New Drugs Approved in FY 2013

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 30, 2013	1	Potassium Iodide Pills 50 mg "Nichi-iko" (Nichi-Iko Pharmaceutical Co., Ltd.)	Change	Potassium iodide	A drug with a new additional indication and a new dosage for the prevention and reduction of internal exposure to radioactive iodine in the thyroid gland. [Expedited review]
1	May 16, 2013	2	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbvie G.K.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of intestinal Behcet's disease in patients who have not responded sufficiently to conventional treatments.
1	Jun. 14, 2013	3	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbvie G.K.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments).
1	Aug. 20, 2013	4	Ora-Bliss Gargle Gran. 11% (Showa Yakuhin Kako Co., Ltd.) Miranor Granule 11% (Oriental Pharmaceutical and Synthetic Chemical Co., Ltd.)	Change Change	Sodium fluoride	Drugs with a new dosage indicated for the prevention of dental caries.
1	Aug. 20, 2013	5	Fosrenol Chewable Tablets 250 mg Fosrenol Chewable Tablets 500 mg Fosrenol Granules 250 mg Fosrenol Granules 500 mg (Bayer Yakuhin, Ltd.)	Change Change Change Change	Lanthanum carbonate hydrate	Drugs with a new indication to extend the indication for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Sep. 13, 2013	6	Lipiodol 480 Injection 10 mL (Guerbet Japan K.K.)	Change	Iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil	A drug with a new route of administration and a new dosage for a new additional indication for the adjustment of drugs or medical devices. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Sep. 13, 2013	7	Nesp Injection 10 μg Plastic Syringe Nesp Injection 15 μg Plastic Syringe Nesp Injection 20 μg Plastic Syringe Nesp Injection 30 μg Plastic Syringe Nesp Injection 40 μg Plastic Syringe Nesp Injection 60 μg Plastic Syringe Nesp Injection 120 μg Plastic Syringe Nesp Injection 180 μg Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change Change	Darbepoetin alfa (genetical recombination)	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of renal anemia.
1	Sep. 13, 2013	8	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 for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
1	Sep. 20, 2013	9	Nesp Injection 5 μg Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval	Darbepoetin alfa (genetical recombination)	A drug with a new additional pediatric dosage in an additional dosage form. The drug is indicated for the treatment of renal anemia.
1	Sep. 20, 2013	10	Oblean Tablets 120 mg (Takeda Pharmaceutical Company Limited)	Approval	Cetilistat	A drug with a new active ingredient indicated for the treatment of obesity (for use only in patients who have both type 2 diabetes mellitus and dyslipidaemia and whose BMI level is 25kg/m^2 or more even with diet and exercise therapies).
1	Jan. 17, 2014	11	Riona Tab. 250 mg (Japan Tobacco Inc.)	Approval	Ferric citrate hydrate	A drug with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic kidney disease.
1	Jan. 17, 2014	12	Savene Injectable 500 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	Dexrazoxane	A drug with a new active ingredient indicated for the treatment of anthracycline extravasation.
1	Feb. 21, 2014	13	Regpara Tablets 25 mg Regpara Tablets 75 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Cinacalcet hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism (HPT) who are unable to undergo parathyroidectomy or who experience recurrent primary HPT after the surgery. [Orphan drug]
1	Mar. 24, 2014	14	Glash Vista Solution for external use 0.03% 3 mL Glash Vista Solution for external use 0.03% 5 mL (Allergan Japan K.K.)	Approval Approval	Bimatoprost	Drugs with a new route of administration for the treatment of eyelashe hypotrichosis.
2	May 31, 2013	15	Ancaron Inj. 150 (Sanofi K.K.)	Change	Amiodarone hydrochloride	A drug with a new additional indication and a new dosage indicated for the treatment of cardiac arrest due to ventricular fibrillation/pulseless ventricular tachycardia, resistant to electrical cardioversion.

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2	Jun. 14, 2013	16	Adalat-CR Tablets 10 Adalat-CR Tablets 20 Adalat-CR Tablets 40 (Bayer Yakuhin, Ltd.)	Change Change Change	Nifedipine	Drugs with a new dosage indicated for the treatment of hypertension.
2	Jun. 14, 2013	17	Maintate Tablets 2.5 mg Maintate Tablets 5 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change	Bisoprolol fumarate	Drugs with a new additional indication and a new dosage for the treatment of tachycardiac atrial fibrillation.
2	Jun. 28, 2013	18	Bisono Tape 4 mg Bisono Tape 8 mg (Toa Eiyo Ltd.)	Approval Approval	Bisoprolol	Drugs with a new active ingredient indicated for the treatment of essential hypertension (mild to moderate).
2	Jun. 28, 2013	19	Irtra Combination Tablets LD Irtra Combination Tablets HD (Shionogi & Co., Ltd.)	Approval Approval	Irbesartan/ trichlormethiazide	New combination drugs indicated for the treatment of hypertension.
2	Aug. 20, 2013	20	Trerief Tablet 25 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change	Zonisamide	A drug with a new dosage indicated for the improvement of wearing-off phenomenon in symptoms of Parkinson's disease.
2	Sep. 13, 2013	21	Samsca Tablets 7.5 mg (Otsuka Pharmaceutical Co., Ltd.)	Change	Tolvaptan	A drug with a new additional indication and a new dosage for the treatment of fluid retention in patients with hepatic cirrhosis who have not responded sufficiently to other diuretics such as loop diuretics.
2	Sep. 20, 2013	22	Complavin Combination Tablets (Sanofi K.K.)	Approval	(1) Clopidogrel sulfate (2) Aspirin	A new combination drug indicated for the treatment of ischemic heart diseases (acute coronary syndrome [unstable angina, non-ST-segment elevation myocardial infarction, ST-segment elevation myocardial infarction], stable angina, old myocardial infarction) to which percutaneous coronary intervention (PCI) is applicable.
2	Sep. 20, 2013	23	Preminent Tablets HD (MSD K.K.)	Approval	(1) Losartan potassium (2) Hydrochlorothiazide	A drug with a new dosage in an additional dosage form. The drug is indicated for the treatment of hypertension.
2	Nov. 22, 2013	24	Onoact 50 for injection (Ono Pharmaceutical Co., Ltd.)	Change	Landiolol hydrochloride	A drug with a new additional indication and a new dosage for the treatment of tachyarrhythmia including atrial fibrillation/flutter in patients with low cardiac function.
2	Jan. 17, 2014	25	Adempas Tablets 0.5 mg Adempas Tablets 1.0 mg Adempas Tablets 2.5 mg (Bayer Yakuhin, Ltd.)	Approval Approval Approval	Riociguat	Drugs with a new active ingredient indicated for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH. [Orphan drug]
2	Mar. 24, 2014	26	Takelda Combination Tablets (Takeda Pharmaceutical Company Limited)	Approval	Lansoprazole/aspirin	A new combination drug indicated for the postoperative inhibition of thrombus and thrombus formation (limited to patients with previous history of gastric or duodenal ulcer) in patients with angina (chronic stable angina, unstable angina), myocardial infraction, ischemic cerebrovascular disorder (transient ischemic attack [TIA], cerebral infarction), and patients who have undergone coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA).
2	Mar. 24, 2014	27	Atedio Combination Tab. (Ajinomoto Pharmaceutical Co., Ltd.)	Approval	Valsartan/cilnidipine	A new combination drug indicated for the treatment of hypertension.
2	Mar. 24, 2014	28	Rasimlo Combination Tablet LD Rasimlo Combination Tablet HD (Novartis Pharma K.K.)	Approval Approval	Aliskiren fumarate/amlodipine besylate	New combination drugs indicated for the treatment of hypertension.
2	Mar. 24, 2014	29	Zacras Combination Tablets LD Zacras Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Azilsartan/amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	Mar. 24, 2014	30	Treprost 20 mg for injection Treprost 50 mg for injection Treprost 100 mg for injection Treprost 200 mg for injection (Mochida Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Treprostinil	Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension (WHO functionalclassification; Class II, III and IV).
2	Mar. 24, 2014	31	Samsca Tablets 7.5 mg Samsca Tablets 15 mg Samsca Tablets 30 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Approval	Tolvaptan	Drugs with a new additional indication and a new dosage, and a drug with a newly-added dosage form indicated for inhibiting the progression of autosomal dominant polycystic kidney disease in patients whose kidney volume already have increased and enlarged at a rapid rate. [Orphan drug]

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2	Mar. 24, 2014	32	Efient Tablets 3.75 mg Efient Tablets 5 mg (Daiichi Sankyo Company, Limited)	Approval Approval	Prasugrel hydrochloride	Drugs with a new active ingredient indicated for the treatment of the following ischemic heart diseases managed with percutaneous coronary intervention (PCI): acute coronary syndrome (unstable angina, non ST-segment elevation myocardial infarction, ST-segment elevation myocardial infarction), stable angina, old myocardial infarction.
(1) - (3) 2 (4) - (6) 2 3-1	Sep. 13, 2013	33	[1] Predonine 10 mg [2] Predonine 20 mg [3] Predonine 50 mg [4] Predonine Tablets 5 mg (Shionogi & Co., Ltd.) [5] Prednisolone Tablets 1 mg (Asahi Kasei) [6] Prednisolone Tablets 5 mg (Asahi Kasei) (Asahi Kasei Pharma Corporation)	Change Change Change Change Change Change	[1] - [3] Prednisolone sodium succinate [4] - [6] Prednisolone	Drugs with a new additional indication and a new dosage for the treatment of acute-phase Kawasaki's disease (cases where the disease is severe and at risk for coronary artery disorder) ([1] - [6]) and Duchenne muscular dystrophy ([4] - [6]). Duchenne muscular dystrophy: [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	May 31, 2013	34	E Keppra Tablets 250 mg E Keppra Tablets 500 mg (UCB Japan Co., Ltd.)	Change Change	Levetiracetam	Drugs with a new additional pediatric dosage indicated for 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	Jun. 14, 2013	35	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.)	Change Change Change Change Change Change Change Change	Aripiprazole	Drugs with a new additional indication and a new dosage for the treatment of depression (for use only in patients who have an inadequate response to antidepressant therapy).
3-1	Jun. 28, 2013	36	E Keppra Dry Syrup 50% (UCB Japan Co., Ltd.)	Approval	Levetiracetam	A drug with a new additional pediatric dosage in an additional dosage form indicated for 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. 20, 2013	37	Xeplion Aqueous Suspension for Intramuscular Injection 25 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 50 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 75 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 100 mg Syringe Xeplion Aqueous Suspension for Intramuscular Injection 150 mg Syringe (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval	Paliperidone palmitate	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Sep. 20, 2013	38	Vyndaqel Capsules 20 mg (Pfizer Japan Inc.)	Approval	Tafamidis meglumine	A drug with a new active ingredient indicated for delaying the peripheral neurologic impairment in transthyretin familial amyloid polyneuropathy. [Orphan drug]
3-1	Nov. 22, 2013	39	Paxil Tablets 5 mg Paxil Tablets 10 mg Paxil Tablets 20 mg (GlaxoSmithKline K.K.)	Change Change Change	Paroxetine hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of posttraumatic stress disorder.
3-1	Nov. 22, 2013	40	Anafranil Tablets 10 mg Anafranil Tablets 25 mg (Alfresa Pharma Corporation)	Change Change	Clomipramine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of cataplexy associated with narcolepsy. [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	Nov. 22, 2013	41	Topina Tablets 25 mg Topina Tablets 50 mg Topina Tablets 100 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change	Topiramate	Drugs with a new additional pediatric dosage. These drugs are indicated for 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	Dec. 20, 2013	42	Concerta Tablets 18 mg Concerta Tablets 27 mg (Janssen Pharmaceutical K.K.)	Change Change	Methylphenidate hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Jan. 17, 2014	43	Topina Fine Granules 10% (Kyowa Hakko Kirin Co., Ltd.)	Approval	Topiramate	A drug with a new additional pediatric dosage in an additional dosage form. The drug is indicated for 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.

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3-1	Jan. 17, 2014	44	Concerta Tablets 36 mg (Janssen Pharmaceutical K.K.)	Approval	Methylphenidate hydrochloride	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of attention deficit/hyperactivity disorder (AD/HD) in adults.
3-1	Mar. 24, 2014	45	Tysabri for I.V. Infusion 300 mg (Biogen Idec Japan Ltd.)	Approval	Natalizumab (genetical recombination)	A drug with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis. [Orphan drug]
3-2	Jun. 14, 2013	46	Precedex Intravenous Solution 200 µg "Hospira" (Hospira Japan Co., Ltd.) Precedex Intravenous Solution 200 µg "Maruishi" (Maruishi Pharmaceutical Co., Ltd.)	Change Change	Dexmedetomidine hydrochloride	Drugs with a new additional indication and a new dosage for sedation of non-intubated patients during surgical and other procedures under local anesthesia.
3-2	Jun. 14, 2013	47	Tramal Capsules 25 mg Tramal Capsules 50 mg (Nippon Shinyaku Co., Ltd.)	Change Change	Tramadol hydrochloride	Drugs with a new additional indication for analgesia in patients with chronic non-cancer pain which cannot be managed by treatments with non-opioid analgesics.
3-2	Jun. 14, 2013	48	Penles Tape 18 mg (Nitto Denko Corporation)	Change	Lidocaine	A drug with a new additional indication and a new dosage for the relief of pain during skin laser radiation therapy.
3-2	Jun. 28, 2013	49	E-fen Buccal Tablets 50 µg E-fen Buccal Tablets 100 µg E-fen Buccal Tablets 200 µg E-fen Buccal Tablets 400 µg E-fen Buccal Tablets 600 µg E-fen Buccal Tablets 800 µg (Teikoku Seiyaku Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Fentanyl citrate	Drugs with a new dosage in a new dosage form for the analgesia of breakthrough pain in patients with cancer receiving a potent opioid analgesic at a fixed time.
3-2	Aug. 20, 2013	50	Lucentis Solution for Intravitreal Injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of macular edema following retinal vein occlusion and choroidal neovascularisasion in pathologic myopia.
3-2	Sep. 20, 2013	51	Tapcom Combination Ophthalmic Solution (Santen Pharmaceutical Co., Ltd.)	Approval	(1) Tafluprost (2) Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension.
3-2	Sep. 20, 2013	52	Abstral Sublingual Tablet 100 µg Abstral Sublingual Tablet 200 µg Abstral Sublingual Tablet 400 µg (Kyowa Hakko Kirin Co., Ltd.)	Approval Approval Approval	Fentanyl citrate	Drugs with a new dosage in a new dosage form indicated for analgesia of breakthrough pain in patients with cancer receiving a potent opioid analgesic at fixed time.
3-2	Sep. 20, 2013	53	Azorga Combination Ophthalmic Suspension (Alcon Japan Ltd.)	Approval	(1) Brinzolamide (2) Timolol maleate	A new combination drug indicated for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other glaucoma drugs.
3-2	Nov. 22, 2013	54	Eylea Intravitreal Injection 40 mg/mL Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Change Change	Aflibercept (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of macular edema following central retinal vein occlusion.
3-2	Dec. 20, 2013	55	Dormicum Injection 10 mg (Astellas Pharma Inc.)	Change	Midazolam	A drug with a new additional indication and a new dosage for sedation during surgeries and other procedures in the field of dentistry and oral surgery.
3-2	Dec. 20, 2013	56	OneDuro Patch 0.84 mg OneDuro Patch 1.7 mg OneDuro Patch 3.4 mg OneDuro Patch 5 mg OneDuro Patch 6.7 mg (Janssen Pharmaceutical K.K.)	Change Change Change Change Change	Fentanyl	Drugs with a new additional indication for analgesia in moderate to severe chronic pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic).
3-2	Feb. 21, 2014	57	Lucentis solution for intravitreal injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Change	Ranibizumab (genetical recombination)	A drug with a new additional indication for the treatment of diabetic macular edema.
3-2	Mar. 24, 2014	58	Tapenta Tablets 25 mg Tapenta Tablets 50 mg Tapenta Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	Tapentadol hydrochloride	Drugs with a new active ingredient indicated for management of moderate to severe pain in various types of cancer.
4	Aug. 20, 2013	59	Cubicin IV 350 mg (MSD K.K.)	Change	Daptomycin	A drug with a new dosage indicated for the treatment of sepsis, infective endocarditis, deep skin infection, secondary infection of trauma, burn and surgical wound, and secondary infection of erosion and ulcer caused by daptomycin-sensitive methicillin-resistant *Staphylococcus aureus* (MRSA).
4	Aug. 20, 2013	60	Synagis for Intramuscular Injection 50 mg Synagis for Intramuscular Injection 100 mg Synagis for Intramuscular Solution 50 mg Synagis for Intramuscular Solution 100 mg (Abbvie G.K.)	Change Change Change Change	Palivizumab (genetical recombination)	Drugs with new indications for the suppression of development of serious lower respiratory tract disease caused by RS viral infection in newborns, infants, and children aged 24 months or less with immunodeficiency and Down syndrome. [Priority review]

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4	Sep. 13, 2013	61	Gentacin Injection 10 Gentacin Injection 40 Gentacin Injection 60 (MSD K.K.)	Change Change Change	Gentamicin sulfate	Drugs with a new dosage indicated for the treatment of sepsis, secondary infection of trauma, burn, and surgical wound, pneumonia, cystitis, pyelonephritis, peritonitis, otitis media caused by following applicable microorganisms: Gentamicin-sensitive *Staphylococcus, Escherichia coli, Klebsiella, Enterobacter, Serratia, Proteus, Morganella morganii, Providencia, Pseudomonas aeruginosa*
4	Sep. 27, 2013	62	Sovriad Capsules 100 mg (Janssen Pharmaceutical K.K.)	Approval	Simeprevir sodium	A drug with a new active ingredient indicated for the improvement of viraemia in following (1) or (2) patient with chronic hepatitis C serogroup 1 (genotype I [1a] or II [1b]): (1) Patient with high level of blood HCV RNA who have untreated or (2) Patients who have not respond to or relapsed with the treatment including interferon. [Priority review]
4	Dec. 20, 2013	63	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Change	Laninamivir octanoate hydrate	A drug with a new additional indication and a new dosage for prophylaxis of influenza A or B virus infections.
4	Dec. 20, 2013	64	Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Meropenem hydrate	Drugs with a new dosage (the daily dose has been changed) in patients with purulent meningitis.
4	Feb. 21, 2014	65	Streptomycin Sulfate 1 g "Meiji" for Injection (Meiji Seika Pharma Co., Ltd.)	Change	Streptomycin sulfate	A drug with a new additional indication and new dosage for the treatment of non-tuberculous mycobacterial infection including mycobacterium avium complex (MAC) caused by streptomycin-sensitive *mycobacterium* as its applicable microorganism. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Feb. 21, 2014	66	Dalacin S Injection 300 mg Dalacin S Injection 600 mg (Pfizer Japan Inc.)	Change Change	Clindamycin phosphate	Drugs with a new additional indication for cellulitis around the jaw bone and jaw inflammation. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Mar. 24, 2014	67	Avigan Tablet 200 mg (Toyama Chemical Co., Ltd.)	Approval	Favipiravir	A drug with a new active ingredient indicated for novel or re-emerging influenza virus infections (for use only in patients who have not responded or not responded sufficiently to other anti-influenza virus drugs). [Priority review]
4	Mar. 24, 2014	68	Sumithrin Lotion 5% (Kracie Pharma, Ltd.)	Approval	Phenothrin	A drug with a new indication and a new dosage for the treatment of scabies. [Priority review]
4	Mar. 24, 2014	69	Tenozet Tablets 300 mg (GlaxoSmithKline K.K.)	Approval	Tenofovir disoproxil fumarate	A drug with a new active ingredient indicated for the growth inhibition of hepatitis B virus in patients with chronic hepatitis B who show liver dysfunction accompanied by proliferation of the virus. [Priority review]
5	May 16, 2013	70	Lunabell Tablets LD (Nobelpharma Co., Ltd.)	Change	Norethisterone/ ethinylestradiol	A drug with a revised indication from "dysmenorrhea associated with endometriosis; functional dysmenorrhea" to "dysmenorrhea."
