

**FY2006 List of Approved Products: New Drugs**

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Active ingredient(s) (underlined: new active ingredient)	Note
1	20-Apr-06	1 Feron (Toray Industries, inc.)	Partial	Interferon-beta	Drug with a new indication and dosage for treatment of viremia in compensated cirrhosis type C (excluding the patients with a high viral load of HCV serogroup 1). [Priority Review]
1	15-Jun-06	2 Takepron Capsules 15 Takepron OD Tablets 15 (Takeda Pharmaceutical Company, Ltd)	Partial Partial	Lansoprazole	Drugs with a new indication and dosage for treatment of non-erosive reflux disease.
1	15-Jun-06	3 Imuran Tablets (GlaxoSmithKline K.K.)	Partial	Azathioprine	Drug with a new indication and dosage indicated for induction and maintenance of remission in steroid-dependent Crohn's disease and maintenance of remission in steroid-dependent ulcerative colitis. [Notification of off-label use]
1	20-Oct-06	4 Aldurazyme for I.V. Infusion 2.9mg (Genzyme Japan KK)	Approval	<u>Laronidase</u> <u>(genetical</u> <u>recombination)</u>	Drug containing a new active ingredient indicated for treatment of mucopolysaccharidosis I. [Orphan Drug]
1	20-Oct-06	5 Takepron Intravenous 30mg (Takeda Pharmaceutical Company, Ltd)	Approval	Lansoprazole	Drug with a new route of administration indicated for patients with gastric ulcer, duodenal ulcer, acute stress ulcer and acute gastric mucosal lesion with bleeding who are unable to take the oral formulations.
1	20-Dec-06	6 Bonalfa High Ointment 20µg/g (Teijin Pharma Limited)	Partial	Tacalcitol	Drug with a revised indication that eliminates a limitation to use in intractable cases, and now indicated for treatment of psoriasis vulgaris regardless of the severity.
1	26-Jan-07	7 Copegus Tablets 200mg (Chugai Pharmaceutical Co., Ltd.) Pegasys Subcutaneous Injection 90µg Pegasys Subcutaneous Injection 180µg (Chugai Pharmaceutical Co., Ltd.)	Approval  Partial Partial	Ribavirin  Peginterferon alfa-2a (genetical recombination)	New drug application for Copegus to treat the following conditions, and additional indications and dosages for Pegasys. a) Ribavirin In combination with peginterferon alfa-2a (genetical recombination), Ribavirin is indicated for the treatment of either of the following viremia in chronic hepatitis C. 1. Patients with a high viral RNA load of HCV serogroup 1 (genotype I (1a) or II (1b)). 2. Patients who are not responding to or relapsing after interferon monotherapy. b) PEG-IFNα-2a In combination with Ribavirin, peginterferon alfa-2a is indicated for the treatment of either of the following viremia in chronic hepatitis C. 1. Patients with a high viral RNA load of HCV serogroup 1 (genotype I (1a) or II (1b)). 2. Patients who are not responding to or relapsing after interferon monotherapy. (the above is the added part of labeline)
1	26-Jan-07	8 Certican Tablets 0.25mg Certican Tablets 0.5mg Certican Tablets 0.75mg (Novartis Pharma K.K.)	Approval Approval Approval	<u>Everolimus</u>	Drugs containing a new active ingredient indicated for the prophylaxis of organ rejection in cardiac transplant. [Priority Review]
1	2-Mar-07	9 Urso Tablets 50mg Urso Tablets 100mg (Mitsubishi Pharma Corporation)	Partial Partial	Ursodeoxycholic acid	Drugs with a new indication and dosage indicated for the improvement of liver enzyme elevations in chronic hepatitis C.
2	20-Apr-06	10 Nu-Lotan Tablets 25 Nu-Lotan Tablets 50 (Banyu Pharmaceutical Co., LTD.)	Partial Partial	Losartan potassium	Addition of a new indication for diabetic nephropathy in patients with type2 diabetes, hypertension, and proteinuria.
