

New Drugs Approved in FY 2012

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Jun. 22, 2012	1	Nexium Capsules 10 mg Nexium Capsules 20 mg (AstraZeneca K.K.)	Change Change	Esomeprazole magnesium hydrate	Drugs 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	Jun. 22, 2012	2	Emend Capsules 80 mg Emend Capsules 125 mg Emend Capsules Set (Ono Pharmaceutical Co., Ltd.)	Change Change Change	Aprepitant	Drugs with a new additional pediatric dosage for patients of 12 years or older. These drugs are indicated for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) (including delayed phase).
1	Jun. 29, 2012	3	Amitiza Capsules 24 µg (Sucampo Pharma. Ltd.)	Approval	<u>Lubiprostone</u>	A drug with a new active ingredient indicated for the treatment of chronic constipation (excluding constipation due to organic diseases).
1	Aug. 24, 2012	4	Pentasa Tablets 250 mg Pentasa Tablets 500 mg (Kyorin Pharmaceutical Co., Ltd.)	Change Change	Mesalazine	Drugs with a new dosage. These drugs are indicated for the treatment of ulcerative colitis.
1	Dec. 21, 2012	5	Radiogardase Capsule 500 mg (Nihon Medi-Physics Co., Ltd.)	Change	Iron (III) hexacyanoferrate (II)	A drug with a new additional indication for the treatment of thallium and thallium compound poisoning.
1	Dec. 25, 2012	6	Moviprep Combination Oral Solution (Ajinomoto Pharmaceutical Co., Ltd.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used for bowel cleansing as a preparation for colonoscopy and large intestine surgery.
1	Dec. 25, 2012	7	Phosribbon Combination Granules (Zeria Pharmaceutical Co., Ltd.)	Approval	Monobasic sodium phosphate monohydrate/dibasic sodium phosphate anhydrous	A drug with a new indication and a new dosage in an additional dosage form for the treatment of hypophosphatemia. [Orphan drug]
1	Feb. 28, 2013	8	Minclea Catapasm for Internal Use 0.8% (Nihon Pharmaceutical Co., Ltd.)	Change	<i>l</i> -Menthol	A drug with a new additional indication for the inhibition of gastric peristalsis in endoscopic therapy for the upper gastrointestinal tract.
1	Mar. 25, 2013	9	Pentasa Suppositories 1 g (Kyorin Pharmaceutical Co., Ltd.)	Approval	Mesalazine	A drug in a new dosage form indicated for the treatment of ulcerative colitis (excluding severe cases).
1	Mar. 25, 2013	10	Acofide Tablets 100 mg (Zeria Pharmaceutical Co., Ltd.)	Approval	<u>Acotiamide hydrochloride</u> <u>hydrate</u>	A drug with a new active ingredient indicated for the treatment of postprandial fullness, upper abdominal bloating, and early satiation in functional dyspepsia.
2	May 25, 2012	11	Kaytwo Syrup 0.2% (Sannova Co., Ltd.)	Change	Menatetrenone	A drug with a new additional indication and a new dosage for the prevention of vitamin K-deficiency hemorrhage in neonates/infants. [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	May 25, 2012	12	Inderal Tablets 10 mg Inderal Tablets 20 mg (AstraZeneca K.K.)	Change Change	Propranolol hydrochloride	Drugs with new additional pediatric dosages for extrasystole (supraventricular/ventricular), the prevention of paroxysmal tachycardia, atrial fibrillation with rapid ventricular response (bradycardiac effect), sinus tachycardia, atrial fibrillation, and the prevention of paroxysmal atrial fibrillation. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	13	Epadel Capsules 300 Epadel S300 Epadel S600 Epadel S900 (Mochida Pharmaceutical Co., Ltd.)	Change Change Change Change	Ethyl icosapentate	Drugs with a new dosage. These drugs are indicated for the treatment of hyperlipemia.
2	Jun. 22, 2012	14	Renivace Tablets 2.5 Renivace Tablets 5 Renivace Tablets 10 (MSD K.K.)	Change Change Change	Enalapril maleate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]

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2	Jun. 22, 2012	15	Zestril Tablets 5 Zestril Tablets 10 Zestril Tablets 20 (AstraZeneca K.K.)	Change Change Change	Lisinopril hydrate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	16	Longes Tablets 5 mg Longes Tablets 10 mg Longes Tablets 20 mg (Shionogi & Co., Ltd.)	Change Change Change	Lisinopril hydrate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun.22, 2012	17	Norvasc Tablets 2.5 mg Norvasc Tablets 5 mg Norvasc OD Tablets 2.5 mg Norvasc OD Tablets 5 mg (Pfizer Japan Inc.) Amlodin Tablets 2.5 mg Amlodin Tablets 5 mg Amlodin OD Tablets 2.5 mg Amlodin OD Tablets 5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change Change Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	18	Amlodipine Tab. 2.5 mg "Amel" Amlodipine Tab. 5 mg "Amel" Amlodipine OD Tab. 2.5 mg "Amel" Amlodipine OD Tab. 5 mg "Amel" (Kyowa Pharmaceutical Industry Co., Ltd.)	Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosages. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	19	Enalart Fine Gran. 1% Enalart Tab. 2.5 mg Enalart Tab. 5 mg Enalart Tab. 10 mg (Kyowa Pharmaceutical Industry Co., Ltd.)	Change Change Change Change	Enalapril maleate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 22, 2012	20	Amlodipine Oral Jelly 2.5 mg "Towa" Amlodipine Oral Jelly 5 mg "Towa" Amlodipine OD Tablets 2.5 mg "Towa" Amlodipine OD Tablets 5 mg "Towa" Amlodipine Tablets 2.5 mg "Towa" Amlodipine Tablets 5 mg "Towa" (Towa Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Amlodipine besilate	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 29, 2012	21	Requip CR Tablets 2 mg Requip CR Tablets 8 mg (GlaxoSmithKline K.K.)	Approval Approval	Ropinirole hydrochloride	Drugs in new dosage forms and with a new dosage. These drugs are indicated for the treatment of Parkinson's disease.
2	Aug. 24, 2012	22	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with a new additional indication for the treatment of the following ischemic heart disease for which percutaneous coronary intervention (PCI) is applied: ST elevation myocardial infarction.
2	Aug. 24, 2012	23	Diovan Tablets 20 mg Diovan Tablets 40 mg Diovan Tablets 80 mg Diovan Tablets 160 mg (Novartis Pharma K.K.)	Change Change Change Change	Valsartan	Drugs with a new additional pediatric dosage. These drugs are indicated for the treatment of hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Sep. 28, 2012	24	Lotriga Granular Capsule 2 g (Takeda Pharmaceutical Company Limited)	Approval	<u>omega-3-acid ethyl esters</u>	A drug with a new active ingredient indicated for the treatment of hyperlipidaemia.
2	Sep. 28, 2012	25	Aimix Combination Tablet LD Aimix Combination Tablet HD (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval	Irbesartan/ amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	Sep. 28, 2012	26	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with a new additional indication and a new dosage for the suppression of embolus/thrombus formation in peripheral arterial diseases.
2	Nov. 21, 2012	27	Tracleer Tablets 62.5 mg (Actelion Pharmaceuticals Japan Ltd.)	Change	Bosentan hydrate	A drug with a new additional indication for the treatment of pulmonary arterial hypertension (WHO functional class II). [Orphan drug]

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2	Dec. 21, 2012	28	Micamlo Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/amlodipine besilate	A drug with a new dosage in an additional dosage form for the treatment of hypertension.
2	Dec. 25, 2012	29	Eliquis Tablets 2.5 mg Eliquis Tablets 5 mg (Bristol-Myers K.K.)	Approval Approval	<u>Apixaban</u>	Drugs with a new active ingredient indicated for prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
2	Feb. 28, 2013	30	Livalo Tablets 1 mg Livalo Tablets 2 mg Livalo Tablets 4 mg (Kowa Company, Ltd.)	Change Change Change	Pitavastatin calcium	Drugs with a new dosage indicated for the treatment of hypercholesterolemia and familial hypercholesterolemia.
2	Feb. 28, 2013	31	Grtpa Inj. 6,000,000 Grtpa Inj. 12,000,000 Grtpa Inj. 24,000,000 (Mitsubishi Tanabe Pharma Corporation) Activacin for Injection 6,000,000 Activacin for Injection 12,000,000 Activacin for Injection 24,000,000 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change	Alteplase (genetical recombination)	Drugs with a new indication and a new dosage for the improvement of functional impairment in association with acute phase of ischemic cerebrovascular disorder (within 4.5 hours after onset). [Public knowledge-based application after PAFSC's preliminary assessment]
2	Feb. 28, 2013	32	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 migraine attack. [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 25, 2013	33	Nourias Tablets 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Istradefylline</u>	A drug with a new active ingredient indicated for the improvement of wearing-off phenomenon in patients with Parkinson's disease on treatment with levodopa-containing products.
2 & 3-1	Dec. 25, 2012	34	[1] Neupro Patch 2.25 mg [2] Neupro Patch 4.5 mg [3] Neupro Patch 9 mg [4] Neupro Patch 13.5 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	<u>Rotigotine</u>	[1] [2] Drugs with a new active ingredient indicated for the treatment of Parkinson's disease and moderate to severe idiopathic restless legs syndrome. [3] [4] Drugs with a new active ingredient indicated for the treatment of Parkinson's disease.
3-1	Jun. 22, 2012	35	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Change Change Change	Pregabalin	Drugs with a new additional indication and a new dosage for the treatment of pain associated with fibromyalgia. [Priority review]
3-1	Aug. 24, 2012	36	Strattera Capsule 5 mg Strattera Capsule 10 mg Strattera Capsule 25 mg Strattera Capsule 40 mg (Eli Lilly Japan K.K.)	Change Change Change Change	Atomoxetine 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	Sep. 28, 2012	37	Zyprexa for Intramuscular Injection 10 mg (Eli Lilly Japan K.K.)	Approval	Olanzapine	A drug with a new route of administration indicated for the treatment of acute agitation associated with schizophrenia.
3-1	Sep. 28, 2012	38	Diacomit Drysyru 250 mg Diacomit Drysyru 500 mg Diacomit Capsules 250 mg (Meiji Seika Pharma Co., Ltd.)	Approval Approval Approval	<u>Stiripentol</u>	Drugs with a new active ingredient indicated for use in conjunction with clobazam and sodium valproate as adjunctive therapy of refractory generalized tonic-clonic and clonic seizures in patients with Dravet's syndrome whose seizures are not adequately controlled with clobazam and sodium valproate. [Orphan drug]
3-1	Nov. 21, 2012	39	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with a new route of administration and an additional indication for the treatment of severe primary axillary hyperhidrosis.
