

Products Approved in FY 2010: New Drugs

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 16, 2010	1	Nesp Injection 10 µg/1 mL Plastic Syringe Nesp Injection 15 µg/1 mL Plastic Syringe Nesp Injection 20 µg/1 mL Plastic Syringe Nesp Injection 30 µg/1 mL Plastic Syringe Nesp Injection 40 µg/1 mL Plastic Syringe Nesp Injection 60 µg/0.6 mL Plastic Syringe Nesp Injection 120 µg/0.6 mL Plastic Syringe Nesp Injection 180 µg/0.9 mL Plastic Syringe (Kyowa Hakko Kirin Co., Ltd.)	Approval Approval Approval Approval Approval Approval Approval	Darbepoetin alfa (genetical recombination)	Drugs with a new route of administration and a new indication for the treatment of renal anemia.
1	Apr. 16, 2010	2	Soliris for Intravenous Infusion 300 mg (Alexion Pharma K.K. (currently Alexion Pharma G.K.))	Approval	<u>Ecuzimab (genetical recombination)</u>	A drug with a new active ingredient indicated to reduce hemolysis in patients with paroxysmal nocturnal hemoglobinuria. [Orphan drug]
1	Jun. 18, 2010	3	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments).
1	Jun. 18, 2010	4	Pariet Tablets 10 mg (Eisai Co., Ltd.)	Change	Sodium rabeprazole	A drug with a new additional indication and a new dosage for the treatment of non-erosive reflux disease.
1	Jul. 23, 2010	5	Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company Limited)	Change Change	Lansoprazole	Drugs with a new additional indication and a new dosage for prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with low-dose aspirin.
1	Aug. 20, 2010	6	Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company Limited)	Change Change	Lansoprazole	Drugs with a new additional indication and a new dosage for prevention of recurrence of gastric ulcer or duodenal ulcer in patients treated with nonsteroidal anti-inflammatory drugs.
1	Oct. 27, 2010	7	Humira 40mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd. )	Change	Adalimumab (genetical recombination)	A drug with new additional indications and a new dosage for the remission induction and maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatment).
1	Oct. 27, 2010	8	Minclea Catapasm for Internal Use 0.8% (Nihon Pharmaceutical Co., Ltd.)	Approval	<u>l-Menthol</u>	A drug with a new additional indication and a new dosage and in an additional dosage form for the inhibition of gastric peristalsis in endoscopy of the upper gastrointestinal tract.
1	Oct. 27, 2010	9	Radiogardase Capsule 500 mg (Nihon Medi-Physics Co., Ltd.)	Approval	<u>Iron(III)hexacyanoferrate(I)</u>	A drug with a new active ingredient indicated for the reduction of internal contamination with radioactive cesium. [Expedited review]
1	Dec. 21, 2010	10	Pariet Tablets 10 mg Pariet Tablets 20 mg (Eisai Co., Ltd.)	Change Change	Sodium rabeprazole	Drugs with new dosages for the treatment of reflux esophagitis.
1	Jan. 21, 2011	11	Altat Capsules 37.5 Altat Capsules 75 (Aska Pharmaceutical Co., Ltd.)	Change Change	Roxatidine acetate hydrochloride	Drugs with new additional pediatric dosages. These drugs are indicated for gastric ulcer, duodenal ulcer, stomal ulcer, Zollinger-Ellison syndrome, reflux esophagitis, preanesthetic medication and improvement of gastric mucosal lesions (erosion, bleeding, redness, edema) during acute gastritis or acute exacerbation phase of chronic gastritis.
1	Mar. 10, 2011	12	Exal for Inj. 10 mg (Nippon Kayaku Co., Ltd.)	Change	Vinblastine sulfate	A drug with a new additional indication and a new dosage for the treatment of Langerhans cell histiocytosis.  [Public knowledge-based application after preliminary assessment by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)]
2	Apr. 16, 2010	13	Unisia Combination Tablets LD Unisia Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Candesartan cilexetil/amlodipine besilate	New combination drugs indicated for the treatment of hypertension.
2	May 13, 2010	14	Tambocor Tablets 50 mg Tambocor Tablets 100 mg (Eisai Co., Ltd.)	Change Change	Flecainide acetate	Drugs with a new additional indication and a new dosage for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia) in children. [Expedited review]
2	Jul. 23, 2010	15	Micamlo Combination Tablets AP (Nippon Boehringer Ingelheim Co., Ltd.)	Approval	Telmisartan/amlodipine besilate	A new combination drug indicated for the treatment of hypertension.
2	Jul. 23, 2010	16	Volibris Tablets 2.5 mg (GlaxoSmithKline K.K.)	Approval	<u>Ambrisentan</u>	A drug with a new active ingredient indicated for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Sep. 10, 2010	17	Ancaron Tablets 100 (Sanofi-Aventis K.K.)	Change	Amiodarone hydrochloride	A drug with a new additional indication for the treatment of arterial fibrillation with cardiac failure (impaired cardiac function).

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2	Oct. 27, 2010	18	Samsca Tablets 15 mg (Otsuka Pharmaceutical Co., Ltd.)	Approval	<u>Tolvaptan</u>	A drug with a new active ingredient indicated for the treatment of fluid retention in heart failure patients who have not responded sufficiently to other diuretics to such as loop diuretics.
2	Oct. 27, 2010	19	Revolade Tablets 12.5 mg Revolade Tablets 25 mg (GlaxoSmithKline K.K.)	Approval Approval	<u>Eltrombopag olamine</u>	Drugs with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura. [Orphan drug]
2	Jan. 21, 2011	20	Memory Tablets 5 mg Memory Tablets 10 mg Memory Tablets 20 mg (Daiichi Sankyo Company, Limited)	Approval Approval Approval	<u>Memantine hydrochloride</u>	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in moderate and severe Alzheimer's dementia.
2	Jan. 21, 2011	21	Reminyl Tablets 4 mg Reminyl Tablets 8 mg Reminyl Tablets 12 mg Reminyl OD Tablets 4 mg Reminyl OD Tablets 8 mg Reminyl OD Tablets 12 mg Reminyl Oral Solution 4 mg/mL (Janssen Pharmaceutical K.K.)	Approval Approval Approval Approval Approval Approval	<u>Galantamine hydrobromide</u>	Drugs with a new active ingredient indicated for inhibition of progression of symptoms of dementia in mild and moderate Alzheimer's dementia.
2	Jan. 21, 2011	22	Prazaxa Capsules 75 mg Prazaxa Capsules 110 mg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	<u>Dabigatran etexilate methanesulfonate</u>	Drugs with a new active ingredient indicated for prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
2	Jan. 21, 2011	23	Romiplate for S.C. Injection 250 µg (Kyowa Hakko Kirin Co., Ltd.)	Approval	<u>Romiplostim (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of chronic idiopathic thrombocytopenic purpura.  [Orphan drug]
2	Jan. 21, 2011	24	Arixtra Injection 5 mg Arixtra Injection 7.5 mg (GlaxoSmithKline K.K.)	Approval Approval	Fondaparinux sodium	Drugs with new additional indications and new dosages for the treatment of acute pulmonary thromboembolism and acute deep vein thrombosis.
2	Feb. 23, 2011	25	Warfarin Tablets 0.5 mg Warfarin Tablets 1 mg Warfarin Tablets 5 mg (Eisai Co., Ltd.)	Change Change Change	Warfarin potassium	Drugs with new additional pediatric dosages. These drugs are indicated for the treatment and prophylaxis of thromboembolism (e.g., phlebotrombosis, myocardial infarction, pulmonary embolism, brain embolism, slowly-progressive cerebral thrombosis).  [Public knowledge-based application after PAFSC's preliminary assessment]
2	Mar. 30, 2011	26	Lipidil Tablets 53.3 mg Lipidil Tablets 80 mg (Aska Pharmaceutical Co., Ltd.)  Tricor Tablets 53.3 mg Tricor Tablets 80 mg (Abbott Japan Co., Ltd.)	Approval Approval Approval	Fenofibrate	Drugs in new dosage forms and with new dosages indicated for the treatment of hyperlipemia (including familial hyperlipemia).
3-1	Apr. 16, 2010	27	Rozerem Tablets 8 mg (Takeda Pharmaceutical Company Limited)	Approval	<u>Ramelteon</u>	A drug with a new active ingredient indicated for the improvement of difficulty with sleep onset in insomnia.
3-1	Apr. 16, 2010	28	Lyrica Capsules 25 mg Lyrica Capsules 75 mg Lyrica Capsules 150 mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Pregabalin</u>	Drugs with a new active ingredient indicated for the treatment of postherpetic neuralgia.
3-1	Jul. 23, 2010	29	E Keppra Tablets 250 mg E Keppra Tablets 500 mg (UCB Japan Co., Ltd.)	Approval Approval	<u>Levetiracetam</u>	Drugs with a new active ingredient 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	Oct. 27, 2010	30	Botox for Injection 50 Units Botox for Injection 100 Units (GlaxoSmithKline K.K.)	Change Change	Botulinum toxin type A	Drugs with new additional indications and new dosages for the treatment of upper and lower limb spasticity.
3-1	Oct. 27, 2010	31	Zyprexa Tablets 2.5 mg Zyprexa Tablets 5 mg Zyprexa Tablets 10 mg Zyprexa Fine Granules 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 manic symptoms in patients with bipolar disorder.
3-1	Oct. 27, 2010	32	Kenketsu Venoglobulin IH 5% I.V. 2.5 g/50 mL (Benesis Corporation)	Change	Polyethylene glycol treated human normal immunoglobulin	A drug with a new additional indication and a new dosage for the improvement of muscular weakness in polymyositis/dermatomyositis (for use only when steroids are not sufficiently effective). [Orphan drug]
3-1	Oct. 27, 2010	33	Invega Tablets 3 mg Invega Tablets 6 mg Invega Tablets 9 mg (Janssen Pharmaceutical K.K.)	Approval Approval Approval	<u>Paliperidone</u>	Drugs with a new active ingredient indicated for the treatment of schizophrenia.
3-1	Oct. 27, 2010	34	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 for the treatment of peripheral neuropathic pain.
3-1	Jan. 21, 2011	35	Nerbloc Intramuscular Injection 2500 Unit (Eisai Co., Ltd.)	Approval	<u>Botulinum toxin type B</u>	A drug with a new active ingredient indicated for the treatment of spasmodic torticollis (cervical dystonia).





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4	Jul. 23, 2010	47	Pasil Intravenous Drip Infusion 300 mg Pasil Intravenous Drip Infusion 500 mg Pasil Intravenous Drip Infusion 1000 mg (Toyama Chemical Co., Ltd.) Pazucross Injection 300 Pazucross Injection 500 Pazucross Injection 1000 mg (Mitsubishi Tanabe Pharma Corporation)	Change Change Approval  Change Change Approval	Pazufloxacin mesilate	Drugs with new additional indications for the treatment of <i>Streptococcus pneumoniae</i> and sepsis and a new dosage in an additional dosage form.
4	Sep. 10, 2010	48	Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)	Approval	<u>Laninamivir octanoate hydrate</u>	A drug with a new active ingredient indicated for the treatment of influenza A or B virus infections.
4	Oct. 27, 2010	49	Cravit Intravenous Drip Infusion 500 mg/100 mL Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Company, Limited)	Approval Approval	Levofloxacin hydrate	Drugs with a new route of administration indicated for the treatment of pneumonia, secondary infection of chronic respiratory disease, typhoid, paratyphoid, anthrax, brucellosis, plague, tularemia and Q fever.
4	Oct. 27, 2010	50	Rapiacta 300 mg Bag for Intravenous Drip Infusion Rapiacta 150 mg Vial for Intravenous Drip Infusion (Shionogi & Co., Ltd.)	Change Change	Peramivir hydrate	Drugs with new additional pediatric dosages for influenza A or B virus infection.
4	Dec. 21, 2010	51	Cravit Ophthalmic Solution 1.5% (Santen Pharmaceutical Co., Ltd.)	Approval	Levofloxacin hydrate	A drug with a new dosage of the 1.5% formulation for the treatment of blepharitis, dacryocystitis, hordeolum, conjunctivitis, meibomianitis, and keratitis (including corneal ulcer) and sterilization during the ophthalmic perioperative period.
4	Mar. 10, 2011	52	Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change	Meropenem hydrate	Drugs with a new dosage (the maximum daily dose has been changed) in patients with general infections that are severe and refractory.
5	Dec. 21, 2010	53	Sodium Phosphate Corrective Injection 0.5 mmol/mL (Otsuka Pharmaceutical Factory, Inc.)	Approval	N/A for this combination drug	A combination prescription drug with similar formulations to be used for the correction of electrolyte levels of electrolyte fluids. [Expedited review]
5	Dec. 21, 2010	54	Lunabell Tablets (Nobelpharma Co., Ltd.)	Change	Norethisterone/ ethinylestradiol	Drugs with a new additional indication for the treatment of functional dysmenorrhoea.
5	Dec. 21, 2010	55	Kindaly 4E Kindaly 4D Kindaly AF-4P (Fuso Pharmaceutical Industries, Ltd.)	Approval Approval Approval	N/A for this combination drug	Combination prescription drugs with similar formulations to be used as the perfusate of dialysis-based artificial kidneys in chronic renal failure (use in patients whose blood sugar level is not controlled well with sugarless dialysate and when other bicarbonate dialysate is not sufficiently effective to improve hyperkalemia and hypermagnesemia, or when hypercalcemia may occur).
5	Jul. 23, 2010	56	Yaz Combination Tablets (Bayer Yakuhin, Ltd.)	Approval	<u>Drospirenone/ethinylestradiol betadex</u>	A new combination drug with a new active ingredient indicated for the treatment of dysmenorrhoea.
5	Feb. 23, 2011	57	Prostandin 20 for Injection (Ono Pharmaceutical Co., Ltd.)	Change	Alprostadil alfadex	A drug with a new route of administration and a new dosage for a new additional indication for the diagnosis of erectile disturbance.
5	Feb. 23, 2011	58	Norlevo Tablets 0.75 mg (Sosei Co., Ltd.)	Approval	Levonorgestrel	A drug with a new additional indication and a new dosage for emergency contraception.
6-1	Apr. 16, 2010	59	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new additional indication and a new dosage for the treatment of ankylosing spondylitis in patients who have not responded sufficiently to conventional treatments. [Orphan drug]
6-1	Apr. 16, 2010	60	Diqas Ophthalmic Solution 3% (Santen Pharmaceutical Co., Ltd.)	Approval	<u>Diquafosol sodium</u>	A drug with a new active ingredient indicated for the treatment of dry eye.
6-1	Jul. 23, 2010	61	Orencia for I.V. Infusion 250 mg (Bristol-Myers K.K.)	Approval	<u>Abatacept (genetical recombination)</u>	A drug with a new active ingredient indicated for the treatment of rheumatoid arthritis (for use only in patients who have not sufficiently responded to conventional treatments).
6-1	Jul. 23, 2010	62	Synvisc Intraarticular Injection 2 mL (Genzyme Japan K.K.)	Approval	<u>Sodium hyaluronate crosslinked polymer and sodium hyaluronate crosslinked polymer crosslinked with vinylsulfone</u>	A drug with a new active ingredient indicated for pain relief in patients with knee osteoarthritis who have not responded sufficiently to conservative non-drug treatment and oral drug treatment.
6-1	Jul. 23, 2010	63	Pulmicort 100 µg Turbuhaler 112 doses Pulmicort 200 µg Turbuhaler 56 doses Pulmicort 200 µg Turbuhaler 112 doses (AstraZeneca K.K.)	Change Change Change	Budesonide	Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma.
6-1	Jul. 23, 2010	64	Allelock Tablets 2.5 Allelock Tablets 5 Allelock OD Tablets 2.5 Allelock OD Tablets 5 (Kyowa Hakko Kirin Co., Ltd.)	Change Change Change Change	Olopatadine hydrochloride	Drugs 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).

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6-1	Oct. 27, 2010	65	Nevanac Ophthalmic Suspension 0.1% (Alcon Japan Ltd.)	Approval	<u>Nepafenac</u>	A drug with a new active ingredient indicated for the treatment of postoperative inflammation in intraocular surgery.
6-1	Oct. 27, 2010	66	Xyzal Tablets 5 mg (GlaxoSmithKline K.K.)	Approval	<u>Levocetirizine</u> <u>hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of allergic rhinitis, urticaria, eczema/dermatitis, prurigo and cutaneous pruritus.
6-1	Oct. 27, 2010	67	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 of ankylosing spondylitis (for use only in patients who have not sufficiently responded to conventional treatment). [Priority review]
6-1	Nov. 16, 2010	68	Pulmicort Respules 0.25 mg Pulmicort Respules 0.5 mg (AstraZeneca K.K.)	Change Change	Budesonide	Drugs with new additional adult and pediatric (5 years of age and older) dosages for the treatment of bronchial asthma.
6-1	Jan. 21, 2011	69	Stelara Subcutaneous Injection 45 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Ustekinumab</u> (genetical recombination)	A drug with a new active ingredient indicated for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional treatments.
6-1	Jan. 21, 2011	70	Alvesco 50 µg Inhaler 112 puffs Alvesco 100 µg Inhaler 112 puffs Alvesco 100 µg Inhaler 56 puffs Alvesco 200 µg Inhaler 56 puffs (Teijin Pharma Limited)	Change Change Approval Change	Ciclesonide	Drugs with a new additional pediatric dosage indicated for the treatment of bronchial asthma.
6-1	Jan. 21, 2011	71	Calonal Fine Gran. 20% Calonal Fine Gran. 50% Calonal Tab. 200 Calonal Tab. 300 Calonal Powder (Showa Yakuhin Kako Co., Ltd.)  Cocaril Dry Syr. 40% Cocaril Tab. 200 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)  Calsil Fine Granules 20% Calsil Tablets 200 (Taiyo Pharmaceutical Industry Co., Ltd.)  Anyrume Fine Granules 20% Anyrume Tablets 200 mg Anyrume Tablets 300 mg Pyrinazin Powder (Choseido Pharmaceutical Co., Ltd.)  Napa (Mylan Seiyaku Ltd.)	Change Change Change Change Change  Change Change  Change Change Change Change  Change	Acetaminophen	Drugs with a new additional indication for the treatment of osteoarthritis and with an expanded dosage of acetaminophen.
6-1	Feb. 23, 2011	72	Rheumatrex Capsules 2 mg (Pfizer Japan Inc.)  Methotrexate Tablets 2 mg "Tanabe" (Mitsubishi Tanabe Pharma Corporation)  Methotrexate Cap. 2 mg "Mylan" (Mylan Seiyaku Ltd.)  Trexamette Capsules 2 mg (Shiono Chemical Co., Ltd.)  Methotrexate Capsules 2 mg "Towa" (Towa Pharmaceutical Co., Ltd.)  Metolate Tablets 2 mg (Santen Pharmaceutical Co., Ltd.)  Methotrexate Cap. 2 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.)	Change  Change  Change  Change  Change  Change	Methotrexate	Drugs with a revised indication and an expanded dosage for the treatment of rheumatoid arthritis (limitation of patients to be treated was abolished).
6-1	Feb. 23, 2011	73	Mohrus Tape 20 mg Mohrus Tape L 40 mg (Hisamitsu Pharmaceutical Co., Inc.)	Change Change	Ketoprofen	Drugs with new additional indications for the treatment of myalgia and post-traumatic swelling/pain.
6-1	Feb. 23, 2011	74	Endoxan for Injection 100 mg Endoxan for Injection 500 mg Endoxan Tablets 50 mg (Shionogi & Co., Ltd.)	Change Change Change	Cyclophosphamide	Drugs with a new additional indication and new dosages for treatment-resistant rheumatic disease in adults and children.  [Public knowledge-based application after PAFSC's preliminary assessment]

Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
6-2	Apr. 16, 2010	75	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	<u>Alogliptin benzoate</u>	Drugs with a new active ingredient indicated for the treatment of type 2 diabetes (for use only in patients with inadequate glycemic control by following treatments: 1. Treatment by diet and exercise only 2. In addition to treatment by diet and exercise, treatment by alpha-glucosidase inhibitor).
6-2	Apr. 16, 2010	76	Metact Combination Tablets LD Metact Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Pioglitazone hydrochloride/metformin hydrochloride	New combination drugs indicated for the treatment of type 2 diabetes (only when a concomitant use of pioglitazone hydrochloride with metformin hydrochloride is deemed appropriate).
6-2	Jun. 18, 2010	77	Amaryl 0.5 mg Tablets Amaryl 1 mg Tablets Amaryl 3 mg Tablets (Sanofi-Aventis K.K.)	Change Change Change	Glimepiride	Drugs with a new dosage 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. 23, 2010	78	Forteo S.C. Injection Kit 600 µg Forteo S.C. Injection Cart 600 µg (Eli Lilly Japan K.K.)	Approval Approval	<u>Teriparatide (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of osteoporosis with a high risk of fracture.
6-2	Jul. 23, 2010	79	Viviant Tablets 20 mg (Pfizer Japan Inc.)	Approval	<u>Bazedoxifene acetate</u>	A drug with a new active ingredient indicated for the treatment of postmenopausal osteoporosis.
6-2	Aug. 20, 2010	80	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Alogliptin benzoate	Drugs with a new additional indication for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to thiazolidinediones along with diet and exercise therapies.
6-2	Oct. 27, 2010	81	Byetta Subcutaneous Injection 5 µg Pen 300 Byetta Subcutaneous Injection 10 µg Pen 600 Byetta Subcutaneous Injection 10 µg Pen 300 (Eli Lilly Japan K.K.)	Approval Approval Approval	<u>Exenatide</u>	Drugs 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 treatment with sulfonylurea [including concomitant treatment with biguanides or thiazolidines] along with diet and exercise therapies).
6-2	Jan. 21, 2011	82	Surepost Tablets 0.25 mg Surepost Tablets 0.5 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval	<u>Repaglinide</u>	Drugs with a new active ingredient indicated for the improvement of postprandial changes of blood glucose in type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] alpha-glucosidase inhibitors along with diet and exercise therapies).
6-2	Jan. 21, 2011	83	Feburic Tablet 10 mg Feburic Tablet 20 mg Feburic Tablet 40 mg (Teijin Pharma Limited)	Approval Approval Approval	<u>Febuxostat</u>	Drugs with a new active ingredient indicated for the treatment of gout and hyperuricemia.
6-2	Jan. 21, 2011	84	Sonias Combination Tablets LD Sonias Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Pioglitazone hydrochloride/glimepiride	New combination drugs indicated for the treatment of type 2 diabetes mellitus (only when a concomitant use of pioglitazone hydrochloride with glimepiride is deemed appropriate).
6-2	Jan. 21, 2011	85	Edirol Capsule 0.5 µg Edirol Capsule 0.75 µg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Eldecalcitol</u>	Drugs with a new active ingredient indicated for the treatment of osteoporosis.
6-2	Feb. 23, 2011	86	Nesina Tablets 6.25 mg Nesina Tablets 12.5 mg Nesina Tablets 25 mg (Takeda Pharmaceutical Company Limited)	Change Change Change	Alogliptin benzoate	Drugs with new additional indications for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to sulfonylureas or biguanides along with diet and exercise therapies.
6-2	Mar. 10, 2011	87	L-Carnit Tablets 100 mg L-Carnit Tablets 300 mg (Otsuka Pharmaceutical Co., Ltd.)	Change Change	Levocarnitine chloride	Drugs with a new additional indication and new dosages for the treatment of carnitine deficiency.  [Public knowledge-based application after PAFSC's preliminary assessment]
6-2	Mar. 23, 2011	88	Novolin R FlexPen Novolin R 100 IU/mL Novolin 30R FlexPen Novolin N FlexPen InnoLet 30R (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval	<u>Insulin human (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of diabetes mellitus in cases where insulin therapy is indicated.  However, 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.
Oncology drugs	Apr. 16, 2010	89	Vectibix for Intravenous Infusion 100 mg (Takeda Pharmaceutical Company Limited) Vectibix for Intravenous Infusion 100 mg "Takeda Bio" (Takeda Bio Development Center Limited)	Approval Approval	<u>Panitumumab (genetical recombination)</u>	Drugs with a new active ingredient indicated for the treatment of unresectable, advanced or recurrent colorectal cancer with wild-type KRAS.
Oncology drugs	Jun. 25, 2010	90	Revlimid Capsules 5 mg (Celgene K.K.)	Approval	<u>Lenalidomide hydrate</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Jun. 18, 2010	91	LenaDex Tablets 4 mg (Celgene K.K.)	Approval	Dexamethasone	A drug with a new additional indication and a new dosage for the treatment of multiple myeloma. [Expedited review]

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Oncology drugs	Jul. 23, 2010	92	Torisel Injection 25 mg (Pfizer Japan Inc.)	Approval	<u>Temsirolimus</u>	A drug with a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma.
Oncology drugs	Jul. 23, 2010	93	Abraxane I.V. Infusion 100 mg (Taiho Pharmaceutical Co., Ltd.)	Approval	Paclitaxel	A drug in a new dosage form and with a new dosage indicated for the treatment of breast cancer.
Oncology drugs	Aug. 20, 2010	94	Immucyst Intravesical 81 mg (Nippon Kayaku Co., Ltd.)	Change	Freeze-dried bacillus of Calmette and Guerin for intravesical use (Connaught strain)	A drug with a new additional dosage indicated for the treatment of superficial bladder cancer and carcinoma in situ of bladder.
Oncology drugs	Aug. 20, 2010	95	Revlimid Capsules 5 mg (Celgene K.K.)	Change	Lenalidomide hydrate	A drug with a new additional indication and a new dosage for the treatment of myelodysplastic syndrome associated with a deletion 5q cytogenetic abnormality. [Orphan drug]
Oncology drugs	Oct. 27, 2010	96	Treakisym Injection 100 mg (SymBio Pharmaceuticals Limited)	Approval	<u>Bendamustine hydrochloride</u>	A drug with a new active ingredient indicated for the treatment of relapsed or refractory indolent B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. [Orphan drug]
Oncology drugs	Nov. 16, 2010	97	Taxotere 20 mg for I.V. Infusion Taxotere 80 mg for I.V. Infusion (Sanofi-Aventis K.K.)	Change Change	Docetaxel hydrate	Drugs with new dosages for the treatment of breast cancer, non-small cell lung cancer, gastric cancer, head and neck cancer and ovarian cancer.
Oncology drugs	Dec. 21, 2010	98	Tasigna Capsules 150 mg Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Approval Change	Nilotinib hydrochloride hydrate	Drugs with new additional indications and a new dosage for the treatment of chronic- or accelerated-phase chronic myelocytic leukaemia.
Oncology drugs	Jan. 21, 2011	99	Vidaza for Injection 100 mg (Nippon Shinyaku Co., Ltd.)	Approval	<u>Azacitidine</u>	A drug with a new active ingredient indicated for the treatment of myelodysplastic syndrome.  [Orphan drug]
Oncology drugs	Feb. 23, 2011	100	Hycamtin for Injection 1.1 mg (Nippon Kayaku Co., Ltd.)	Change	Nogitecan hydrochloride	A drug with a new additional indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 23, 2011	101	Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent gastric cancer.  [Public knowledge-based application after PAFSC's preliminary assessment]
Oncology drugs	Feb. 23, 2011	102	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change Change	Gemcitabine hydrochloride	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	Mar. 10, 2011	103	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 unresectable advanced or recurrent gastric cancer with HER2 overexpression.  [Priority review]
AIDS drugs	Dec. 8, 2010	104	Kaletra Combination Tablets (Abbott Japan Co., Ltd.)	Change	Lopinavir/ritonavir	A drug with new dosages for the treatment of HIV infection. [Orphan drug]
Biologicals	Oct. 27, 2010	105	Adsorbed Pandemic Influenza Vaccine (H5N1) "Kaketsuken" (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	<u>Inactivated influenza virus, H5N1 (whole virion)</u>	A drug with a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Biologicals	Jan. 14, 2011	106	Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine "Hokken" (The Kitasato Institute)	Approval	<u>Freeze-dried live attenuated measles, rubella combined vaccine</u>	A drug with a new active ingredient indicated for the prevention of measles and rubella.
Biologicals	Jan. 17, 2011	107	Encevac for Subcutaneous Injection (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Approval	<u>Freeze-dried, cell culture-derived Japanese encephalitis vaccine (inactivated)</u>	A drug with a new active ingredient indicated for the prevention of Japanese encephalitis.  [Expedited review]
Blood products	May 13, 2010	108	Venoglobulin IH 5% I.V. 2.5 g/50 mL (Benesis Corporation)	Change	Polyethylene glycol treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	109	Kenketsu Venilon-I for Intravenous Injection 2500 mg (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute])	Change	Freeze-dried sulfonated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	110	Kenketu Glovenin-I for I.V. Injection 2500 mg (Nihon Pharmaceutical Co., Ltd.)	Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.



Review Category	Approval Date	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
Blood products	May 13, 2010	111	Nisseki Polyglobin-N 5% I.V. 2.5 g/50 mL (Japanese Red Cross Society)	Change	pH4-treated acidic human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	112	Sanglopor I.V. Infusion 2.5 g (CSL Behring AG; designated marketing authorization holder, CSL Behring K.K.)	Change	Freeze-dried pH4 treated human immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	May 13, 2010	113	Gammagard for Intravenous Injection 2.5 g (Baxter Limited)	Change	Freeze-dried ion-exchange-resin treated human normal immunoglobulin	A drug with a new dosage indicated for the treatment of hypogammaglobulinemia or agammaglobulinemia.
Blood products	Jun. 18, 2010	114	Epogin Subcutaneous Injection Syringe 24000 (Chugai Pharmaceutical Co., Ltd.)	Approval	Epoetin beta (genetical recombination)	A drug with a new dosage in a new additional dosage form indicated for autologous blood storage.