2	26-Jul-06	11 Mozavaptan Hydrochloride Physulime Tablets 30mg (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Mozavaptan</u> <u>hydrochloride</u>	Drugs with a new active ingredient indicated for improvement of hyponatremia in syndrome of inappropriate secretion of antidiuretic hormone due to paraneoplastic syndrome of inappropriate antidiuretic hormone secretion (used only when conventional therapies are not sufficiently effective). [Orphan Drug]

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2	26-Jul-06	12 Polidocasklerol 0.5% Inj. 2mL Polidocasklerol 1% Inj. 2mL Polidocasklerol 3% Inj. 2mL (Sakai Chemical Industry Co.,Ltd.)	Approval Approval Approval	Polidocanol	Drugs with a new route of administration, used as a sclerosant to treat primary varicose veins of the lower extremity (excluding the varicosity of the main stem of the saphenous vein).
2	20-Oct-06	13 Ropinirole Hydrochloride ReQuip Tablets 0.25mg ReQuip Tablets 1mg ReQuip Tablets 2mg (GlaxoSmithKline K.K.)	Approval Approval Approval Approval	<u>Ropinirole hydrochloride</u>	Drugs with a new active ingredient, indicated for Parkinson's Disease.
2	20-Oct-06	14 Preminent Tablets (Banyu Pharmaceutical Co., LTD.)	Approval	Losartan potassium / Hydrochlorothiazide	A new combination drug indicated for hypertension.
2	20-Oct-06	15 Onoact 50 for Injection (Ono Pharmaceutical Co., Ltd.)	Partial	Landiolo hydrochloride	Additional indication for emergency treatment of postoperative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) under hemodynamic monitoring.
2	26-Jan-07	16 Ancaron Injection 150 (sanofi-aventis K.K.)	Approval	Amiodarone hydrochloride	Drug with a new route of administration, used for emergency treatment of refractory arrhythmias (ventricular fibrillation and hemodynamically unstable ventricular tachycardia). [Orphan Drug]
2	26-Jan-07	17 Comtan Tablets (Novartis Pharma K.K.)	Approval	<u>Entacapone</u>	Drug containing a new active ingredient used in combination with levodopa/carbidopa or levodopa/benserazide hydrochloride to improve daily fluctuation, or 'wearing-off' phenomena, in Parkinson's disease.
3	20-Apr-06	18 Sertraline Hydrochloride Pfizer J Zolofit Tablets 25mg J Zolofit Tablets 50mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Sertraline hydrochloride</u>	Drugs containing a new active ingredient, indicated for depression and panic disorder.
3	15-Jun-06	19 Neoral Oral Solution Neoral 10mg Capsules Neoral 25mg Capsules Neoral 50mg Capsules (Novartis Pharma K.K.)	Partial Partial Partial Partial	Ciclosporine	Addition of a new indication for systemic myasthenia gravis (in cases where post-thymectomy steroid therapy is not sufficiently effective or not well tolerated due to adverse drug reactions). [Notification of off-label use]
3	26-Jul-06	20 Gabapentin Pfizer Gabapen Tablets 200mg Gabapen Tablets 300mg Gabapen Tablets 400mg (Pfizer Japan Inc.)	Approval Approval Approval Approval	<u>Gabapentin</u>	Drugs containing a new active ingredient indicated for use as adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondarily generalized seizure) in patients with epilepsy, to whom other antiepileptic therapies are not sufficiently effective.
3	26-Jul-06	21 Avonex IM Injection Syringe 30µg (Genzyme Japan K.K.)	Approval	<u>Interferon beta-1a (genetical recombination)</u>	Drug containing a new active ingredient, indicated for relapse prevention of multiple sclerosis. [Orphan Drug]
3	20-Oct-06	22 Ultiva Intravenous 2mg Ultiva Intravenous 5mg (Janssen Pharmaceutical K.K.)	Approval Approval	<u>Remifentanyl hydrochloride</u>	Drugs with a new active ingredient, used for analgesia during induction and maintenance of general anesthesia. [Expedited Review]
3	20-Oct-06	23 OxiNorm Powder 0.5% (Shionogi & Co., Ltd.)	Approval	Oxycodone hydrochloride hydrate	Drug with a new dosage form used as an analgesic agent for moderate to severe pain associated with various types of cancer.
3	26-Jan-07	24 Gabalon for Intrathecal Infusion 0.005% Gabalon for Intrathecal Infusion 0.05% Gabalon for Intrathecal Infusion 0.2% (Daiichi Pharmaceutical Co., Ltd.)	Partial Partial Partial	Baclofen	Addition of pediatric dosage for treatment of severe spastic paralysis resulting from cerebrospinal disorders (used only when conventional therapies are not sufficiently effective). [Orphan Drug]
3	26-Jan-07	25 Modiodal Modiodal Tablets 100mg (Alfresa Pharma Corporation)	Approval Approval	<u>Modafinil</u>	Drugs containing a new active ingredient indicated for treatment of excessive daytime sleepiness associated with narcolepsy. [Orphan Drug]

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4	20-Apr-06	26 AmBisome 50mg for Intravenous Drip Infusion (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	Amphotericin B	Various infections caused by <i>Aspergillus</i> species, <i>Candida</i> species or <i>Cryptococcus</i> species (drug with a new dosage and dosage form).
4	20-Apr-06	27 Zyvox Injection 600mg Zyvox Tablets 600mg (Pfizer Japan Inc.)	Partial Partial	Linezolid	Addition of a new indication for methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).
4	20-Apr-06	28 Funguard for Infusion 25mg Funguard for Infusion 50mg Funguard for Infusion 75mg (Astellas Pharma Inc.)	Approval Partial Partial	Micafungin sodium	Addition of a new pediatric dosage and a dosage form of 25 mg.
4	26-Jul-06	29 Vegamox Ophthalmic Solution 0.5% (Alcon Japan Ltd.)	Approval	Moxifloxacin hydrochloride	Drug with a new route of administration, indicated for blepharitis, dacryocystitis, hordeolum, conjunctivitis, meibomianitis, keratitis (including corneal ulcer), and perioperative sterilization in ophthalmological surgery.
4	26-Jul-06	30 Itrazole Oral Solution 1% (Janssen Pharmaceutical K.K.)	Approval	Itraconazole	Addition of a new dosage form and dosage for treatment of oropharyngeal candidiasis and oesophageal candidiasis.
4	26-Jul-06	31 Baraclude Tablets 0.5mg (Bristol Pharmaceuticals Y.K.)	Approval	<u>Entecavir hydrate</u>	Drug containing a new active ingredient indicated for use to improve levels of viral marker, liver function, and the histology of the liver affected by chronic hepatitis B in patients with evidence of hepatitis B virus replication and associated abnormal liver function. [Priority Review]
4	21-Aug-06	32 Stromectol Tablets 3mg (Banyu Pharmaceutical Co., LTD.)	Partial	Ivermectin	Addition of a new indication and dosage for treatment of scabies. [Notification of off-label use]
4	13-Sep-06	33 Valtrex Tablets 500 Valtrex Tablets Granules 50% (GlaxoSmithKline K.K.)	Partial Partial	Valaciclovir hydrochloride	Addition of a new indication and dosage indicated for the suppression of recurrent genital herpes. [Notification of off-label use]
4	20-Oct-06	34 Itrazole Injection 1% (Janssen Pharmaceutical K.K.)	Approval	Itraconazole	Drug with a new route of administration indicated for treatment of fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, esophageal candidiasis, blastomycosis, and histoplasmosis, caused by <i>Aspergillus</i> species, <i>Candida</i> species, <i>Cryptococcus</i> species, <i>Blastomyces</i> species or <i>Histoplasma</i> species and febrile neutropenia suspected of having fungal infections.