5	Jun. 28, 2013	71	Lunabell Tablets ULD (Nobelpharma Co., Ltd.)	Approval	Norethisterone/ ethinylestradiol	A drug with a new indication and a new dosage in an additional dosage form indicated for the treatment of dysmenorrhea.
5	Sep. 20, 2013	72	(1) Reguneal HCa 1.5 Peritoneal Dialysis Solution Reguneal HCa 2.5 Peritoneal Dialysis Solution Reguneal HCa 4.25 Peritoneal Dialysis Solution (2) Reguneal LCa 1.5 Peritoneal Dialysis Solution Reguneal LCa 2.5 Peritoneal Dialysis Solution Reguneal LCa 4.25 Peritoneal Dialysis Solution (Baxter Limited)	 Approval Approval Approval Approval Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations indicated for the treatment of (1) peritoneal dialysis in patients with chronic renal failure (used when the peritoneal dialysis is not sufficiently effective to improve hypermagnesemia), (2) peritoneal dialysis in patients with chronic renal failure (used when the peritoneal dialysis is not sufficiently effective to improve hypermagnesemia and when hypercalcaemia may occur due to the treatment with calcium preparation or active vitamin D preparation).
5	Jan. 17, 2014	73	Zalutia 2.5 mg Tablets Zalutia 5 mg Tablets (Eli Lilly Japan K.K.)	Approval Approval	Tadalafil	Drugs with a new indication and a new dosage in a new additional dosage form indicated for the treatment of dysuria associated with benign prostatic hypertrophy.

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5	Feb. 21, 2014	74	Estrana Tape 0.72 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change	Estradiol	A drug with a new additional indication and new dosages for the treatment of hypoestrogenism caused by hypogonadism, gonadectomy or primary ovarian insufficiency. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Mar. 24, 2014	75	Racol-NF Semisolid for Enteral Use (EN Otsuka Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding for especially patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
5	Mar. 24, 2014	76	Enevo Liquid for Enteral Use (Abbott Japan Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations indicated for tube feeding for especially patients with long-term oral feeding difficulties. It also generally can be used for nutrient retention for postoperative patients.
6-1	Jun. 14, 2013	77	Prograf Capsules 0.5 mg Prograf Capsules 1 mg (Astellas Pharma Inc.)	Change Change	Tacrolimus hydrate	Drugs with a new additional indication and new dosage for the treatment of interstitial pneumonia associated with polymyositis/dermatomyositis. [Orphan drug]
6-1	Jun. 28, 2013	78	Orencia SC 125 mg Syringe 1 mL (Bristol-Myers K.K.)	Approval	Abatacept (genetical recombination)	A drug with a new route of administration and a new dosage in a new dosage form indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Jun. 28, 2013	79	Accelio Intravenous Injection 1000 mg (Terumo Corporation)	Approval	Acetaminophen	A drug with a new route of administration indicated for the treatment of pain and pyrexia which cannnot be managed by oral preparations and suppositories.
6-1	Aug. 20, 2013	80	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 dosage indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Sep. 20, 2013	81	Flutiform 50 Aerosol 56 puffs Flutiform 125 Aerosol 56 puffs Flutiform 50 Aerosol 120 puffs Flutiform 125 Aerosol 120 puffs (Kyorin Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	(1) Fluticasone propionate (2) Formoterol fumarate hydrate	New combination drugs indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Sep. 20, 2013	82	Alesion Ophthalmic Solutoin 0.05% (Santen Pharmaceutical Co., Ltd.)	Approval	Epinastine hydrochloride	A drug with a new route of administration indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 20, 2013	83	Relvar 100 Ellipta 14 doses Relvar 100 Ellipta 30 doses Relvar 200 Ellipta 14 doses Relvar 200 Ellipta 30 doses (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	(1) Vilanterol trifenatate (2) Fluticasone furoate	New combination drugs with a new active ingredient indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta-2 agonist is needed).
