

New Drugs Approved in FY 2014

| Review Category | Approval Date | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Active Ingredient(s) (underlined: new active ingredient) | Notes |
|-----------------|---------------|-----|---|--|--|--|
| 1 | Jul. 4, 2014 | 1 | Dovobet Ointment (Leo Pharma K.K.) | Approval | (1) Calcipotriol hydrate/ (2) Betamethasone dipropionate | A new combination drug indicated for the treatment of psoriasis vulgaris. |
| 1 | Aug. 29, 2014 | 2 | Rituxan Injection 10 mg/mL (Zenyaku Kogyo Co., Ltd.) | Change | Rituximab (genetical recombination) | A drug with a new additional indication and a new dosage for the treatment of refractory nephrotic syndrome (for use in patients with frequent recurrence or steroid-dependent). [Orphan drug] |
| 1 | Sep. 19, 2014 | 3 | Thymoglobuline for Intravenous Infusion 25 mg (Sanofi K.K.) | Change | Anti-human thymocyte immunoglobulin, rabbit | A drug with a new additional indication and a new dosage for the treatment of acute rejection after the liver, heart, lungs, pancreas, or small intestinal transplantation. |
| 1 | Sep. 26, 2014 | 4 | Fomepizole Intravenous Infusion 1.5 g "Takeda" (Takeda Pharmaceutical Company Limited) | Approval | <u>Fomepizole</u> | A drug with a new active ingredient indicated for the treatment of ethylene glycol and methanol poisonings. |
| 1 | Dec. 26, 2014 | 5 | Pariet Tablets 5 mg Pariet Tablets 10 mg (Eisai Co., Ltd.) | Approval Change | Rabeprazole sodium | A drug with a new additional indication and a new dosage in a newly-added dosage form, and a drug with a new additional indication and a new dosage for the prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with low-dose aspirin. |
| 1 | Dec. 26, 2014 | 6 | Takecab Tablets 10 mg Takecab Tablets 20 mg (Takeda Pharmaceutical Company Limited) | Approval Approval | <u>Vonoprazan fumarate</u> | Drugs with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis, prevention of recurrence of gastric or duodenal ulcer in patients treated with low-dose aspirin, prevention of recurrence of gastric or duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs (NSAIDs), and aid to eradication of <i>Helicobacter pylori</i> in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, <i>Helicobacter pylori</i> gastritis, and stomach after endoscopic treatment for early gastric cancer. |
| 1 | Dec. 26, 2014 | 7 | Methylene Blue Intravenous Injection 50 mg "Daiichi Sankyo" (Daiichi Sankyo Company, Limited) | Approval | <u>Methylthionium chloride hydrate</u> | A drug with a new active ingredient indicated for the treatment of toxic methemoglobinemia. |
| 1 | Dec. 26, 2014 | 8 | Bepio Gel 2.5% (Maruho Co., Ltd.) | Approval | <u>Benzoyl peroxide</u> | A drug with a new active ingredient indicated for the treatment of acne vulgaris. |
| 2 | Jul. 4, 2014 | 9 | Stalevo Combination Tablets L50 Stalevo Combination Tablets L100 (Novartis Pharma K.K.) | Approval Approval | Levodopa/ Carbidopa hydrate/ Entacapone | New combination drugs indicated for the treatment of Parkinson's disease [for use in patients having wearing-off phenomenon in the symptoms following administration of levodopa/carbidopa]. |
| 2 | Sep. 19, 2014 | 10 | Aricept Tablets 3 mg Aricept Tablets 5 mg Aricept Tablets 10 mg Aricept D Tablets 3 mg Aricept D Tablets 5 mg Aricept D Tablets 10 mg Aricept Fine Granules 0.5% Aricept Oral Jelly 3 mg Aricept Oral Jelly 5 mg Aricept Oral Jelly 10 mg Aricept Dry Syrup 1% (Eisai Co., Ltd.) | Change Change Change Change Change Change Change Change Change Change | Donepezil hydrochloride | Drugs with a new additional indication and a new dosage for inhibiting progress of dementia symptoms in patients with dementia with Lewy bodies. |
| 2 | Sep. 26, 2014 | 11 | Lixiana Tablets 15 mg Lixiana Tablets 30 mg Lixiana Tablets 60 mg (Daiichi Sankyo Company, Limited) | Change Change Approval | Edoxaban tosilate hydrate | Drugs with new additional indications and new dosages, and a drug with a newly-added dosage form indicated for prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation, or for the treatment and prevention of the recurrence of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism). |

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| 2 | Nov. 18, 2014 | 12 | Inderal Tablets 10 mg Inderal Tablets 20 mg (AstraZeneca K.K.) | Change Change | Propranolol hydrochloride | Drugs with a new additional indication and a new dosage for the prevention of hypoxic attack caused by right ventricular outflow tract obstruction. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)] |
| 2 | Feb. 20, 2015 | 13 | Adempas Tablets 0.5 mg Adempas Tablets 1.0 mg Adempas Tablets 2.5 mg (Bayer Yakuhin, Ltd.) | Change Change Change | Riociguat | Drugs with a new additional indication for the treatment of pulmonary arterial hypertension. |
| 2 | Mar. 26, 2015 | 14 | Opsumit Tablet 10 mg (Actelion Pharmaceuticals Japan Ltd.) | Approval | <u>Macitentan</u> | A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. |
| 3-1 | Jul. 4, 2014 | 15 | E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.) | Approval | Levetiracetam | A drug with a new route of administration indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizure (including secondary generalized seizure) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs. It is used as an alternative therapy for levetiracetam oral formulation in patients who are temporarily unable to be administered orally. |
| 3-1 | Aug. 29, 2014 | 16 | Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.) | Change Change | Lamotrigine | Drugs with a new additional indication and a new dosage for use in the monotherapy for treatment of partial seizures (including secondary generalized seizure) and tonic-clonic seizures in patients with epilepsy. |
| 3-1 | Sep. 26, 2014 | 17 | Belsomra Tablets 15 mg Belsomra Tablets 20 mg (MSD K.K.) | Approval Approval | <u>Suvorexant</u> | Drugs with a new active ingredient indicated for the treatment of insomnia. |
| 3-1 | Sep. 26, 2014 | 18 | Midafresa Injection 0.1% (Alfresa Pharma Corporation) | Approval | Midazolam | A drug with a new additional indication and a new dosage in an additional dosage form indicated for the treatment of status epilepticus. |
| 3-1 | Feb. 20, 2015 | 19 | E Keppra Tablets 250 mg E Keppra Tablets 500 mg E Keppra Dry Syrup 50% E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.) | Change Change Change Change | Levetiracetam | Drugs with a revised indication and a new dosage for the treatment of partial seizure in patients with epilepsy (including secondary generalized seizure). |
| 3-1 | Mar. 20, 2015 | 20 | J Zoloft Tablets 25 mg J Zoloft Tablets 50 mg J Zoloft Tablets 100 mg J Zoloft OD Tablets 25 mg J Zoloft OD Tablets 50 mg J Zoloft OD Tablets 100 mg (Pfizer Japan Inc.) | Change Change Change Change Change Change | Sertraline hydrochloride | Drugs with a new additional indication for the treatment of posttraumatic stress disorder. |
| 3-1 | Mar. 26, 2015 | 21 | ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg ABILIFY Prolonged Release Aqueous Suspension for IM Injection 300 mg Syringe ABILIFY Prolonged Release Aqueous Suspension for IM Injection 400 mg Syringe (Otsuka Pharmaceutical Co., Ltd.) | Approval Approval Approval Approval | Aripiprazole hydrate | Drugs with a new route of administration indicated for the treatment of schizophrenia. |
| 3-2 | Jun. 20, 2014 | 22 | Fentos Tape 1 mg Fentos Tape 2 mg Fentos Tape 4 mg Fentos Tape 6 mg Fentos Tape 8 mg (Hisamitsu Pharmaceutical Co., Inc.) | Change Change Change Change Change | Fentanyl citrate | Drugs with a new 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 | Sep. 19, 2014 | 23 | 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 for the treatment of choroidal neovascularization in patients with pathologic myopia. |

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| 3-2 | Sep. 26, 2014 | 24 | Glanatec Ophthalmic Solution 0.4% (Kowa Company, Ltd.) | Approval | <u>Ripasudil hydrochloride hydrate</u> | A drug with a new active ingredient indicated for the treatment of glaucoma or ocular hypertension in patients who have not sufficiently responded to other therapeutic drugs for glaucoma or who are unable to use them. |
| 3-2 | Nov. 18, 2014 | 25 | 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 diabetic macular edema. |
| 3-2 | Dec. 26, 2014 | 26 | Nopicor Capsules 2.5 µg (Toray Medical Co., Ltd.) | Approval | <u>Nalfurafine hydrochloride</u> | A drug with a new active ingredient indicated for the improvement of pruritus in patients with chronic liver diseases (for use only when conventional therapies are not sufficiently effective). |
| 3-2 | Mar. 26, 2015 | 27 | Onetram Tablets 100 mg (Nippon Shinyaku Co., Ltd.) | Approval | Tramadol hydrochloride | A drug in a new dosage form indicated for analgesia in patients with cancers-associated pain or chronic pain, which cannot be managed by treatments with non-opioid analgesics. |
| 4 | May 23, 2014 | 28 | Vancomycin Hydrochloride for Intravenous Drip Infusion 0.5 g (Shionogi & Co., Ltd.) | Change | Vancomycin hydrochloride | A drug with new additional indications for the treatment of: (1) sepsis, infective endocarditis, secondary infection of trauma, burn or surgical wounds, osteomyelitis, arthritis, peritonitis and purulent meningitis caused by vancomycin-sensitive methicillin-resistant coagulase-negative <i>Staphylococcus</i> (MRCNS); or (2) febrile neutropenia which is suspected of MRSA or MRCNS infection. [Public knowledge-based application after PAFSC's preliminary assessment] |
| 4 | Jul. 4, 2014 | 29 | Clenafin Topical Solution 10% for Nail (Kaken Pharmaceutical Co., Ltd.) | Approval | <u>Efinaconazole</u> | A drug with a new active ingredient indicated for the treatment of tinea unguium caused by dermatophyte (<i>trichophyton</i>). |
| 4 | Jul. 4, 2014 | 30 | Delytba Tablets 50 mg (Otsuka Pharmaceutical Co., Ltd.) | Approval | <u>Delamanid</u> | A drug with a new active ingredient indicated for the treatment of multidrug-resistant pulmonary tuberculosis caused by delamanid-sensitive <i>Mycobacterium tuberculosis</i> . [Orphan drug] |