4	26-Jan-07	35 Pariet Tablets 10mg (Eisai Co., Ltd.) Pasetocin Capsules Pasetocin Fine Granules Pasetocin Tablets 250 (Kyowa Hakko Kogyo Co., Ltd.) Amopenixin Capsules 250 (Nipro Pharma Corporation) Sawacillin Capsules Sawacillin Fine Granules Sawacillin Tablets 250 (Astellas Pharma Inc.) Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200mg (Abbott Japan Co., Ltd.)	Partial  Partial Partial Partial  Partial Partial Partial  Partial Partial	Sodium rabeprazole  Amoxicillin       Clarithromycin	Addition of a new dosage indicated for a combination therapy with sodium rabeprazole, amoxicillin, and clarithromycin to eradicate <i>Helicobacter pylori</i> in patients with gastric or duodenal ulcer.
4	26-Jan-07	36 Relenza (GlaxoSmithKline K.K.)	Partial	Zanamivir hydrate	Addition of a new indication for prophylaxis of influenza typeA or typeB infections. [Expedited Review]

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4	26-Jan-07	37 Funguard for Infusion 50mg Funguard for Infusion 75mg Funguard for Infusion 25mg (Astellas Pharma Inc.)	Partial Partial Partial	Micafungin sodium	Drugs with a new indication and dosage for prophylaxis of aspergillosis and candidiasis in hematopoietic stem cell transplant patients.
4	31-Jan-07	38 Omepral Tablets 10 Omepral Tablets 20 (AstraZeneca K.K.) Omeprazon Tablets 10mg Omeprazon Tablets 20mg (Mitsubishi Pharma Corporation) Pasetocin Capsules Pasetocin Tablets 250 (Kyowa Hakko Kogyo Co., Ltd.) Sawacillin Capsules Sawacillin Tablets 250 (Astellas Pharma Inc.) Amoxicillin Capsules "TOWA" (Towa Pharmaceutical Co., Ltd.) Clarith Tab. 200 (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200mg (Abbott Japan Co., Ltd.)	Partial Partial  Partial Partial  Partial Partial  Partial Partial  Partial Partial	Omeprazole            Amoxicillin            Clarithromycin	Revision of the dosage for a combination therapy of amoxicillin, clarithromycin, and omeprazole indicated for treatment of <i>Helicobacter pylori</i> infections in patients with gastric ulcer or duodenal ulcer.
5	20-Apr-06	39 Vesicare Powder Vesicare Tablets 2.5mg Vesicare Tablets 5mg (Astellas Pharma Inc.)	Approval Approval Approval	<u>Solifenacin succinate</u>	Drugs with a new active ingredient indicated for treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
5	20-Apr-06	40 Detrusitol Capsules 2mg Detrusitol Capsules 4mg (Pfizer Japan Inc.)	Approval Approval	<u>Tolterodine tartrate</u>	Drugs with a new active ingredient indicated for treatment of urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder.
5	20-Apr-06	41 Cetrorelix Acetate for Injection 0.25mg "Shionogi" Cetrorelix Acetate for Injection 3mg "Shionogi" (Shionogi & Co., Ltd.) Cetrotide for Injection 0.25mg Cetrotide for Injection 3mg (Nippon Kayaku Co., Ltd.)	Approval Approval  Approval Approval	<u>Cetrorelix acetate</u>	Drugs containing a new active ingredient, indicated for prevention of premature ovulation during controlled ovarian stimulation.
5	20-Oct-06	42 L'estrogel 0.06% (Shiseido Co., Ltd.)	Approval	Estradiol	Drug with a new dosage form indicated for vasomotor symptoms (hot flush and sweating) associated with menopausal disorders and ovarian deficiency symptoms.
