change	Ribavirin	A drug with a new additional indication for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]
4	Mar. 24, 2017	52	Copegus Tablet 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change	Ribavirin	A drug with a new additional indication for the improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis type C in neither Serogroup 1 (genotype 1) nor Serogroup 2 (genotype 2). [Expedited review]
4	Mar. 24, 2017	53	Tamiflu Dry Syrup 3% (Chugai Pharmaceutical Co., Ltd.)	Change	Osetamivir phosphate	A drug with a new additional dosage for newborns and infants for the treatment of influenza A or B virus infection. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 4, 2016	54	Onecrinone 90mg Progesterone vaginal gel (Merck Serono Co., Ltd.)	Approval	Progesterone	A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women.
5	Jul. 4, 2016	55	Elineopa-NF No. 1 Injection Elineopa-NF No. 2 Injection (Otsuka Pharmaceutical Factory Inc.)	Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the supplementation of water, electrolytes, calories, amino acids, 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.
5	Sep. 28, 2016	56	Ovidrel Syringe 250 µg (Merck Serono Co., Ltd.)	Approval	<u>Chorionic gonadotropin alfa (genetical recombination)</u>	A drug with a new active ingredient indicated for: • Induction of ovulation and luteinization in patients with anovulation or oligoovulation associated with hypothalamic-pituitary dysfunction • Induction of final follicular maturation and luteinization as part of assisted reproductive technology for infertile women.
5	Dec. 2, 2016	57	Dinigest Tablets 1 mg Dinigest OD Tablets 1 mg (Mochida Pharmaceutical Co., Ltd.)	Change Change	Dienogest	Drugs with a new additional indication for the alleviation of pain associated with uterine adenomyosis.
5	Dec. 19, 2016	58	YazFlex Combination Tablets (Bayer Yakuhin Ltd.)	Approval	Drospirenone /Ethinylestradiol betadex	A drug with new indications and a new dosage in an additional dosage form indicated for the alleviation of pain associated with endometriosis, and dysmenorrhea.
5	Mar. 30, 2017	59	D Dry 2.75S (Nikkiso Co., Ltd.)	Approval	N/A for this combination drug	A prescription drug with similar formulations to approved combination drugs used as perfusion fluids for hemodialysis in patients with chronic renal failure.

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6-1	May 13, 2016	60	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new dosage indicated for plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional treatments.
6-1	Jul. 4, 2016	61	Taltz 80mg Syringe for SC Injection Taltz 80mg Auto-Injector for SC Injection (Eli Lilly Japan K.K.)	Approval Approval	<u>Ixekizumab</u> (genetical recombination)	Drugs 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	Jul. 4, 2016	62	Lumicef Subcutaneous Injection 210 mg Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Brodalumab</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	Aug. 26, 2016	63	Spiriva 2.5 µg Respimat 60 puffs Spiriva 1.25 µg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Change Approval	Tiotropium bromide hydrate	Drugs with a new additional indication, dosage, and dosage form for the relief of symptoms secondary to airway obstructive disorders in mild to moderate persistent bronchial asthma.
6-1	Sep. 28, 2016	64	Desalex Tablets 5 mg (MSD K.K.)	Approval	<u>Desloratadine</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. 28, 2016	65	Bilanoa Tablet 20 mg (Taiho Pharmaceutical Co. Ltd.)	Approval	<u>Bilastine</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. 28, 2016	66	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 (AbbVie GK)	Change Change Change	Adalimumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of non-infectious intermediate, posterior, and panuveitis in patients who have not responded sufficiently to conventional therapies.
6-1	Sep. 28, 2016	67	Colchicine Tablets 0.5 mg "Takata" (Takata Pharmaceutical Co.,Ltd.)	Change	Colchicine	A drug with a new additional indication and a new dosage for the treatment of familial Mediterranean fever. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Dec. 2, 2016	68	Relvar 100 Ellipta 14 dose Relvar 100 Ellipta 30 dose (GlaxoSmithKline K.K.)	Change Change	Vilanterol trifenate/ Fluticasone furoate	Drugs with a new additional indication and a new dosage for the relief of symptoms in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (who require a combination therapy with an inhaled corticosteroid and a long-acting beta-2 agonist).
6-1	Dec. 19, 2016	69	Otezla Tablets 10 mg Otezla Tablets 20 mg Otezla Tablets 30 mg (Celgene K.K.)	Approval Approval Approval	<u>Apremilast</u>	Drugs with a new active ingredient indicated for the treatment of plaque psoriasis in patients who have not responded sufficiently to topical therapy or psoriatic arthritis.
6-1	Dec. 19, 2016	70	Ilaris for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change	Canakinumab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of patients with familial Mediterranean fever who have not responded sufficiently to conventional therapies, TNF receptor-associated periodic syndrome, or hyper IgD syndrome (mevalonate kinase deficiency). [Orphan drug]
6-1	Mar. 24, 2017	71	Xolair for S.C. Injection 150 mg Xolair for S.C. Injection 75 mg (Novartis Pharma K.K.)	Change Change	Omalizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of chronic idiopathic urticaria (for use only in patients who have not responded sufficiently to conventional therapies).
6-1	Mar. 24, 2017	72	Beriner P I.V. Injection 500 (CSL Behring K.K.)	Change	Lyophilized human C1- inactivator concentrate	A drug with a new additional indication and a new dosage for inhibiting onset of acute attacks of hereditary angioedema caused by invasive procedures. [Public knowledge-based application after PAFSC's preliminary assessment]

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6-1	Mar. 30, 2017	73	Arnuity 100 µg Ellipta 14 doses Arnuity 100 µg Ellipta 30 doses Arnuity 200 µg Ellipta 14 doses Arnuity 200 µg Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	Fluticasone furoate	Drugs with a new dosage and other characteristics indicated for the treatment of bronchial asthma.
6-2	May. 23, 2016	74	Feburic Tablets 10 mg Feburic Tablets 20 mg Feburic Tablets 40 mg (Teijin Pharma Limited)	Change Change Change	Febuxostat	Drugs with a new additional indication and a new dosage for the treatment of hyperuricemia in patients receiving cancer chemotherapy.
6-2	Sep. 28, 2016	75	Signifor LAR Kit for i.m. injection 20 mg Signifor LAR Kit for i.m. injection 40 mg Signifor LAR Kit for i.m. injection 60 mg (Novartis Pharma K.K.)	Approval Approval Approval	<u>Pasireotide pamoate</u>	Drugs with a new active ingredient indicated for the improvement of hypersecretion of growth hormone and IGF-I (somatomedin-C) and related symptoms in acromegaly and pituitary gigantism (when surgical therapies are not sufficiently effective or are difficult to perform).
6-2	Sep. 28, 2016	76	Inisync Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Alogliptin benzoate/ Metformin hydrochloride	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of alogliptin benzoate with metformin hydrochloride is deemed appropriate).
6-2	Sep. 28, 2016	77	Reclast for i.v. infusion 5 mg (Asahi Kasei Pharma Corporation)	Approval	Zoledronic acid hydrate	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of osteoporosis.
6-2	Sep. 28, 2016	78	Carbaglu Dispersible Tablets 200 mg (Pola Pharma Inc.)	Approval	<u>Carlumic acid</u>	A drug with a new active ingredient indicated for the treatment of hyperammonemia due to N-acetylglutamate synthetase deficiency, isovaleric acidemia, methylmalonic acidemia, and propionic acidemia. [Orphan drug]
6-2	Sep. 28, 2016	79	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Change Change	Insulin degludec (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Dec. 19, 2016	80	Lyxumia 300 µg solution for injection (Sanofi K.K.)	Change	Lixisenatide	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Dec. 19, 2016	81	Humalog Cart Humalog Miriopen (Eli Lilly Japan K.K.)	Change Change	Insulin lispro (genetical recombination)	Drugs with a new dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
<i>In vivo diagnostics</i>	Mar. 30, 2017	82	(1) Optiray 350 Injection 20 mL (2) Optiray 350 Injection 50 mL (3) Optiray 350 Injection 100 mL (4) Optiray 350 Injection Syringe 100 mL (5) Optiray 350 Injection Syringe 135 mL (Fuji Pharma Co., Ltd.)	Change Change Change Change Approval	Ioversol	Drugs with a new additional indication and a new dosage, and an additional dosage form used as contrast media in abdominal computed tomography.
Radio pharma ceuticals	Dec. 19, 2016	83	Amyvid Injection (Fujifilm RI Pharma Co., Ltd.)	Approval	<u>Florbetapir (¹⁸F)</u>	A drug with a new active ingredient indicated for visualization of beta-amyloid plaques in the brain of patients with cognitive impairment suspected to be Alzheimer's disease.
Oncology drugs	May 23, 2016	84	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication for the treatment of advanced or recurrent cervical cancer. [Orphan drug]
Oncology drugs	May 23, 2016	85	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent colorectal cancer.
Oncology drugs	Jun. 20, 2016	86	Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.)	Change Change	Ramucirumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced/relapsed non-small cell lung cancer.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Jul. 4, 2016	87	Kyprolis for Intravenous Injection 10 mg Kyprolis for Intravenous Injection 40 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval	<u>Carfilzomib</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Aug. 26, 2016	88	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]
Oncology drugs	Aug. 26, 2016	89	Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Change	Bendamustine hydrochloride	A drug with a new additional indication and a new dosage for the treatment of chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Aug. 26, 2016	90	Afinitor Tablets 5 mg Afinitor Tablets 2.5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with a revised indication from "pancreatic neuroendocrine tumor" to "neuroendocrine tumor."
Oncology drugs	Aug. 26, 2016	91	Xeloda Tablets 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new additional indication and a new dosage for adjuvant chemotherapy for rectal cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 28, 2016	92	Keytruda Injection 20 mg Keytruda Injection 100 mg (MSD K.K.)	Approval Approval	<u>Pembrolizumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Sep. 28, 2016	93	Empliciti for I.V. Infusion 300 mg Empliciti for I.V. Infusion 400 mg (Bristol-Myers Squibb Company)	Approval Approval	<u>Elotuzumab</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 28, 2016	94	Iclusig Tablets 15 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Ponatinib</u> hydrochloride	A drug with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies, and recurrent or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Sep. 28, 2016	95	Treakisym Injection 25 mg (SymBio Pharmaceuticals Limited)	Approval	Bendamustine hydrochloride	A drug with a new additional indication, dosage, and dosage form for the treatment of chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Dec. 2, 2016	96	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new additional indication for the treatment of relapsed or refractory classical Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	Dec. 2, 2016	97	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Change	Ibrutinib	A drug with a new additional indication and a new dosage for the treatment of relapsed or refractory mantle cell lymphoma. [Orphan drug]
Oncology drugs	Dec. 19, 2016	98	Erwinase for Intramuscular Injection 10000 (Ohara Pharmaceutical Co., Ltd.)	Approval	<u>Crisantaspase</u>	A drug with a new active ingredient indicated for the treatment of acute leukemia (including blast crisis of chronic leukemia) and malignant lymphoma (only for patients who experienced hypersensitivity to L-asparaginase preparations).
Oncology drugs	Dec. 19, 2016	99	Mozobil Injection 24 mg (Sanofi K.K.)	Approval	<u>Plerixafor</u>	A drug with a new active ingredient indicated for the enhancement of mobilization of hematopoietic stem cells to the peripheral blood for autologous peripheral blood stem cell transplantation. [Orphan drug]
Oncology drugs	Dec. 19, 2016	100	Treakisym Injection 100 mg Treakisym Injection 25 mg (SymBio Pharmaceuticals Ltd.)	Change Change	Bendamustine hydrochloride	Drugs with a revised indication and a new dosage for the treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Dec. 19, 2016	101	Keytruda Injection 100 mg Keytruda Injection 20 mg (MSD K.K.)	Change Change	<u>Pembrolizumab</u> (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of patients with PD-L1-positive, unresectable, recurrent or advanced non-small cell lung cancer.
Oncology drugs	Mar. 2, 2017	102	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	<u>Lenalidomide hydrate</u>	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory adult T-cell leukemia/lymphoma. [Orphan drug]
Oncology drugs	Mar. 24, 2017	103	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 relapse or distant metastasis of head and neck cancer. [Priority review]
Oncology drugs	Mar. 30, 2017	104	Zaltrap 100 mg I.V. Infusion Zaltrap 200 mg I.V. Infusion (Sanofi K.K.)	Approval Approval	<u>Aflibercept beta</u> (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer.
Oncology drugs	Mar. 30, 2017	105	Mundesine Capsule 100 mg (Mundipharma K.K.)	Approval	<u>Forodesine hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 30, 2017	106	Ninlaro Capsules 2.3 mg Ninlaro Capsules 3 mg Ninlaro Capsules 4 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	<u>Ixazomib citrate</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
AIDS drugs	Jun. 17, 2016	107	Genvoya Combination Tablets (Japan Tobacco Inc.)	Approval	<u>Elvitegravir/ Cobicistat/ Emtricitabine/ 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. 22, 2016	108	Prezcobix Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	<u>Darunavir ethanolate/ Cobicistat</u>	A new combination drug with a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Dec. 9, 2016	109	Descovy Combination Tablets LT Descovy Combination Tablets HT (Japan Tobacco Inc.)	Approval Approval	<u>Emtricitabine/ Tenofovir alafenamide fumarate</u>	New combination drugs indicated for the treatment of HIV-1 infection. [Orphan drug]
Vaccines	Dec. 19, 2016	110	Vaxem Hib Suspension Liquid for Injection (Takeda Pharmaceutical Company Limited)	Change	<u>Haemophilus influenzae type b vaccine adsorbed (mutated diphtheria toxin CRM197 conjugate)</u>	A drug with a new dosage indicated for the prophylaxis of <i>Haemophilus influenzae</i> type b infections.
Blood products	Sep. 28, 2016	111	Idelvion I.V. Injection 250 Idelvion I.V. Injection 500 Idelvion I.V. Injection 1000 Idelvion I.V. Injection 2000 (CSL Behring K.K.)	Approval Approval Approval Approval	<u>Albutrepenonacog alfa</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	Mar. 30, 2017	112	Kcentra for I.V. Injection 500 Kcentra for I.V. Injection 1000 (CSL Behring K.K.)	Approval Approval	<u>Freeze-dried human prothrombin complex concentrated</u>	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients treated with vitamin K antagonists at the time of acute serious bleeding or an emergency surgery/procedures in which serious bleeding is expected. [Orphan drug]

***Review Categories of New Drugs**

Review Category	Products
1	Gastrointestinal drugs, dermatologic drugs, immunosuppressive drugs, and others (not classified as other categories)
2	Cardiovascular drugs, antiparkinsonian drugs, anti-Alzheimer's drugs
3-1	Central/peripheral nervous system drugs (excluding anesthetic drugs)
3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
4	Antibacterial drugs, antiviral drugs (excluding AIDS drugs), antifungal drugs, antiprotozoal drugs, anthelmintic drugs
5	Reproductive system drugs, drugs for urogenital system, combination drugs
6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs (drugs for inflammatory diseases)
6-2	Hormone drugs, drugs for metabolic disorders (including diabetes mellitus, osteoporosis, gout, and inborn errors of metabolism)
AIDS drugs	Anti-HIV drugs
Oncology drugs	Antineoplastic drugs
Blood products	Blood products
Vaccines	Vaccines (only those to be used for prevention of infection), antitoxic serum, etc.
Radio-pharmaceuticals	Radiopharmaceuticals
In vivo diagnostics	Contrast agents, reagents for function tests (excluding in-vitro diagnostics)
Bio-CMC	Quality of biologics, biosimilars