| 4 | Jul. 4, 2014 | 31 | Anaemetro Intravenous Infusion 500 mg (Pfizer Japan Inc.) | Approval | Metronidazole | A drug with a new route of administration indicated for the treatment of different kinds of anaerobic bacterial infections, infectious enteritis, and amebic dysentery. |
| 4 | Jul. 4, 2014 | 32 | Daklinza Tablets 60 mg (Bristol-Myers K.K.) Sunvepra Capsules 100 mg (Bristol-Myers K.K.) | Approval Approval | <u>Daclatasvir hydrochloride</u> <u>Asunaprevir</u> | Drugs with new active ingredients indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1) who are untreated and ineligible for, or are intolerant to therapy including interferon; or who did not respond to therapy including interferon. [Priority review] |
| 4 | Sep. 19, 2014 | 33 | Telaviv 250 mg Tablet (Mitsubishi Tanabe Pharma Corporation) | Change | Telaprevir | A drug with a new additional indication for the improvement of viremia in serogroup 2 (genotype III [2a] or IV [2b]) chronic hepatitis C in patients who did not respond to, or in whom the symptom relapsed with, interferon monotherapy or interferon-ribavirin combination therapy. [Priority review] |
| 4 | Sep. 26, 2014 | 34 | Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg Vfend Dry Syrup 2800 mg (Pfizer Japan Inc.) | Change Change Change Approval | Voriconazole | Drugs with new additional pediatric dosages, and a drug with a new additional pediatric dosage in an additional dosage form of dry syrup indicated for the treatment of severe or refractory fungus infection. |
| 4 | Sep. 26, 2014 | 35 | Vanihep Capsules 150 mg (MSD K.K.) | Approval | <u>Vaniprevir</u> | A drug with a new active ingredient indicated for the improvement of viremia in the following patients with serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C: Patients with high levels of blood HCV RNA who are treatment-naive, or Patients who are non-responders or relapsed to therapy including interferon. [Priority review] |

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| 4 | Nov. 18, 2014 | 36 | Valtrex Tablets 500 Valtrex Granules 50% (GlaxoSmithKline K.K.) | Change Change | Valaciclovir hydrochloride | Drugs with a new additional indication and revised indications with a new dosage for prevention of herpes simplex virus infection in adult or pediatric haematopoietic stem cell transplant patients, for treatment of herpes simplex /herpes zoster, and for prevention of recurrent genital herpes in pediatric patients. |
| 4 | Dec. 18, 2014 | 37 | Cancidas for Intravenous Drip Infusion 50 mg Cancidas for Intravenous Drip Infusion 70 mg (MSD K.K.) | Change Change | Caspofungin acetate | Drugs with a new additional pediatric dosage indicated for the treatment of febrile neutropenia with suspected fungal infection, esophageal candidiasis, invasive candidiasis, and aspergillosis caused by <i>Candida</i> or <i>Aspergillus</i> . |
| 4 | Dec. 26, 2014 | 38 | Rozex Gel 0.75% (Galderma S.A.) | Approval | Metronidazole | A drug with a new route of administration indicated for disinfection/deodorisation of odorous fungating tumours. |
| 4 | Mar. 20, 2015 | 39 | Pentacillin for Injection 1 g Pentacillin for Injection 2 g Pentacillin Intravenous Injection 1 g Bag Pentacillin Intravenous Injection 2 g Bag (Toyama Chemical Co., Ltd.) | Approval Approval Approval Approval | Piperacillin sodium | Drugs with a new dosage indicated for the treatment of sepsis, acute bronchitis, pneumonia, lung abscess, thoracic empyema, secondary infection of chronic respiratory disease, cystitis, pyelonephritis, cholecystitis, choledochitis, Bartholinitis, intrauterine infection, uterine adnexitis, parametritis, and purulent meningitis. |
| 4 | Mar. 20, 2015 | 40 | Daklinza Tablets 60 mg (Bristol-Myers K.K.) Sunvepra Capsules 100 mg (Bristol-Myers K.K.) | Change Change | Daclatasvir hydrochloride Asunaprevir | Drugs with a revised indication for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 1 (genotype 1). [Priority review] |
| 4 | Mar. 26, 2015 | 41 | Duac Combination Gel (GlaxoSmithKline K.K.) | Approval | Clindamycin phosphate hydrate/ <u>Benzoyl peroxide</u> | A new combination drug with a new active ingredient indicated for the treatment of acne vulgaris. |
| 4 | Mar. 26, 2015 | 42 | Sovaldi Tablets 400 mg (Gilead Sciences K.K.) | Approval | <u>Sofosbuvir</u> | A drug with a new active ingredient indicated for the improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2) . [Priority review] |
| 4 | Mar. 26, 2015 | 43 | Copegus Tablets 200 mg (Chugai Pharmaceutical Co., Ltd.) | Change | Ribavirin | A drug with a new additional indication and a new dosage for the improvement of viremia with the concomitant use of sofosbuvir in patients with chronic hepatitis C or compensated cirrhosis type C in serogroup 2 (genotype 2) . [Expedited review] |
| 4 | Mar. 26, 2015 | 44 | Aldreb for Injection 150 mg (GlaxoSmithKline K.K.) | Approval | Colistin sodium methanesulfonate | A drug with a new route of administration indicated for the treatment of infections caused by colistin-sensitive <i>Escherichia coli</i> , <i>Citrobacter</i> , <i>Klebsiella</i> , <i>Enterobacter</i> , <i>Pseudomonas aeruginosa</i> , and <i>Acinetobacter</i> (limited to the strains resistant to other antimicrobial drugs). [Orphan drug] |
| 5 | Jun. 20, 2014 | 45 | Mirena 52 mg (Bayer Yakuin, Ltd.) | Change | Levonorgestrel | A drug with a new additional indication for the treatment of hypermenorrhea. [Public knowledge-based application after PAFSC's preliminary assessment] |
| 5 | Jul. 4, 2014 | 46 | Pareplus for IV. Infusion (Ajinomoto Pharmaceutical Co., Ltd.) | Approval | N/A for this combination drug | A combination prescription drug with similar formulations indicated for the supplementation of amino acids, electrolyte, hydrosoluble vitamins, and water. It is used in patients with mild hypoproteinemia or in a mild malnutrition state due to insufficient oral intake or used in perioperative patients. |
| 5 | Sep. 26, 2014 | 47 | Lutinus Vaginal Tablet 100 mg (Ferring Pharmaceuticals Co.,Ltd.) | Approval | Progesterone | A drug with a new route of administration indicated for luteal support as part of assisted reproductive technology for infertile women. |

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| 5 | Nov. 18, 2014 | 48 | Mirena 52 mg (Bayer Yakuhin, Ltd.) | Change | Levonorgestrel | A drug with a new additional indication for the treatment of dysmenorrhoea. [Public knowledge-based application after PAFSC's preliminary assessment] |
| 6-1 | Jul. 4, 2014 | 49 | Anoro Ellipta 7 doses Anoro Ellipta 30 doses (GlaxoSmithKline K.K.) | Approval Approval | (1) <u>Umeclidinium bromide</u> / (2) Vilanterol trifenate | New combination drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema) (when a combination treatment of an inhaled long-acting anticholinergic and a long-acting beta-2 agonist is needed). |
| 6-1 | Jul. 4, 2014 | 50 | Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.) | Approval | <u>Sirolimus</u> | A drug with a new active ingredient indicated for the treatment of lymphangioleiomyomatosis. [Orphan drug] |
| 6-1 | Jul. 4, 2014 | 51 | kenketu Glovenin-I for I.V. Injection 2500 mg kenketu Glovenin-I for I.V. Injection 500 mg kenketu Glovenin-I for I.V. Injection 5000 mg (Nihon Pharmaceutical Co., Ltd.) | Change Change Change | Freeze-dried polyethylene glycol treated human normal immunoglobulin | Drugs with new additional indications for the treatment of Stevens-Johnson syndrome and toxic epidermal necrolysis (for use when steroid drugs are not sufficiently effective). [Orphan drug] |
| 6-1 | Aug. 29, 2014 | 52 | Solu-Medrol for Intravenous Use 40 mg Solu-Medrol for Intravenous Use 125 mg Solu-Medrol for Intravenous Use 500 mg Solu-Medrol for Intravenous Use 1000 mg (Pfizer Japan Inc.) | Change Change Change Change | Methylprednisolone sodium succinate | Drugs with new additional indications and a new dosage for the treatment of the following treatment-resistant rheumatic diseases: systemic vasculitis (including microscopic polyangiitis, Wegener's granulomatosis, polyarteritis nodosa, Churg-Strauss syndrome, aortitis syndrome), systemic lupus erythematosus, polymyositis, dermatomyositis, scleroderma, mixed connective tissue disease, and refractory rheumatic disease. [Public knowledge-based application after PAFSC's preliminary assessment] |
| 6-1 | Sep. 26, 2014 | 53 | Calonal Tab. 500 (Showa Yakuhin Kako Co., Ltd.) | Approval | Acetaminophen | A drug in an additional dosage form. Note: the product was submitted for an approval application as a drug with a new additional indication for the treatment of osteoarthritis and with an expanded dosage of acetaminophen in an additional dosage form. The new additional indication and the expanded dosage were approved on January 21, 2011, whereas approval of the additional dosage form had been under review. |
| 6-1 | Nov. 18, 2014 | 54 | Spiriva 2.5 µg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.) | Change | Tiotropium bromide hydrate | A drug with a new additional indication for the relief of symptoms secondary to airway obstructive disorders in bronchial asthma (for use only in patients with the severe persistent type). |
| 6-1 | Dec. 26, 2014 | 55 | Allergen Extract for Subcutaneous Injection-HDM "TORII"100,000 JAU/mL Allergen Extract for Subcutaneous Injection-HDM "TORII"10,000 JAU/mL (Torii Pharmaceutical Co., Ltd.) | Approval Approval | <u><i>Dermatophagoides farinae</i> extract 10,000 AU/mL</u> , <u><i>Dermatophagoides pteronyssinus</i> extract 10,000 AU/mL</u> | Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis and bronchial asthma. |
| 6-1 | Dec. 26, 2014 | 56 | Cosentyx for S.C. Injection 150 mg Syringe Cosentyx for S.C. Injection 150 mg (Novartis Pharma K.K.) | Approval Approval | <u>Secukinumab (genetical recombination)</u> | Drugs with a new active ingredient indicated for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional therapies. |
| 6-1 | Dec. 26, 2014 | 57 | Allergen Extract for Scratch Test - HDM "TORII" 100,000 JAU/mL (Torii Pharmaceutical Co., Ltd.) | Approval | <u><i>Dermatophagoides farinae</i> extract 10,000 AU/mL</u> , <u><i>Dermatophagoides pteronyssinus</i> extract 10,000 AU/mL</u> | A drug with new active ingredients indicated for the identification of allergen in patients with allergic diseases. |
| 6-1 | Mar. 20, 2015 | 58 | Dopram Injectable 400 mg (Kissei Pharmaceutical Co., Ltd.) | Change | Doxapram hydrochloride hydrate | A drug with a new additional indication and a new dosage for the treatment of primary apnoea (apnea of prematurity) in immature or low birth weight infants who have not responded sufficiently to conventional therapies. |

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| 6-1 | Mar. 26, 2015 | 59 | Eklira 400 µg Genuair 30 doses Eklira 400 µg Genuair 60 doses (Kyorin Pharmaceutical Co., Ltd.) | Approval Approval | <u>Acclidinium bromide</u> | Drugs with a new active ingredient indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema). |
| 6-1 | Mar. 26, 2015 | 60 | Actair 100 IR Sublingual Tablets-HDM Actair 300 IR Sublingual Tablets-HDM (Shionogi & Co., Ltd.) | Approval Approval | <u>Dermatophagoides farinae extract bulk powder</u> , <u>Dermatophagoides pteronyssinus extract bulk powder</u> | Drugs with new active ingredients indicated for the allergen immunotherapy for house dust mite antigen-induced allergic rhinitis. |
| 6-1 | Mar. 26, 2015 | 61 | Encruse 62.5 µg Ellipta 7 doses Encruse 62.5 µg Ellipta 30 doses (GlaxoSmithKline K.K.) | Approval Approval | Umeclidinium bromide | Other drugs with a new dosage indicated for the relief of symptoms secondary to airway obstructive disorder in chronic obstructive pulmonary disease (chronic bronchitis, emphysema). |
| 6-2 | May 23, 2014 | 62 | Januvia Tablets 12.5 mg Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.) Glactiv Tablets 12.5 mg Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.) | Change Change Change Change Change Change Change Change | Sitagliptin phosphate hydrate | Drugs with a new indication for the treatment of type 2 diabetes mellitus. |
| 6-2 | May 23, 2014 | 63 | Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited) | Change Change Change | Alogliptin benzoate | Drugs with a new indication for the treatment of type 2 diabetes mellitus. |
| 6-2 | May 23, 2014 | 64 | Aredia for I.V. Infusion 15 mg Aredia for I.V. Infusion 30 mg (Novartis Pharma K.K.) | Change Change | Pamidronate disodium hydrate | Drugs with a new additional indication and a new dosage for the treatment of osteogenesis imperfecta. [Public knowledge-based application after PAFSC's preliminary assessment] |
| 6-2 | Jul. 4, 2014 | 65 | Canaglu Tablets 100 mg (Mitsubishi Tanabe Pharma Corporation) | Approval | <u>Canagliflozin hydrate</u> | A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus. |
| 6-2 | Jul. 4, 2014 | 66 | Vpriv for Intravenous Injection 400 U (Shire Japan KK) | Approval | <u>Vela glucerase alfa (genetical recombination)</u> | A drug with a new active ingredient indicated for the improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone disease). [Orphan drug] |
| 6-2 | Jul. 4, 2014 | 67 | Nicystagon Capsules 50 mg Nicystagon Capsules 150 mg (Mylan Seiyaku Ltd.) | Approval Approval | <u>Cysteamine bitartrate</u> | Drugs with a new active ingredient indicated for the treatment of nephropathic cystinosis. [Orphan drug] |
| 6-2 | Aug. 29, 2014 | 68 | Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.) | Change | Liraglutide (genetical recombination) | A drug with a new indication for the treatment of type 2 diabetes mellitus. |
| 6-2 | Aug. 29, 2014 | 69 | Metgluco Tablets 250 mg Metgluco Tablets 500 mg (Sumitomo Dainippon Pharma Co., Ltd.) | Change Change | Metformin hydrochloride | Drugs with a new dosage indicated for the treatment of type 2 diabetes mellitus (for pediatric use). |
| 6-2 | Nov. 18, 2014 | 70 | Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Sumitomo Dainippon Pharma Co., Ltd.) | Change Change | Repaglinide | Drugs with a revised indication for the treatment of type 2 diabetes mellitus. |
| 6-2 | Dec. 26, 2014 | 71 | Orfadin Capsules 2 mg Orfadin Capsules 5 mg Orfadin Capsules 10 mg (Astellas Pharma Inc.) | Approval Approval Approval | <u>Nitisinone</u> | Drugs with a new active ingredient indicated for the treatment of type I hypertryrosinemia. |
| 6-2 | Dec. 26, 2014 | 72 | Jardiance Tablets 25 mg Jardiance Tablets 10 mg (Nippon Boehringer Ingelheim Co., Ltd.) | Approval Approval | <u>Empagliflozin</u> | Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus. |

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| 6-2 | Dec. 26, 2014 | 73 | Vimizim Intravenous Infusion 5 mg (BioMarin Pharmaceutical Japan K.K.) | Approval | <u>Elosulfase alfa</u> (<u>genetical</u> <u>recombination</u>) | A drug with a new active ingredient indicated for the treatment of mucopolysaccharidosis type IVA. [Orphan drug] |
| 6-2 | Mar. 26, 2015 | 74 | Zafatek Tablets 50 mg Zafatek Tablets 100 mg (Takeda Pharmaceutical Company Limited) | Approval Approval | <u>Trelagliptin succinate</u> | Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus. |
