

Table-18. A List of Approved Articles in 2005 (New Drugs)

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
1	11-Apr-05	1 Actemra Liquid Concentrate Actemra for Intravenous Infusion 200 (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Tocilizumab (genetical recombination)</u>	Drugs containing a new active ingredient indicated for improving various symptoms and laboratory findings associated with Castleman's disease for which lymphadenectomy is not indicated. [Orphan drug]
1	16-Sep-05	2 Zefix Tablets 100 (GlaxoSmithKline K.K.)	Partial	Lamivudine	A new indication for "improving viral markers in patients with hepatitis B cirrhosis complicated by proliferation of hepatitis B virus and with abnormal hepatic function to be confirmed" in monotherapy [Priority review]
1	11-Oct-05	3 Propecia Tablets-1mg Propecia Tablets-0.2mg (Banyu Pharmaceutical Co., Ltd.)	Approval	<u>Finasteride</u>	Drugs containing a new active ingredient used for delaying progression of male pattern alopecia in men.
1	11-Oct-05	4 Seibule Tablets 25mg Seibule Tablets 50mg Seibule Tablets 75mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval	<u>Miglitol</u>	Drugs containing a new active ingredient, an α -glucosidase inhibitor, indicated for improving postprandial hyperglycemia in patients with type 2 diabetes.
1	22-Dec-05	5 PegIntron Sterile Powder for Injection (50 μ g/0.5 mL) PegIntron Sterile Powder for Injection (100 μ g/0.5 mL) PegIntron Sterile Powder for Injection (150 μ g/0.5 mL) (Schering-plough K.K.)	Partial	<u>Peginterferon alfa-2b (genetical recombination)</u>	A new indication for either case of chronic hepatitis C mentioned below in combined therapy (1) Patients with high blood levels of HCV-RNA except serogroup 1
		Rebetol Capsule 200 (Schering-plough K.K.)	Partial	Ribavirin	(2) Patients with no response to monotherapy with interferon preparation, or patients relapsing after monotherapy with interferon preparation [Priority review]
2	11-Apr-05	6 Tracleer Tablets 62.5 mg (Actelion Japan)	Approval	<u>Bosentan hydrate</u>	A drug containing a new active ingredient, the endothelin-receptor antagonist, indicated for pulmonary arterial hypertension [Orphan drug]
2	25-Jul-05	7 Cleactor Injection 400,000 Cleactor Injection 800,000 Cleactor Injection 1,600,000 (Eisai Co., Ltd.)	Partial Partial Partial	<u>Monteplase (genetical recombination)</u>	A new indication for "lysis of pulmonary artery thrombosis caused by acute pulmonary embolism in the presence of hemodynamic instability" [Orphan drug]
2	11-Oct-05	8 Activacin for Injection 6,000,000 Activacin for Injection 12,000,000 Activacin for Injection 24,000,000 (Kyowa Hakko Kogyo Co., Ltd.) Grutopa for Injection 6,000,000 Grutopa for Injection 12,000,000 Grutopa for Injection 24,000,00 (Mitsubishi Pharma Corporation)	Partial Partial Partial Partial Partial Partial	<u>Alteplase (genetical recombination)</u>	A new indication for improving dysfunction caused by acute ischemic cerebrovascular diseases [Priority review]
2	11-Oct-05	9 Blopess Tablets 2 Blopess Tablets 4 Blopess Tablets 8 (Takeda Pharmaceutical Company Limited)	Partial Partial Partial	candesartan cilexetil	A new indication for chronic heart failure, extended from use as an angiotensin-converting enzyme inhibitor
2	31-Oct-05	10 Bayaspirin 100mg Aspirin "Bayer" (Bayer Yakuhin, Ltd.)	Partial Approval	Aspirin	A new indication for "Kawasaki disease" [Notification of off label use]
2	31-Oct-05	11 Bufferin 81 mg Tablets (Lion Corporation) Nitogis Tablets 81 mg (Shiono Chemical Co.,Ltd.) Bassamin Tablets 81 mg (Taiyo Yakuhin Co., Ltd.) Famoter 81mg Tablets (Tsuruhara Pharmaceutical Co., Ltd.) Asphanate Tablets 81 mg (Nakakita Yakuhin Co., Ltd.) Aspirin "Metal" (Nakakita Yakuhin Co., Ltd.) aspirin "Yoshida" (Yoshida Pharmaceutical Co., Ltd.) Aspirin "Hoei" (Merck Hoei Ltd.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Aspirin dialminate Aspirin	A new indication for "Kawasaki disease" [Notification of off label use]
2	23-Jan-06	12 Clopidogrel sulfate (Sanofi-Synthelabo Daiichi K.K.) Plavix Tablets 25 mg Plavix Tablets 75 mg (Daiichi Pharmaceutical Co.,Ltd.)	Approval Approval Approval	<u>Clopidogrel sulfate</u>	Drugs containing a new active ingredient indicated for preventing recurrences of ischemic cerebrovascular diseases (except cardiogenic cerebral infarction) [Prompt review]
3	11-Apr-05	13 Gabalon 0.005% 1 mL Gabalon 0.05% 20 mL Gabalon 0.2% 5 mL (Daiichi Pharmaceutical Co.,Ltd.)	Approval Approval Approval	Baclofen	Drugs with a new route of intrathecal infusion indicated for the treatment of severe spasticity resulting from cerebrospinal diseases [Orphan drug]

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3	25-Jul-05	14 Salagen Tablets 5 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	<u>Pilocarpine hydrochloride</u>	Drug with a new route of oral administration indicated for the treatment of symptoms of dry mouth caused by radiotherapy for head and neck cancer
3	30-Sep-05	15 Pacif Capsules 30 mg Pacif Capsules 60 mg Pacif Capsules 120 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Morphine hydrochloride	Drugs with a new formulation, a sustained-release preparation containing morphine hydrochloride given once a day
3	11-Oct-05	16 Luvox Tablets 25 Luvox Tablets 50 (Solvay Seiyaku K.K.) Depromel Tablets 25 Depromel Tablets 50 (Meiji Seika Kaisha, Ltd.)	Partial Partial Partial Partial	Fluvoxamine maleate	A new indication for the treatment of "social anxiety disorder"
3	23-Jan-06	17 Aripiprazole Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Powder 1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	<u>Aripiprazole</u>	Drugs containing a new active ingredient indicated for schizophrenia, with partial agonist activity at D2 receptor
3	23-Jan-06	18 Paxil Tablets 10 mg Paxil Tablets 20 mg (GlaxoSmithKline K.K.)	Partial Partial	Paroxetine hydrochloride hydrate	A new indication for the treatment of "obsessive compulsive disorder"
4	11-Apr-05	19 Luliconazole (Nihon Nohyaku Co., Ltd.) Lulicon Cream 1% Lulicon Solution 1% (Pola Kasei Kogyo KK)	Approval Approval Approval	<u>Luliconazole</u>	Drugs containing a new active ingredient, an imidazole anti-fungal agent
4	11-Apr-05	20 Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Voriconazole</u>	Drugs containing a new active ingredient, a triazole anti-fungal agent
4	25-Jul-05	21 Finibax for Intravenous Infusion 0.25 g Finbax for Intradermal Test (Shionogi & Co., Ltd.)	Approval Approval	<u>Doripenem hydrate</u>	Drugs containing a new active ingredient, a carbapenem antimicrobial agent
4	11-Oct-05	22 Augmentin ES Dry Syrups for Children (GlaxoSmithKline K.K.)	Approval	Clavulante potassium · amoxicillin	A combination prescription drug with a new composition ratio
4	11-Oct-05	23 Avelox Tablets 400 mg (Bayer Yakuhin, Ltd.)	Approval	<u>Moxifloxacin Hydrochloride</u>	A drug containing a new active ingredient, a new quinolone antimicrobial agent
4	14-Oct-05	24 Synagis Intramuscular 50 mg Synagis Intramuscular 100 mg (Abbott Japan Co., Ltd.)	Partial Partial	Palivizumab (genetical recombination)	Drugs with a new indication for preventing serious lower respiratory tract disease caused by RS virus infections in newborns, infants and children under 24 months of age with haemodynamically significant congenital heart disease [Priority review drug]
4	23-Jan-06	25 Ozex Ophthalmic Solution 0.3% (Toyama Chemical Co., Ltd.) Tosuflo Ophthalmic Solution 0.3% (Nidek Co., Ltd.)	Approval Approval	Tosufloxacin tosilate	Drugs with a new route of administration (eye drops) indicated for the treatment of blepharitis, dacryoadenitis, hordeolum, conjunctivitis, inflammation of the tarsal glands, inflammation of the cornea (including corneal ulcer), and aseptic treatment during ophthalmic surgery.
4	17-Feb-06	26 Relenza (GlaxoSmithKline K.K.)	Partial	Zanamivir hydrate	A new pediatric dosage regimen indicated for the treatment of influenza virus infection
4	23-Feb-06	27 Gatiflo Tablets 100 mg (Kyorin Pharmaceutical Co., Ltd.)	Partial	Gatifloxacin	A new indication for the treatment of genus Legionella infection [Notification of off label use]
4	23-Feb-06	28 Clarith Tablets 200 Clarith Tablets 50 for Pediatric Clarith Dry Syrup for Pediatric (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200 mg Klaricid Tablets 50 mg for Pediatric Klaricid Dry Syrups for Pediatric (Abbott Japan Co., Ltd.)	Partial Partial Partial Partial Partial Partial	Clarithromycin	A new indication for the treatment of genus Legionella infection [Notification of off label use]
4	23-Feb-06	29 Ciproxan-I.V.200 Ciproxan-I.V.300 Ciproxan 100 Ciproxan 200 (Bayer Yakuhin, Ltd.)	Partial Partial Partial Partial	Ciprofloxacin Ciprofloxacin hydrochloride	A new indication for the treatment of genus Legionella infection [Notification of off label use]
4	23-Feb-06	30 Cravit Tablets Cravit Fine Granules (Daiichi Pharmaceutical Co., Ltd.)	Partial Partial	Levofloxacin	A new indication for the treatment of genus Legionella infection [Notification of off label use]
5	11-Apr-05	31 Follistim Injection 75 Follistim Injection 150 (Organon-Japan)	Approval Approval	<u>Follitropin beta (genetical recombination)</u>	Drugs containing a new active ingredient, a human follicle-stimulating hormone (genetical recombination), indicated for "regularly stimulating the ovary to develop multiple follicles in
5	23-Jan-06	32 Gonalef 75 (Subcutaneous) Gonalef 150 (Subcutaneous) (Serono Japan Co., Ltd.)	Approval Approval	<u>follitropin alfa (genetical recombination)</u>	Drugs containing a new active ingredient indicated for induction of spermatogenesis in male hypogonadotropic hypogonadism in combination with human chorionic gonadotropin [Orphan drug]
5	23-Jan-06	33 Profasi 5000 (Injection) (Serono Japan Co., Ltd.)	Partial	Chorionic Gonadotrophin	A new indication and a new route of subcutaneous administration for induction of spermatogenesis in male hypogonadotropic hypogonadism in combination with follitropin alpha [Prompt review drug]

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6	23-Jan-06	42 Loxonin Pap 100mg (Lead Chemical Co., Ltd.)	Approval	Loxoprofen Sodium	A drug with a new route of administration indicated for the treatment of osteoarthritis, myalgia, post-traumatic swelling/pain and anti-inflammatory/analgesic effects on these symptoms
Radiopharmaceuticals	25-Jul-05	43 FDGscan Injectable (Nihon Mediphysics Co., Ltd.) FDGscan-MP Injectable (The Medical & Pharmacological Research Center Foundation)	Approval Approval	<u>fludeoxyglucose (F18)</u>	Drugs containing a new active ingredient used for making a diagnosis of malignant tumors accompanied by accelerated glucose metabolism, ischemic heart diseases or epilepsy
In vivo diagnostics	11-Apr-05	44 Adenoscan Injection 60mg Adenoscan Injection 90mg (Daiichi Suntory Pharma Co., Ltd.)	Approval Approval	<u>adenosine</u>	Drugs containing a new active ingredient used for load induction to make a diagnosis of heart disease based on myocardial perfusion scintigraphy in patients unable to tolerate sufficient exercise load
In vivo diagnostics	11-Oct-05	45 Inulin (Kanto Kagaku) Inulead Injection (Fujiyakuin Co., Ltd.)	Approval Approval	<u>Inulin</u>	Drugs containing a new active ingredient used for renal function tests based on measurement of glomerular filtration rate
Oncology drugs	11-Apr-05	46 Tamibarotene "Toko" Amnolake Tablet 2 mg (Toko Pharmaceutical Industrial Co., Ltd.)	Approval Approval	<u>tamibarotene</u>	Drugs containing a new active ingredient indicated for the treatment of acute promyelocytic leukemia [Orphan drug]
Oncology drugs	31-May-05	47 Navelbine Injection 10 Navelbine Injection 40 (Kyowahakko Co., Ltd.)	Partial Partial	Vinorelbine ditartrate	A new indication for the treatment of inoperable or recurrent breast cancer, in addition to the current indication for lung cancer
Oncology drugs	31-May-05	48 Taxol Injection (Bristol Seiyaku KK)	Partial	Paclitaxel	A new indication for the treatment of cancer of the uterus body, in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer and stomach cancer
Oncology drugs	25-Jul-05	49 Mylotarg Injection 5 mg (Wyeth K.K.)	Approval	<u>Gemtuzumab Ozogamicin (Genetical Recombination)</u>	A drug containing a new active ingredient indicated for the treatment of relapsing or intractable CD33 positive acute myeloid [Orphan drug]
Oncology drugs	18-Aug-05	50 Taxotere Injection (Aventis Pharma Ltd.)	Partial	Docetaxel hydrate	A new indication for the treatment of "cancer of the uterus body", in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer, stomach cancer, head and neck carcinoma, and esophageal carcinoma
Oncology drugs	18-Aug-05	51 Leuplin SR For Injection Kit 11.25 (Takeda Pharmaceutical Company Limited)	Partial	leuprorelin acetate	A new indication for the treatment of "premenopausal breast cancer", in addition to the current indication for prostatic cancer
Oncology drugs	15-Sep-05	52 Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer [Combination chemotherapy with anti-cancer drgs]
Oncology drugs	15-Sep-05	53 Farmorubicin Injection Farmorubicin RTU Inj (Pfizer Japan Inc.) Epirubicin Hydrochloride Injection 10 mg "Merck" Epirubicin Hydrochloride Injection 50 mg "Merck" (Merck Hoei Ltd.)	Partial Partial Partial	Epirubicin hydrochloride	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer [Combination chemotherapy with anti-cancer drgs]
		Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	
Oncology drugs	15-Sep-05	54 Randa Injection (Nippon Kayaku Co., Ltd.) Briplatin Injection (Bristol Seiyaku KK) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.) Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial Partial Partial Partial Partial Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant lymphoma [Combination chemotherapy with anti-cancer drgs]
		Solu-Medrol 40 Solu-Medrol 125 Solu-Medrol 500 (Pfizer Japan Inc.) Decacort 125 Decacort 500 (Sawai Pharmaceutical Co., Ltd.) Sol-melcort Injection 40 Sol-melcort Injection 125 Sol-melcort Injection 500 (Fuji Pharma Co., Ltd.) Pridol for Injection 40 Pridol for Injection 125 Pridol for Injection 500 (Sankyo Yell Yakuhin Co., Ltd.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial	Methylprednisolone sodium succinate	

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Oncology drugs	15-Sep-05	55 Randa Injection (Nippon Kayaku Co., Ltd.)	Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant solid tumors of childhood [Combination chemotherapy with anti-cancer drgs]
		Briplatin Injection (Bristol Seiyaku KK)	Partial		
		Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.)	Partial Partial Partial		
		Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.)	Partial		
		Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial		
		Paraplatin For Injection 150 mg Paraplatin Injection (Bristol Seiyaku KK)	Partial Partial	Carboplatin	
		Carbomerck for Injection 1% (Merck Hoei Ltd.)	Partial		
		Carboplatin Injection 1% (Nippon Hexal Corporation)	Partial		
		Cosmegen (Banyu Pharmaceutical Co., Ltd.)	Partial	Actinomycin D	
Oncology drugs	15-Sep-05	56 Decadron Tablets (Banyu Pharmaceutical Co., Ltd.)	Partial	Dexamethasone	A new indication and a new dosage regimen for the treatment of gastrointestinal (nausea, vomiting) symptoms associated with administration of antitumor agents [Combination chemotherapy with anti-cancer drgs]
		Dexamethasone Tablets 0.5 mg "Taiyo" (Taiyo Yakuhin Co., Ltd)	Partial		
		Decadron Phosphate Injection Orgadron Injection (Banyu Pharmaceutical Co., Ltd.)	Partial Partial		
		Dexart Injection (Fuji Pharma Co., Ltd.)	Partial	Dexamethasone Sodium Phosphate	
Oncology drugs	14-Nov-05	57 TS-1 Capsule 20 TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Partial Partial	Tegafur/Gimeracil/Oteracil potassium	A new indication for the treatment of "inoperable or recurrent breast cancer"
Oncology drugs	23-Jan-06	58 Femara Femara 2.5 mg Tablet (Nihon Ciba-Geigy K.K..)	Approval Approval	<u>Letrozole</u>	Drugs containing a new active ingredient indicated for the treatment of post-menopausal breast cancer
Biological products	25-Jul-05	59 Mearubik (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella
Biological products	14-Oct-05	60 Freeze-Dried Live Attenuated Measles and Rubella Combined Vaccine "Takeda" (Takeda Pharmaceutical Company Limited)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella