

## New Drugs Approved in FY 2015

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	May 26, 2015	1	Iribow Tablets 2.5 µg Iribow Tablets 5 µg Iribow OD Tablets 2.5 µg Iribow OD Tablets 5 µg (Astellas Pharma Inc.)	Change Change Change Change	Ramosetron hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of diarrhea-predominant irritable bowel syndrome in women.
1	Jul. 3, 2015	2	Xiaflex Inj. (Asahi Kasei Pharma Corporation)	Approval	<u>Collagenase</u> ( <u>Clostridium</u> <u>histolyticum</u> )	A drug with a new active ingredient indicated for the treatment of Dupuytren's contracture.
1	Sep. 28, 2015	3	P-Tol Chewable Tab. 250 mg P-Tol Chewable Tab. 500 mg (Kissei Pharmaceutical Co., Ltd.)	Approval Approval	<u>Sucroferri</u> <u>oxyhydroxide</u>	Drugs with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic kidney disease who are receiving dialysis.
1	Sep. 28, 2015	4	Zagallo Capsules 0.1 mg Zagallo Capsules 0.5 mg (GlaxoSmithKline K.K.)	Approval Approval	Dutasteride	A drug with a new indication and a new dosage in an additional dosage form, and a drug with a new indication and a new dosage, indicated for the treatment of the male pattern hair loss (androgenetic alopecia) in men.
1	Nov. 20, 2015	5	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 bullous pemphigoid (for use when steroid drugs are not sufficiently effective).
1	Feb. 29, 2016	6	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 prophylaxis of antibody-mediated rejection in patients who underwent ABO-incompatible kidney or liver transplantation. [Orphan drug]
1	Feb. 29, 2016	7	Kiklin Capsules 250 mg (Astellas Pharma Inc.)	Change	Bixalomer	A drug with a new expanded indication for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Mar. 18, 2016	8	Proemend for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Change	Fosaprepitant meqlumine	A drug with new additional pediatric dosages indicated for the treatment of gastrointestinal symptoms (nausea and vomiting, including delayed phase) associated with administration of antineoplastic drugs (cisplatin, etc.).
1	Mar. 28, 2016	9	Marduox Ointment (Chugai Pharmaceutical Co., Ltd.)	Approval	Maxacalcitol / Betamethasone butyrate propionate	A new combination drug indicated for the treatment of psoriasis vulgaris.
2	Jun. 26, 2015	10	Livalo Tablets 1 mg Livalo Tablets 2 mg Livalo OD Tablets 1 mg Livalo OD Tablets 2 mg (Kowa Company, Ltd.)	Change Change Change Change	Pitavastatin calcium	Drugs with a new additional pediatric dosage indicated for the treatment of familial hypercholesterolemia.
2	Aug. 24, 2015	11	Tracleer Tablets 62.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change	Bosentan hydrate	A drug with a new additional indication for inhibiting development of digital ulcer in patients with systemic sclerosis (only for patients who currently have digital ulcers or have a history of digital ulcer.) [Orphan drug]
2	Aug. 24, 2015	12	INOflo for Inhalation 800 ppm (INO Therapeutics LLC)	Change	Nitric oxide	A drug with a new additional indication and a new dosage for the improvement of pulmonary hypertension in the perioperative period of cardiac surgery. [Orphan drug]

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2	Aug. 24, 2015	13	Artist Tablets 2.5 mg Artist Tablets 10 mg Artist Tablets 20 mg (Daiichi Sankyo Company, Limited)	Change Change Change	Carvedilol	Drugs with a new additional indication and a new dosage for the treatment of tachycardiac atrial fibrillation.
2	Aug. 24, 2015	14	Exelon Patch 4.5 mg Exelon Patch 9 mg Exelon Patch 13.5 mg Exelon Patch 18 mg (Novartis Pharma K.K.)  Rivastach Patch 4.5 mg Rivastach Patch 9 mg Rivastach Patch 13.5 mg Rivastach Patch 18 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change Change  Change Change Change Change	Rivastigmine	Drugs with a new dosage indicated for inhibiting progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Sep. 24, 2015	15	Xarelto Tablets 10 mg Xarelto Tablets 15 mg (Bayer Yakuhin, Ltd.)	Change Change	Rivaroxaban	Drugs with a new additional indication and a new dosage for the treatment and prevention of recurrence of deep vein thrombosis and pulmonary thromboembolism.
2	Sep. 28, 2015	16	Mulpleta Tablets 3 mg (Shionogi & Co., Ltd.)	Approval	<u>Lusutrombopag</u>	A drug with a new active ingredient indicated for the improvement of thrombocytopenia in patients with chronic liver disease for whom an elective invasive procedure is planned.
2	Sep. 28, 2015	17	Ventavis inhalation solution 10 µg (Bayer Yakuhin, Ltd.)	Approval	<u>Iloprost</u>	A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension.
2	Sep. 28, 2015	18	Tracleer pediatric dispersible tablets 32 mg (Actelion Pharmaceuticals Japan Ltd.)	Approval	Bosentan hydrate	A drug with a new indication and a new dosage in a new additional dosage form indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Dec. 21, 2015	19	Eliquis Tablets 2.5 mg Eliquis Tablets 5 mg (Bristol-Myers K.K.)	Change Change	Apixaban	Drugs with a new additional indication and a new dosage for the treatment and prevention of the recurrence of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism).
2	Dec. 21, 2015	20	FP-OD Tablet 2.5 (FP Pharmaceutical Corporation)	Change	Selegiline hydrochloride	A drug with a revised indication and a new dosage for the treatment of Parkinson's disease (When used in combination with levodopa-containing products; patients are classified as Stage I to IV on the Hoehn and Yahr scale, and when not used in combination with levodopa-containing products; patients are classified as Stage I to III on the Hoehn and Yahr scale).
2	Jan. 22, 2016	21	Repatha-SC Injection 140 mg Syringe Repatha-SC Injection 140 mg Pen (Amgen Astellas BioPharma K.K.)	Approval Approval	<u>Evolocumab (genetical recombination)</u>	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).
3-1	May 26, 2015	22	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of pain associated with fibromyalgia.
3-1	Jun. 26, 2015	23	Botox for injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of strabismus.
3-1	Jun. 26, 2015	24	Radicut Inj. 30 mg Radicut Bag for I.V. Infusion 30 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Edaravone	Drugs with a new additional indication and a new dosage for delaying the functional disorder in patients with amyotrophic lateral sclerosis (ALS). [Orphan drug]

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3-1	Sep. 24, 2015	25	Lamictal Tablets 2 mg for Children Lamictal Tablets 5 mg for Children Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Change Change Change Change	Lamotrigine	Drugs with a new additional indication and a new dosage for use in the monotherapy for the treatment of typical absence seizures in patients with epilepsy.
3-1	Sep. 28, 2015	26	Effexor SR Capsules 37.5 mg Effexor SR Capsules 75 mg (Pfizer Japan Inc.)	Approval Approval	<u>Venlafaxine hydrochloride</u>	Drugs with a new active ingredient indicated for the treatment of depression.
3-1	Sep. 28, 2015	27	Copaxone S.C. Injection 20 mg Syringe (Takeda Pharmaceutical Company Limited)	Approval	<u>Glatiramer acetate</u>	A drug with a new active ingredient indicated for the prevention of relapse in multiple sclerosis. [Orphan drug]
3-1	Nov. 20, 2015	28	Lexapro Tablets 10 mg (Mochida Pharmaceutical Co., Ltd.)	Change	Escitalopram oxalate	A drug with a new additional indication for the treatment of social anxiety disorder.
3-1	Feb. 29, 2016	29	E Keppra Tablets 250 mg E Keppra Tablets 500 mg E Keppra Dry Syrup 50% E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)	Change Change Change Change	Levetiracetam	Drugs with a new additional indication for use as an adjunctive therapy with other antiepileptic drugs to treat tonic-clonic seizures in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Feb. 29, 2016	30	Risperdal Tablets 1 mg Risperdal Tablets 2 mg Risperdal Fine Granules 1% Risperdal OD Tablets 0.5 mg Risperdal OD Tablets 1 mg Risperdal OD Tablets 2 mg Risperdal Oral Solution 1 mg/mL (Janssen Pharmaceutical K.K.)	Change Change Change Change Change Change Change	Risperidone	Drugs with a new additional indication and a new dosage for the treatment of irritability associated with autism spectrum disorder in children and adolescents.
