

Table 1. Products Approved in FY 2011: New Drugs

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 22, 2011	1	Lipacreon Granules 300 mg Sachet Lipacreon Capsules 150 mg (Abbott Japan Co., Ltd.)	Approval Approval	<u>Pancrelipase</u>	Drugs with a new active ingredient indicated for the replacement of pancreatic digestive enzymes in pancreatic exocrine insufficiency.
1	Apr. 22, 2011	2	Mircera Injection Syringe 25 µg Mircera Injection Syringe 50 µg Mircera Injection Syringe 75 µg Mircera Injection Syringe 100 µg Mircera Injection Syringe 150 µg Mircera Injection Syringe 200 µg Mircera Injection Syringe 250 µg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	<u>Epoetin beta pegol</u> ( <u>genetical recombination</u> )	Drugs with a new active ingredient indicated for the treatment of renal anemia.
1	Apr. 22, 2011	3	Thymoglobuline for Intravenous Infusion 25 mg (Genzyme Japan 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 renal transplantation.  [Expedited review]
1	May 20, 2011	4	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.)  Sol-Melcort for Injection 40 Sol-Melcort for Injection 125 Sol-Melcort for Injection 500 Sol-Melcort for Injection 1,000 (Fuji Pharma Co., Ltd.)	Change Change Change Change  Change Change Change Change	Methylprednisolone sodium succinate	Drugs with a new additional indication and a new dosage for the treatment of nephrotic syndrome.  [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
1	Jul. 1, 2011	5	Nexium Capsules 10 mg (AstraZeneca K.K.)	Approval	<u>Esomeprazole magnesium</u> <u>hydrate</u>	A drug with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease and Zollinger-Ellison syndrome, prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal antiinflammatory drugs, and aid to eradication of <i>Helicobacter pylori</i> in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and stomach after endoscopic treatment for early gastric cancer.
			Nexium Capsules 20 mg (AstraZeneca K.K.)	Approval	<u>Esomeprazole magnesium</u> <u>hydrate</u>	A drug with a new active ingredient indicated for the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis and Zollinger-Ellison syndrome, prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal antiinflammatory drugs, and aid to eradication of <i>Helicobacter pylori</i> in patients with gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and stomach after endoscopic treatment for early gastric cancer.
1	Jul. 1, 2011	6	Pegasys S.C. 90 µg  Copegus Tablets 200 mg (Chugai Pharmaceutical Co., Ltd.)	Change  Change	Peginterferon alfa-2a (genetical recombination)  Ribavirin	Drugs with a new additional indication for the improvement of viremia in patients with compensated cirrhosis C. A new dosage of Pegasys S.C. 90 µg has also been approved.  [Priority review]

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1	Jul. 1, 2011	7	Ditripentat-Cal Injection 1000 mg  Zinc-Tripentat Injection 1055 mg (Nihon Medi-Physics Co., Ltd.)	Approval  Approval	<u>Pentetate calcium trisodium</u>  <u>Pentetate zinc trisodium</u>	Drugs with a new active ingredient indicated for the reduction of internal contamination with transuranium elements (plutonium, americium, and curium).  [Expedited review]
1	Aug. 17, 2011	8	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombi	A drug with a new dosage indicated for the treatment of Crohn's disease.  [Orphan drug]
1	Sep. 16, 2011	9	Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change	Cyclophosphamide hydrate	A drug with a new additional indication and a new dosage for the treatment of nephrotic syndrome (for use only in patients who have not sufficiently responded to adequate treatment with corticosteroids).  [Public knowledge-based application after PAFSC's preliminary assessment]
1	Sep. 16, 2011	10	Cellcept Capsule 250 (Chugai Pharmaceutical Co., Ltd.)	Change	Mycophenolate mofetil	A drug with a new additional pediatric dosage indicated for the prevention of rejection in renal transplantation.  [Public knowledge-based application after PAFSC's preliminary assessment]
1	Sep. 26, 2011	11	Proemend for Intravenous Infusion 150 mg (Ono Pharmaceutical Co., Ltd.)	Approval	<u>Fosaprepitant meglumine</u>	A drug with a new active ingredient indicated for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) (including delayed phase).
1	Sep. 26, 2011	12	Pegasys S.C. 180 µg Pegasys S.C. 90 µg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Peginterferon alfa-2a (genetical recombination)	Drugs with a new additional indication and a new dosage for the improvement of viremia in patients with chronic active hepatitis B.  [Priority review]
1	Nov. 25, 2011	13	Beselna Cream 5% (Mochida Pharmaceutical Co., Ltd.)	Change	Imiquimod	A drug with a new additional indication and a new dosage for the treatment of actinic keratosis (limited to the face or baldness).
1	Dec. 22, 2011	14	Kytril Fine Granule 0.4% Kytril Tablet 1 mg Kytril Tablet 2 mg Kytril Injection 1 mg Kytril Injection 3 mg Kytril Intravenous Bag 3 mg/50 mL Kytril Intravenous Bag 3 mg/100 mL (Chugai Pharmaceutical Co., Ltd.)	Change Change Change Change Change Change Change	Granisetron hydrochloride	Drugs with a new additional indication for the treatment of gastrointestinal symptoms (nausea and vomiting) associated with radiation.  [Public knowledge-based application after PAFSC's preliminary assessment]
1	Dec. 22, 2011	15	Certican Tablets 0.25 mg Certican Tablets 0.5 mg Certican Tablets 0.75 mg (Novartis Pharma K.K.)	Change Change Change	Everolimus	Drugs with a new additional indication and a new dosage for the inhibition of rejection in renal transplantation.