5	26-Jan-07	43 Mirena 52mg (Nihon Schering K.K.)	Approval	Levonorgestrel	Drug with a new route of administration, indicated for use in contraception. (intrauterine contraceptive system)
5	26-Jan-07	44 Follistim Injection 50 Follistim Injection 75 (Organon Japan )	Approval Partial	Follitropin beta (genetical recombination)	Drugs with a new indication and dosage indicated for the induction of ovulation in patients with anovulation and oligoovulation associated to hypothalamo-pituitary dysfunction.
5	2-Mar-07	45 Carbostar Dialysate L Carbostar Dialysate M Carbostar Dialysate P (Ajinomoto Co., Inc.)	Approval Approval Approval	(combination drug)	A combination drug similar to other products. (Dialysate)
6-1	26-Jul-06	46 Pulmicort Respules 0.25mg Pulmicort Respules 0.5mg (AstraZeneca K.K.)	Approval Approval	Budesonide	Drugs with new dosages and dosage forms indicated for use in children from 6 months and under 5 years of age to treat asthma. [Expedited Review]
6-1	26-Jul-06	47 Patanol Ophthalmic Solution 0.1% (Alcon Japan Ltd.)	Approval	Olopatadine hydrochloride	Drug with a new route of administration indicated for allergic conjunctivitis.

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6-1	20-Oct-06	48 Allegra Tablets 60mg Allegra Tablets 30mg (sanofi-aventis K.K.)	Partial Approval	Fexofenadine hydrochloride	Addition of new dosages and dosage form indicated for use in small children.
6-1	26-Jan-07	49 Celecoxib (Pfizer Japan Inc.) Celecox Tablets 100mg Celecox Tablets 200mg (Astellas Pharma Inc.)	Approval  Approval Approval	<u>Celecoxib</u>	Drugs with a new active ingredient indicated for relief of inflammation and pain associated with rheumatoid arthritis and osteoarthritis.
6-1	26-Jan-07	50 Remicade for I.V. Infusion 100 (Tanabe Seiyaku Co.,Ltd.)	Partial	Infliximab (genetical recombination)	Addition of an indication for refractory uveoretinitis associated with Behcet's disease (used only when conventional therapies are not sufficiently effective). [Orphan Drug]
6-2	20-Apr-06	51 Humatrope C6mg Humatrope C12mg (Eli Lilly Japan K.K.)	Partial Partial	Somatropin (genetical recombination)	Addition of an indication and dosage for treatment of adult growth hormone deficiency (used only in severe cases).
6-2	26-Jul-06	52 Fosamac Tablets 35mg (Banyu Pharmaceutical Co., LTD.) Bonalon Tablets 35mg (Teijin Pharma Limited)	Approval  Approval	Alendronate sodium hydrate	Addition of once-a-week dosage and dosage forms indicated for treatment of osteoporosis.
6-2	26-Jul-06	53 Genotropin 5.3mg Genotropin MiniQuick S.C. Inj. 0.4mg Genotropin MiniQuick S.C. Inj. 0.6mg Genotropin MiniQuick S.C. Inj. 0.8mg Genotropin MiniQuick S.C. Inj. 1.0mg Genotropin MiniQuick S.C. Inj. 1.2mg Genotropin MiniQuick S.C. Inj. 1.4mg Genotropin MiniQuick S.C. Inj. 1.6mg Genotropin MiniQuick S.C. Inj. 1.8mg Genotropin MiniQuick S.C. Inj. 2.0mg Genotropin Inj. 12mg (Pfizer Japan Inc.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Somatropin (genetical recombination)	Addition of an indication for treatment of adult growth hormone deficiency (used only in severe cases).