3-1	Feb. 29, 2016	31	Tryptanol Tablets 10 Tryptanol Tablets 25 (Nichi-Iko Pharmaceutical Co., Ltd.)  Amitriptyline Hydrochloride Tablets 10 mg "Sawai" Amitriptyline Hydrochloride Tablets 25 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change Change  Change Change	Amitriptyline hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of peripheral neuropathic pain. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
3-1	Mar. 18, 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 chronic low back pain.
3-1	Mar. 28, 2016	33	Sabril Granule Sachets 500 mg (Sanofi K.K.)	Approval	<u>Vigabatrin</u>	A drug with a new active ingredient indicated for the treatment of infantile spasms. [Orphan drug]
3-1	Mar. 28, 2016	34	Sycrest Sublingual Tablets 5 mg Sycrest Sublingual Tablets 10 mg (Meiji Seika Pharma Co., Ltd.)	Approval Approval	<u>Asenapine maleate</u>	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Mar. 28, 2016	35	Fycompa Tablets 2 mg Fycompa Tablets 4 mg (Eisai Co., Ltd.)	Approval Approval	<u>Perampanel hydrate</u>	Drugs with a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) and tonic-clonic seizures in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.

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3-2	Jun. 26, 2015	36	Emla Cream (Sato Pharmaceutical Co., Ltd.)	Change	Lidocaine/Propitocaine	A drug with a new additional indication and a new dosage for adults indicated for the relief of pain during pricking with injection needles and intravenous indwelling needles, and with a new pediatric dosage indicated for the relief of pain during skin laser radiation therapy and pricking with injection needles and intravenous indwelling needles.
3-2	Jun. 26, 2015	37	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a revised indication for the treatment of macular edema following retinal vein occlusion.
3-2	Dec. 21, 2015	38	(1) Xylocaine Injection Polyamp 0.5% (AstraZeneca K.K.)  (2) Lidocaine Hydrochloride Injection 0.5% [Pfizer] (Mylan Seiyaku Ltd.)	Change Change	(1) Lidocaine hydrochloride monohydrate  (2) Lidocaine hydrochloride	Drugs with a new additional indication and a new dosage for the intravenous regional anesthesia in upper extremity surgery. [Public knowledge-based application after PAFSC's preliminary assessment]
4	May 26, 2015	39	Diflucan Capsules 50 mg Diflucan Capsules 100 mg (Pfizer Japan Inc.)	Change Change	Fluconazole	Drugs with new additional indications and a new dosage for the treatment of vaginitis and vulvovaginitis caused by <i>Candida</i> .
4	May 26, 2015	40	Clavamox combination Dry Syrup for pediatric (GlaxoSmithKline K.K.)	Change	Clavulanate potassium/Amoxicillin hydrate	A drug with a new additional indication for the treatment of sinusitis.
4	Jun. 26, 2015	41	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 a new additional indication and a new dosage for the treatment of febrile neutropenia.
4	Jul. 3, 2015	42	Harvoni Combination Tablets (Gilead Sciences, Inc.)	Approval	<u>Ledipasvir</u> <u>acetate</u> /Sofosbuvir	A new combination drug with new active ingredients 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	Jul. 3, 2015	43	Olanedine Antiseptic Solution 1.5% Olanedine Solution 1.5% Antiseptic Applicator 10 mL Olanedine Solution 1.5% Antiseptic Applicator 25 mL (Otsuka Pharmaceutical Factory, Inc.)	Approval Approval Approval	<u>Olanexidine gluconate</u>	Drugs with a new active ingredient indicated for skin antiseptics at surgical sites (in surgical fields).
4	Aug. 24, 2015	44	Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg Vfend Dry Syrup 2800 mg (Pfizer Japan Inc.)	Change Change Change Change	Voriconazole	Drugs with a new additional indication and new dosages for the prophylaxis of deep mycosis in patients after hematopoietic stem cell transplantation.
4	Aug. 24, 2015	45	(1) Cravit Tablets 250 mg (2) Cravit Tablets 500 mg (3) Cravit Fine Granules 10% (Daiichi Sankyo Company, Limited)  (4) Levofloxacin Tablets 250 mg "DSEP" (5) Levofloxacin Tablets 500 mg "DSEP" (6) Levofloxacin Fine Granules 10% "DSEP" (Daiichi Sankyo Espha Co., Ltd.)	Change Change Change  Change Change Change	Levofloxacin hydrate	Drugs with new additional indications and a new dosage for the treatment of pulmonary tuberculosis and other tuberculosis.

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4	Sep. 24, 2015	46	Ciproxan-I.V. 200 (Bayer Yakuhin, Ltd.)	Change	Ciprofloxacin	A drug with a new increased dose for adults indicated for the treatment of sepsis, pneumonia, etc., and also with new indications and new dosages for children for both the treatment of complicated cystitis, pyelonephritis and anthrax, and the improvement of symptoms associated with respiratory infection caused by <i>Pseudomonas aeruginosa</i> in cystic fibrosis.
4	Sep. 24, 2015	47	Cravit Intravenous Drip Infusion 500 mg/100 mL Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Company, Limited)	Change Change	Levofloxacin hydrate	Drugs with new additional indications for the treatment of cystitis, pyelonephritis, secondary infection of trauma, burns or surgical wounds, and others.
4	Sep. 28, 2015	48	Zebiax Lotion 2% (Maruho Co., Ltd.)	Approval	<u>Ozenoxacin</u>	A drug with a new active ingredient indicated for the treatment of superficial skin infections and acne (accompanied by purulent inflammation).
4	Sep. 28, 2015	49	Viekirax Combination Tablets (AbbVie G.K.)	Approval	<u>Ombitasvir hydrate/Paritaprevir hydrate/Ritonavir</u>	A new combination drug with new active ingredients 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	Jan. 22, 2016	50	Luconac Solution 5% (Sato Pharmaceutical Co., Ltd.)	Approval	Luliconazole	A drug with a new indication in a new dosage form indicated for the treatment of tinea unguium.
4	Mar. 28, 2016	51	Malarone Combination Tablets Malarone Pediatric Combination Tablets (GlaxoSmithKline K.K.)	Change Approval	Atovaquone / Proguanil hydrochloride	A drug with a revised pediatric dosage and an additional dosage form indicated for the treatment and prevention of malaria.
4	Mar. 28, 2016	52	Primaquine Tablets 15 mg "Sanofi" (Sanofi K.K.)	Approval	<u>Primaquine phosphate</u>	A drug with a new active ingredient indicated for the treatment of malaria caused by <i>Plasmodium vivax</i> and <i>Plasmodium oval</i> .
5	Jan. 22, 2016	53	Utrogestan Vaginal Capsules 200 mg (Fuji Pharma 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	Mar. 28, 2016	54	Luteum Vaginal Suppository 400 mg (Aska Pharmaceutical 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.
6-1	May 26, 2015	55	Talion Tablets 5 mg Talion Tablets 10 mg Talion OD Tablets 5 mg Talion OD Tablets 10 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change Change Change	Bepotastine besilate	Drugs with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, cutaneous pruritus).
6-1	May 26, 2015	56	Cimzia 200 mg Syringe for S.C. Injection (UCB Japan Co. Ltd.)	Change	Certolizumab pegol (genetical recombination)	A drug with a revised indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage).
6-1	May 26, 2015	57	Solu-Cortef Injection 100 mg Solu-Cortef for Intravenous Use 250 mg Solu-Cortef for Intravenous Use 500 mg (Pfizer Japan Inc.)	Change Change Change	Hydrocortisone sodium succinate	Drugs with a new additional indication and a new dosage for the treatment of bronchial asthma. [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Jul. 3, 2015	58	Plaquenil Tablets 200 mg (Sanofi K.K.)	Approval	<u>Hydroxychloroquine sulfate</u>	A drug with a new active ingredient indicated for the treatment of cutaneous lupus erythematosus and systemic lupus erythematosus.

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6-1	Jul. 3, 2015	59	Ofev Capsules 100 mg Ofev Capsules 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	<u>Nintedanib</u> <u>ethanesulfonate</u>	Drugs with a new active ingredient indicated for the treatment of idiopathic pulmonary fibrosis. [Orphan drug]
6-1	Aug. 24, 2015	60	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of entero-Behcet's disease, neuro-Behcet's disease, and vasculo-Behcet's disease in patients who have not responded sufficiently to conventional therapies. [Orphan drug]
6-1	Sep. 28, 2015	61	Spiolto Respimat 28 puffs Spiolto Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Tiotropium bromide hydrate/ <u>Olodaterol hydrochloride</u>	New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (when a combination treatment of an inhaled long-acting anticholinergic and a long-acting beta-2 agonist is needed).
6-1	Sep. 28, 2015	62	Loqoa Tape (Taisho Pharmaceutical Co., Ltd.)	Approval	<u>Esfurlbiprofen</u> /Mentha oil	A new combination drug with a new active ingredient indicated for the relief of inflammation and pain associated with osteoarthritis.
6-1	Sep. 28, 2015	63	Miticure House Dust Mite Sublingual Tablets 3,300 JAU Miticure House Dust Mite Sublingual Tablets 10,000 JAU (Torii Pharmaceutical Co., Ltd.)	Approval Approval	<u>Dermatophagoides farinae extract</u> , <u>Dermatophagoides pteronyssinus extract</u>	Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis.
6-1	Dec. 21, 2015	64	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of acute-phase Kawasaki's disease in patients who have not responded sufficiently to conventional therapies. [Orphan drug]
6-1	Dec. 21, 2015	65	Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg (Novartis Pharma K.K.)	Change Change	Secukinumab (genetical recombination)	Drugs with a new additional indication for the treatment of pustular psoriasis in patients who have not responded sufficiently to conventional therapies.
6-1	Mar. 28, 2016	66	Nucala for s.c. Injection 100 mg (GlaxoSmithKline K.K.)	Approval	<u>Mepolizumab (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).
6-2	Jul. 3, 2015	67	Lantus XR Inj. SoloStar (Sanofi K.K.)	Approval	Insulin glargine (genetical recombination)	A drug in a new dosage form indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Jul. 3, 2015	68	Trulicity Subcutaneous Injection 0.75 mg Ateos (Eli Lilly Japan K.K.)	Approval	<u>Dulaglutide (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jul. 3, 2015	69	Strensiq Subcutaneous Injection 12 mg/0.3 mL Strensiq Subcutaneous Injection 18 mg/0.45 mL Strensiq Subcutaneous Injection 28 mg/0.7 mL Strensiq Subcutaneous Injection 40 mg/1 mL Strensiq Subcutaneous Injection 80 mg/0.8 mL (Alexion Pharma G.K.)	Approval Approval Approval Approval	<u>Asfotase alfa (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of hypophosphatasia. [Orphan drug]
6-2	Aug. 24, 2015	70	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Change Change	Insulin degludec (genetical recombination)	Drugs with a new additional pediatric dosage indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.

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6-2	Sep. 28, 2015	71	Marizev Tablets 25 mg Marizev Tablets 12.5 mg (MSD K.K.)	Approval Approval	<u>Omarigliptin</u>	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Sep. 28, 2015	72	EquiMet Combination Tablets LD EquiMet Combination Tablets HD (Novartis Pharma K.K.)	Approval Approval	Vildagliptin/Metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of vildagliptin with metformin hydrochloride is deemed appropriate).
6-2	Dec. 21, 2015	73	Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change	Anagliptin	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Jan. 22, 2016	74	Bonviva Tablet 100 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	Ibandronate sodium hydrate	A drug with a new route of administration indicated for the treatment of osteoporosis.
6-2	Mar. 28, 2016	75	Kanuma Intravenous Infusion 20 mg (Alexion Pharma G.K.)	Approval	<u>Sebelipase alfa</u> ( <u>genetical</u> <u>recombination</u> )	A drug with a new active ingredient indicated for the treatment of lysosomal acid lipase deficiency. [Orphan drug]
<i>In vivo</i> diagnostics	Sep. 28, 2015	76	Allergen Scratch Extract Positive control "TORII" Histamine dihydrochloride (Japan Tobacco Inc.)	Approval	Histamine dihydrochloride	A drug with a new indication and a new dosage in a newly-added dosage form indicated for positive control in skin tests when diagnosing allergy.
<i>In vivo</i> diagnostics	Jan. 22, 2016	77	Provocholine Powder for Inhalation Solution 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)  Kenbran Powder for Inhalation Solution 100 mg (Santen Pharmaceutical Co., Ltd.)	Approval  Approval	<u>Methacholine chloride</u>	Drugs with a new active ingredient indicated for tests in the diagnosis of bronchial airway hyperresponsiveness.
<i>In vivo</i> diagnostics	Mar. 28, 2016	78	ColomforT Oral Suspension 25% (Fushimi Pharmaceutical Co.,Ltd.)	Approval	Barium sulfate	A drug with a new indication and a new dosage in an additional dosage form indicated for the support of computed tomographic colonography with labelling of bowel contents.
Radio-pharmaceuticals	Sep. 28, 2015	79	Octreoscan Injection (Fujifilm RI Pharma Co.,Ltd.)	Approval	<u>Indium pentetoreotide</u> ( <sup>111</sup> In)	A drug with a new active ingredient indicated for the diagnosis of neuroendocrine tumor by using somatostatin receptor scintigraphy.
Oncology drugs	May 26, 2015	80	Laserphyrin 100 mg for Injection (Meiji Seika Pharma Co., Ltd)	Change	Talaporfin sodium	A drug with a new additional indication for the treatment of recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy. [Orphan drug]
Oncology drugs	May 26, 2015	81	Pegintron Powder for Injection 50 µg/0.5 mL Pegintron Powder for Injection 100 µg/0.5 mL Pegintron Powder for Injection 150 µg/0.5 mL (MSD K.K.)	Change Change Change	Peginterferon alfa-2b (genetical recombination)	Drugs with a new additional indication and a new dosage for the adjuvant treatment of melanoma. [Orphan drug]
Oncology drugs	May 26, 2015	82	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with a new dosage for the treatment of CD20-positive, B-cell non-Hodgkin's lymphoma. [Orphan drug]
Oncology drugs	Jun. 26, 2015	83	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new additional indication and a new dosage for the treatment of patients with mantle cell lymphoma. [Orphan drug]

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Oncology drugs	Jun. 26, 2015	84	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review]
Oncology drugs	Jun. 26, 2015	85	Prednisolone Tablets 5 mg "Takeda" Prednisolone Powder 1% "Takeda" (Takeda Pharmaceutical Company Limited)  Predonine Tablets 5 mg (Shionogi & Co., Ltd.)	Change Change  Change	Prednisolone	Drugs with revised indications and a new dosage for the treatment of malignant lymphoma and similar diseases (closely-related diseases). [Expedited review]
Oncology drugs	Jul. 3, 2015	86	Yervoy Injection 50 mg (Bristol-Myers K.K.)	Approval	<u>Ipilimumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Jul. 3, 2015	87	Farydak Capsules 10 mg Farydak Capsules 15 mg (Novartis Pharma K.K.)	Approval Approval	<u>Panobinostat lactate</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Sep. 24, 2015	88	Jakavi Tablets 5 mg (Novartis Pharma K.K.)	Change	Ruxolitinib phosphate	A drug with a new additional indication and a new dosage for the treatment of polycythemia vera (use only when conventional therapies are not sufficiently effective or inappropriate).
Oncology drugs	Sep. 24, 2015	89	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.)  Paclitaxel Inj. 30 mg/5 mL "NK" Paclitaxel Inj. 100 mg/16.7 mL "NK" (Nippon Kayaku Co., Ltd.)  Paclitaxel I.V. Infusion 30 mg/5 mL "Hospira" Paclitaxel I.V. Infusion 100 mg/16.7 mL "Hospira" (Hospira Japan Co., Ltd.)  Paclitaxel Injection 30 mg "Sawai" Paclitaxel Injection 100 mg "Sawai" Paclitaxel Injection 150 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)  Paclitaxel Intravenous Infusion 30 mg "Sandoz" Paclitaxel Intravenous Infusion 100 mg "Sandoz" (Sandoz K.K.)  Paclitaxel Injection 30 mg "NP" Paclitaxel Injection 100 mg "NP" (Nipro Corporation)  Paclitaxel Injection 30 mg "Pfizer" Paclitaxel Injection 100 mg "Pfizer" (Mylan Seiyaku Ltd.)	Change Change  Change Change  Change Change  Change Change  Change Change  Change Change	Paclitaxel	Drugs with a new dosage indicated for the treatment of gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Sep. 28, 2015	90	Caprelsa Tablets 100 mg (AstraZeneca K.K.)	Approval	<u>Vandetanib</u>	A drug with a new active ingredient indicated for the treatment of unresectable medullary thyroid cancer. [Orphan drug]
Oncology drugs	Sep. 28, 2015	91	Leuplin Pro for Injection Kit 22.5 mg (Takeda Pharmaceutical Company Limited)	Approval	Leuprorelin acetate	A drug in a new dosage form indicated for the treatment of prostate cancer and premenopausal breast cancer.
Oncology drugs	Sep. 28, 2015	92	Yondelis I.V. infusion 0.25 mg Yondelis I.V. infusion 1 mg (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	<u>Trabectedin</u>	Drugs with a new active ingredient indicated for the treatment of patients with soft tissue sarcoma. [Orphan drug]



Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Nov. 20, 2015	93	(1) Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.)  (2) Elplat I.V. Infusion Solution 50 mg (3) Elplat I.V. Infusion Solution 100 mg (4) Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.)	Change  Change Change Change	(1) Capecitabine (2) - (4) Oxaliplatin	Drugs with a revised indication for the treatment of gastric cancer.
Oncology drugs	Nov. 20, 2015	94	Hycamtin for Injection 1.1 mg (Nippon Kayaku Co., Ltd.)	Change	Nogitecan hydrochloride	A drug with a new additional indication and a new dosage for the treatment of advanced or recurrent cervical cancer.
Oncology drugs	Nov. 20, 2015	95	Tykerb Tablets 250 mg (GlaxoSmithKline K.K.)	Change	Lapatinib tosilate hydrate	A drug with new dosages indicated for the treatment of inoperable or recurrent breast cancer with HER2 overexpression.
Oncology drugs	Dec. 17, 2015	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 and a new dosage for the treatment of unresectable advanced/relapsed non-small-cell lung cancer. [Priority review]
Oncology drugs	Dec. 21, 2015	97	Revlimid Capsules 2.5 mg Revlimid Capsules 5 mg (Celgene K.K.)	Change Change	Lenalidomide hydrate	Drugs with a revised indication for the treatment of multiple myeloma.
Oncology drugs	Jan. 22, 2016	98	Targretin Capsules 75 mg (Minophagen Pharmaceutical Co., Ltd.)	Approval	<u>Bexarotene</u>	A drug with a new active ingredient indicated for the treatment of cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Feb. 29, 2016	99	Halaven Injection 1 mg (Eisai Co., Ltd.)	Change	Eribulin mesylate	A drug with a new additional indication for the treatment of soft tissue sarcoma. [Orphan drug]
Oncology drugs	Feb. 29, 2016	100	Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.)	Change	Sorafenib tosilate	A drug with a revised indication for the treatment of unresectable thyroid cancer. [Orphan drug]
Oncology drugs	Feb. 29, 2016	101	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change	Nivolumab (genetical recombination)	Drugs with a new dosage indicated for the treatment of unresectable melanoma. [Orphan drug]
Oncology drugs	Mar. 28, 2016	102	Tafinlar Capsules 50 mg Tafinlar Capsules 75 mg (Novartis Pharma K.K.)	Approval Approval	<u>Dabrafenib mesilate</u>	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF mutation. [Orphan drug]
Oncology drugs	Mar. 28, 2016	103	Mekinist Tablets 0.5 mg Mekinist Tablets 2 mg (Novartis Pharma K.K.)	Approval Approval	<u>Trametinib dimethyl sulfoxide</u>	Drugs with a new active ingredient indicated for the treatment of unresectable melanoma with BRAF mutation. [Orphan drug]
Oncology drugs	Mar. 28, 2016	104	Xofigo Injection (Bayer Yakuhin, Ltd.)	Approval	<u>Radium (<sup>223</sup>Ra) dichloride</u>	A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer with bone metastases.
Oncology drugs	Mar. 28, 2016	105	Zykadia Capsules 150 mg (Novartis Pharma K.K.)	Approval	<u>Ceritinib</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced/relapsed anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer with resistance or intolerance to crizotinib.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Mar. 28, 2016	106	Tagrisso Tablets 40 mg Tagrisso Tablets 80 mg (AstraZeneca K.K.)	Approval Approval	<u>Osimertinib mesilate</u>	Drugs with a new active ingredient indicated for the treatment of inoperable or recurrent epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer with resistance to EGFR tyrosine kinase inhibitors.
Oncology drugs	Mar. 28, 2016	107	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Ibrutinib</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma.
Vaccines	Jan. 22, 2016	108	Vaxem Hib Suspension Liquid for Injection (Takeda Pharmaceutical Company Limited)	Approval	<u>Haemophilus influenzae type b vaccine adsorbed (mutated diphtheria CRM<sub>197</sub> conjugate)</u>	A drug with a new active ingredient indicated for the prophylaxis of <i>Haemophilus influenzae</i> type b infections.
Vaccines	Feb. 29, 2016	109	Tribik (The Research Foundation for Microbial Diseases of Osaka University)	Change	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	A drug with a new dosage indicated for the prevention of pertussis, diphtheria, and tetanus.
Vaccines	Mar. 18, 2016	110	Freeze-dried Live Attenuated Varicella Vaccine "Biken" (The Research Foundation for Microbial Diseases of Osaka University)	Change	Freeze-dried live attenuated varicella vaccine	A drug with a new additional indication for the prevention of herpes zoster in individuals 50 years of age and older.
Vaccines	Mar. 18, 2016	111	Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 30µg/mL "Kitasato Daiichi Sankyo" (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Change	Adsorbed cell culture-derived influenza vaccine (H5N1)	A drug with a new additional pediatric dosage indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	Jul. 3, 2015	112	Acoalan Injection 600 (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Antithrombin gamma (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of thrombophilia due to congenital antithrombin (AT) deficiency (CAD) and disseminated intravascular coagulation (DIC) accompanied by a decrease in AT.
Blood products	Mar. 28, 2016	113	Adynovate Intravenous 250 Adynovate Intravenous 500 Adynovate Intravenous 1000 Adynovate Intravenous 2000 (Baxter Limited)	Approval Approval Approval Approval	<u>Rurioctocog 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	Mar. 28, 2016	114	Kovaltry for iv injection 250 Kovaltry for iv injection 500 Kovaltry for iv injection 1000 Kovaltry for iv injection 2000 Kovaltry for iv injection 3000 Kovaltry for iv injection Kit 250 Kovaltry for iv injection Kit 500 Kovaltry for iv injection Kit 1000 Kovaltry for iv injection Kit 2000 Kovaltry for iv injection Kit 3000 (Bayer Yakuhiin, Ltd.)	Approval Approval Approval Approval Approval Approval Approval Approval Approval Approval	<u>Octocog beta (genetical recombination)</u>	Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency.
Bio-CMC	Mar. 28, 2016	115	Insulin Glargine BS Injection Kit "FFP" Insulin Glargine BS Injection 100 Unit/mL "FFP" (Fujifilm Pharma Co., Ltd.)	Approval Approval	Insulin glargine (genetical recombination) [insulin glargine biosimilar 2]	Follow-on biologics indicated for the treatment of diabetes mellitus 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