

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 | Ecilizumab (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 | <u>Cetilistat</u> | 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 | <u>Ferric citrate hydrate</u> | 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 | <u>Dexrazoxane</u> | 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 eyelashes 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 | <u>Bisoprolol</u> | Drugs with a new active ingredient indicated for the treatment of essential hypertension (mild to moderate). |
| 2 | Jun. 28, 2013 | 19 | Iltra Combination Tablets LD Iltra Combination Tablets HD (Shionogi & Co., Ltd.) | Approval Approval | Irbesartan/ trichlormethiazide | New combination drugs indicated for the treatment of hypertension. |
| 2 | Aug. 20, 2013 | 20 | Trierief 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 | <u>Riociguat</u> | 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 infarction, 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 | <u>Treprostinil</u> | Drugs with a new active ingredient indicated for the treatment of pulmonary arterial hypertension (WHO functional classification; 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 New | 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] |
| 2 | Mar. 24, 2014 | 32 | Efient Tablets 3.75 mg Efient Tablets 5 mg (Daiichi Sankyo Company, Limited) | Approval Approval | <u>Prasugrel hydrochloride</u> | 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. |

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| (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 | <u>Paliperidone palmitate</u> | 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 | <u>Tafamidis meglumine</u> | 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. |
| 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 | <u>Natalizumab (genetical recombination)</u> | 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] |

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| 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 neovascularisation 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 | <u>Tapentadol hydrochloride</u> | 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 <i>Staphylococcus aureus</i> (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] |
| 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 <i>Staphylococcus</i> , <i>Escherichia coli</i> , <i>Klebsiella</i> , <i>Enterobacter</i> , <i>Serratia</i> , <i>Proteus</i> , <i>Morganella morganii</i> , <i>Providencia</i> , <i>Pseudomonas aeruginosa</i> |
| 4 | Sep. 27, 2013 | 62 | Sovriad Capsules 100 mg (Janssen Pharmaceutical K.K.) | Approval | <u>Simeprevir sodium</u> | 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] |

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| 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 <i>mycobacterium</i> 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. |
| 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] |

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| 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 cannot 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 Solution 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) <u>Vilanterol trifenate</u> (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 Pollen 200 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Pollen 2,000 JAU/mL bottle Cedartolen Sublingual Drop-Japanese Cedar Pollen 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. |
| 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 | <u>Topiroxostat</u> | 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 | <u>Lixisenatide</u> | 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 | <u>Ibandronate sodium hydrate</u> | A drug with a new active ingredient indicated for the treatment of osteoporosis. |

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| 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 | <u>Ipragliflozin L-proline</u> | 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 | <u>Betaine</u> | 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 | <u>Dapagliflozin propylene glycolate hydrate</u> | 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 | <u>Luseogliflozin hydrate</u> | 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 | <u>Tofogliflozin hydrate</u> | 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 | <u>loflupane (123I)</u> | 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 <i>EGFR</i> 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 | <u>Pertuzumab (genetical recombination)</u> | 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] |
| Oncology drugs | Sep. 20, 2013 | 107 | Unitalc Intrapleural 4 g (Nobelpharma Co., Ltd.) | Approval | <u>Sterile talc</u> | 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 | <u>Trastuzumab emtansine (genetical recombination)</u> | 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 | Eiplat I.V. Infusion Solution 50 mg Eiplat I.V. Infusion Solution 100 mg Eiplat 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] |

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| 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 | <u>Afatinib maleate</u> | 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 | <u>Brentuximab vedotin (genetical recombination)</u> | 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 | <u>Trifluridine/tipiracil hydrochloride</u> | 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 | <u>Enzalutamide</u> | A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer. [Priority review] |
| (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 | <u>Dolutegravir sodium</u> | 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 | <u>Cell culture-derived influenza vaccines (prototype)</u> | 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 | <u>Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM₁₉₇ conjugate)</u> | 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 | <u>Cell culture-derived influenza vaccine (H5N1)</u> | Drugs with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug] |

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| 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 | 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 | <u>Cell culture-derived influenza emulsion HA vaccine (H5N1)</u> | 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 | <u>Adsorbed cell culture-derived influenza vaccine (H5N1)</u> | 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 | <u>pH4-treated normal human immunoglobulin (subcutaneous injection)</u> | 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 | <u>Turoctocog alpha (genetical recombination)</u> | Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with blood coagulation factor VIII deficiency. |
| 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 |
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| 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 |
| <i>In vivo</i> diagnostics | Contrast media |
| Bio-CMC | Biosimilars, quality of biologics |