6-1	Sep. 20, 2013	84	Ultibro Inhalation Capsules (Novartis Pharma K.K.)	Approval	(1) Indacaterol maleate (2) Glycopyrronium bromide	A new combination drug 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	Jan. 17, 2014	85	Allegra 5% Dry Syrup (Sanofi K.K.)	Approval	Fexofenadine hydrochloride	A drug with a new additional pediatric (6 months of age and older and less than 7 years of age) dosage in an additional dosage form of dry syrup. This drug is indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin diseases (eczema/dermatitis, pruritus cutaneous, atopic dermatitis).
6-1	Jan. 17, 2014	86	Cedartolen Sublingual Drop-Japanese Cedar Polllen 200 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Polllen 2,000 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Polllen 2,000 JAU/mL pack (Torii Pharmaceutical Co., Ltd.)	Approval Approval Approval	Standardized Japanese cedar pollen extract original solution 10,000 JAU/mL	Drugs with a new route of administration indicated for the treatment of Japanese cedar pollinosis. (Allergen immunotherapy).
6-1	Jan. 17, 2014	87	Xyzal Syrup 0.05% (GlaxoSmithKline K.K.)	Approval	Levocetirizine hydrochloride	A drug with a new additional pediatric (6 months of age and older and less than 7 years of age) dosage in an additional dosage form of dry syrup. This drug is indicated for the treatment of allergic rhinitis, urticaria and itching associated with skin disease. (eczema/dermatitis and pruritus cutaneous)
6-1	Mar. 17, 2014	88	Allermist 27.5 μg 56 metered Nasal Spray (GlaxoSmithKline K.K.)	Change	Fluticasone furoate	A drug with a new additional pediatric dosage indicated for the treatment of allergic rhinitis.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Mar. 24, 2014	89	Respia Injection or oral solution 60 mg (Nobelpharma Co., Ltd.)	Approval	Anhydrous caffeine	A drug with a new route of administration indicated for the treatment of primary apnea (apnea of prematurity) in immature or low birth weight infants. [Orphan drug]
6-2	Jun. 28, 2013	90	Topiloric Tablets 20 mg Topiloric Tablets 40 mg Topiloric Tablets 60 mg (Fujiyakuhin Co., Ltd.) Uriadec Tab. 20 mg Uriadec Tab. 40 mg Uriadec Tab. 60 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Topiroxostat	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.
6-2	Jun. 28, 2013	91	Lyxumia 300 µg solution for injection (Sanofi K.K.)	Approval	Lixisenatide	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either treatment (1) or (2): (1) Use of sulfonylureas (including combination with biguanides) in addition to diet and exercise therapies; (2) Use of long-acting soluble insulin or intermediate-acting insulin preparations (including combination with sulfonylureas) in addition to diet and exercise therapies.
6-2	Jun. 28, 2013	92	Bonviva IV Injection 1 mg Syringe (Chugai Pharmaceutical Co., Ltd.)	Approval	Ibandronate sodium hydrate	A drug with a new active ingredient indicated for the treatment of osteoporosis.
6-2	Sep. 13, 2013	93	Glufast Tab. 5 mg Glufast Tab. 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change Change	Mitiglinide calcium hydrate	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Dec. 20, 2013	94	Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)	Change	Teneligliptin hydrobromide hydrate	A drug with a revised indication for the treatment of type 2 diabetes mellitus.
6-2	Jan. 17, 2014	95	Suglat Tablets 25 mg Suglat Tablets 50 mg (Astellas Pharma Inc.)	Approval Approval	Ipragliflozin L-proline	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jan. 17, 2014	96	Cystadane (ReqMed Company, Ltd.)	Approval	Betaine	A drug with a new active ingredient indicated for the treatment of homocystinuria. [Orphan drug]
6-2	Mar. 24, 2014	97	Forxiga Tablets 5 mg Forxiga Tablets 10 mg (Bristol-Myers K.K.)	Approval Approval	Dapagliflozin propylene glycolate hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 24, 2014	98	Lusefi Tab. 2.5 mg Lusefi Tab. 5 mg (Taisho Pharmaceutical Co., Ltd.)	Approval Approval	Luseogliflozin hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 24, 2014	99	Deberza Tablets 20 mg (Kowa Company, Ltd.) Apleway 20 mg Tablets (Sanofi K.K.)	Approval Approval	Tofogliflozin hydrate	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
Radio-pharmaceuticals	Sep. 20, 2013	100	DaTscan Intravenous Injection (Nihon Medi-Physics Co., Ltd.)	Approval	Ioflupane (123I)	A drug with a new active ingredient indicated for dopamine transporter scintigraphy in the diagnoses of Parkinson's syndrome and dementia with Lewy bodies.
Oncology drugs	Jun. 14, 2013	101	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 and a new dosage for the treatment of malignant glioma. [Orphan drug]
Oncology drugs	Jun. 14, 2013	102	Tarceva Tablet 25 mg Tarceva Tablet 100 mg Tarceva Tablet 150 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Erlotinib hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent non-small cell lung cancer with *EGFR* gene mutation in patients who have not been treated with chemotherapy.
Oncology drugs	Jun. 14, 2013	103	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new dosage for the treatment of breast cancer with HER2 overexpression. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 14, 2013	104	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 pediatric malignant solid tumors. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Jun. 28, 2013	105	Perjeta Intravenous Infusion 420 mg/14 mL (Chugai Pharmaceutical Co., Ltd.)	Approval	Pertuzumab (genetical recombination)	A drug with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer.
Oncology drugs	Aug. 20, 2013	106	Stivarga Tablets 40 mg (Bayer Yakuhin, Ltd.)	Change	Regorafenib hydrate	A drug with a new additional indication for the treatment of gastrointestinal stromal tumor which has progressed after cancer chemotherapy. [Priority review]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Sep. 20, 2013	107	Unitalc Intrapleural 4 g (Nobelpharma Co., Ltd.)	Approval	Sterile talc	A drug with a new active ingredient indicated for the suppression of recurrence of malignant pleural effusions.
Oncology drugs	Sep. 20, 2013	108	Kadcyla Intravenous Infusion 100 mg Kadcyla Intravenous Infusion 160 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Trastuzumab emtansine (genetical recombination)	Drugs with a new active ingredient indicated for the treatment of unresectable or recurrent HER2-positive breast cancer. [Priority review]
Oncology drugs	Sep. 20, 2013	109	Laserphyrin 100 mg for Injection (Meiji Seika Pharma Co., Ltd.)	Change	Talaporfin sodium	A drug with a new additional indication and a new dosage for the treatment of primary malignant brain tumor (only for the case where surgical excision of tumor is performed). [Orphan drug]
Oncology drugs	Nov. 22, 2013	110	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 ovarian cancer.
Oncology drugs	Nov. 22, 2013	111	Farmorubicin for Injection 10 mg Farmorubicin for Injection 50 mg (Pfizer Japan Inc.)	Change Change	Epirubicin hydrochloride	Drugs with a new additional dosage indicated for transcatheter arterial chemo-embolization (TACE) in hepatocellular carcinoma. [Public knowledge-based application]
Oncology drugs	Dec. 20, 2013	112	Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat I.V. Infusion Solution 200 mg (Yakult Honsha Co., Ltd.)	Change Change Change	Oxaliplatin	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	113	Campto 40 mg for I.V. Infusion Campto 100 mg for I.V. Infusion (Yakult Honsha Co., Ltd.)	Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	114	Topotecin Intravenous Drip Infusion 40 mg Topotecin Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited)	Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	115	Isovorin Injection 25 mg Isovorin Injection 100 mg (Pfizer Japan Inc.)	Change Change	Levofolinate calcium	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	116	Levofolinate for I.V. Infusion 25 mg "Yakult" Levofolinate for I.V. Infusion 100 mg "Yakult" (Yakult Honsha Co., Ltd.)	Change Change	Levofolinate calcium	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Dec. 20, 2013	117	5-FU Injection 250 mg 5-FU Injection 1000 mg (Kyowa Hakko Kirin Co., Ltd.)	Change Change	Fluorouracil	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review], [Expedited review]
Oncology drugs	Jan. 17, 2014	118	Giotrif Tablets 20 mg Giotrif Tablets 30 mg Giotrif Tablets 40 mg Giotrif Tablets 50 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval Approval Approval	Afatinib maleate	Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer with EGFR gene mutation.
Oncology drugs	Jan. 17, 2014	119	Adcetris for Intravenous Drip Infusion 50 mg (Takeda Pharmaceutical Company Limited)	Approval	Brentuximab vedotin (genetical recombination)	A drug with a new active ingredient indicated for the treatment of relapsed or refractory CD30-positive Hodgkin's lymphoma and anaplastic large-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 17, 2014	120	Zoladex LA 10.8 mg depot (AstraZeneca K.K.)	Change	Goserelin acetate	A drug with a new additional indication for the treatment of premenopausal breast cancer.
Oncology drugs	Mar. 17, 2014	121	Afinitor Tablets 2.5 mg Afinitor Tablets 5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with a new additional indication and a new dosage for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Mar. 17, 2014	122	Votrient Tablets 200 mg (GlaxoSmithKline K.K.)	Change	Pazopanib hydrochloride	A drug with a new additional indication for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Mar. 17, 2014	123	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Change	Mogamulizumab (genetical recombination)	A drug with new additional indications for the treatment of relapsed or refractory CCR4-positive peripheral T-cell lymphoma and relapsed or refractory CCR4-positive cutaneous T-cell lymphoma. [Orphan drug]
Oncology drugs	Mar. 24, 2014	124	Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	Trifluridine/tipiracil hydrochloride	New combination drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer (for use only if refractory or intolerant to standard therapies).
Oncology drugs	Mar. 24, 2014	125	Xtandi Capsules 40 mg (Astellas Pharma Inc.)	Approval	Enzalutamide	A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer. [Priority review]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
(1) Oncology drugs (2) 6-1	Jun. 14, 2013	126	Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.)	Change	Rituximab (genetical recombination)	A drug with new additional indications and a new dosage for the treatment of (1) CD 20-positive B-cell lymphoproliferative disorders in immunocompromised patients and (2) Wegener's granulomatosis and microscopic polyangiitis. [Public knowledge-based application after PAFSC's preliminary assessment]
AIDS drugs	Mar. 24, 2014	127	Tivicay Tablets 50 mg (ViiV Healthcare K.K.)	Approval	Dolutegravir sodium	A drug with a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
Vaccines	Apr. 26, 2013	128	Cell Culture-derived Influenza Vaccine (prototype) "Baxter" (Baxter Limited) Cell Culture-derived Influenza Vaccine (prototype) "Takeda" 5 mL (Takeda Pharmaceutical Company Limited)	Approval Approval	Cell culture-derived influenza vaccines (prototype)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza. [Orphan drug]
Vaccines	Jun. 18, 2013	129	Prevenar 13 Suspension Liquid for Injection (Pfizer Japan Inc.)	Approval	Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM_{197} conjugate)	A drug with a new active ingredient indicated for the prophylaxis of pneumococcal invasive disease (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F).
Vaccines	Jun. 18, 2013	130	Cell Culture-derived Influenza Vaccine H5N1 "Baxter" (Baxter Limited) Cell Culture-derived Influenza Vaccine H5N1 "Takeda" 5 mL (Takeda Pharmaceutical Company Limited)	Approval Approval	Cell culture-derived influenza vaccine (H5N1)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 17, 2014	131	Heptavax-II (MSD K.K.) Bimmugen Bimmugen Injection 0.25 mL Bimmugen Injection 0.5 mL (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change Change Change Change	Recombinant adsorbed hepatitis B vaccine (prepared from yeast)	Drugs with a revised dosage indicated for the prevention of perinatal hepatitis B virus infection (concomitant use with anti-Hepatitis B surface [HBs] human immunoglobulin). [Public knowledge-based application after PAFSC's preliminary assessment]
Vaccines	Mar. 24, 2014	132	Cell Culture-derived Influenza Emulsion HA Vaccine H5N1 for Intramuscular Injection “Kaketsuken” (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	Cell culture-derived influenza emulsion HA vaccine (H5N1)	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Vaccines	Mar. 24, 2014	133	Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 30μg/mL “Kitasato Daiichi Sankyo” Adsorbed Cell Culture-derived Influenza Vaccine H5N1 for Intramuscular Injection 60μg/mL “Kitasato Daiichi sankyo” (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Approval Approval	Adsorbed cell culture-derived influenza vaccine (H5N1)	Drugs with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	May 16, 2013	134	NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new dosage to add single-dose administration for the prevention of bleeding in patients with congenital hemophilia who have inhibitors against blood coagulation factor VIII or IX. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 13, 2013	135	Fibrogammin P I.V. Injection (CSL Behring K.K.)	Change	Lyophilized human blood coagulation factor XIII concentrate	A drug with a new additional indication for the treatment of bleeding tendency caused by acquired blood coagulation factor XIII deficiency. [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 27, 2013	136	Hizentra 20% S.C. Injection 1 g/5 mL Hizentra 20% S.C. Injection 2 g/10 mL Hizentra 20% S.C. Injection 4 g/20 mL (CSL Behring K.K.)	Approval Approval Approval	pH4-treated normal human immunoglobulin (subcutaneous injection)	Drugs with a new active ingredient indicated for the treatment of agammaglobulinemia or hypogammaglobulinemia.
Blood products	Jan. 17, 2014	137	NovoEight i.v.injection 250 NovoEight i.v.injection 500 NovoEight i.v.injection 1000 NovoEight i.v.injection 1500 NovoEight i.v.injection 2000 NovoEight i.v.injection 3000 (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval Approval	Turoctocog alpha (genetical recombination)	Drugs with a new active ingredient indicated for inhibition 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(s) (underlined: new active ingredient)	Notes
Bio-CMC	Mar. 24, 2014	138	Filgrastim BS Inj.75 μg Syringe “Sandoz” Filgrastim BS Inj.150 μg Syringe “Sandoz” Filgrastim BS Inj.300 μg Syringe “Sandoz” (Sandoz K.K.)	Approval Approval Approval	Filgrastim (genetical recombination) [Filgrastim biosimilar 3]	Follow-on biologics indicated for mobilization of hematopoietic stem cell to peripheral blood, promotion of increase in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia and congenital/idiopathic neutropenia.

**Review Categories of New Drugs*

Review Category	Products
1	Gastrointestinal drugs, dermatologic drugs
2	Cardiovascular drugs, antiparkinsonian drugs, antithrombotics, 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, vermifuge, antifungal drugs, antiviral drugs (excluding AIDS 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 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	Globulin, blood coagulation factor products
Vaccines	Vaccines, antitoxic serum
Radio-pharmaceuticals	Radiopharmaceuticals
In vivo diagnostics	Contrast media
Bio-CMC	Biosimilars, quality of biologics