3-1	Dec. 25, 2012	40	Choreazine Tablets 12.5 mg (Alfresa Pharma Corporation)	Approval	<u>Tetrabenazine</u>	A drug with a new active ingredient indicated for the treatment of chorea associated with Huntington's disease. [Orphan drug]
3-1	Feb. 28, 2013	41	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Change Change Change	Pregabalin	Drugs with a new indication for the treatment of neuropathic pain.

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3-1	Mar. 25, 2013	42	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 a new additional indication and a new dosage for the treatment of acute exacerbation of multiple sclerosis. [Public knowledge-based application after PAFSC's preliminary assessment]
3-1	Mar. 25, 2013	43	Regtect Tablets 333 mg (Nippon Shinyaku Co., Ltd.)	Approval	<u>Acamprosate calcium</u>	A drug with a new active ingredient indicated for use as an aid for maintenance of abstinence in patients with alcohol dependence.
3-1	Mar. 25, 2013	44	Inovelon Tablets 100 mg Inovelon Tablets 200 mg (Eisai Co., Ltd.)	Approval Approval	<u>Rufinamide</u>	Drugs with a new active ingredient indicated for use as a concomitant therapy with other antiepileptic drugs to treat tonic and atonic seizures in patients with Lennox-Gastaut syndrome who have not responded sufficiently to other antiepileptic drugs. [Orphan drug]
3-2	Jun. 22, 2012	45	Penles Tape 18 mg (Nitto Denko Corporation)	Change	Lidocaine	A drug with a new additional indication and a new dosage for pain relief at the resection of molluscum contagiosum.
3-2	Sep. 28, 2012	46	Eylea Intravitreal Injection 40 mg/mL, Eylea Intravitreal Injection Kit 40 mg/mL (Bayer Yakuhin, Ltd.)	Approval Approval	<u>Aflibercept (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization.
3-2	Sep. 28, 2012	47	Methapain Tablet 5 mg Methapain Tablet 10 mg (Teikoku Seiyaku Co., Ltd.)	Approval Approval	<u>Methadone hydrochloride</u>	Drugs with a new active ingredient indicated for achieving analgesia of moderate to severe pain associated with various types of cancer which can not be managed by treatment with other strong opioid analgesics.
4	May 25, 2012	48	Finibax for Intravenous Infusion 0.25 g Finibax for Intravenous Infusion 0.5 g Finibax Kit for Intravenous Infusion 0.25 g (Shionogi & Co., Ltd.)	Change Change Change	Doripenem hydrate	Drugs with a new additional pediatric dosage and with a new additional indication for the treatment of purulent meningitis.
4	May 25, 2012	49	Vicillin 0.25 g for Injection Vicillin 0.5 g for Injection Vicillin 1 g for Injection Vicillin 2 g for Injection (Meiji Seika Pharma Co., Ltd.)	Change Change Change Change	Ampicillin sodium	Drugs with a new additional indication for <i>Listeria monocytogenes</i> as an applicable microorganism and with new additional pediatric and neonate dosages. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jun. 22, 2012	50	Meiact MS Fine Granules 10% for Pediatric (Meiji Seika Pharma Co., Ltd.)	Change	Cefditoren pivoxil	A drug with a new additional dosage for the treatment of pneumonia, otitis media, and sinusitis.
4	Jun. 22, 2012	51	Zithromac Intravenous Use 500 mg Zithromac Tablets 250 mg (Pfizer Japan Inc.)	Change Change	Azithromycin hydrate	Drugs with a new additional indication and a new dosage for the treatment of pelvic inflammatory diseases.
4	Aug. 10, 2012	52	Flagyl Oral Tablet 250 mg (Shionogi & Co., Ltd.)	Change	Metronidazole	A drug with new additional indications and a new dosage for the treatment of anaerobic bacterial infection, infectious enteritis, amoebic dysentery, and <i>Giardia lamblia</i> infection. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Aug. 10, 2012	53	Baktar Combination Tablets Baktar Combination Granules (Shionogi & Co., Ltd.) Bactramin Combination Tablet Bactramin Combination Granule (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change	Sulfamethoxazole/ trimethoprim	Drugs with a new additional indication and a new dosage for the treatment and prevention of <i>Pneumocystis pneumonia</i> . [Public knowledge-based application after PAFSC's preliminary assessment]
4	Aug. 10, 2012	54	Unasyn-S for Intravenous Use 0.75 g Unasyn-S for Intravenous Use 1.5 g Unasyn-S Kit for Intravenous Use 1.5 g Unasyn-S Kit for Intravenous Use 3 g (Pfizer Japan Inc.)	Change Change Change Change	Subbactam sodium/ampicillin sodium	Drugs with new additional indications for <i>Streptococcus Pneumoniae</i> and <i>Moraxella catarrhalis</i> as applicable microorganisms. A new dosage has been added to enable high-dosage use for severe infections.

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4	Sep. 28, 2012	55	Tobi Inhalation Solution 300 mg (Novartis Pharma K.K.)	Approval	<u>Tobramycin</u>	A drug with a new route of administration indicated for the improvement of symptoms associated with respiratory infection caused by <i>Pseudomonas aeruginosa</i> in cystic fibrosis patients.
4	Sep. 28, 2012	56	Zosyn for Intravenous Injection 2.25 Zosyn for Intravenous Injection 4.5 (Taiho Pharmaceutical Co., Ltd.)	Change Change	<u>Tazobactam/ piperacillin hydrate</u>	Drugs with new additional indications for the treatment of peritonitis, intraperitoneal abscess, cholecystitis, and cholangitis.
4	Sep. 28, 2012	57	Tygacil Injection 50 mg (Pfizer Japan Inc.)	Approval	<u>Tigecycline</u>	A drug with a new active ingredient indicated for the treatment of deep skin infection, chronic pyoderma, secondary infection of trauma, burn, and surgical wounds, secondary infection of erosion and ulcer, peritonitis, intraperitoneal abscess, and cholecystitis. [Priority review]
4	Nov. 21, 2012	58	Zyvox Tablets 600 mg Zyvox Injection 600 mg (Pfizer Japan Inc.)	Change Change	<u>Linezolid</u>	Drugs with a new additional pediatric dosage. These drugs are indicated for sepsis, deep skin infection, chronic pyoderma, secondary infection of trauma, burn, and surgical wounds, and pneumonia. [Public knowledge-based application after PAFSC's preliminary assessment]
4	Dec. 25, 2012	59	Malarone Combination Tablets (GlaxoSmithKline K.K.)	Approval	<u>Atovaquone/proguanil hydrochloride</u>	A new combination drug with a new active ingredient indicated for the treatment and prevention of malaria. [Priority review]
4	Dec. 25, 2012	60	Ameparomo Capsules 250 mg (Pfizer Japan Inc.)	Approval	<u>Paromomycin sulfate</u>	A drug with a new active ingredient indicated for the treatment of intestinal amoebiasis.
4	Feb. 21, 2013	61	Famvir Tab. 250 mg (Asahi Kasei Pharma Corporation)	Change	<u>Famciclovir</u>	A drug with a new additional indication and a new dosage for the treatment of herpes simplex.
4	Feb. 21, 2013	62	(1) Takepron capsules 15 Takepron capsules 30 (2) Takepron OD Tablets 15 Takepron OD Tablets 30 (Takeda Pharmaceutical Company Limited) (3) Omepral Tablets 10 Omepral Tablets 20 (AstraZeneca K.K.) (4) Omeprazon Tablets 10 mg Omeprazon Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation) (5) Omeprazole Tablets 10 mg "Mylan" Omeprazole Tablets 20 mg "Mylan" (Mylan Seiyaku Ltd.) (6) Pariet Tablets 10 mg (Eisai Co., Ltd.) (7) Rabeprazole Na Tablets 10 mg "Ohara" (Ohara Pharmaceutical Co., Ltd.) (8) Nexium Capsules 10 mg Nexium Capsules 20 mg (AstraZeneca K.K.)	Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change Change	(1)(2) <u>Lansoprazole</u> (3)(4)(5) <u>Omeprazole</u> (6)(7) <u>Rabeprazole sodium</u> (8) <u>Esomeprazole magnesium hydrate</u> (9)(10)(11)(12)(13)(14) <u>Amoxicillin hydrate</u> (15)(16)(17)(18) <u>Clarithromycin</u> (19) <u>Metronidazole</u> (20) <u>Lansoprazole/amoxicillin hydrate/clarithromycin</u>	Drugs with a new additional indication for the treatment of gastritis induced by <i>Helicobacter pylori</i> infection.

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			(9) Pasetocin Capsules 125 Pasetocin Capsules 250 (10) Pasetocin Tablets 250 (Kyowa Hakko Kirin Co., Ltd.) (11) Sawacillin Capsules 125 Sawacillin Capsules 250 (12) Sawacillin Tablets 250 (Astellas Pharma Inc.) (13) Amolin Capsules 125 Amolin Capsules 250 (14) 10% Amolin Fine Granules (Takeda Pharmaceutical Company Limited) (15) Clarith tab. 200 (Taisho Pharmaceutical Co., Ltd.) (16) Klaricid Tablets 200 mg (Abbott Japan Co., Ltd.) (17) Clarithromycin Tab. 200 mg "Mylan" (Mylan Seiyaku Ltd.) (18) Clarithromycin Tablets 200 mg "Takata" (Takata Seiyaku Co., Ltd.) (19) Flagyl Oral Tablet 250 mg (Shionogi & Co., Ltd.) (20) Lansap 400 Lansap 800 (21) Lampion Pack (Takeda Pharmaceutical Company Limited)	Change Change Change Change Change Change Change Change Change Change Change	(21) Lansoprazole/amoxicillin hydrate/metronidazole	
5	Dec. 21, 2012	63	Minirinmelt OD Tablets 120 µg Minirinmelt OD Tablets 240 µg (Ferring Pharmaceuticals Co., Ltd.)	Change Change	Desmopressin acetate hydrate	Drugs with a new indication and a new dosage for the treatment of central diabetes insipidus.
5	Dec. 25, 2012	64	Toviaz Tablet 4 mg Toviaz Tablet 8mg (Pfizer Japan Inc.)	Approval Approval	<u>Fesoterodine fumarate</u>	Drugs with a new active ingredient indicated for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
5	Dec. 25, 2012	65	Minirinmelt OD Tablets 60 µg (Ferring Pharmaceuticals Co., Ltd.)	Approval	Desmopressin acetate hydrate	A drug with a new indication and a new dosage in an additional dosage form for the treatment of central diabetes insipidus.
5	Mar. 25, 2013	66	Magsent Injection 100 mL Magnesol for Intravenous Injection 20 mL Magsent Injection Syringe 40 mL (Toa Pharmaceuticals Co., Ltd.)	Change Change Change	Magnesium sulfate hydrate/glucose	Drugs with a new additional indication and a new dosage for the prevention and treatment of eclampsia in patients with severe pregnancy- induced hypertension. [Public knowledge-based application after PAFSC's preliminary assessment]
5	Mar. 25, 2013	67	Voluven Solution for Infusion 6% (Fresenius Kabi Japan K.K.)	Approval	<u>Hydroxyethylated starch</u> <u>130000</u>	A drug with a new active ingredient indicated for maintenance of circulating blood volume.
5	Mar. 25, 2013	68	Neoxy Tape 73.5 mg (Hisamitsu Pharmaceutical Co., Inc.)	Approval	Oxybutynin hydrochloride	A drug with a new route of administration and new indications for the treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
6-1	May 25, 2012	69	Thaled Capsule 50 Thaled Capsule 100 (Fujimoto Pharmaceutical Corporation)	Change Change	Thalidomide	Drugs with a new additional indication and a new dosage for the treatment of erythema nodosum leprosum. [Orphan drug]
6-1	May 25, 2012	70	Nasonex Nasal 50 µg 56 sprays Nasonex Nasal 50 µg 112 sprays (MSD K.K.)	Change Change	Mometasone furoate hydrate	Drugs with a new additional pediatric dosage for the treatment of allergic rhinitis.
6-1	Jun. 22, 2012	71	Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.)	Change Change	Budesonide/formoterol fumarate hydrate	Drugs with a new dosage for inhalation as needed in addition to periodic inhalation as a maintenance therapy. These drugs are 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	Jun. 29, 2012	72	Kolbet Tablets 25 mg (Toyama Chemical Co., Ltd.) Careram Tablets 25 mg (Eisai Co., Ltd.)	Approval Approval	<u>Iguratiomod</u>	Drugs with a new active ingredient indicated for the treatment of rheumatoid arthritis.

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6-1	Jun. 29, 2012	73	Oxis 9 µg Turbuhaler 28 doses Oxis 9 µg Turbuhaler 60 doses (AstraZeneca K.K.)	Approval Approval	Formoterol fumarate hydrate	Drugs with a new indication and a new dosage for the alleviation of various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
6-1	Aug. 10, 2012	74	Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.)	Change	Adalimumab (genetical recombination)	A drug with a new additional indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage).
6-1	Aug. 10, 2012	75	Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.)	Change Change	Budesonide/formoterol fumarate hydrate	Drugs with a new additional indication and a new dosage for the relief of symptoms of chronic obstructive pulmonary diseases (chronic bronchitis, emphysema).
6-1	Sep. 28, 2012	76	Seebri Inhalation Capsules 50 µg (Novartis Pharma K.K.)	Approval	<u>Glycopyrronium bromide</u>	A drug 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	Nov. 21, 2012	77	MaQaid Intravitreal Injection 40 mg (Wakamoto Pharmaceutical Co., Ltd.)	Change	Triamcinolone acetonide	A drug with a new additional indication and a new dosage for the treatment of diabetic macular edema.
6-1	Dec. 25, 2012	78	Cimzia 200 mg Syringe for S.C. Injection (UCB Japan Co., Ltd.)	Approval	<u>Certolizumab pegol</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-1	Dec. 25, 2012	79	Dellegra Combination Tablets (Sanofi K.K.)	Approval	Fexofenadine hydrochloride/ pseudoephedrine hydrochloride	A new combination drug indicated for the treatment of allergic rhinitis.
6-1	Mar. 25, 2013	80	Neoral 10 mg Capsules Neoral Solution 10% Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Ciclosporin	Drugs with a new indication and a new dosage for the treatment of non-Behcet's, non-infectious uveitis (active non-infectious uveitis in the intermediate or posterior area in patients who have not responded sufficiently to conventional treatments and may involve deterioration of visual acuity). [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Mar. 25, 2013	81	Ciclosporin Cap. 10 mg "Mylan" Ciclosporin Cap. 25 mg "Mylan" Ciclosporin Cap. 50 mg "Mylan" Ciclosporin Fine Granules 17% "Mylan" (Mylan Seiyaku Ltd.)	Change Change Change Change	Ciclosporin	Drugs with a new indication and a new dosage for the treatment of non-Behcet's, non-infectious uveitis (active non-infectious uveitis in the intermediate or posterior area in patients who have not responded sufficiently to conventional treatments and may involve deterioration of visual acuity). [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Mar. 25, 2013	82	Xeljanz Tablets 5 mg (Pfizer Japan Inc.)	Approval	<u>Tofacitinib citrate</u>	A drug with a new active ingredient for the treatment of rheumatoid arthritis in patients who have not sufficiently responded to conventional treatments.
6-1	Mar. 25, 2013	83	Actemra 162 mg Syringe for SC Injection Actemra 162 mg Auto-Injector for SC Injection (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Tocilizumab (genetical recombination)	Drugs with a new route of administration indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-2	Jun. 22, 2012	84	NovoRapid 100 U/ml (Novo Nordisk Pharma Ltd.)	Change	Insulin aspart (genetical recombination)	A drug with a new route of administration and a new dosage. This drug is indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Jun. 29, 2012	85	Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)	Approval	<u>Teneligliptin hydrobromide hydrate</u>	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Jun. 29, 2012	86	Somatuline Subcutaneous Injection 60 mg Somatuline Subcutaneous Injection 90 mg Somatuline Subcutaneous Injection 120 mg (Teijin Pharma Limited)	Approval Approval Approval	<u>Lanreotide acetate</u>	Drugs with a new active ingredient for the improvement of hypersecretion of growth hormone and IGF-I (somatomedin-C) and related symptoms in acromegaly and pituitary gigantism (when surgical therapies are not sufficiently effective or are difficult to perform).

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Aug. 24, 2012	87	Growject BC for Injection 8 mg Growject for Injection 8 mg Growject for Injection 1.33 mg (JCR Pharmaceuticals Co., Ltd.)	Change Change Change	Somatropin (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of SGA (small-for-gestational age) dwarfism not associated with epiphyseal closure.
6-2	Sep. 28, 2012	88	Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Beskoa Tab. 100 mg (Kowa Pharmaceutical Co. Ltd.)	Approval Approval	<u>Anagliptin</u>	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Sep. 28, 2012	89	Tresiba Flex Touch Tresiba Penfill (Novo Nordisk Pharma Ltd.)	Approval Approval	<u>Insulin degludec (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Sep. 28, 2012	90	Buphenyl Tablet 500 mg Buphenyl Granule 94% (CMIC Holdings, Co., Ltd.)	Approval Approval	<u>Sodium phenylbutyrate</u>	Drugs with a new active ingredient indicated for the treatment of urea cycle disorder. [Orphan drug]
6-2	Dec. 25, 2012	91	L-Cartin FF Oral Solution 10% L-Cartin FF Injection 1000 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Levocarnitine</u>	Drugs with a new active ingredient indicated for the treatment of carnitine deficiency.
6-2	Dec. 25, 2012	92	Ryzodeg Combination Injection FlexTouch Ryzodeg Combination Injection Penfill (Novo Nordisk Pharma Ltd.)	Approval Approval	Insulin degludec (genetical recombination)/insulin aspart (genetical recombination)	New combination drugs indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.
6-2	Dec. 25, 2012	93	Actonel Tablets 75 mg (Ajinomoto Pharmaceutical Co., Ltd.) Benet Tablets 75 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	Sodium risedronate hydrate	Drugs with a new dosage in a new additional dosage form. These drugs are indicated for the treatment of osteoporosis.
6-2	Feb. 28, 2013	94	Equa Tablets 50 mg (Novartis Pharma K.K.)	Change	Vildagliptin	A drug with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Feb. 28, 2013	95	Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change	Repaglinide	Drugs with a new indication for the improvement of postprandial changes of blood glucose in type 2 diabetes mellitus.
6-2	Feb. 28, 2013	96	Denotas Chewable Combination Tablets (Nitto Pharmaceutical Industries, Ltd.)	Approval	Precipitated calcium carbonate/cholecalciferol/ magnesium carbonate	A combination prescription drug with a similar formulation indicated for the treatment and prevention of hypocalcemia in association with administration of RANKL inhibitors (e.g. denosumab [genetical recombination]) [Expedited review]
6-2	Mar. 25, 2013	97	Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Change	Linagliptin	A drug with a new indication for the treatment of type 2 diabetes mellitus.
6-2	Mar. 25, 2013	98	Pralia Subcutaneous Injection 60 mg Syringe (Daiichi Sankyo Company, Limited)	Approval	Denosumab (genetical recombination)	A drug with a new indication and a new dosage for the treatment of osteoporosis.
6-2	Mar. 25, 2013	99	Onglyza Tablets 2.5 mg Onglyza Tablets 5 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Saxagliptin hydrate</u>	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus.
6-2	Mar. 25, 2013	100	Metreleptin for Subcutaneous Injection 11.25 mg "Shionogi" (Shionogi & Co., Ltd.)	Approval	<u>Metreleptin (genetical recombination)</u>	A drug with a new active ingredient for the treatment of lipodystrophy. [Orphan drug]
In vivo diagnostics	May 25, 2012	101	Thyrogen for Intramuscular Injection 0.9 mg (Sato Pharmaceutical Co., Ltd.)	Change	Thyrotropin human alfa (genetical recombination)	A drug with a new additional indication for adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. [Orphan drug]
In vivo diagnostics	Aug. 10, 2012	102	Sonazoid for Injection 16 µL (Daiichi Sankyo Company, Limited)	Change	Perflubutane	A drug with a new additional indication as a contrast agent for breast mass lesion in ultrasonography.

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
In vivo diagnostics	Mar. 25, 2013	103	Alabel Oral 1.5 g (Nobelpharma Co., Ltd.) Alaglio Internal Medicine 1.5 g (SBI Pharmaceuticals Co., Ltd.)	Approval Approval	<u>Aminolevulinic acid hydrochloride</u>	Drugs with a new active ingredient indicated for the visualization of tumor tissues during tumorectomy for malignant glioma. [Orphan drug]
Oncology drugs	Jun. 29, 2012	104	Gonax 80 mg for Subcutaneous Injection Gonax 120 mg for Subcutaneous Injection (Astellas Pharma Inc.)	Approval Approval	<u>Degarelix acetate</u>	Drugs with a new active ingredient indicated for the treatment of prostate cancer.
Oncology drugs	Jun. 29, 2012	105	Inlyta Tablets 1 mg Inlyta Tablets 5 mg (Pfizer Japan Inc.)	Approval Approval	<u>Axitinib</u>	Drugs with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Aug. 10, 2012	106	Sutent Capsule 12.5 mg (Pfizer Japan Inc.)	Change	Sunitinib malate	A drug with a new additional indication and a new dosage for pancreatic neuroendocrine tumour. [Orphan drug]
Oncology drugs	Sep. 28, 2012	107	Gliadel for Intracerebral Implant 7.7 mg (Nobelpharma Co., Ltd.)	Approval	<u>Carmustine</u>	A drug with a new active ingredient indicated for the treatment of malignant glioma. [Orphan drug]
Oncology drugs	Sep. 28, 2012	108	Votrient Tablets 200 mg (GlaxoSmithKline K.K.)	Approval	<u>Pazopanib hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of soft tissue sarcoma. [Orphan drug]
Oncology drugs	Nov. 21, 2012	109	Afinitor Tablets 5 mg Afinitor Tablets 2.5 mg (Novartis Pharma K.K.)	Change Change	Everolimus	Drugs with new additional indications and a new dosage for the treatment of renal angiomyolipoma associated with tuberous sclerosis complex and subependymal giant cell astrocytoma associated with tuberous sclerosis complex. [Orphan drug]
Oncology drugs	Dec. 21, 2012	110	Erbix Injection 100 mg (Merck Serono Co., Ltd.)	Change	Cetuximab (genetical recombination)	A drug with a new additional indication for the treatment of head and neck cancer. [Priority review]
Oncology drugs	Dec. 21, 2012	111	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new route of administration indicated for the treatment of multiple myeloma.
Oncology drugs	Dec. 25, 2012	112	Afinitor Dispersible Tablet 2 mg Afinitor Dispersible Tablet 3 mg (Novartis Pharma K.K.)	Approval Approval	Everolimus	Drugs with a new additional indication and a new dosage in an additional dosage form for the treatment of subependymal giant cell astrocytoma associated with tuberous sclerosis complex (currently in the reexamination period). [Orphan drug]
Oncology drugs	Feb. 21, 2013	113	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Change	Paclitaxel	A drug with new additional indications and a new dosage for the treatment of gastric cancer and non- small cell lung cancer.
Oncology drugs	Feb. 21, 2013	114	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.) Gemcitabine for I.V. infusion 200 mg "Yakult" Gemcitabine for I.V. infusion 1 g "Yakult" (Takata Seiyaku Co., Ltd.) Gemcitabine for i.v. infusion 200 mg "Sawai" Gemcitabine for i.v. infusion 1 g "Sawai" (Sawai Pharmaceutical Co., Ltd.) Gemcitabine for I.V. Infusion 200 mg "NK" Gemcitabine for I.V. Infusion 1 g "NK" (Nippon Kayaku Co., Ltd.) Gemcitabine for I.V. Infusion 200 mg "Hospira" Gemcitabine for I.V. Infusion 1 g "Hospira" (Hospira Japan Co., Ltd.)	Change Change Change Change Change Change Change Change	Gemcitabine hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of relapsed or refractory malignant lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Oncology drugs	Feb. 21, 2013	115	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.) Paclitaxel Inj. 30 mg/5 mL "NK" Paclitaxel Inj. 100 mg/16.7 mL "NK" (Nippon Kayaku Co., Ltd.) Paclitaxel Injection 30 mg "Sawai" Paclitaxel Injection 100 mg "Sawai" Paclitaxel Injection 150 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change Change Change Change Change	Paclitaxel	Drugs with new additional indications and a new dosage for the treatment of relapsed or refractory germ cell tumors (testicular tumors, ovarian tumors, extragonadal tumors). [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 21, 2013	116	Leunase Injection 5000 Leunase Injection 10000 (Kyowa Hakko Kirin Co., Ltd.)	Change Change	L-Asparaginase	Drugs with a new route of administration. These drugs are indicated for acute leukemia (including blast crisis of chronic leukemia) and malignant lymphoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	117	Campto 40 mg for I.V. infusion Campto 100 mg for I.V. infusion (Yakult Honsha Co., Ltd.) Topotecin Intravenous Drip Infusion 40 mg Topotecin Intravenous Drip Infusion 100 mg (Daiichi Sankyo Company, Limited) Irinotecan Hydrochloride Intravenous Drip Infusion 40 mg "Sawai" Irinotecan Hydrochloride Intravenous Drip Infusion 100 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Irinotecan Hydrochloride I.V. Infusion 40 mg "Taiho" Irinotecan Hydrochloride I.V. Infusion 100 mg "Taiho" (Taiho Pharmaceutical Co., Ltd.) Irinotecan Hydrochloride I.V. Infusion 40 mg "Hospira" Irinotecan Hydrochloride I.V. Infusion 100 mg "Hospira" (Hospira Japan Co., Ltd.)	Change Change Change Change Change Change Change Change	Irinotecan hydrochloride hydrate	Drugs with a new additional indication and a new dosage for the treatment of pediatric malignant solid tumor. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	118	Endoxan for Injection 100 mg Endoxan for Injection 500 mg (Shionogi & Co., Ltd.)	Change Change	Cyclophosphamide hydrate	Drugs with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	119	Dacarbazine Injection 100 (Kyowa Hakko Kirin Co., Ltd.)	Change	Dacarbazine	A drug with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	120	Oncovin for Inj. 1 mg (Nippon Kayaku Co., Ltd.)	Change	Vincristine sulfate	A drug with a new additional indication and a new dosage for the treatment of pheochromocytoma. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	121	Hydrea Capsules 500 mg (Bristol-Myers K.K.)	Change	Hydroxycarbamide	A drug with new additional indications for the treatment of essential thrombocythemia and polycythemia vera. [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 25, 2013	122	Arzerra for I.V. infusion 100 mg Arzerra for I.V. infusion 1000 mg (GlaxoSmithKline K.K.)	Approval Approval	<u>Ofatumumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of relapsed or refractory CD20-positive chronic lymphocytic leukemia. [Orphan drug]
Oncology drugs	Mar. 25, 2013	123	Evoltra Intravenous Drip Infusion 20 mg (Genzyme Japan K.K.)	Approval	<u>Clofarabine</u>	A drug with a new active ingredient for the treatment of recurrent or refractory acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Mar. 25, 2013	124	Stivarga tablets 40 mg (Bayer Yakuhin, Ltd.)	Approval	<u>Regorafenib hydrate</u>	A drug with a new active ingredient indicated for the treatment of unresectable advanced or recurrent colorectal cancer. [Priority review]

Review Category*	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
AIDS drugs	May 18, 2012	125	Edurant Tablets 25 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Rilpivirine hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Mar. 25, 2013	126	Stribild Combination Tab. (Japan Tobacco Inc.)	Approval	<u>Elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate</u>	A new combination drug with a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
Biologicals	Apr. 27, 2012	127	Imovax Polio Subcutaneous Injection (Sanofi Pasteur)	Approval	<u>Inactivated poliomyelitis vaccine (Salk vaccine)</u>	A drug with a new active ingredient indicated for the prevention of acute poliomyelitis. [Expedited review]
Biologicals	Jul. 27, 2012	128	Tetrabik Subcutaneous Injection Syringe (The Research Foundation for Microbial Diseases of Osaka University)	Approval	<u>Adsorbed diphtheria-purified pertussis-tetanus- inactivated polio (Sabin strain) combined vaccine</u>	A drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis.
Biologicals	Jul. 27, 2012	129	Quattrovac Subcutaneous Injection Syringe (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	<u>Adsorbed diphtheria-purified pertussis-tetanus- inactivated polio (Sabin strain) combined vaccine</u>	A drug with a new active ingredient indicated for the prevention of pertussis, diphtheria, tetanus, and acute poliomyelitis.
Vaccines	Mar. 15, 2013	130	Aimmugen (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Freeze-dried inactivated tissue culture hepatitis A vaccine	A drug with a new pediatric dosage. The drug is indicated for the prevention of hepatitis A.
Vaccines	Mar. 25, 2013	131	Adsorbed Influenza Vaccine (H5N1) "Seiken" 1 mL (Denka Seiken Co., Ltd.)	Approval	<u>Adsorbed influenza vaccine (H5N1)</u>	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Blood products	Mar. 25, 2013	132	Normosang Infusion 250 mg (CMIC Holdings Co., Ltd.)	Approval	<u>Hemin</u>	A drug with a new active ingredient indicated for the improvement of symptoms of acute attack in patients with acute porphyria. [Orphan drug]
Bio-CMC	Nov. 21, 2012	133	Filgrastim BS Injection 75 µg Syringe "Mochida" Filgrastim BS Injection 150 µg Syringe "Mochida" Filgrastim BS Injection 300 µg Syringe "Mochida" (Mochida Pharmaceutical Co., Ltd.) Filgrastim BS Injection 75 µg Syringe "F" Filgrastim BS Injection 150 µg Syringe "F" Filgrastim BS Injection 300 µg Syringe "F" (Fuji Pharma Co., Ltd.)	Approval Approval Approval Approval Approval Approval	Filgrastim (genetical recombination)	Follow-on biologics indicated for mobilization of hematopoietic stem cells to peripheral blood, promotion of increases 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.
Bio-CMC	Feb. 28, 2013	134	Filgrastim BS Inj. 75 µg Syringe "NK" Filgrastim BS Inj. 150 µg Syringe "NK" Filgrastim BS Inj. 300 µg Syringe "NK" (Nippon Kayaku Co., Ltd.) Filgrastim BS Injection 75 µg Syringe "Teva" Filgrastim BS Injection 150 µg Syringe "Teva" Filgrastim BS Injection 300 µg Syringe "Teva" (Teva Pharma Japan Inc.)	Approval Approval Approval Approval Approval Approval	Filgrastim (genetical recombination) [filgrastim biosimilar 2]	Follow-on biologics indicated for mobilization of hematopoietic stem cells to peripheral blood, promotion of increases in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia, and congenital/idiopathic neutropenia.

**Review Categories of New Drugs*

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