

New Drugs Approved in May 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	May 23, 2014	1	Imunomax-γ for Injection 50 Imunomax-γ for Injection 100 (Shionogi & Co., Ltd.)	Change Change	<u>Interferon gamma-1a</u> (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	2	Ranmark Subcutaneous Injection 120 mg (Daiichi Sankyo Company, Limited)	Change	<u>Denosumab</u> (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of giant cell tumor of bone. [Orphan drug]
6-2	May 23, 2014	3	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	<u>Sitagliptin phosphate hydrate</u>	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	May 23, 2014	4	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	<u>Alogliptin benzoate</u>	Drugs with a new indication for the treatment of type 2 diabetes mellitus.
6-2	May 23, 2014	5	Aredia for I.V. Infusion 15 mg Aredia for I.V. Infusion 30 mg (Novartis Pharma K.K.)	Change Change	<u>Pamidronate disodium hydrate</u>	Drugs with a new additional indication and a new dosage for the treatment of osteogenesis imperfecta. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
4	May 23, 2014	6	Vancomycin Hydrochloride for Intravenous Drip Infusion 0.5 g (Shionogi & Co., Ltd.)	Change	<u>Vancomycin hydrochloride</u>	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]

New Drugs Approved in June 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Jun. 20, 2014	7	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]
3-2	Jun. 20, 2014	8	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).
Blood products	Jun. 20, 2014	9	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.
Vaccines	Jun. 20, 2014	10	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.
5	Jun. 20, 2014	11	Mirena 52 mg (Bayer Yakuhin, Ltd.)	Change	Levonorgestrel	A drug with a new additional indication for the treatment of hypermenorrhea. [Public knowledge-based application after PAFSC's preliminary assessment]

New Drugs Approved in July 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Jul. 4, 2014	12	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.
3-1	Jul. 4, 2014	13	E Kepra 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.
4	Jul. 4, 2014	14	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	15	Delyba 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]
6-1	Jul. 4, 2014	16	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).
Oncology drugs	Jul. 4, 2014	17	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	18	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]
Vaccines	Jul. 4, 2014	19	Menaetra 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).
4	Jul. 4, 2014	20	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.
Oncology drugs	Jul. 4, 2014	21	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	22	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]
Blood products	Jul. 4, 2014	23	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]
6-1	Jul. 4, 2014	24	Rapalimus Tablets 1 mg (Nobelpharma Co., Ltd.)	Approval	<u>Sirrolimus</u>	A drug with a new active ingredient indicated for the treatment of lymphangioleiomyomatosis. [Orphan drug]

1	Jul. 4, 2014	25	Dovobet Ointment (Leo Pharma K.K.)	Approval	(1) Calcipotriol hydrate/ (2) Betamethasone dipropionate	A new combination drug indicated for the treatment of psoriasis vulgaris.
6-2	Jul. 4, 2014	26	Vpriv for Intravenous Injection 400 U (Shire Japan K.K.)	Approval	<u>Velaqlucerase 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	27	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]
Vaccines	Jul. 4, 2014	28	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.
Blood products	Jul. 4, 2014	29	Alprolix Intravenous 250 Alprolix Intravenous 500 Alprolix Intravenous 1000 Alprolix Intravenous 2000 Alprolix Intravenous 3000 (Biogen Idec Japan Ltd.)	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.
4	Jul. 4, 2014	30	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]
6-1	Jul. 4, 2014	31	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]
Oncology drugs	Jul. 4, 2014	32	Opdivo Intravenous Infusion 20 mg Opdivo Intravenous Infusion 100 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval	<u>Nivolumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of unresectable malignant melanoma. [Orphan drug]
5	Jul. 4, 2014	33	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.
Bio-CMC	Jul. 4, 2014	34	(1) Infliximab BS for I.V. Infusion 100 mg "NK" (Nippon Kayaku Co., Ltd.) (1) Infliximab BS for I.V. Infusion 100 mg "CTH" (Celltrion Inc.)	Approval Approval	Infliximab (genetical recombination) [infiximab 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).
2	Jul. 4, 2014	35	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].

New Drugs Approved in August 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Aug. 29, 2014	36	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]
3-1	Aug. 29, 2014	37	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.
6-2	Aug. 29, 2014	38	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	39	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).
6-1	Aug. 29, 2014	40	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]

New Drugs Approved in September 2014

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
2	Sep. 19, 2014	41	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.
3-2	Sep. 19, 2014	42	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.
1	Sep. 19, 2014	43	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.
4	Sep. 19, 2014	44	Telavic 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]
3-1	Sep. 26, 2014	45	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.
Oncology drugs	Sep. 26, 2014	46	G-Lasta Subcutaneous Injection 3.6 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Pegfilgrastim (genetical 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	47	Agrylin Capsules 0.5 mg (Shire Japan KK)	Approval	<u>Anagrelide hydrochloride hydrate</u>	A drug with a new active ingredient indicated for the treatment of essential thrombocythemia. [Orphan drug]
3-1	Sep. 26, 2014	48	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.
3-2	Sep. 26, 2014	49	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.
2	Sep. 26, 2014	50	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).
1	Sep. 26, 2014	51	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.
5	Sep. 26, 2014	52	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.
4	Sep. 26, 2014	53	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.

Oncology drugs	Sep. 26, 2014	54	MabCampath Intravenous infusion 30 mg (Sanofi K.K.)	Approval	<u>Alemtuzumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia. [Orphan drug]
4	Sep. 26, 2014	55	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]
Oncology drugs	Sep. 26, 2014	56	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]
Oncology drugs	Sep. 26, 2014	57	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]
6-1	Sep. 26, 2014	58	Calonal Tab. 500 (Showa Yakuin 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.

**Review Categories of New Drugs*

Review Category	Products
1	Gastrointestinal drugs, dermatologic drugs
2	Cardiovascular drugs, antiparkinsonian drugs, antithrombotics, anti-Alzheimer's drugs
3-1	Central/peripheral nervous system drugs (excluding anesthetic drugs)
3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
4	Antibacterial drugs, vermifuge, antifungal drugs, antiviral drugs (excluding AIDS drugs)
5	Reproductive system drugs, drugs for urogenital system, combination drugs
6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs for inflammatory diseases
6-2	Hormone drugs, drugs for metabolic disorders (including diabetes mellitus, osteoporosis, gout, and inborn errors of metabolism)
AIDS drugs	Anti-HIV drugs
Oncology drugs	Antineoplastic drugs
Blood products	Globulin, blood coagulation factor products
Vaccines	Vaccines, antitoxic serum
Radio-pharmaceuticals	Radiopharmaceuticals
<i>In vivo</i> diagnostics	Contrast media
Bio-CMC	Biosimilars, quality of biologics