

Table 18 A list of approved items in 2004 (new drugs)

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (<u>Underlined: New active ingredients</u>)	Note
1	April 24, 2004	1 Sandostatin LAR for intramuscular injection 10mg Sandostatin LAR for intramuscular injection 20mg Sandostatin LAR for intramuscular injection 30mg (Nihon Chiba-Geigy K.K.)	Approval Approval Approval	Octreotide Acetate	New form drug with a new administration route administered once every four weeks and which has the following indications: alleviation of various symptoms associated with gastrointestinal hormone-producing tumors and alleviation of excessive secretions of growth hormone and somatomedin-C and other various symptoms in acromegaly and pituitary gigantism
1	July 9, 2004	2 Zione Injection / Lidocaine Zione Injection (Mitsubishi Pharmaceutical Co., Ltd.)	Approval Approval	Aluminum potassium sulfate, tannic acid	A new compound agent for local injection with indications for internal hemorrhoids associated with prolapse and is used for internal hemorrhoid sclerotherapy.
1	October 22, 2004	3 Hepsera Tablet 10 (Glaxo SmithKline K.K.)	Approval	<u>Adefovir pivoxil</u>	A nucleotide analogue of adenosine monophosphate which selectively inhibits HBV DNA polymerase, a new drug containing a new active ingredient with indications for improving hepatic function and levels of viral markers through combined use with lamivudine in chronic hepatitis B and hepatitis B cirrhosis in which abnormality of hepatic function with persistent regrowth of hepatitis B viruses has been confirmed during administration of lamivudine. <Priority assessment>
		Zefix Tablets 100 (Glaxo SmithKline K.K.)	Supplemental Change	Lamivudine	Addition to indications for improving the levels of viral markers and hepatic function in chronic hepatitis B and hepatitis B cirrhosis in which an abnormality of the hepatic function with persistent regrowth of type B hepatitis viruses has been confirmed during administration of this drug combined with adefovir pivoxil. <Priority assessment>

1	October 22, 2004	4 Intron A for injection 300 Intron A for injection 600 Intron A for injection 1000 (Schering Plough K.K.)	Supplemental Change Supplemental Change Supplemental Change	Interferon alfa-2b (Genetical Recombination)	When this drug is combined with ribavirin, the directions and dosage of ribavirin must be changed. <Priority assessment>
		Rebetol capsule 200mg (Schering Plough K.K.)	Supplemental Change	Ribavirin	Addition to indications of combined use with Peginterferon alfa-2b (Genetical recombination) to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA in serogroup 1. <Priority assessment>
		PegIntron Sterile Powder for Injection 50µg/0.5mL PegIntron Sterile Powder for Injection 100µg/0.5mL PegIntron Sterile Powder for Injection 150µg/0.5mL (Schering Plough K.K.)	Approval Approval Approval	Peginterferon alfa-2b (Genetical recombination)	A drug containing a new active ingredient which enables weekly administration through chemical modification of interferon alfa-2b by polyethylene glycol (PEG) to prolong the drug elimination time in blood and has indications combined with ribavirin to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA levels for serogroup 1. <Priority assessment>
2	June 22, 2004	5 Flolan for injection 0.5mg Flolan for injection 1.5mg (Glaxo SmithKline K.K.)	Supplemental Change Supplemental Change	Epoprostenol sodium	Addition to indications of pulmonary hypertension associated with specific diseases and a change of the description from "primary pulmonary hypertension" to "pulmonary arterial hypertension" <Orphan drug>
2	October 22, 2004	6 Fenofibrate fine powder Lipidil capsule 67 Lipidil capsule 100 (Grelan Pharmaceutical Co., Ltd.) Tricor capsule 67mg Tricor capsule 100mg (Taisho Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Fenofibrate	Pulverization enables a reduction in the dosage to two thirds of the current dosage for hyperlipidemia (including familial hyperlipidemia).
2	January 19, 2005	7 Crestor 2.5mg Crestor 5mg Crestor 10mg (AstraZeneca K.K.)	Approval Approval Approval	Rosuvastatin calcium	A drug containing a new active ingredient with indications for HMG-CoA reductase inhibition for hypercholestelemia and familial hypercholestelemia.
3	October	8		<u>Tiotropium</u>	A drug containing a new active

