

Table 1. FY 2008 List of Approved Products: New Drugs

Category	Approval Date		Brand Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined: new active ingredient)	Notes
1	Apr. 16, 2008	1	Exjade Dispersible Tablets 125 mg Exjade Dispersible Tablets 500 mg (Novartis Pharma K.K.)	Approval Approval	<u>Deferasirox</u>	Drugs with a new active ingredient indicated for the treatment of chronic iron overload due to blood transfusions (In patients for whom injection of iron chelating agents is inappropriate). [Priority review]
1	Jun. 6, 2008	2	Simulect I.V. Injection 10 mg for Pediatric (Novartis Pharma K.K.)	Approval	Basiliximab (genetical recombination)	A drug with a new dosage and in a new dosage form indicated for suppression of acute organ rejection after renal transplantation. [Orphan drug]
1	Jul. 16, 2008	3	Irribow Tablets 2.5 µg Irribow Tablets 5 µg (Astellas Pharma Inc.)	Approval Approval	Ramosectron hydrochloride	Drugs with a new indication and new dosages for the treatment of diarrhea-predominant irritable bowel syndrome in men.
1	Jul. 16, 2008	4	Graceptor Capsules 0.5 mg Graceptor Capsules 1 mg Graceptor Capsules 5 mg (Astellas Pharma Inc.)	Approval Approval Approval	Tacrolimus hydrate	Drugs in a new dosage form indicated for suppression of organ rejection in renal, liver, heart, lung, and pancreatic transplantation, as well as for suppression of graft rejection and graft versus host disease (GVHD) in bone marrow transplantation.
1	Jul. 16, 2008	5	Differin Gel 0.1% (Galderma S.A.)	Approval	<u>Adapalene</u>	A drug containing a new active ingredient indicated for the treatment of acne vulgaris.
1	Oct. 16, 2008	6	Sumiferon 300 Sumiferon 600 Sumiferon DS 300 Sumiferon DS 600 (Dainippon Sumitomo Pharma Co., Ltd.)	Change Change Change Change	Interferon alfa (NAMALWA)	Drugs with a new indication and a new dosage for the treatment of viremia in patients with compensated cirrhosis type C (excluding patients with high blood levels of serogroup 1 HCV-RNA).
1	Oct. 16, 2008	7	Fosrenol Chewable Tablets 250 mg Fosrenol Chewable Tablets 500 mg (Bayer Yakuhin Ltd.)	Approval Approval	<u>lanthanum carbonate hydrate</u>	Drugs containing a new active ingredient indicated for the treatment of hyperphosphatemia in dialysis patients with chronic renal failure.
1	Oct. 16, 2008	8	Kenketu Glovenin-I-Nichiyaku (Nihon Pharmaceutical Co., Ltd.)	Change	Freeze-dried polyethylene glycol treated human normal immunoglobulin	A drug with a new indication and a new dosage for the treatment of pemphigus (for use when steroid drugs are not sufficiently effective).
1	Nov. 25, 2008	9	Oxarol Ointment 25 µg/g Oxarol Lotion 25 µg/g (Chugai Pharmaceutical Co., Ltd.)	Change Change	Maxacalcitol	Drugs with a new indication for the treatment of palmoplantar pustulosis.
1	Dec. 22, 2008	10	Pentasa Tablets 250 Pentasa Tablets 500 (Nissin Kyorin Pharmaceutical Co., Ltd. (currently Kyorin Pharmaceutical Co., Ltd.))	Change Change	Mesalazine	Drugs with a new dosage indicated for the treatment of ulcerative colitis (excluding severe cases).
2	Apr. 16, 2008	11	Irbetan Tablets 50 mg Irbetan Tablets 100 mg (Shionogi & Co., Ltd.) Avapro Tablets 50 mg Avapro Tablets 100 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval Approval Approval Approval	<u>Irbesartan</u>	Drugs containing a new active ingredient indicated for the treatment of hypertension.
2	May 20, 2008	12	Arixtra Injection 1.5 mg Arixtra Injection 2.5 mg (GlaxoSmithKline K.K.)	Change Change	Fondaparinux sodium	Drugs with a new indication for prophylaxis of venous thromboembolism in patients undergoing abdominal surgery who are at a high risk of developing venous thromboembolism. [Priority review]
2	Jul. 16, 2008	13	INOflo for Inhalation 800 ppm (INO therapeutics LLC)	Approval	<u>Nitric oxide</u>	A drug containing a new active ingredient indicated for the treatment of hypoxic respiratory failure (HRF) with concurrent pulmonary hypertension in neonates. [Orphan drug]
2	Jul. 16, 2008	14	Novastan HI Inj. 10 mg/2mL (Mitsubishi Tanabe Pharma Corporation) Slonnon HI Injection 10 mg/2mL (Daichi Sankyo Co., Ltd.)	Change Change	Argatroban hydrate	Drugs with a new indication and a new dosage for prophylaxis of thrombosis in patients with heparin-induced thrombocytopenia (HIT) type II. [Orphan drug]
2	Oct. 16, 2008	15	Bepicor Tablets 50 mg Bepicor Tablets 100 mg (Schering-plough K.K.)	Change Change	Bepidil hydrochloride hydrate	Drugs with a new indication for the treatment of persistent atrial fibrillation in patients in whom other antiarrhythmic drugs are contraindicated or who have not responded to other antiarrhythmic drugs. [Priority review]
2	Jan. 21, 2009	16	Trierief Tablets 25 mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Zonisamide	A drug with a new indication and a new dosage for the treatment of Parkinson's disease (in patients who have been treated with other anti-Parkinson drugs in combination with a levodopa-containing agent, but sufficient therapeutic effect was not obtained).
2	Jan. 21, 2009	17	Co-Dio Combination Tablets MD Co-Dio Combination Tablets EX (Novartis Pharma K.K.)	Approval Approval	Valsartan/ hydrochlorothiazide	New combination drugs indicated for the treatment of hypertension.
2	Jan. 21, 2009	18	Ecard Combination Tablets LD Ecard Combination Tablets HD (Takeda Pharmaceutical Company Limited)	Approval Approval	Candesartan cilexetil/hydrochlorothiazide	New combination drugs indicated for the treatment of hypertension.
2	Feb. 23, 2009	19	Clexane Subcutaneous Injection Kit 2000 IU (Sanofi-Aventis K.K.)	Change	Enoxaparin sodium	A drug with a new additional indication for prophylaxis of venous thromboembolism in patients undergoing abdominal surgery who are at a high risk of developing venous thromboembolism.

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2	Feb. 23, 2009	20	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	Amlodipine besilate	Drugs with a new dosage indicated for the treatment of hypertension and angina pectoris.
3	Apr. 16, 2008	21	Popscaine 0.75% Inj. 75 mg/10 mL Popscaine 0.75% Inj. 150 mg/20 mL Popscaine 0.25% Inj. 25 mg/10 mL Popscaine 0.25% Inj. Bag 250 mg/100 mL Popscaine 0.75% Inj. Syringe 75 mg/10 mL Popscaine 0.25% Inj. Syringe 25 mg/10 mL (Maruishi Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	<u>Levobupivacaine hydrochloride</u>	Drugs containing a new active ingredient. The 0.25% formulation is indicated for postoperative analgesia, and the 0.75% formulation is indicated for epidural anaesthesia.
3	Jul. 16, 2008	22	AtvagoReverse Intravenous Injection Syringe 3 mL AtvagoReverse Intravenous Injection Syringe 6 mL (Terumo Corporation)	Approval Approval	Neostigmine methylsulfate/ atropine sulfate hydrate	New combination drugs indicated for reversal of nondepolarizing muscle relaxants.
3	Jul. 16, 2008	23	Macugen Ivt Inj. Kit 0.3 mg (Pfizer Japan Inc.)	Approval	<u>Pegaptanib sodium</u>	A drug containing a new active ingredient indicated for treatment of age-related macular degeneration with concurrent choroidal neovascularization. [Orphan drug]
3	Oct. 16, 2008	24	Lamictal Tablets 2 mg for Children Lamictal Tablets 5 mg for Children Lamictal Tablets 25 mg Lamictal Tablets 100 mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	<u>Lamotrigine</u>	Drugs containing a new active ingredient indicated for use as adjunctive treatment with other antiepileptic drugs for partial seizures (including secondary generalized seizures), tonic-clonic seizures, and generalized seizures associated with Lennox-Gastaut syndrome in patients with epilepsy for whom other antiepileptic drugs are not sufficiently effective.
3	Oct. 16, 2008	25	Tapros Ophthalmic Solution 0.0015% (Santen Pharmaceutical Co., Ltd.)	Approval	<u>Tafloprost</u>	A drug containing a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3	Oct. 16, 2008	26	Noberbar 250 mg for Injection (Nobelpharma Co., Ltd.)	Approval	Phenobarbital sodium	A drug with a new route of administration indicated for the treatment of 1) neonatal seizures and 2) status epilepticus. [Orphan drug: 1]
3	Jan. 21, 2009	27	Remitch Capsules 2.5 µg (Toray Industries, Inc.)	Approval	<u>Nalfurafine hydrochloride</u>	A drug containing a new active ingredient indicated for the treatment of pruritus in hemodialysis patients (for use only when conventional therapies are not sufficiently effective).
3	Jan. 21, 2009	28	Lucentis Solution for Intravitreal Injection 2.3 mg/0.23 mL (Novartis Pharma K.K.)	Approval	<u>Ranibizumab (genetical recombination)</u>	A drug containing a new active ingredient indicated for treatment of age-related macular degeneration with concurrent choroidal neovascularization. [Orphan drug]
3	Jan. 21, 2009	29	Botox Vista Injection 50 Units (GlaxoSmithKline K.K.)	Approval	Botulinum toxin type A	A drug with a new indication and a new dosage for the temporary improvement in the appearance of glabellar lines between the brows in adults aged under 65 years.
3	Feb. 23, 2009	30	Botox Injection 50 Botox Injection 100 (GlaxoSmithKline K.K.)	Change	Botulinum toxin type A	Drugs with a new additional indication and a new dosage for the treatment of equinus deformity associated with lower limb spasticities in juvenile cerebral palsy in patients 2 years or older.
4	Apr. 16, 2008	31	Famvir Tab. 250 mg Famciclovir (Asahi Kasei Pharma Corporation)	Approval Approval	<u>Famciclovir</u>	A drug containing a new active ingredient indicated for the treatment of herpes zoster.
4	Jul. 16, 2008	32	Zosyn 2.25 g for Intravenous Injection Zosyn 4.5 g for Intravenous Injection (Taiho Pharmaceutical Co., Ltd.)	Approval Approval	Tazobactam/ piperacillin hydrate	New combination drugs indicated for the treatment of septicemia, pneumonia, pyelonephritis, and complicated cystitis.
4	Jul. 16, 2008	33	Mycobutin Capsules 150 mg (Pfizer Japan Inc.)	Approval	<u>Rifabutin</u>	A drug containing a new active ingredient indicated for the treatment of 1) tuberculosis, 2) non-tuberculous mycobacteriosis including mycobacterium avium complex (MAC) infections, and 3) prophylaxis of disseminated MAC infections in patients with HIV disease.
4	Aug. 29, 2008	34	Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200 mg (Abbott Japan Co., Ltd.)	Change Change	Clarithromycin	Drugs with a new indication and a new dosage for non-tuberculous mycobacteriosis including mycobacterium avium complex (MAC) infections.
4	Sep. 24, 2008	35	Hepsera Tablets 10 (GlaxoSmithKline K.K.)	Change	Adefovir dipivoxil	A drug with a new indication for inhibition of hepatitis B virus replication in patients with type B chronic liver disease in whom abnormal hepatic function was observed in association with proliferation of hepatitis B virus.
4	Jan. 21, 2009	36	Zithromac SR Dry Syrup 2 g for Adults (Pfizer Japan Inc.)	Approval	Azithromycin hydrate	A drug with a new additional indication for Neisseria gonorrhoeae infections, with a new dosage in a new dosage form. Conversion from an immediate release formulation of azithromycin to a sustained release formulation.

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5	Apr. 16, 2008	37	Julina Tablets 0.5 mg (Bayer Yakuin, Ltd.)	Approval	Estradiol	A drug with a new route of administration indicated for the treatment of vasomotor symptoms (hot flushes and sweating) and vaginal atrophy symptoms associated with climacteric disturbance and ovarian deficiency symptoms.
5	Apr. 16, 2008	38	Lunabell Tablets (Nobelpharma Co., Ltd.)	Approval	Norethisterone/ ethinylestradiol	A new combination drug indicated for the treatment of dysmenorrhea associated with endometriosis.
5	Jul. 16, 2008	39	Ganirest Subcutaneous 0.25 mg Syringe (Nippon Organon K.K.)	Approval	<u>Ganirelix acetate</u>	A drug containing a new active ingredient indicated for prevention of premature ovulation during controlled ovarian stimulation.
5	Sep. 1, 2008	40	Gonatropin 5000 (ASKA Pharmaceutical Co., Ltd.)	Change	[JP] Human chorionic gonadotrophin (extract from human urine)	A drug with a new route of administration and a new indication for induction of spermatogenesis in male hypogonadotropic hypogonadism. [Expedited review]
5	Oct. 16, 2008	41	Menoaid Combipatch (ASKA Pharmaceutical Co., Ltd.)	Approval	Estradiol/norethisterone acetate	A new combination drug indicated for the treatment of vasomotor symptoms (hot flushes and sweating associated with climacteric disturbance and ovarian deficiency symptoms).
5	Mar. 31, 2009	42	Elneopa No. 1 Injection Elneopa No. 2 Injection (Otsuka Pharmaceutical Factory, Inc.)	Approval Approval	N/A for this combination drug	A combination drug similar to other products indicated for the supplementation of water, electrolytes, calories (a calorie source), amino acids, vitamins, Zn, Fe, Mn, and I in patients in whom peroral or enteral nutrition is impossible or insufficient, and who have to rely on parenteral nutrition.
6-1	Apr. 16, 2008	43	Actemra 80 mg for Intravenous Infusion Actemra 200 mg for Intravenous Infusion Actemra 400 mg for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Approval Change Approval	Tocilizumab (genetical recombination)	Drugs with a new indication and a new dosage in a new dosage form for the treatment of rheumatoid arthritis (including prevention of structural damage of joint) that cannot be treated sufficiently with conventional therapies, active juvenile idiopathic arthritis in multiple joints, and systemic juvenile idiopathic arthritis. [Priority review] [Expedited review]
6-1	Apr. 16, 2008	44	Humira 40mg for S.C. Injection (Abbott Japan Co., Ltd.)	Approval	<u>Adalimumab</u> (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of rheumatoid arthritis (for use only when conventional therapies are not sufficiently effective).
6-1	Jul. 16, 2008	45	Nasonex Nasal Suspension 50 µg 56 spray Nasonex Nasal Suspension 50 µg 112 spray (Schering-Plough K.K.)	Approval Approval	<u>Mometasone furoate</u> <u>hydrate</u>	Drugs containing a new active ingredient indicated for the treatment of allergic rhinitis.
6-1	Sep. 24, 2008	46	Rheumatrex Capsules 2 mg (Wyeth K.K.) Trexamette Capsules 2 mg (Shiono Chemical Co., Ltd.) Methotrexate Cap. 2 mg "Sawai" (Sawai Pharmaceutical Co., Ltd.) Methotrexate Capsules 2 mg "Towa" (Towa Pharmaceutical Co., Ltd.) Methotrexate Cap. 2 mg "Mylan" (Mylan Seiyaku Ltd.) Metolate Tablets 2 mg (Santen Pharmaceutical Co., Ltd.) Methotrexate Tablets 2 mg "Tanabe" (Mitsubishi Tanabe Pharma Corporation)	Change Change Change Change Change Change	Methotrexate	Drugs with a new indication and a new dosage for the treatment of juvenile idiopathic arthritis accompanied by articular symptoms. [Expedited review]
6-1	Oct. 16, 2008	47	Neoral solution Neoral 10 mg Capsules Neoral 25 mg Capsules Neoral 50 mg Capsules (Novartis Pharma K.K.)	Change Change Change Change	Cyclosporine	Drugs with a new indication and a new dosage for the treatment of atopic dermatitis (in patients in whom conventional therapies are not sufficiently effective).
6-1	Oct. 16, 2008	48	Pirespa Tablets 200 mg (Shionogi & Co., Ltd.)	Approval	<u>Pirfenidone</u>	A drug containing a new active ingredient indicated for the treatment of idiopathic pulmonary fibrosis. [Orphan drug]
6-1	Jan. 21, 2009	49	Xolair for S.C. Injection (Novartis Pharma K.K.)	Approval	<u>Omalizumab</u> (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies).
6-1	Jan. 21, 2009	50	Adoair 250 Diskus (GlaxoSmithKline K.K.)	Change	Salmeterol xinafoate/fluticasone propionate	A drug with a new additional indication and a new dosage for the alleviation of various symptoms associated with chronic obstructive pulmonary disease (chronic bronchitis and emphysema) (for use when concomitant use of inhaled corticosteroid and long-acting β <sub>2</sub> -agonist is required).
6-1	Jan. 21, 2009	51	Adoair 100 Diskus Adoair 50 Air 120 puffs (GlaxoSmithKline K.K.)	Change Approval	Salmeterol xinafoate/fluticasone propionate	A drug with a new additional pediatric dosage in a new dosage form indicated for the treatment of bronchial asthma (for use when concomitant use of inhaled corticosteroid and long-acting β <sub>2</sub> -agonist is required). [Expedited review]

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6-2	Apr. 16, 2008	52	Aroglycem Capsules 25 mg (Schering-plough K.K.)	Approval	<u>Diazoxide</u>	A drug containing a new active ingredient indicated for the treatment of hyperinsulinemic hypoglycemia. [Priority review]
6-2	Jul. 16, 2008	53	Biopten Granules 2.5% (Asubio Pharma Co., Ltd.)	Change	Sapropterin hydrochloride	A drug with a new indication and a new dosage for reduction of serum phenylalanine levels in patients with hyperphenylalaninemia (tetrahydrobiopterin-responsive hyperphenylalaninemia) caused by tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency. [Orphan drug]
6-2	Jul. 16, 2008	54	Actonel Tab. 17.5 mg (Ajinomoto Co., Inc.) Benet Tablets 17.5 mg. (Takeda Pharmaceutical Co., Ltd.)	Change Change	Risedronate sodium hydrate	Drugs with a new indication and a new dosage for the treatment of Paget's disease of bone. [Orphan drug]
6-2	Oct. 16, 2008	55	1) Wellnara Combination Tablets (Bayer Yakuhin, Ltd.) 2) Julina 0.5 mg (Bayer Yakuhin, Ltd.)	Approval Change	1) Estradiol/levonorgestrel 2) Estradiol	1) A new combination drug and 2) a drug with a new indication and a new dosage for the treatment of postmenopausal osteoporosis.
6-2	Oct. 16, 2008	56	Genotropin 5.3 mg Genotropin MiniQuick S.C. Inj. 0.4 mg Genotropin MiniQuick S.C. Inj. 0.6 mg Genotropin MiniQuick S.C. Inj. 0.8 mg Genotropin MiniQuick S.C. Inj. 1.0 mg Genotropin MiniQuick S.C. Inj. 1.4 mg Genotropin Inj. 12 mg (Pfizer Japan Inc.)	Change Change Change Change Change Change Change	Somatropin (genetical recombination)	Drugs with a new indication and a new dosage for the treatment of dwarfism with no epiphyseal closure in patients born small-for-gestational age (SGA).
6-2	Dec. 22, 2008	57	Seibule Tablets 25 mg Seibule Tablets 50 mg Seibule Tablets 75 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change Change Change	Miglitol	Drugs with a new indication for the treatment of postprandial hyperglycemia in Type 2 diabetes mellitus (for use only in patients who have not benefited sufficiently from taking insulin preparations in conjunction with dietary and exercise regimens) and the treatment of postprandial hyperglycemia in Type 1 diabetes mellitus (for use only in patients who have not benefited sufficiently from dietary and exercise regimens or from taking sulfonylurea or insulin preparations in conjunction with dietary and exercise regimens).
6-2	Dec. 22, 2008	58	Fastic Tablets 30 Fastic Tablets 90 (Ajinomoto Co., Inc.) Starsis Tablets 30 mg Starsis Tablets 90 mg (Astellas Pharma Inc.)	Change Change Change Change	Nateglinide	Drugs with a new additional indication for the treatment of postprandial glucose excursions in Type 2 diabetes mellitus (for use only when treatment with thiazolidines in conjunction with dietary and exercise regimens is not sufficiently effective).
6-2	Dec. 22, 2008	59	Actos Tablets 15 Actos Tablets 30 (Takeda Pharmaceutical Company Limited)	Change Change	Pioglitazone hydrochloride	Drugs with a new additional indication for the treatment of Type 2 diabetes mellitus (for use only in patients in whom treatment with biguanides in conjunction with dietary and exercise regimens is not sufficiently effective, and insulin resistance is suspected).
6-2	Jan. 21, 2009	60	Recalbon Tablets 1 mg (Ono Pharmaceutical Co., Ltd.) Bonoteo Tablets 1 mg (Astellas Pharma Inc.)	Approval Approval	<u>Minodronic acid hydrate.</u>	Drugs containing a new active ingredient indicated for the treatment of osteoporosis.
6-2	Feb. 23, 2009	61	Glufast Tab. 5 mg Glufast Tab. 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change Change	Mitiglinide calcium hydrate	Drugs with a new additional indication for the treatment of postprandial glucose excursions in Type 2 diabetes mellitus in patients who have not benefited sufficiently from taking thiazolidines in conjunction with dietary and exercise regimens.
6-2	Mar. 24, 2009	62	Actos Tablets 15 Actos Tablets 30 (Takeda Pharmaceutical Company Limited)	Change Change	Pioglitazone hydrochloride	Drugs with a new indication and a new dosage for the treatment of Type 2 diabetes mellitus in patients who have not benefited sufficiently from taking insulin preparations in conjunction with dietary and exercise regimens in whom insulin resistance is suspected.
Oncology drugs	Apr. 16, 2008	63	Sutent Capsule 12.5 mg (Pfizer Japan Inc.)	Approval	<u>Sunitinib malate</u>	A drug containing a new active ingredient indicated for the treatment of imatinib-resistant gastrointestinal stromal tumors, and unresectable or metastatic renal cell carcinomas. [Priority review]
Oncology drugs	May 20, 2008	64	Fludara for IV Inj.50 mg (Bayer Yakuhin, Ltd.)	Change	Fludarabine phosphate	A drug with a new indication and a new dosage for use as a conditioning prior to allogeneic hematopoietic stem cell transplantation in the following diseases: acute myeloid leukemia, myelodysplastic syndrome, chronic myeloid leukemia, chronic lymphocytic leukemia, malignant lymphoma, and multiple myeloma.
Oncology drugs	Jul. 16, 2008	65	Erbix Injection 100 mg (Merck KGaA)	Approval	<u>Cetuximab</u> (genetical recombination)	A drug containing a new active ingredient indicated for the treatment of EGFR-expressing, unresectable and advanced/recurrent colorectal carcinomas. [Priority review]
Oncology drugs	Aug. 29, 2008	66	Taxotere Injection (Sanofi-Aventis K.K.)	Change	Docetaxel hydrate	A drug with a new indication and a new dosage for the treatment of prostate cancer. [Priority review]

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Oncology drugs	Oct. 16, 2008	67	Thaled Capsule 100 (Fujimoto Pharmaceutical Corporation)	Approval	<u>Thalidomide</u>	A drug containing a new active ingredient indicated for the treatment of relapsed or refractory multiple myeloma. [Orphan drug]
Oncology drugs	Nov. 25, 2008	68	Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.)	Change	Gemcitabine hydrochloride	Drugs with a new additional indication for the treatment of urothelial carcinoma.
Oncology drugs	Jan. 21, 2009	69	Tasigna Capsules 200 mg (Novartis Pharma K.K.)	Approval	<u>Nilotinib hydrochloride hydrate</u>	A drug containing a new active ingredient indicated for the treatment of imatinib-resistant, chronic phase and accelerated phase chronic myelogenous leukemia. [Orphan drug]
Oncology drugs	Jan. 21, 2009	70	Sprycel Tablets 20 mg Sprycel Tablets 50 mg (Bristol-Myers K.K.)	Approval Approval	<u>Dasatinib hydrate</u>	Drugs containing a new active ingredient indicated for the treatment of 1) imatinib-resistant chronic myelogenous leukemia and 2) recurrent or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan drug]
Oncology drugs	Mar. 24, 2009	71	Leustatin Injection 8 mg (Janssen Pharmaceutical K.K.)	Change	Cladribine	A drug with a new additional dosage indicated for the treatment of recurrent, relapsing, or refractory indolent B-cell non-Hodgkin's lymphoma including follicular lymphoma, and mantle cell lymphoma.
AIDS drugs	Jun. 24, 2008	72	Isentress Tablets 400 mg (Banyu Pharmaceutical Co., Ltd.)	Approval	<u>Raltegravir potassium</u>	A drug containing a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]
AIDS drugs	Dec. 25, 2008	73	Intencelece Tablets 100 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Etravirine</u>	A drug containing a new active ingredient indicated for the treatment of HIV-1 infection. [Orphan drug]
AIDS drugs	Dec. 25, 2008	74	Celsentri Tablets 150 mg (Pfizer Japan Inc.)	Approval	<u>Maraviroc</u>	A drug containing a new active ingredient indicated for the treatment of CCR5-tropic HIV-1 infection. [Orphan drug]
<i>In vivo</i> Diagnostics	Oct. 16, 2008	75	Thyrogen IM Injection 0.9 mg (Sato Pharmaceutical Co., Ltd.)	Approval	<u>Thyrotropin human alfa (genetical recombination)</u>	A drug containing a new active ingredient indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine scintigraphy in patients with differentiated thyroid cancer who have undergone near total or total thyroidectomy. [Orphan drug]
<i>In vivo</i> Diagnostics	May 20, 2008	76	Imeron 350 Imeron 350 Syringe (Bracco-Eisai Co., Ltd.)	Change Change	Iomeprol	A drug with a new dosage (Imeron 350) and a drug with a new dosage in a new dosage form (Imeron 350 Syringe) indicated for use in angiocardiology, thoracic angiography, abdominal angiography, angiography of the extremities, intravenous digital angiography, arterial digital angiography, computed tomography, and intravenous urography.
<i>In vivo</i> Diagnostics	Feb. 23, 2009	77	Patch test tapes "Nickel sulfate" 160 µg "Potassium dichromate" 19 µg "Cobalt chloride" 16 µg "Mercaptobenzothiazole" 61 µg  "Formaldehyde" 150 µg  "Thimerosal" 6.5 µg (Sato Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Nickel sulfate Potassium dichromate Cobalt chloride Mercaptobenzothiazole  <u>N-hydroxymethyl succinimide</u>  Thimerosal	Drugs indicated for use in patch tests to identify allergens in patients with allergic dermatitis.
Biologicals	Feb. 23, 2009	78	Jebik V (Research Foundation for Microbial Diseases of Osaka University)	Approval	<u>Inactivated Japanese encephalitis virus (Beijing strain)</u>	A drug containing a new active ingredient indicated for prophylaxis against Japanese encephalitis.
Blood products	Jul. 16, 2008	79	Thymoglobuline for Intravenous Infusion 25 mg (Sanofi-Aventis K.K.)	Approval	<u>Anti-human thymocyte immunoglobulin, Rabbit</u>	A drug containing a new active ingredient indicated for the treatment of moderate to very severe aplastic anemia, for use as pretreatment prior to hematopoietic stem cell transplantation, and for the treatment of acute graft-versus-host disease after hematopoietic stem cell transplantation. [Orphan drug]