| 6-2 | Mar. 26, 2015 | 75 | Cerdelga Capsule 100 mg (Genzyme Japan K.K) | Approval | <u>Eliugustat tartrate</u> | A drug with a new active ingredient indicated for the improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone disease). [Orphan drug] |
| In vivo diagnostics | Dec. 26, 2014 | 76 | Patch Test Panel (S) (Sato Pharmaceutical Co., Ltd.) | Approval | N/A for this drug used for patch tests | A drug indicated for use in patch tests to identify allergens in patients with allergic dermatitis. |
| In vivo diagnostics | Mar. 26, 2015 | 77 | Gadovist IV Inj. 1.0 mol/L 7.5 mL Gadovist IV Inj. 1.0 mol/L Syringe 5 mL Gadovist IV Inj. 1.0 mol/L Syringe 7.5 mL Gadovist IV Inj. 1.0 mol/L Syringe 10 mL (Bayer Yakuhin, Ltd.) | Approval Approval Approval Approval | <u>Gadobutrol</u> | Drugs with a new active ingredient indicated for visibility of brain/spinal cord and trunk/extremities in magnetic resonance computer tomographic imaging as a contrast agent. |
| Oncology drugs | May 23, 2014 | 78 | Imunomax-γ for Injection 50 Imunomax-γ for Injection 100 (Shionogi & Co., Ltd.) | Change Change | Interferon gamma-1a (genetical recombination) | Drugs with new additional indications and a new dosage for the treatment of mycosis fungoides and Sézary syndrome. [Orphan drug] |
| Oncology drugs | May 23, 2014 | 79 | Ranmark Subcutaneous Injection 120 mg (Daiichi Sankyo Company, Limited) | Change | Denosumab (genetical recombination) | A drug with a new additional indication and a new dosage for the treatment of giant cell tumor of bone. [Orphan drug] |
| Oncology drugs | Jun. 20, 2014 | 80 | Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.) | Change | Sorafenib tosilate | A drug with a new additional indication for the treatment of unresectable differentiated thyroid carcinoma. [Orphan drug] |
| Oncology drugs | Jul. 4, 2014 | 81 | Zytiga Tablets 250 mg (Janssen Pharmaceutical K.K.) | Approval | <u>Abiraterone acetate</u> | A drug with a new active ingredient indicated for the treatment of castration-resistant prostate cancer. [Priority review] |
| Oncology drugs | Jul. 4, 2014 | 82 | Jevtana 60 mg I.V. Infusion (Sanofi K.K.) | Approval | <u>Cabazitaxel acetate</u> | A drug with a new active ingredient indicated for the treatment of prostate cancer. [Priority review] |
| Oncology drugs | Jul. 4, 2014 | 83 | Jakavi Tablets 5 mg (Novartis Pharma K.K.) | Approval | <u>Ruxolitinib phosphate</u> | A drug with a new active ingredient indicated for the treatment of myelofibrosis. [Orphan drug] |
| Oncology drugs | Jul. 4, 2014 | 84 | Alecensa Capsule 20 mg Alecensa Capsule 40 mg (Chugai Pharmaceutical Co., Ltd.) | Approval Approval | <u>Alectinib hydrochloride</u> | Drugs with a new active ingredient indicated for the treatment of unresectable advanced/relapsed ALK fusion gene-positive non-small-cell lung cancer. [Orphan drug] |
| Oncology drugs | Jul. 4, 2014 | 85 | Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.) | Approval Approval | <u>Nivolumab</u> (<u>genetical</u> <u>recombination</u>) | Drugs with a new active ingredient indicated for the treatment of unresectable malignant melanoma. [Orphan drug] |
| Oncology drugs | Sep. 26, 2014 | 86 | G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Hakko Kirin Co., Ltd.) | Approval | <u>Pegfilgrastim</u> (<u>genetical</u> <u>recombination</u>) | A drug with a new active ingredient indicated for decreasing the incidence of cancer chemotherapy-induced febrile neutropenia. |
| Oncology drugs | Sep. 26, 2014 | 87 | Agrylin Capsules 0.5 mg (Shire Japan KK) | Approval | <u>Anagrelide</u> <u>hydrochloride hydrate</u> | A drug with a new active ingredient indicated for the treatment of essential thrombocythemia. [Orphan drug] |
| Oncology drugs | Sep. 26, 2014 | 88 | MabCampath Intravenous infusion 30 mg (Sanofi K.K.) | Approval | <u>Alemtuzumab</u> (<u>genetical</u> <u>recombination</u>) | A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia. [Orphan drug] |
| Oncology drugs | Sep. 26, 2014 | 89 | Bosulif Tablets 100 mg (Pfizer Japan Inc.) | Approval | <u>Bosutinib hydrate</u> | A drug with a new active ingredient indicated for the treatment of chronic myelogenous leukemia with resistance or intolerance to prior drug therapies. [Orphan drug] |

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| Oncology drugs | Sep. 26, 2014 | 90 | Zanosar for Intravenous Injection 1 g (Nobelpharma Co., Ltd.) | Approval | <u>Streptozocin</u> | A drug with a new active ingredient indicated for the treatment of neuroendocrine tumors of the pancreas and gastrointestinal tract. [Orphan drug] |
| Oncology drugs | Dec. 18, 2014 | 91 | Nesp Injection 5 µg Plastic Syringe 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 | Darbeoetin alfa (genetical recombination) | Drugs with a new additional indication and a new dosage for the treatment of anemia due to myelodysplastic syndrome. [Orphan drug] |