6-2	26-Jan-07	54 Somavert for S.C. Injection 10mg Somavert for S.C. Injection 15mg Somavert for S.C. Injection 20mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Pegvisomant</u> (genetical recombination)	Drugs with a new active ingredient used to treat excessive secretion of IGF-I (somatomedin C) and other related symptoms in patients with acromegaly (used in cases where other surgical and pharmaceutical therapies are not sufficiently effective or practicable.) [Orphan Drug]
6-2	26-Jan-07	55 Prograf Capsules 0.5mg Prograf Capsules 1mg (Astellas Pharma Inc.)	Partial Partial	Tacrolimus hydrate	Drugs with a new indication for lupus nephritis (in cases where steroid therapy is not sufficiently effective or well tolerated due to side effects). [Orphan Drug]
6-2	6-Feb-07	56 Replagal for Intravenous Infusion 3.5mg (Dainippon Sumitomo Pharma Co., Ltd.)	Approval	<u>Agalsidase alfa</u> (genetical recombination)	Drug with a new active ingredient indicated for treatment of Fabry disease. [Orphan Drug]
In vivo Diagnostic s	20-Apr-06	57 Bothdel Oral Solution 10 (Meiji Dairies Corporation) Bothdel Oral Solution 10 (Kyowa Hakko Kogyo Co., Ltd.)	Approval  Approval	Manganese chloride tetrahydrate	Drugs with a new indication and dosage for use as a negative gastrointestinal contrast medium in Magnetic Resonance Cholangio-Pancreatography.
In vivo Diagnostic s	20-Oct-06	58 Sonazoid for Injection (Daiichi Pharmaceutical Co., Ltd.)	Approval	<u>Perflubutane</u>	Drug with a new active ingredient used as a contrast agent for ultrasound imaging of lesions associated with hepatic tumors.
Oncology drugs	20-Apr-06	59 Zometa Injection Solution 4mg (Novartis Pharma K.K.)	Partial	Zoledronic acid hydrate	Drug with a new indication and revised dosage indicated for bone lesions of multiple myeloma or bone metastasis from solid cancers.

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Oncology drugs	15-Jun-06	60 Gemzar Injection 200mg Gemzar Injection 1g (Eli Lilly Japan K.K.)	Partial Partial	Gemcitabine hydrochloride	Addition of an indication for biliary tract cancer.
Oncology drugs	26-Jul-06	61 Busulfex Injection 60mg (Kirin Brewery Company, Limited)	Approval	Busulfan	Drug with a new route of administration used for conditioning regimen prior to allogeneic hematopoietic stem cell transplantation. [Orphan Drug]
Oncology drugs	26-Jul-06	62 Temodal Capsules 20mg Temodal Capsules 100mg (Schering-plough K.K.)	Approval Approval	<u>Temozolomide</u>	Drugs containing a new active ingredient indicated for treatment of malignant glioma. [Priority Review]
Oncology drugs	10-Aug-06	63 TS-1 Capsule 20 TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Partial Partial	Combination drug containing Tegafur, Gimeracil, and Oteracil potassium.	Addition of an indication for pancreatic cancer.
Oncology drugs	20-Oct-06	64 Velcade Injection 3mg (Janssen Pharmaceutical K.K.)	Approval	<u>Bortezomib</u>	Drug containing a new active ingredient indicated for treatment of relapsed or refractory multiple myeloma. [Orphan Drug]
Oncology drugs	20-Oct-06	65 Busulfex Injection 60mg (Kirin Brewery Company, Limited)	Partial	Busulfan	Addition of pediatric dosage for conditioning regimen prior to allogeneic hematopoietic stem cell transplantation, and autologous hematopoietic stem cell transplantation in Ewing sarcoma family tumors and neuroblastoma. [Orphan Drug]
Oncology drugs	4-Jan-07	66 Alimta Injection 500mg (Eli Lilly Japan K.K.) Randa Inj. (Nippon Kayaku Co., Ltd.) Briplatin Injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) Cisplatin Inj. 'Maruko' (Maruko Pharmaceutical Co., Ltd.) Cisplamerck Injection Solution 0.05% (Merck Seiyaku Ltd.) Cisplatin Injection 10mg 'Nichi iko' Cisplatin Injection 25mg 'Nichi iko' Cisplatin Injection 50mg 'Nichi iko' (Nichi-Iko Pharmaceutical Co., Ltd.)	Approval Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	<u>Pemetrexed sodium hydrate</u> Cisplatin	Combination therapy with a drug containing a new active ingredient and a drug with a new indication and dosage, for use to treat malignant pleural mesothelioma. [Priority Review] [Expedited Review]
Oncology drugs	26-Jan-07	67 Fludara Tab. 10mg (Nihon Schering K.K.)	Approval	Fludarabine phosphate	Drug with a new route of administration and indications for treatment of low-grade B cell non-Hodgkin lymphoma and mantle-cell lymphoma
Oncology drugs	31-Jan-07	68 Glivec Tablets 100mg (Novartis Pharma K.K.)	Partial	Imatinib mesilate	Drug with a new indication and dosage for treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia. [Orphan Drug]
AIDS drugs	1-Sep-06	69 Invirase Capsules 200mg Invirase Tablets 500mg (Chugai Pharmaceutical Co., Ltd.)	Partial Approval	Saquinavir mesilate	Addition of a new dosage and dosage form of 500mg tablets, indicated for treatment of HIV infection. [Orphan Drug]
AIDS drugs	1-Sep-06	70 Kaletra Tablets (Abbott Japan Co., Ltd.)	Approval	Lopinavir/Ritonavir	Drug with a new dosage indicated for treatment of HIV infection. [Orphan Drug]
AIDS drugs	4-Jan-07	71 Doxil Injection 20mg (Janssen Pharmaceutical K.K.)	Approval	Doxorubicin hydrochloride	Drug with a new indication and dosage for treatment of AIDS-related Kaposi's sarcoma. [Orphan Drug]

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Blood products	20-Apr-06	72 Epogin Injection Ampoule 750 Epogin Injection Ampoule 1500 Epogin Injection Ampoule 3000 Epogin Injection Syringe 750 Epogin Injection Syringe 1500 Epogin Injection Syringe 3000 (Chugai Pharmaceutical Co.,Ltd.)	Partial Partial Partial Partial Partial	Epoetin beta (genetical recombination)	Addition of a new indication for anemia in premature infants.
Blood products	22-May-06	73 Feiba (Baxter Limited)	Partial	Anti-inhibitor coagulant complex	Drug with a revised indication for "the control of bleeding by promoting blood coagulation in plasma in patients with inhibitors to blood coagulation factor VIII or factor IX." [Notification of off-label use]
Blood products	20-Oct-06	74 Anaect C for Injection 2500 Units (Kaketsuken)	Partial	Freeze-dried human activated protein C concentrated	Addition of an indication and dosage for treatment of purpura fulminans caused by congenital protein C deficiency. [Orphan Drug]
Blood products	20-Oct-06	75 Advate for Injection 250 Advate for Injection 500 Advate for Injection 1000 (Baxter Limited)	Approval Approval Approval	<u>Rurioctocog alfa</u> (genetical recombination)	Drugs containing a new active ingredient, indicated for the control of bleeding tendency by supplementing blood coagulation factor VIII in patients with blood coagulation factor VIII deficiency (new product that eliminates the addition of human- and animal-derived components).
Biologicals	20-Oct-06	76 Pneumovax NP (Banyu Pharmaceutical Co., Ltd.)	Approval	<u>Pneumococcal vaccine</u>	Revision to the test procedures and acceptance criteria as well as to the manufacturing process for drug substance and formulation of pneumococcal capsular serotype polysaccharide.
Biologicals	26-Jan-07	77 ActHIB (Sanofi Pasteur-Daiichi Vaccines Co., Ltd.)	Approval	<u>Haemophilus influenzae type b polysaccharide- tetanus toxoid conjugate vaccine</u>	Drug containing a new active ingredient indicated for vaccination against <i>Haemophilus influenzae</i> type b infections.