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1	Dec. 22, 2011	16	(1) Pegintron Powder for Injection 50 µg/0.5 mL Pegintron Powder for Injection 100 µg/0.5 mL Pegintron Powder for Injection 150 µg/0.5 mL (2) Rebetol Capsules 200 mg (MSD K.K.)	Change Change Change Change	(1) Peginterferon alfa-2b (genetical recombination)  (2) Ribavirin	Drugs with a new additional indication and a new dosage for the improvement of viremia in patients with compensated cirrhosis C by concomitant use.  [Priority review]
1	Mar. 30, 2012	17	Kiklin Capsules 250 mg (Astellas Pharma Inc.)	Approval	<u>Bixalomer</u>	A drug with a new active ingredient indicated for the improvement of hyperphosphatemia in patients with chronic renal failure under dialysis.
2	Apr. 22, 2011	18	Mirapex-LA Tablets 0.375 mg Mirapex-LA Tablets 1.5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Pramipexole hydrochloride hydrate	Drugs in new dosage forms and with new dosages indicated for the treatment of Parkinson's disease.
2	Apr. 22, 2011	19	Exelon Patch 4.5 mg Exelon Patch 9 mg Exelon Patch 13.5 mg Exelon Patch 18 mg (Novartis Pharma K.K.)  Rivastach Patch 4.5 mg Rivastach Patch 9 mg Rivastach Patch 13.5 mg Rivastach Patch 18 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval  Approval Approval Approval Approval	<u>Rivastigmine</u>	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Apr. 22, 2011	20	Lixiana Tablets 15 mg Lixiana Tablets 30 mg (Daiichi Sankyo Company, Limited)	Approval Approval	<u>Edoxaban tosilate hydrate</u>	Drugs with a new active ingredient indicated for prevention of venous thromboembolism in patients undergoing orthopedic surgery of lower limbs including total knee arthroplasty, total hip arthroplasty and hip fracture surgery.
2	May 20, 2011	21	Novastan HI Inj. 10 mg/2 mL (Mitsubishi Tanabe Pharma Corporation)  Slonnon HI Injection 10 mg/2 mL (Daiichi Sankyo Company, Limited)	Change  Change	Argatroban hydrate	Drugs with new additional indications and new dosages for the prevention of perfusion blood coagulation during blood extracorporeal circulation (hemodialysis) in patients with heparin-induced thrombocytopenia (HIT) type II and in addition for the prevention of blood coagulation during percutaneous coronary intervention in HIT type II patients (including the patients who have the risk for HIT).  [Orphan drug]
2	May 20, 2011	22	Vasolan for Intravenous Injection 5 mg (Eisai Co., Ltd.)	Change	Verapamil hydrochloride	A drug with a new additional dosage indicated for the treatment of tachyarrhythmia in pediatric patients (paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, paroxysmal atrial flutter).  [Public knowledge-based application after PAFSC's preliminary assessment]

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2	May 20, 2011	23	Vasolan Tablets 40 mg (Eisai Co., Ltd.)	Change	Verapamil hydrochloride	A drug with a new additional indication and a new dosage for the treatment of tachyarrhythmia in pediatric patients (atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia).  [Public knowledge-based application after PAFSC's preliminary assessment]
2	May 20, 2011	24	Maintate Tablets 2.5 Maintate Tablets 5 Maintate Tablets 0.625 (Mitsubishi Tanabe Pharma Corporation)	Change Change Change	Bisoprolol fumarate	Drugs with a new additional indication and new dosages for the treatment of chronic heart failure secondary to ischemic heart disease or dilated cardiomyopathy in patients receiving basic treatment with angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists, diuretics, digitalis preparations, etc.  [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 16, 2011	25	Depakene Tablets 100 Depakene Tablets 200 Depakene Fine Granules 20% Depakene Fine Granules 40% Depakene-R Tablets 100 Depakene-R Tablets 200 Depakene Syrup 5% (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change Change Change Change	Sodium valproate	Drugs with a new additional indication and a new dosage for prevention of migraine attack.  [Public knowledge-based application after PAFSC's preliminary assessment]
2	Jun. 16, 2011	26	Selenica-R Granules 40% Selenica-R Tab.200 mg Selenica-R Tab.400 mg (Kowa Company, Ltd.)	Change Change Change	Sodium valproate	Drugs with a new additional indication and a new dosage for prevention of migraine attack.
2	Jul. 1, 2011	27	Corebeta for Intravenous 12.5 mg (Ono Pharmaceutical Co., Ltd.)	Approval	Landiolol hydrochloride	A drug with a new indication, a new dosage, and an additional dosage form indicated for the improvement of visualization of coronary arteries at high heart rate in coronary angiography by computed tomography.
2	Dec. 22, 2011	28	Plavix 25 mg Tablets Plavix 75 mg Tablets (Sanofi-Aventis K.K.)	Change Change	Clopidogrel sulfate	Drugs with new additional indications for the treatment of the following ischemic heart disease for which percutaneous coronary intervention (PCI) is applied: stable angina and old myocardial infarction.
2	Jan. 18, 2012	29	Azilva Tablets 20 mg Azilva Tablets 40 mg (Takeda Pharmaceutical Company Limited)	Approval Approval	<u>Azilsartan</u>	Drugs with a new active ingredient indicated for the treatment of hypertension.
2	Jan. 18, 2012	30	Xarelto Tablets 15 mg Xarelto Tablets 10 mg (Bayer Yakuhin, Ltd.)	Approval Approval	<u>Rivaroxaban</u>	Drugs with a new active ingredient indicated for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

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2	Mar. 30, 2012	31	Apokyn Subcutaneous Injection 30 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Apomorphine hydrochloride hydrate</u>	A drug with a new active ingredient indicated for the treatment of "off" episodes associated with Parkinson's disease (when levodopa-containing products that are frequently administered and other anti-Parkinson drugs at increased doses are not sufficiently effective).  [Orphan drug]
3-1	Apr. 22, 2011	32	Lexapro Tablets 10 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	<u>Escitalopram oxalate</u>	A drug with a new active ingredient indicated for the treatment of depression.
3-1	Jul. 1, 2011	33	Fostoin 750mg for injection (Nobelpharma Co., Ltd.)	Approval	<u>Fosphenytoin sodium hydrate</u>	A drug with a new active ingredient indicated for: 1. treatment of status epilepticus 2. prevention of seizures occurring in connection with neurosurgery, and/or consciousness disorder (head trauma, etc.) 3. temporary substitution of oral phenytoin therapy in epilepsy patients.
3-1	Jul. 1, 2011	34	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 the prevention of recurrence/relapse of mood episodes in patients with bipolar disorder.
3-1	Jul. 1, 2011	35	Gabapen Tablets 200 mg Gabapen Tablets 300 mg Gabapen Tablets 400 mg Gabapen Syrop 5% (Pfizer Japan Inc.)	Change Change Change Approval	Gabapentine	Drugs with a new additional pediatric dosage and an additional dosage form indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy who have not responded sufficiently to other antiepileptic drugs.
3-1	Sep. 26, 2011	36	Venoglobulin IH 5% I.V. 0.5 g/10 mL Venoglobulin IH 5% I.V. 1 g/20 mL Venoglobulin IH 5% I.V. 2.5 g/50 mL Venoglobulin IH 5% I.V. 5 g/100 mL (Benesis Corporation)	Change Change Change Change	Polyethylene glycol treated human normal immunoglobulin	Drugs with a new additional indication for the treatment of generalized myasthenia gravis (for use only in patients who have not sufficiently responded to steroids or other immunosuppressants). [Orphan drug]
3-1	Sep. 26, 2011	37	Imusera Capsules 0.5 mg (Mitsubishi Tanabe Pharma Corporation)  Gilenya Capsules 0.5 mg (Novartis Pharma K.K.)	Approval  Approval	<u>Fingolimod hydrochloride</u>	Drugs with a new active ingredient indicated for the prevention of relapse and for delaying the accumulation of physical disability in multiple sclerosis.  [Orphan drug]
3-1	Nov. 25, 2011	38	Modiodal Tablets 100 mg (Alfresa Pharma Corporation)	Change	Modafinil	A drug with a new additional indication for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea syndrome who receive treatment of airway obstruction with continuous positive airway pressure (CPAP) therapy, etc.
3-1	Jan. 18, 2012	39	Lunesta Tablets 1 mg Lunesta Tablets 2 mg Lunesta Tablets 3 mg (Eisai Co., Ltd.)	Approval Approval Approval	<u>Eszopiclone</u>	Drugs with a new active ingredient indicated for the treatment of insomnia.
3-1	Jan. 18, 2012	40	Regnite Tablets 300 mg (Astellas Pharma Inc.)	Approval	<u>Gabapentin enacarbil</u>	A drug with a new active ingredient indicated for the treatment of moderate to severe idiopathic restless legs syndrome.

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3-1	Jan. 18, 2012	41	[1] Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Tablets 12 mg Abilify Powder 1% Abilify Oral Solution 0.1% [2] Abilify OD Tablets 3 mg Abilify OD Tablets 6 mg Abilify OD Tablets 12 mg Abilify OD Tablets 24 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change Change Change Approval Approval Approval Approval	Aripiprazole	Drugs with a new additional indication and a new dosage in new dosage forms for the improvement of manic symptoms in patients with bipolar disorder.
3-1	Feb. 22, 2012	42	Zyprexa Tablets 2.5 mg Zyprexa Tablets 5 mg Zyprexa Tablets 10 mg Zyprexa Fine Granule 1% Zyprexa Zydys Tablets 5 mg Zyprexa Zydys Tablets 10 mg (Eli Lilly Japan K.K.)	Change Change Change Change Change Change	Olanzapine	Drugs with a new additional indication and a new dosage for the improvement of depressive symptoms in patients with bipolar disorder.
3-1	Feb. 22, 2012	43	Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.)	Change Change	Duloxetine hydrochloride	Drugs with a new additional indication for the treatment of pain associated with diabetic neuropathy.
3-2	Jan. 18, 2012	44	Aiphagan Ophthalmic Solution 0.1% (Senju Pharmaceutical Co., Ltd.)	Approval	<u>Brimonidine tartrate</u>	A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension when other glaucoma drugs are not sufficiently effective or cannot be used.
3-2	Jan. 18, 2012	45	Emla Cream (Sato Pharmaceutical Co., Ltd.)	Approval	Lidocaine/ <u>propitocaine</u>	A new combination drug with a new active ingredient indicated for the relief of pain in skin laser radiation therapy.
3-2	Jan. 18, 2012	46	OxyFast Injection 10 mg OxyFast Injection 50 mg (Shionogi & Co., Ltd.)	Approval Approval	Oxycodone hydrochloride hydrate	Drugs with a new route of administration indicated for analgesia in various types of cancer with moderate to severe pain.
3-2	Apr. 22, 2011	47	Suprane Liquid for Inhalation (Baxter Limited)	Approval	<u>Desflurane</u>	A drug with a new active ingredient indicated for the maintenance of general anesthesia.
3-2	Apr. 22, 2011	48	Tramcet Combination Tablets (Janssen Pharmaceutical K.K.)	Approval	Tramadol hydrochloride/ acetaminophen	A new combination drug indicated for analgesia of chronic non-cancer pain and pain after tooth extraction which are not managed by treatments with non-opioid analgesics.
3-2	Apr. 22, 2011	49	Popsaine 0.5% Inj. 50 mg/10 mL Popsaine 0.5% Inj. syringe 50 mg/10 mL Popsaine 0.25% Inj. 25 mg/10 mL Popsaine 0.25% Inj. syringe 25 mg/10 mL (Maruishi Pharmaceutical Co., Ltd.)	Approval Approval Change Change	Levobupivacaine hydrochloride	Drugs with a new route of administration, a new additional indication and new dosages indicated for conduction anesthesia.
4	Apr. 22, 2011	50	Finibax 0.25 g IV Solution Finibax 0.25 g IV Solution Kit (Shionogi & Co., Ltd.)	Change Change	Doripenem hydrate	Drugs with a new dosage that enables high-dose (1 g three times daily) use.

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4	May 20, 2011	51	Rifadin Capsules 150 mg (Daiichi Sankyo Company, Limited)  Rifampicin Capsules 150 mg "Sandoz" (Sandoz K.K.)	Change  Change	Rifampicin	Drugs with a new additional indication and a new dosage for the treatment of nontuberculous mycobacteriosis including <i>Mycobacterium avium</i> complex (MAC) infection.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	May 20, 2011	52	Foscarnir Infusion Solution 24 mg/mL (AstraZeneca K.K.)	Change	Foscarnet sodium hydrate	A drug with new additional indications and a new dosage for the treatment of cytomegalovirus viremia and cytomegalovirus infection in patients undergoing hematopoietic stem cell transplantation.
4	May 20, 2011	53	Esanbutol Tablets 125 mg Esanbutol Tablets 250 mg (Sandoz K.K.)  Ebutol 125 mg Tablets Ebutol 250 mg Tablets (Kaken Pharmaceutical Co., Ltd.)	Change Change  Change Change	Ethambutol hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of nontuberculous mycobacteriosis including <i>Mycobacterium avium</i> complex (MAC) infection.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jul. 1, 2011	54	Cubicin IV 350 mg (MSD K.K.)	Approval	<u>Daptomycin</u>	A drug with a new active ingredient indicated for the treatment of sepsis, infective endocarditis, deep skin infection, secondary infection of trauma, burn, and surgical wounds, and secondary infection of erosion and ulcer caused by daptomycin-sensitive methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).
4	Jul. 1, 2011	55	Zithromac Tablets 250 mg (Pfizer Japan Inc.)	Change	Azithromycin hydrate	A drug with a new additional indication for <i>Legionella pneumophila</i> as applicable microorganism.
			Zithromac Intravenous Use 500 mg (Pfizer Japan Inc.)	Approval		A drug with a new route of administration indicated for the treatment of pneumonia.
4	Aug. 17, 2011	56	Gracevit Tablets 50 mg Gracevit Fine Granules 10% (Daiichi Sankyo Company, Limited)	Change Change	Sitafloxacin hydrate	Drugs with a new dosage indicated for the treatment of pharyngitis and laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, cystitis, pyelonephritis, urethritis, cervicitis, otitis media, sinusitis, periodontal inflammation, pericoronitis, and jaw inflammation.
4	Sep. 26, 2011	57	Telavic 250 mg Tablet (Mitsubishi Tanabe Pharma Corporation)	Approval	<u>Telaprevir</u>	A drug with a new active ingredient indicated for the improvement of viremia in serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C in: (1) untreated patients with high blood HCV RNA; or (2) patients who did not respond to, or in whom the symptom relapsed with, interferon monotherapy or interferon-ribavirin combination therapy.  [Priority review]

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4	Sep. 26, 2011	58	Itrazole Oral Solution 1% (Janssen Pharmaceutical K.K.)	Change	Itraconazole	A drug with new indications for (1) the treatment of fungal infection, (2) the treatment of febrile neutropenia with suspected fungal infection, and (3) the prevention of deep mycosis in patients with hematologic malignancy or hematopoietic stem cell transplantation in whom neutropenia is anticipated.
4	Nov. 25, 2011	59	Diflucan Intravenous Solution 50 mg Diflucan Intravenous Solution 100 mg Diflucan Intravenous Solution 200 mg Diflucan Capsules 50 mg Diflucan Capsules 100 mg (Pfizer Japan Inc.)	Change Change Change Change Change	Fluconazole	Drugs with a new additional pediatric dosage and a new additional indication for the prevention of deep mycosis in patients with hematopoietic stem cell transplantation.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	Dec. 22, 2011	60	Claforan Injection 0.5 g Claforan Injection 1 g (Sanofi-Aventis K.K.)  Cefotax Injection 0.5 g Cefotax Injection 1 g (Sanofi-Aventis Nichi-Iko K.K.)	Change Change  Change Change	Cefotaxime sodium	Drugs with a new dosage for the treatment of pediatric purulent meningitis.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	Jan. 18, 2012	61	Samtarel Oral Suspension 15% (GlaxoSmithKline K.K.)	Approval	<u>Atovaquone</u>	A drug with a new active ingredient indicated for the treatment and prevention of Pneumocystis pneumonia.  [Priority review]
4	Jan. 18, 2012	62	Cancidas for Intravenous Drip Infusion 50 mg Cancidas for Intravenous Drip Infusion 70 mg (MSD K.K.)	Approval Approval	<u>Caspofungin acetate</u>	Drugs with a new active ingredient indicated for the treatment of febrile neutropenia suspected of a fungal infection and fungal infections due to <i>Candida</i> or <i>Aspergillus</i> (esophageal candidiasis, invasive candidiasis, aspergillosis).
4	Feb. 22, 2012	63	Sawacillin Fine Granules 10% Sawacillin Capsules 125 Sawacillin Capsules 250 Sawacillin Tablets 250 (Astellas Pharma Inc.)  Pasetocin Fine Granules 10% Pasetocin Capsules 125 Pasetocin Capsules 250 Pasetocin Tablets 250 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change  Change Change Change Change	Amoxicillin hydrate	Drugs with a revised maximum dosage for pediatric patients indicated for the treatment of infections except <i>Helicobacter pylori</i> infection.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	Feb. 22, 2012	64	Penicillin G Potassium 200000 Units for Injection Penicillin G Potassium 1000000 Units for Injection (Meiji Seika Pharma Co., Ltd.)	Change Change	Benzylpenicillin potassium	Drugs with a new route of administration and a new dosage for a new additional indication for the treatment of syphilis.  [Public knowledge-based application after PAFSC's preliminary assessment]
4	Mar. 21, 2012	65	Flagyl Oral Tablet 250 mg Flagyl Vaginal Tablet 250 mg (Shionogi & Co., Ltd.)	Change Change	Metronidazole	Drugs with a new indication and new dosages for the treatment of bacterial vaginosis.  [Public knowledge-based application after PAFSC's preliminary assessment]

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5	May 20, 2011	66	Anti-D Globulin for I.M. Injection 1000 "Nichiyaku" (Nihon Pharmaceutical Co., Ltd.)	Change	Dry anti-Rho(D) immune human globulin	A drug with a new indication and a new dosage for the prevention of sensitization to the D(Rho) factor in women who are D(Rho) negative and are not already sensitized to the D(Rho) factor, to be used at around 28 weeks of pregnancy or in the case of possible sensitization such as after delivery, miscarriage, artificial abortion, ectopic pregnancy, testing/procedure during pregnancy (e.g., amniocentesis, external cephalic version) or abdominal bruise.  [Public knowledge-based application after PAFSC's preliminary assessment]
5	May 20, 2011	67	Anti-D Human Immunoglobulin I.M. 1000-Benesis (Benesis Corporation)	Change	Dry anti-Rho(D) immune human globulin	A drug with a new indication and a new dosage for the prevention of sensitization to the D(Rho) factor in women who are D(Rho) negative and are not already sensitized to the D(Rho) factor, to be used at around 28 weeks of pregnancy or in the case of possible sensitization such as after delivery, miscarriage, artificial abortion, ectopic pregnancy, testing/procedure during pregnancy (e.g., amniocentesis, external cephalic version) or abdominal bruise.  [Public knowledge-based application after PAFSC's preliminary assessment]
5	May 20, 2011	68	Gonalef for Subcutaneous Injection 150 (Merck Serono Co., Ltd.)	Change	Follitropin alfa (genetical recombination)	A drug with a new additional indication and a new dosage for induction of ovulation in patients with anovulation and infrequent ovulation associated with hypothalamic-pituitary dysfunction or polycystic ovarian syndrome.
5	May 20, 2011	69	Leuplin for Injection 1.88 Leuplin for Injection 3.75 (Takeda Pharmaceutical Company Limited)	Change Change	Leuprorelin acetate	Drugs with a new additional dosage indicated for the treatment of central precocious puberty.  [Public knowledge-based application after PAFSC's preliminary assessment]
5	Jul. 1, 2011	70	Betanis Tablet 25 mg Betanis Tablet 50 mg (Astellas Pharma Inc.)	Approval Approval	<u>Mirabegron</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	Nov. 25, 2011	71	L'estrogel 0.06% (Shiseido Company, Limited)	Change	Estradiol	A drug with a new dosage. This drug is indicated for the treatment of vasomotor symptoms (hot flush and sweating) associated with menopausal disorder and ovarian deficiency symptoms.
5	Mar. 30, 2012	72	Minirinmelt OD Tablets 120 µg Minirinmelt OD Tablets 240 µg (Ferring Pharmaceuticals Co., Ltd.)	Approval Approval	Desmopressin acetate hydrate	Drugs with a new route of administration indicated for the treatment of nocturnal enuresis associated with decreased urine osmolality or urinary specific gravity.

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6-1	May 20, 2011	73	Imuran Tablets 50 mg (GlaxoSmithKline K.K.)  Azanin Tablets 50 mg (Mitsubishi Tanabe Pharma Corporation)	Change  Change	Azathioprine	Drugs with new additional indications and a new dosage for the treatment of the following treatment-resistant rheumatic diseases: systemic vasculitis (e.g., microscopic polyangiitis, Wegener granulomatosis, polyarteritis nodosa, Churg-Strauss syndrome, aortitis syndrome), systemic lupus erythematosus (SLE), polymyositis, dermatomyositis, pachyderma, mixed connective tissue disease and refractory rheumatic disease.  [Public knowledge-based application after PAFSC's preliminary assessment]
6-1	Jul. 1, 2011	74	Allelock Granule 0.5% (Kyowa Hakko Kirin Co., Ltd.)	Approval	Olopatadine hydrochloride	A drug with an additional dosage form of granules and with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin disease (eczema/dermatitis and pruritus cutaneous).
6-1	Jul. 1, 2011	75	Simponi Subcutaneous Injection 50 mg Syringe (Janssen Pharmaceutical K.K.)	Approval	<u>Golimumab (genetical reco</u>	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	Jul. 1, 2011	76	Onbrez Inhalation Capsules 150 µg (Novartis Pharma K.K.)	Approval	<u>Indacaterol maleate</u>	A drug with a new active ingredient indicated for the alleviation of various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
6-1	Jul. 1, 2011	77	Humira 40 mg for S.C. Injection Syringe 0.8 mL Humira 20 mg for S.C. Injection Syringe 0.4 mL (Abbott Japan Co., Ltd.)	Change Approval	Adalimumab (genetical recombination)	Drugs with a new additional indication, a new dosage, and an additional dosage form for the treatment of polyarticular-course juvenile idiopathic arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Aug. 17, 2011	78	Patanol EX Ophthalmic Solution 0.2% (Alcon Japan Ltd.)	Approval	Olopatadine hydrochloride	A drug with a new dosage and an additional dosage form indicated for the treatment of allergic conjunctivitis.
6-1	Sep. 26, 2011	79	Ilaris for S.C. Injection 150 mg (Novartis Pharma K.K.)	Approval	<u>Canakinumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of cryopyrin-associated periodic syndrome.  [Orphan drug]
6-1	Sep. 26, 2011	80	Mucosta Ophthalmic Solution UD 2% (Otsuka Pharmaceutical Co., Ltd.)	Approval	Rebamipide	A drug with a new route of administration indicated for the treatment of dry eye.
6-1	Dec. 22, 2011	81	Celecox Tablets 100 mg Celecox Tablets 200 mg (Astellas Pharma Inc.)	Change Change	Celecoxib	Drugs with a new additional indication and a new dosage for the relief of inflammation and pain after operation, trauma, and tooth extraction.
6-1	Dec. 22, 2011	82	Onon Drysyrup 10% (Ono Pharmaceutical Co., Ltd.)	Change	Pranlukast hydrate	A drug with a new additional indication for the treatment of allergic rhinitis in pediatric patients.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-1	Mar. 21, 2012	83	Enbrel 25 mg for S.C. Injection Enbrel 25 mg Syringe 0.5 mL for S.C. Injection Enbrel 10 mg for S.C. Injection Enbrel 50 mg Syringe 1.0 mL for S.C. Injection (Pfizer Japan Inc.)	Change	Etanercept (genetical recombination)	Drugs with a new additional indication for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.
6-1	Mar. 30, 2012	84	Pulmozyme Inhalation Solution 2.5 mg (Chugai Pharmaceutical Co., Ltd.)	Approval	<u>Dornase alfa (genetical recombination)</u>	A drug with a new active ingredient indicated for the improvement of lung function in patients with cystic fibrosis.  [Orphan drug]
6-2	Apr. 22, 2011	85	Glubes Combination Tab. (Kissei Pharmaceutical Co., Ltd.)	Approval	Mitiglinide calcium hydrate/voglibose	A new combination drug indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of mitiglinide calcium hydrate with voglibose is deemed appropriate).
6-2	May 20, 2011	86	Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.)  Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.)	Change Change Change  Change Change Change	Sitagliptin phosphate hydrate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to alpha-glucosidase inhibitors along with diet and exercise therapies.
6-2	May 20, 2011	87	Forteo for S.C. Injection Kit 600 µg (Eli Lilly Japan K.K.)	Change	Teriparatide (genetical recombination)	A drug with a new dosage with a revised treatment period from "up to 18 months" to "up to 24 months" indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Jul. 1, 2011	88	Liovel Combination Tablets LD Liovel Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Alogliptin benzoate/pioglitazone hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes mellitus.
6-2	Jul. 1, 2011	89	Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	<u>Linagliptin</u>	A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to diet and exercise therapies alone).
6-2	Jul. 1, 2011	90	Recalbon Tablets 50 mg (Ono Pharmaceutical Co., Ltd.)  Bonoteo Tablets 50 mg (Astellas Pharma Inc.)	Approval  Approval	Minodronic acid hydrate	Drugs with a new dosage and an additional dosage form indicated for the treatment of osteoporosis.
6-2	Sep. 16, 2011	91	Levemir Penfill Levemir FlexPen Levemir InnoLet (Novo Nordisk Pharma Ltd.)	Approval Approval Approval	<u>Insulin detemir (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.  This application applies only to the change in manufacturing method of the drug substance, and thus formulation, manufacturing method, indications and dosage and administration of the product are the same as the approved product.

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Sep. 16, 2011	92	Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.)  Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (MSD K.K.)	Change Change Change  Change Change Change	Sitagliptin phosphate hydrate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to insulin along with diet and exercise therapies.
6-2	Sep. 26, 2011	93	Teribone Inj. 56.5 µg (Asahi Kasei Pharma Corporation)	Approval	Teriparatide acetate	A drug with a new route of administration, a new indication, and a new dosage indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Nov. 25, 2011	94	Metopirone Capsules 250 mg (Novartis Pharma K.K.)	Change	Metyrapone	A drug with a new additional indication and a new dosage for the treatment of Cushing's syndrome.  [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Jan. 18, 2012	95	Bonalon Bag for I.V. Infusion 900 µg (Teijin Pharma Limited)	Approval	Alendronate sodium hydrate	A drug with a new dosage in a new additional dosage form indicated for the treatment of osteoporosis (not in the reexamination period).
6-2	Mar. 30, 2012	96	Brazaves Capsules 100 mg (Actelion Pharmaceuticals Japan Ltd.)	Approval	<u>Miglustat</u>	A drug with a new active ingredient indicated for the treatment of Niemann-Pick disease Type C. [Orphan drug]
6-2	Mar. 30, 2012	97	Bydureon for Subcutaneous Injection 2 mg (Eli Lilly Japan K.K.)	Approval	Exenatide	A drug with a new additional indication and a new dosage in a new dosage form for the treatment of type 2 diabetes mellitus.
Blood products	Jun. 16, 2011	98	NovoSeven for Injection 1.2 mg NovoSeven for Injection 4.8 mg NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.)	Change Change Change Change Change	Eptacog alfa (activated) (genetical recombination)	Drugs with a new additional indication and a new dosage for inhibition of bleeding tendency in patients with Glanzmann thrombasthenia with alloantibodies against platelet, and with past or present refractoriness to platelet transfusions.  [Public knowledge-based application after PAFSC's preliminary assessment]
Blood products	Sep. 26, 2011	99	TachoSil Tissue Sealing Sheet (CSL Behring K.K.)	Approval	Human fibrinogen/thrombin fraction	A new combination drug indicated for the adhesion and closure of wounds in tissues at surgery in the fields of hepatic surgery, pulmonary surgery, cardiovascular surgery, obstetrics and gynecology, and urologic surgery.
Oncology drugs	Apr. 22, 2011	100	Halaven Injection 1 mg (Eisai Co., Ltd.)	Approval	<u>Eribulin mesylate</u>	A drug with a new active ingredient indicated for the treatment of inoperable or recurrent breast cancer.  [Priority review]
Oncology drugs	Jun. 16, 2011	101	Sprycel Tablets 20 mg Sprycel Tablets 50 mg (Bristol-Myers K.K.)	Change Change	Dasatinib hydrate	Drugs with a new additional indication and a new dosage for the treatment of chronic myelocytic leukemia.

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Oncology drugs	Jul. 1, 2011	102	Tarceva Tablets 25 mg Tarceba Tablets 100 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change	Erlotinib hydrochloride	Drugs with a new additional indication and a new dosage for the treatment of unresectable pancreatic cancer.
Oncology drugs	Jul. 1, 2011	103	Zolinza Capsules 100 mg (MSD K.K.)	Approval	<u>Vorinostat</u>	A drug with a new active ingredient indicated for the treatment of cutaneous T-cell lymphoma.
Oncology drugs	Sep. 16, 2011	104	Velcade Injection 3 mg (Janssen Pharmaceutical K.K.)	Change	Bortezomib	A drug with a new indication and a new dosage for the treatment of multiple myeloma.  [Orphan drug]
Oncology drugs	Sep. 16, 2011	105	Predonine Tablets 5 mg (Shionogi & Co., Ltd.)  Prednisolone Tablets 1 mg (Asahi Kasei) Prednisolone Tablets 5 mg (Asahi Kasei) (Asahi Kasei Pharma Corporation)  Prednisolone Tablets 5 mg "Takeda" Prednisolone Powder 1% "Takeda" (Takeda Pharmaceutical Company Limited)	Change  Change Change  Change Change	Prednisolone	Drugs with a new indication for the treatment of multiple myeloma.  [Expedited review]
Oncology drugs	Sep. 26, 2011	106	Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)	Approval	<u>Fulvestrant</u>	A drug with a new active ingredient indicated for the treatment of postmenopausal breast cancer.
Oncology drugs	Sep. 26, 2011	107	Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Change Change	Bevacizumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of unresectable or recurrent breast cancer.
Oncology drugs	Nov. 25, 2011	108	Paraplatin Injection 50 mg Paraplatin Injection 150 mg Paraplatin Injection 450 mg (Bristol-Myers K.K.)	Change Change Change	Carboplatin	Drugs with a new additional indication and new dosages for the treatment of breast cancer.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	109	Sandostatin LAR for I.M. Injection 10 mg Sandostatin LAR for I.M. Injection 20 mg Sandostatin LAR for I.M. Injection 30 mg (Novartis Pharma K.K.)	Change Change Change	Octreotide acetate	Drugs with a new additional indication and a new dosage for the treatment of gastrointestinal neuroendocrine tumor.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	110	Elplat for Injection 50 mg Elplat for Injection 100 mg Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg (Yakult Honsha Co., Ltd.)	Change Change Change Change	Oxaliplatin	Drugs with a new dosage for post-operative adjuvant chemotherapy for colon cancer.

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Oncology drugs	Nov. 25, 2011	111	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150 (Chugai Pharmaceutical Co., Ltd.)	Change Change	Trastuzumab (genetical recombination)	Drugs with a new additional indication and a new dosage for the treatment of breast cancer with HER2 overexpression.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Nov. 25, 2011	112	Iressa Tablets 250 (AstraZeneca K.K.)	Change	Gefitinib	A drug with a revised indication for the treatment of unresectable advanced or recurrent non-small cell lung cancer in patients with EGFR gene mutation.
Oncology drugs	Dec. 22, 2011	113	Afinitor Tablets 5 mg (Novartis Pharma K.K.)	Change	Everolimus	A drug with a new additional indication and a new dosage for the treatment of pancreatic neuroendocrine tumor.
Oncology drugs	Jan. 18, 2012	114	Ranmark Subcutaneous Injection 120 mg (Daiichi Sankyo Company, Limited)	Approval	<u>Denosumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of bone lesions due to multiple myeloma and bone lesions due to bone metastasis of solid tumor.
Oncology drugs	Feb. 22, 2012	115	Vepesid Capsules 25 mg Vepesid Capsules 50 mg (Bristol-Myers K.K.)  Lastet S Cap. 25 mg Lastet S Cap. 50 mg (Nippon Kayaku Co., Ltd.)	Change Change  Change Change	Etoposide	Drugs with a new additional indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 22, 2012	116	Randa Inj. 10 mg/20 mL Randa Inj. 25 mg/50 mL Randa Inj. 50 mg/100 mL (Nippon Kayaku Co., Ltd.)  Briplatin Injection 10 mg Briplatin Injection 25 mg Briplatin Injection 50 mg (Bristol-Myers K.K.)  Cisplatin Injection 10 mg 'Nichi-iko' Cisplatin Injection 25 mg 'Nichi-iko' Cisplatin Injection 50 mg 'Nichi-iko' (Nichi-Iko Pharmaceutical Co., Ltd.)  Cisplatin for I.V. Infusion 10 mg 'Maruko' Cisplatin for I.V. Infusion 25 mg 'Maruko' Cisplatin for I.V. Infusion 50 mg 'Maruko' (Nichi-Iko Pharmaceutical Co., Ltd.)  Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.)	Change Change Change  Change Change Change  Change Change Change  Change Change Change	Cisplatin	Drugs with a new additional indication and a new dosage for the treatment of biliary tract cancer.  [Public knowledge-based application after PAFSC's preliminary assessment]

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Oncology drugs	Feb. 22, 2012	117	Glivec Tablets 100 mg (Novartis Pharma K.K.)	Change	Imatinib mesilate	A drug with new additional indications and a new dosage for the treatment of FIP1L1-PDGFR $\alpha$ -positive hypereosinophilic syndrome or chronic eosinophilic leukemia.  [Public knowledge-based application after PAFSC's preliminary assessment] [Orphan drug]
Oncology drugs	Mar. 21, 2012	118	Ifomide for Injection 1 g (Shionogi & Co., Ltd.)	Change	Ifosfamide	A drug with a new additional indication and a new dosage for the treatment of malignant lymphoma.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 21, 2012	119	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.)  Paclitaxel Intravenous Infusion 30 mg 'Sandoz' Paclitaxel Intravenous Infusion 100 mg 'Sandoz' (Sandoz K.K.)	Change Change  Change Change  Change Change	Paclitaxel	Drugs with new additional indications and new dosages for the treatment of relapsed or metastatic head and neck cancer, relapsed or metastatic esophagus cancer, angiosarcoma, advanced or relapsed cervical cancer. A new dosage for once-weekly administration for ovarian cancer has also been added.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Mar. 30, 2012	120	Poteligeo Injection 20 mg (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Mogamulizumab (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of recurrent or relapsed CCR4-positive adult T-cell leukemia/lymphoma. [Orphan drug]
Oncology drugs	Mar. 30, 2012	121	Xalkori Capsules 200 mg Xalkori Capsules 250 mg (Pfizer Japan Inc.)	Approval	<u>Crizotinib</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]
Biologicals	Jul. 1, 2011	122	Rotarix Oral Solution (GlaxoSmithKline K.K.)	Approval	<u>Live attenuated human rotavirus vaccine, oral</u>	A drug with a new active ingredient indicated for the prevention of gastroenteritis due to rotavirus.
Biologicals	Jul. 1, 2011	123	Gardasil Aqueous Suspension for Intramuscular Injection Gardasil Aqueous Suspension for Intramuscular Injection Syringe (MSD K.K.)	Approval Approval	<u>Recombinant adsorbed quadrivalent human papillomavirus virus-like particle vaccine (yeast origin)</u>	Drugs with a new active ingredient indicated for the prevention of cervical cancer and its precursor lesions, vulvar intraepithelial neoplasia, vaginal intraepithelial neoplasia, and condyloma acuminatum caused by infection with human papillomavirus types 6, 11, 16 and 18.
Biologicals	Aug. 8, 2011	124	Influenza HA Vaccine "Kaketsuken" TF Influenza HA Vaccine "Kaketsuken" Influ "Kaketsuken" Syringe (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza.  [Expedited review]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Biologicals	Aug. 8, 2011	125	Influenza HA Vaccine "Biken" Flubik HA Flubik HA Syringe (The Research Foundation for Microbial Diseases of Osaka University)	Change Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza.  [Expedited review]
Biologicals	Aug. 8, 2011	126	Influenza HA Vaccine "Seiken" Flu-Syringe "Seiken" (Denka Seiken Co., Ltd.)	Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza.  [Expedited review]
Biologicals	Aug. 8, 2011	127	Influenza HA Vaccine "Kitasatodaiichisankyo" Influenza HA Vaccine "S Hokken" Influenza HA Vaccine "Kitasatodaiichisankyo" Syringe (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)	Change  Change Change	Influenza HA Vaccine	Drugs with a new pediatric dosage indicated for the prevention of influenza.  [Expedited review]
Biologicals	Jan. 18, 2012	128	RotaTeq Oral Solution (MSD K.K.)	Approval	<u>Live attenuated rotavirus vaccine, oral, pentavalent</u>	A drug with a new active ingredient indicated for the prevention of gastroenteritis due to rotavirus.
In vivo diagnosis	Feb. 22, 2012	129	Diagnogreen for Injection 25 mg (Daiichi Sankyo Company, Limited)	Change	Indocyanine green	A drug with a new additional indication and a new dosage for the use of cerebral angiography (by fluorescence measurement in infrared-ray irradiation) in neurosurgical operation.  [Public knowledge-based application after PAFSC's preliminary assessment]
Radio- pharmac euticals	May 20, 2011	130	MyoMIBG-I123 Injection (Fujifilm RI Pharma Co., Ltd.)	Change	3-iodobenzylguanidine ( <sup>123</sup> I) injection	A drug with a new additional indication and a new dosage for diagnosis of melanocytoma in tumor scintigraphy.  [Public knowledge-based application after PAFSC's preliminary assessment]