| Oncology drugs | Dec. 18, 2014 | 92 | Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.) | Change | Paclitaxel | A drug with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer. [Priority review] |
| Oncology drugs | Dec. 18, 2014 | 93 | Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.) | Change | Mogamulizumab (genetical recombination) | A drug with a revised indication and a new dosage for the treatment of CCR4-positive adult T-cell leukemia/lymphoma. [Expedited review] |
| Oncology drugs | Dec. 18, 2014 | 94 | Adriacin Injection 10 Adriacin Injection 50 (Kyowa Hakko Kirin Co., Ltd.) | Change Change | Doxorubicin hydrochloride | Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review] |
| Oncology drugs | Dec. 18, 2014 | 95 | Doxorubicin Hydrochloride for Injection 10 mg "NK" Doxorubicin Hydrochloride for Injection 50 mg "NK" (Nippon Kayaku Co., Ltd.) | Change Change | Doxorubicin hydrochloride | Drugs with a revised indication and a new dosage for the relief of symptoms of malignant lymphoma. [Expedited review] |
| Oncology drugs | Dec. 18, 2014 | 96 | Cylocide Injection 20 mg Cylocide Injection 40 mg Cylocide Injection 60 mg Cylocide Injection 100 mg Cylocide Injection 200 mg (Nippon Shinyaku Co., Ltd.) | Change Change Change Change Change | Cytarabine | Drugs with a new route of administration indicated for the treatment of acute leukemia (including acute erythroid leukemia and blast crisis of chronic myelogenous leukemia). [Expedited review] |
| Oncology drugs | Dec. 18, 2014 | 97 | Cymerin 50 mg Injection Cymerin 100 mg Injection (Mitsubishi Tanabe Pharma Corporation) | Change Change | Ranimustine | Drugs with a new dosage indicated for the treatment of malignant lymphoma. [Expedited review] |
| Oncology drugs | Dec. 26, 2014 | 98 | Zelboraf Tablet 240 mg (Chugai Pharmaceutical Co., Ltd.) | Approval | <u>Vemurafenib</u> | A drug with a new active ingredient indicated for the treatment of unresectable malignant melanoma with BRAF mutation. [Orphan drug] |
| Oncology drugs | Mar. 20, 2015 | 99 | Lonsurf Combination Tablet T15 Lonsurf Combination Tablet T20 (Taiho Pharmaceutical Co., Ltd.) | Change Change | (1) Trifluridine (2) Tipiracil hydrochloride | Drugs with a revised indication for the treatment of unresectable advanced or recurrent colorectal cancer. [Expedited review] |
| Oncology drugs | Mar. 20, 2015 | 100 | 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 advanced or recurrent gastric cancer. [Public knowledge-based application after PAFSC's preliminary assessment] |
| Oncology drugs | Mar. 26, 2015 | 101 | Lenvima Capsule 4 mg Lenvima Capsule 10 mg (Eisai Co., Ltd.) | Approval Approval | <u>Lenvatinib mesilate</u> | Drugs with a new active ingredient indicated for the treatment of unresectable thyroid cancer. [Orphan drug] |
| Oncology drugs | Mar. 26, 2015 | 102 | Pomalyst Capsules 1 mg Pomalyst Capsules 2 mg Pomalyst Capsules 3 mg Pomalyst Capsules 4 mg (Celgene K.K.) | Approval Approval Approval Approval | <u>Pomalidomide</u> | Drugs with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug] |
| Oncology drugs | Mar. 26, 2015 | 103 | Cyramza Injection 100 mg Cyramza Injection 500 mg (Eli Lilly Japan K.K.) | Approval Approval | <u>Ramucirumab (genetical recombination)</u> | Drugs with a new active ingredient indicated for the treatment of unresectable advanced or recurrent gastric cancer. [Priority review] |

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| HIV/AIDS drugs | Nov. 18, 2014 | 104 | Complera Combination Tablets (Janssen Pharmaceutical K.K.) | Approval | Rilpivirine hydrochloride, Emtricitabine, Tenofovir disoproxil fumarate | A new combination drug indicated for the treatment of HIV-1 infection. [Orphan drug] |
| HIV/AIDS drugs | Mar. 16, 2015 | 105 | Triumeq Combination Tablets (ViiV Healthcare K.K.) | Approval | Dolutegravir sodium, Abacavir sulfate, Lamivudine | A new combination drug indicated for the treatment of HIV infection. [Orphan drug] |
| Vaccines | Jun. 20, 2014 | 106 | Prevenar 13 Suspension Liquid for Injection (Pfizer Japan Inc.) | Change | Pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM ₁₉₇ conjugate) | A drug with a new additional indication and a new dosage for the prophylaxis of pneumococcal disease. (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in the elderly. |
| Vaccines | Jul. 4, 2014 | 107 | Menactra Intramuscular Injection (Sanofi K.K.) | Approval | <u>Meningococcal quadrivalent vaccine (diphtheria toxoid conjugate)</u> | A drug with a new active ingredient indicated for the prophylaxis of invasive meningococcal disease. (serotypes A, C, Y, and W-135). |
| Vaccines | Jul. 4, 2014 | 108 | Squarekids Subcutaneous Injection Syringe (Kitasato Daiichi Sankyo Vaccine Co., Ltd.) | Approval | Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (salk vaccine) combined vaccine | A new combination drug indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis. |
| Vaccines | Mar. 26, 2015 | 109 | Cell Culture-derived Influenza Emulsion HA Vaccine (prototype) for Intramuscular Injection "Kaketsuken" (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute]) | Approval | <u>Cell culture-derived influenza emulsion HA vaccines (prototype)</u> | A drug with a new active ingredient indicated for the prevention of pandemic influenza. [Orphan drug] |
| Vaccines | Mar. 26, 2015 | 110 | Synflorix Aqueous Suspension for Intramuscular Injection (Japan Vaccine Co., Ltd.) | Approval | <u>Pneumococcal 10-valent conjugate vaccine adsorbed (Non-Typeable Haemophilus influenzae (NTHi) protein D, diphtheria or tetanus toxoid conjugates)</u> | A drug with a new active ingredient indicated for the prophylaxis of pneumonia and pneumococcal invasive disease. (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) |
| Blood products | Jun. 20, 2014 | 111 | Feiba NF for Injection 500 Feiba NF for Injection 1000 (Baxter Limited) | Change Change | Anti-inhibitor coagulant complex | Drugs with a revised indication and a new dosage for inhibition of bleeding tendency by promoting the blood coagulation in the plasma in patients with inhibitors to blood coagulation factor VIII or factor IX. |
| Blood products | Jul. 4, 2014 | 112 | Byclot Combination Intravenous Injection (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute]) | Approval | <u>Freeze-dried activated human blood coagulation factor VII concentrate containing factor X</u> | A new combination drug with a new active ingredient indicated for prevention of bleeding in patients who have inhibitors against blood coagulation factor VIII or IX. [Orphan drug] |
| Blood products | Jul. 4, 2014 | 113 | Alprolix Intravenous 250 Alprolix Intravenous 500 Alprolix Intravenous 1000 Alprolix Intravenous 2000 Alprolix Intravenous 3000 (Biogen Idec Japan Ltd.) | Approval Approval Approval Approval Approval | <u>Eftrenonacog alfa (genetical recombination)</u> | Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with blood coagulation factor IX deficiency. |
| Blood products | Dec. 26, 2014 | 114 | Rixubis Intravenous 250 Rixubis Intravenous 500 Rixubis Intravenous 1000 Rixubis Intravenous 2000 Rixubis Intravenous 3000 (Baxter Limited) | Approval Approval Approval Approval Approval | <u>Nonacog gamma (genetical recombination)</u> | Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor IX deficiency. |
| Blood products | Dec. 26, 2014 | 115 | Eloctate Intravenous 250 Eloctate Intravenous 500 Eloctate Intravenous 750 Eloctate Intravenous 1000 Eloctate Intravenous 1500 Eloctate Intravenous 2000 Eloctate Intravenous 3000 (Biogen Idec Japan Ltd.) | Approval Approval Approval Approval Approval Approval Approval | <u>Efralococog alfa (genetical recombination)</u> | Drugs with a new active ingredient indicated for the control of bleeding tendency in patients with blood coagulation factor VIII deficiency. |

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| Blood products | Feb. 2, 2015 | 116 | Venoglobulin IH 5% I.V. 2.5 g/50 mL (Japan Blood Products Organization) | Change | Polyethylene glycol treated human normal immunoglobulin | A drug with a new indication and a new dosage for the prevention of acute otitis media, acute bronchitis, or pneumonia caused by <i>Pneumococcus</i> or <i>Haemophilus influenzae</i> in patients associated with a decrease in serum IgG2 levels. (for use only in patients who have not responded sufficiently to prevention by vaccination and other appropriate treatments, and have repeated the relapse of these diseases). |
| Blood products | Mar. 26, 2015 | 117 | NovoThirteen i.v.injection 2500 (Novo Nordisk Pharma Ltd.) | Approval | <u>Catridecacog (genetical recombination)</u> | A drug with a new active ingredient indicated for the control of bleeding tendency in patients with congenital blood coagulation factor XIII A-subunit deficiency. [Orphan drug] |
| Bio-CMC | Jul. 4, 2014 | 118 | (1) Infliximab BS for I.V. Infusion 100 mg "NK" (Nippon Kayaku Co., Ltd.) (2) Infliximab BS for I.V. Infusion 100 mg "CTH" (Celltrion Inc.) | Approval Approval | Infliximab (genetical recombination) [infliximab biosimilar 1] | Follow-on biologics indicated for the treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments (including prevention of structural joint damage), the treatment and maintenance therapy of Crohn's disease (for use only in patients in an active phase of moderate to severe Crohn's disease or with external fistula who have not responded sufficiently to conventional treatments), or the treatment of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments). |
| Bio-CMC | Dec. 26, 2014 | 119 | Insulin Glargine BS Inj. Cartridges [Lilly] Insulin Glargine BS Inj. MirioPen [Lilly] (Eli Lilly Japan K.K.) | Approval Approval | Insulin glargine (genetical recombination) [Insulin glargine biosimilar 1] | Follow-on biologics indicated for the treatment of diabetes mellitus where insulin therapy is indicated. |

**Review Categories of New Drugs*

| Review Category | Products |
|----------------------------|---|
| 1 | Gastrointestinal drugs, dermatologic drugs |
| 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) |
| HIV/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 |