	22, 2004	Tiotropium Bromide Hydrate Spiriva Inhalation Capsules 18µg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	<u>Bromide Hydrate</u>	ingredient with indications for anticholinergic bronchodilation to alleviate various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
3	October 22, 2004	9 P Guard Tablets 20mg P Guard Tablets 30mg P Guard Tablets 60mg P Guard Tablets 120mg (Tanabe Seiyaku Co., Ltd.)	Approval Approval Approval Approval	Morphine sulfate	A new formulation of opioid drug for daily administration with indications as analgesia for moderate to severe pain in various cancers.
3	October 22, 2004	10 Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Takeda Pharmaceutical Co., Ltd.) Morphine hydrochloride (Sankyo Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Shionogi & Co., Ltd.) Anpec (Dainippon Pharmaceutical Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Tanabe Seiyaku Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Morphine hydrochloride	Addition of new routes of administration (epidural and intrathecal administration), besides previous subcutaneous or intravenous administration.
3	January 19, 2005	11 Enbrel 25mg for S.C. Injection (Wyeth K.K.)	Approval	<u>Etanercept (genetic recombination)</u>	A drug containing a new active ingredient, humanized fusion protein having an inhibitory action on the binding of the tumor necrosis factor (TNF) to a TNF

					receptor that has indications for rheumatoid arthritis
3	January 19, 2005	12 Qval 50 Qval 100 (Dainippon Pharmaceutical Co., Ltd.)	Supplemental Change Supplemental Change	Beclometasone dipropionate	Addition of a pediatric dosage for bronchial asthma
3	January 19, 2005	13 Alesion Dry Syrup 1% (Nippon Boehringer Ingerheim Co., Ltd.)	Approval	Epinastine hydrochloride	A pediatric preparation with indications for allergic rhinitis, urticaria, skin diseases (eczema, dermatitis, skin pruritus)
3	March 4, 2005	14 Epipen injection 0.15mg Epipen injection 0.3mg (Merck Ltd.)	Approval Supplemental Change	Epinephrine	Addition of its pediatric application and indications for adjunctive therapy for anaphylactic reaction induced by food, drug and others.
Anti-infective	April 23, 2004	15 Meropen for intravenous drip infusion 0.25g Meropen for intravenous drip infusion 0.5g (Sumitomo Pharmaceutical Co., Ltd.)	Supplemental Change Supplemental Change	Meropenem trihydrate	A carbapenem antibacterial agent. Addition of indications for purulent meningitis and dosage for pediatric patients.
Anti-infective	May 21, 2004	16 Zithromac Tablets 250mg (Pfizer Japan Inc.)	Supplemental Change	Azithromycin hydrate	Addition of indications for Chlamydia trachomatis, urethritis and uterine cervicitis and to dosage regimen.
Anti-infective	June 22, 2004	17 Rocephin 0.5g Rocephin 1g Rocephin 1g Bag (Chugai Pharmaceutical Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Ceftriaxone Sodium	Addition of indications for gonococcus and gonococcal pharyngitis, gonococcal urethritis, gonococcal uterine cervicitis, gonococcal pelvic inflammatory diseases, gonococcal epididymitis, gonococcal proctitis, and to dosage regimen.
Anti-infective	July 9, 2004	18 Gatiflo 0.3% ophthalmic solution (Senju Pharmaceutical Co., Ltd.)	Approval	Gatifloxacin hydrate	New quinolone antibacterial agent. An ophthalmic solution with indications for blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, aseptic therapy for ophthalmologic perioperative period.
Anti-infective	July 9, 2004	19 Tamiflu capsule 75 (Chugai Pharmaceutical Co., Ltd.)	Supplemental Change	Oseltamivir Phosphate	Addition of indications to prevent influenza A or B viral infections and dosage regimen.
Anti-infective	September 16, 2004	20 Maxipime for	Supplemental	Cefepime dihydrochloride	Addition of indications on febrile neutropenia

		injection 0.5g Maxipime for injection 1g (Bristol Myers K.K.)	Change Supplemental Change		
Anti-infective	October 22, 2004	21 Vancomycin for I.V.Infusion (Eli Lilly Japan K.K.)	Supplemental Change	Vancomycin hydrochloride	Additions of indications for sepsis, pneumonia, and purulent meningitis caused by penicillin-resistant-Streptococcus. <orphan drug>
Anti-infective	February 22, 2005	22 Pasil 300mg Pasil 500mg (Toyama Chemical Co., Ltd.) Pazucross injection 300 Pazucross injection 500 (Mitsubishi Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Pazufloxacin mesilate	Addition of indications for legionella infection.
5	April 23, 2004	23 Levitra 5mg Levitra 10mg (Bayer Yakuhin, Ltd.)	Approval Approval	<u>Vardenafil hydrochloride</u>	A drugs containing a new active ingredient with indications for phosphodiesterase-5 inhibitor in erectile dysfunction
Radioactive	April 23, 2004	24 Benzodine Injectable (Nihon Medi-Physics Co., Ltd.)	Approval	<u>Iomazenil (¹²³I)</u>	A drug containing a new active ingredient with indications for detection of epileptic focus in epilepsy by the central benzodiazepine-receptor scintigraphy.
In vivo diagnostic	October 22, 2004	25 Pralmorelin hydrochloride GHRP Kaken 100 (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	<u>Pralmorelin hydrochloride</u>	A diagnostic agent used for examination of secretory functions of growth hormones.
Oncology drug	May 31, 2004	26 Bleo (Nippon Kayaku Co., Ltd.)	Supplemental Change	Bleomycin hydrochloride	Addition of indications for germ cell tumors and dosage regimen
		Lastet Inj. (Nippon Kayaku Co., Ltd) VePesid Injection (Bristol Pharmaceuticals Y.K.)	Supplemental Change	Etoposide	

		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 Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	October 22, 2004	27 Zometa (Nihon Ciba-Geigy K.K.)	Approval	<u>Zoledronic Acid Hydrate</u>	A drug containing a new active ingredient which has a bone-absorption-inhibitory action and has indications for hypercalcemia caused by malignant tumors.
Oncology drug	October 22, 2004	28 Sandostatin 50µg Sandostatin 100µg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Octreotide Acetate	Addition of indications to alleviate digestive symptoms associated with digestive obstruction in patients with advanced or recurrent cancer.
Oncology drug	October 22, 2004	29 Anhydrous ethanol (Fuso) (Fuso Pharmaceutical Industries, Ltd.) Anhydrous ethanol (Shimizu) (Shimizu Pharmaceutical Co., Ltd.) Anhydrous ethanol (Merck) (Merck Hoei Ltd)	Approval Approval Approval	Anhydrous ethanol	A drug with a new administration route with indications for percutaneous ethanol injection therapy in hepatocellular carcinoma.
Oncology drug	October 22, 2004	30 Trisenox Injection 10mg (Nippon Shinyaku Co., Ltd.)	Approval	Arsenic Trioxide	A drug with a new administration route with indications for relapsed or refractory acute promyelocytic leukemia. <Priority review>
Oncology drug	December 14, 2004	31 TS-1 capsule 20	Supplemental	Tegafur, Gimeracil,	An addition to indications of non-small cell lung cancer to

		TS-1 capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Change Supplemental Change	Oteracil potassium	current indications of gastric cancer, rectal and colonic cancers and head and neck cancers.
Oncology drug	December 14, 2004	32 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of relapsed or refractory germ cell tumors (testicular tumor, ovarian tumor, extragonadal tumors) and to dosage regimen.
		Exal for Inj. 10mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vinblastine sulfate	
Oncology drug	January 19, 2005	33 Aredia 15mg Aredia 30mg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Pamidronate Disodium	Addition to indications of combined use with chemotherapy, endocrine therapy, or radiotherapy for osteolytic bone metastases of breast cancer. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	34 Adriacin injection (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in pre- or postoperative chemotherapy for operable cases of breast cancer and to dosage regimen.
Oncology drug	February 14, 2005	35 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in postoperative chemotherapy or chemotherapy for metastasis or recurrence of endometrial cancer <Combined therapy with anti-cancer agents>
		Randa Inj. (Nippon Kayaku Co., Ltd)	Supplemental Change	Cisplatin	
		Briplatin injection (Bristol Pharmaceuticals Y.K.)	Supplemental Change		
		Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.)	Supplemental Change Supplemental Change Supplemental Change		
		CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change		
Oncology drug	February 14, 2005	36 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents for malignant bone tumors and to dosage regimen.

		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 Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	<Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	37 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents for malignant bone and soft tissue tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifosfamide for malignant bone and soft tissue tumors, an addition to dosage for inhibiting the development of urological impairment associated with administration of said ifosfamide. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	38 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents on pediatric malignant solid tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		VePesid Injection (Bristol Pharmaceuticals Y.K.) Lastet Inj. (Nippon Kayaku Co., Ltd)	Supplemental Change Supplemental Change	Etoposide	

		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifofamide for pediatric malignant solid tumors, an addition to dosage for inhibiting the development of urological impairment associated with the administration of said ifosfamide. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	39 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with anticancer agents for colonic and rectal cancers and to dosage regimen. <Combined therapy with anticancer agents>
		Isovolin injection 25mg (Wyeth K.K.)	Supplemental Change	Levofolinate Calcium	
Oncology drug	February 14, 2005	40 Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	Addition to indications of combined therapy with anticancer agents for multiple myeloma and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Decadron Phosphate Injection (Banyu Phamaceutical Co., Ltd.) Orgadrone Injection (Nippon Organon K.K.) Dexart (Fuji Pharma Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Dexamethasone sodium phosphate	
Oncology drug	February 14, 2005	41 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with other anticancer agents for head and neck cancers and to dosage regimen. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	42 Natulan (Chugai Pharmaceutical Co., Ltd.)	Supplemental Change	Procarbazine hydrochloride	Addition to indications of combined therapy with other anticancer agents for glioma which possesses components of malignant astrocytoma and oligodendroglioma and to dosage regimen. <Combined therapy with anticancer agents>
		Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	
Oncology drug	March 18, 2005	43 Elplat for Injection 100mg (Yakult Honsha	Approval	<u>Oxaliplatin</u>	A drug containing a new active ingredient with indications for colonic and rectal cancers. <Priority review>

		Co., Ltd)			
AIDS	November 5, 2004	44 VALIXA Tablets 450mg (Tanabe Seiyaku Co., Ltd.)	Approval	<u>Valganciclovir hydrochloride</u>	A drug containing a new active ingredient, L-valine ester of ganciclovir, with indications for treatment of retinitis caused by cytomegalovirus in patients with acquired immune deficiency syndrome (AIDS) and dosage regimen. <Orphan drug>
AIDS	December 24, 2004	45 Lexiva Tablets 700 (Glaxo Smith Kline K.K.)	Approval	<u>Fosamprenavir Calcium Hydrate</u>	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	December 24, 2004	46 Epzicom Tablets (Glaxo Smith Kline K.K.)	Approval	Lamivudine, Abacavir Sulfate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	December 24, 2004	47 Ziagen Tablets (Glaxo Smith Kline K.K.)	Supplemental Change	Abacavir Sulfate	Addition to dosage regimen of "daily 600mg, once a day" to the current ones of "300mg per dose, twice a day." < Orphan drug >
AIDS	March 23, 2005	48 Emtriva Capsules 200mg (Japan Tobacco Inc.)	Approval	<u>Emtricitabine</u>	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >
AIDS	March 23, 2005	49 Truvada Tablets (Japan Tobacco Inc.)	Approval	<u>Emtricitabine,</u> Tenofovir disoproxil fumarate	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >