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 (Underlined: New active ingredients)	Note
1	23-Apr-04	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	9-Jul-04	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	22-Oct-04	3 Hepsera Tablet 10 (Glaxo SmithKline K.K.)	Approval	Adefovir pivoxil	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	22-Oct-04	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	22-Jun-04	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	22-Oct-04	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).

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
2	19-Jan-05	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	22-Oct-04	8 Tiotropium Bromide Hydrate Spiriva Inhalation Capsules 18μg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Tiotropium Bromide Hydrate	A drug containing a new active 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	22-Oct-04	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	22-Oct-04	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 Supplemental Change Supplemental Change 	Morphine hydrochloride	Addition of new routes of administration (epidural and intrathecal administration), besides previous subcutaneous or intravenous administration.
3	19-Jan-05	11 Enbrel 25mg for S.C. Injection (Wyeth K.K..)	Approval	Etanercept (genetic recombination)	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	19-Jan-05	12 Qval 50 Qval 100 (Dainippon Pharmaceutical. Co., Ltd.)	 Supplemental Change Supplemental Change	Beclometasone dipropionate	Addition of a pediatric dosage for bronchial asthma
3	19-Jan-05	13 Alesion Dry Syrup 1% (Nippon Boehringe Ingerheim Co., Ltd.)	Approval	Epinastine hydrochloride	A pediatric preparation with indications for allergic rhinitis, urticaria, skin diseases (eczema, dermatitis, skin pruritus)
3	4-Mar-05	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	23-Apr-04	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	21-May-04	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	22-Jun-04	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	9-Jul-04	18 Gatiflo 0.3% ophthalmic solution (Senju Pharmaceutical. Co., Ltd.)	Approval	Gatifloxacin hydrate	New quinolone antibacterial agent. An ophthalomic solution with indications for blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, aseptic therapy for ophthalmologic perioperative period.

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Anti-infective	9-Jul-04	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	16-Sep-04	20 Maxipime for injection 0.5g Maxipime for injection 1g (Bristol Myers K.K.)	Supplemental Change Supplemental Change	Cefepime dihydrochloride	Addition of indications on febrile neutropenia
Anti-infective	22-Oct-04	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	22-Feb-05	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 Chanee	Pazufloxacin mesilate	Addition of indications for legionella infection.
5	23-Apr-04	23 Levitra 5mg Levitra 10mg (Bayer Yakuhin, Ltd.)	Approval Approval	Vardenafil hydrochloride	A drugs containing a new active ingredient with indications for phosphodiesterase-5 inhibitor in erectile dysfunction.
Radioacitve	23-Apr-04	24 Benzodine Injectable (Nihon Medi-Physics Co., Ltd.)	Approval	Iomazenil (^{123}I)	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	22-Oct-04	25 Pralmorelin hydrochloride GHRP Kaken 100 (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	Pralmorelin hydrochloride	A diagnostic agent used for examination of secretory functions of growth hormones.
Oncology drug	31-May-04	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 Supplemental Change	Cisplatin	
Oncology drug	22-Oct-04	27 Zometa (Nihon Ciba-Geigy K.K.)	Approval	Zoledronic Acid Hydrate	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	22-Oct-04	28 Sandostatin 50μg Sandostatin 100μg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Chanee	Octreotide Acetate	Addition of indications to alleviate digestive symptoms associated with digestive obstruction in patients with advanced or recurrent cancer.
Oncology drug	22-Oct-04	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.

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Oncology drug	22-Oct-04	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	14-Dec-04	31 TS-1 capsule 20 TS-1 capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Supplemental Change Supplemental Change	Tegafur, Gimeracil, Oteracil potassium	An addition to indications of non-small cell lung cancer to current indications of gastric cancer, rectal and colonic cancers and head and neck cancers.
Oncology drug	14-Dec-04	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	19-Jan-05	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	14-Feb-05	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	14-Feb-05	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) 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	14-Feb-05	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. <Combined therapy with anticancer agents>
		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	14-Feb-05	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>

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
Oncology drug	14-Feb-05	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	14-Feb-05	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	14-Feb-05	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	14-Feb-05	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	14-Feb-05	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	18-Mar-05	43 Elplat for Injection 100mg (Yakult Honsha Co., Ltd)	Approval	Oxaliplatin	A drug containing a new active ingredient with indications for colonic and rectal cancers. <Priority review>
AIDS	5-Nov-04	44 VALIXA Tablets 450mg (Tanabe Seiyaku Co., Ltd.)	Approval	Valganciclovir hydrochloride	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	24-Dec-04	45 Lexiva Tablets 700 (Glaxo Smith Kline K.K.)	Approval	Fosamprenavir Calcium Hydrate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	24-Dec-04	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 >

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
AIDS	24-Dec-04	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	23-Mar-05	48 Emtriva Capsules 200mg (Japan Tobacco Inc.)	Approval	Emtricitabine	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >
AIDS	23-Mar-05	49 Truvada Tablets (Japan Tobacco Inc.)	Approval	Emtricitabine, Tenofovir disoproxil fumarate	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >