

Table 1. FY2007 List of Approved Products: New Drugs

Category	Approval Date		Trade Name (Applicant Company)	Approval/ Partial Change	Active Ingredient(s) (underlined, new active ingredient)	Notes
1	Apr. 18, 2007	1	Visiclear Tablets (Zeria Pharmaceutical Co., Ltd.)	Approval	Monobasic sodium phosphate monohydrate/dibasic sodium phosphate anhydrous	A new combination drug indicated for bowel cleansing as a preparation for colonoscopy.
1	Apr. 18, 2007	2	Nesp Injection Syringe 10 µg Nesp Injection Syringe 15 µg Nesp Injection Syringe 20 µg Nesp Injection Syringe 30 µg Nesp Injection Syringe 40 µg Nesp Injection Syringe 60 µg Nesp Injection Syringe 120 µg (Kirin Brewery Co., Ltd.)	Approval Approval Approval Approval Approval Approval	<u>Darbepoetin alfa</u> (<u>genetical recombination</u>)	Drugs containing a new active ingredient indicated for the treatment of renal anemia in dialysis patients.
1	May 24, 2007	3	Omepral Tablets 10 (AstraZeneca K.K.) Omeprazon Tablets 10 mg (Mitsubishi Pharma Corporation)	Change Change	Omeprazole	Drugs with a new indication and dosage for the treatment of non-erosive reflux disease.
1	Sep. 28, 2007	4	Cyanokit Injection Set (Merck Ltd., Japan)	Approval	Hydroxocobalamin	Drugs with a new indication and dosage for the treatment of cyanogen and cyanide poisoning.
1	Oct. 19, 2007	5	Regpara Tablets 25 mg Regpara Tablets 75 mg (Kirin Pharma Co., Ltd.)	Approval Approval	<u>Cinacalcet hydrochloride</u>	A drug containing a new active ingredient indicated for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis.
1	Nov. 13, 2007	6	Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation)	Change	Infliximab (genetical recombination)	A drug with a new indication and dosage for use as maintenance therapy in Crohn's disease. [Orphan drug]
1	Feb. 29, 2008	7	Pentasa Tablets 250 (Nisshin Kyorin Pharmaceutical Co., Ltd.)	Change	Mesalazine	A drug with a new dosage for use in pediatric patients for the treatment of ulcerative colitis (excluding severe patients) and Crohn's disease.
1	Feb. 29, 2008	8	Hebsbulin-IH for Intravenous (Benesis Corporation)	Change	Polyethylene glycol-treated human anti-HBs immunoglobulin	A drug with a new indication and dosage for the prevention of hepatitis B recurrence in HBs antigen-positive recipients after liver transplantation and of hepatitis B occurrence in recipients after liver transplantation from HBc antigen-positive donors.
2	Apr. 18, 2007	9	Arixtra Injection for Subcutaneous 1.5 mg Arixtra Injection for Subcutaneous 2.5 mg (GlaxoSmithKline K.K.)	Approval Approval	<u>Fondaparinux sodium</u>	Drugs containing a new active ingredient indicated for the prevention of venous thromboembolism in high-risk patients who have undergone lower-extremity orthopedic surgery. [Priority review]
2	Apr. 18, 2007	10	Zetia Tablets 10 mg (Schering-plough K.K.)	Approval	<u>Ezetimibe</u>	A drug containing a new active ingredient indicated for the inhibition of cholesterol absorption.
2	Jul. 31, 2007	11	Selara Tablets 25 mg Selara Tablets 50 mg Selara Tablets 100 mg (Pfizer Japan Inc.)	Approval Approval Approval	<u>Eplerenone</u>	Drugs containing a new active ingredient indicated for the treatment of hypertension.
2	Jun. 21, 2007	12	Tambocor Tablets 50 mg Tambocor Tablets 100 mg (Eisai Co., Ltd.)	Change Change	Flecainide acetate	Drugs with a new indication for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation and flutter).
2	Jun. 21, 2007	13	Ephedrine Hydrochloride Injection Fuso (Fuso Pharmaceutical Industries, Ltd.) Ephedrine Nagai Injection 40 mg (Dainippon Sumitomo Pharma Co., Ltd.) Ephedrine Hydrochloride Injection Sanken (Sanwa Kagaku Kenkyusho Co., Ltd.)	Change Change Change	Ephedrine hydrochloride	Drugs with a new indication and route of administration, or the intravenous route for the treatment of hypotension occurring during anesthesia, G20 and without intramuscular injection administered for their approved indications.

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2	Aug. 23, 2007	14	Aricept Tablets 3 mg Aricept Tablets 5 mg Aricept Tablets 10 mg Aricept D Tablets 3 mg Aricept D Tablets 5 mg Aricept D Tablets 10 mg Aricept Fine Granules 0.5% (Eisai Co., Ltd.)	Change Change Approval Change Change Approval Change	<u>Donepezil hydrochloride</u>	Drugs with a new indication and dosage for patients with severe dementia of the Alzheimer's type.
2	Oct. 19, 2007	15	Careload LA Tablets 60 µg (Toray Industries, Inc.) Berasus LA Tablets 60 µg (Kaken Pharmaceutical Co., Ltd.)	Approval Approval	<u>Beraprost sodium</u>	Drugs with a new indication and dosage and in a new dosage form for the treatment of pulmonary arterial hypertension. [Priority review]
2	Oct. 19, 2007	16	Sigmat Injection 2 mg Sigmat Injection 12 mg Sigmat Injection 48 mg (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	<u>Nicorandil</u>	Drugs with a new indication and dosage for the treatment of acute cardiac failure including the acute exacerbation period of chronic cardiac failure.
2	Oct. 19, 2007	17	Plavix Tablets 25 mg Plavix Tablets 75 mg (Sanofi-Aventis K.K.)	Change Change	<u>Clopidogrel sulfate</u>	Drugs with a new indication and dosage for acute coronary syndrome (unstable angina and non-ST-elevation myocardial infarction) in patients in whom percutaneous coronary intervention (PCI) is considered. [Priority review]
2	Jan. 25, 2008	18	Clexane Subcutaneous Injection Kit 2000 IU (Sanofi-Aventis K.K.)	Approval	<u>Enoxaparin sodium</u>	A drug containing a new active ingredient indicated for the prevention of venous thromboembolism in patients who have undergone total hip replacement, total knee replacement and hip fracture surgery. [Priority review]
2	Jan. 25, 2008	19	Amerge Tablets 2.5 mg (GlaxoSmithKline K.K.)	Approval	<u>Naratriptan hydrochloride</u>	A drug containing a new active ingredient indicated for the treatment of migraine.
2	Jan. 25, 2008	20	Recomodulin Injection 12800 (Asahi Kasei Pharma Corporation)	Approval	<u>Thrombomodulin alfa (genetical recombination)</u>	A drug containing a new active ingredient indicated for the treatment of disseminated intravascular coagulation (DIC).
2	Jan. 25, 2008	21	Revatio Tablets 20 mg (Pfizer Japan Inc.)	Approval	<u>Sildenafil citrate</u>	A drug with a new indication and dosage for the treatment of pulmonary arterial hypertension. [Orphan drug]
2	Feb. 29, 2008	22	Vasolan Tablets 40 mg (Eizai Co., Ltd.)	Change	<u>Verapamil hydrochloride</u>	A drug with a new indication for the treatment of tachyarrhythmia (atrial fibrillation and flutter, and paroxysmal supraventricular tachycardia).
2	Mar. 19, 2008	23	Brevibloc Injection 100 mg (Maruishi Pharmaceutical Co., Ltd.)	Change	<u>Esmolol hydrochloride</u>	A drug with a new dosage indicated for the emergency treatment of supraventricular tachyarrhythmia occurring during surgery.
3	Apr. 18, 2007	24	Mikelan LA Ophthalmic Solution 1% Mikelan LA Ophthalmic Solution 2% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval	<u>Carteolol hydrochloride</u>	Drugs in a new dosage form indicated for the treatment of glaucoma and ocular hypertension.
3	Jul. 31, 2007	25	Topina Topina Tablets 50 mg Topina Tablets 100 mg (Kyowa Hakko Kogyo Co., Ltd.)	Approval Approval Approval	<u>Topiramate</u>	Drugs containing a new active ingredient indicated for use as an adjunctive therapy with other antiepileptic drugs to treat partial seizures (including secondary generalized seizures) in patients with epilepsy not fully responding to other antiepileptic therapies.
3	Jul. 31, 2007	26	Eslax Intravenous 1% (Organon Japan)	Approval	<u>Rocuronium bromide</u>	A drug containing a new active ingredient indicated for inducing muscular relaxation during anesthesia and tracheal intubation.
3	Jul. 31, 2007	27	Travatanz Ophthalmic Solution 0.004% (Alcon Japan Ltd.)	Approval	<u>Travoprost</u>	A drug containing a new active ingredient indicated for the treatment of glaucoma and ocular hypertension.
3	Aug. 23, 2007	28	Fentanyl Injection 0.1 mg Sankyo Fentanyl Injection 0.25 mg Sankyo (Daiichi Sankyo Propharma Co., Ltd.)	Change	<u>Fentanyl citrate</u>	Drugs with a new dosage for use in pediatric patients for inducing general anesthesia and for inducing analgesia during general anesthesia. Expedited review.
3	Oct. 19, 2007	29	Salagen Tablets 5 mg (Kissei Pharmaceutical Co., Ltd.)	Change	<u>Pilocarpine hydrochloride</u>	A drug with a new indication for the treatment of oral dryness in patients with Sjögren's syndrome.

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4	Jan. 25, 2008	40	Gracevit Tablets 50 mg Gracevit Fine Granules 10% (Daiichi Sankyo Co., Ltd.)	Approval Approval	<u>Sitafloxacin hydrate</u>	A drug containing a new active ingredient indicated for the treatment of laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, infections secondary to chronic respiratory disease, cystitis, pyelonephritis, urethritis, cervicitis, otitis media, sinusitis, periodontal inflammation, pericoronitis and jaw inflammation.
4	Nov. 13, 2007	41	Rocephin Intravenous 0.5 g Rocephin Intravenous 1 g Rocephin Intravenous Drip 1 g Bag (Chugai Pharmaceutical Co., Ltd.)	Change Change Change	Ceftriaxone sodium	Drugs with a new dosage for use in children, premature infants, and neonates.
4	Feb. 29, 2008	42	Habekacin Injection 25 mg Habekacin Injection 75 mg Habekacin Injection 100 mg Habekacin Injection 200 mg (Meiji Seika Kaisha, Ltd.)	Change Change Change Approval	Arbekacin sulfate	Drugs with a new dosage and in a new dosage form indicated for the treatment of septicemia and pneumonia caused by arbekacin-sensitive methicillin-resistant <i>staphylococcus aureus</i> (MRSA).
5	Apr. 18, 2007	43	Imidafenacin Uritos Tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.) Staybla Tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.)	Approval Approval	<u>Imidafenacin</u>	Drugs containing a new active ingredient indicated for the treatment of micturition urgency, pollakiuria, and urge incontinence associated with overactive bladder.
5	Jul. 31, 2007	44	Divigel 1 mg (Pola Pharma Inc.)	Approval	Estradiol	A drug in a new dosage form, or gel, indicated for the treatment of vasomotor symptoms (hot flushes and sweating) associated with menopausal disorders and ovarian deficiency symptoms.
5	Jul. 31, 2007	45	Cialis Tablets 5 mg Cialis Tablets 10 mg Cialis Tablets 20 mg (Eli Lilly Japan K.K.)	Approval Approval Approval	<u>Tadalafil</u>	Drugs containing a new active ingredient indicated for the treatment of erectile dysfunction (patients unable to obtain or maintain erections sufficient for satisfactory sexual activity).
5	May 24, 2007	46	Levitra Tablets 5 mg Levitra Tablets 10 mg Levitra Tablets 20 mg (Bayer Yakuhin Ltd.)	Change Change Approval	Vardenafil hydrochloride hydrate	Drugs with a new dosage indicated for the treatment of erectile dysfunction (patients unable to obtain or maintain erections sufficient for satisfactory sexual activity).
5	Oct. 19, 2007	47	Dinagest Tablets 1 mg (Mochida Pharmaceutical Co., Ltd.)	Approval	<u>Dienogest</u>	A drug containing a new active ingredient indicated for the treatment of endometriosis.
5	Oct. 19, 2007	48	Artcereb Irrigation and Perfusion Solution for Cerebrospinal Surgery (Ostuka Pharmaceutical Factory, Inc.)	Approval	N/A because of a new combination drug	A new combination drug indicated for irrigation during craniotomy/trepanation and spinal surgery, and perfusion during endoscopic neurosurgery.
5	Mar. 19, 2008	49	Bicanate Infusion (Ostuka Pharmaceutical Factory, Inc.)	Approval	N/A because of a combination drug	A combination drug similar to other products indicated for the supply/correction of extracellular fluid in the cases where circulating blood and interstitial fluid decrease, and for the correction of metabolic acidosis.
6-1	Apr. 18, 2007	50	Alvesco 50 µg Inhaler 112 puffs Alvesco 100 µg Inhaler 112 puffs Alvesco 200 µg Inhaler 112 puffs Alvesco 200 µg Inhaler 56 puffs (Teijin Pharma Ltd.)	Approval Approval Approval Approval	<u>Ciclesonide</u>	Drugs containing a new active ingredient indicated for the treatment of asthma.
6-1	Apr. 18, 2007	51	Adoair 100 Diskus Adoair 250 Diskus Adoair 500 Diskus (GlaxoSmithKline K.K)	Approval Approval Approval	Salmeterol xinafoate/Fluticasone propionate	A new combination drug indicated for the treatment of asthma (in the case where a combination of inhaled corticosteroids and inhaled long-acting β_2 agonists is necessary).
6-1	Jul. 31, 2007	52	Singulair Fine Granules 4 mg (Banyu Pharmaceutical Co., Ltd.) Kipres Fine Granules 4 mg (Kyorin Pharmaceutical Co., Ltd.)	Approval Approval	Montelukast sodium	Drugs with a new dosage and in a new dosage form, or fine granules, indicated for the treatment of asthma in children aged 1 or more and less than 6 years.

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6-1	Sep. 28, 2007	53	Calonal Fine Granules 20%	Change	Acetaminophen	Drugs with a new indication and dosage for use as an antipyretic/analgesic in pediatric patients. Expedited review.
			Calonal Fine Granules 50%	Change		
			Calonal Tablets 200	Change		
			Calonal Tablets 300	Change		
			Calonal Syrup 2%	Change		
			Calonal Suppositories 100	Change		
			Calonal Suppositories 200	Change		
			(Showa Yakuhin Kako Co., Ltd.)			
			Pyriminazin Powder	Change		
			(Astellas Pharma Inc.)			
			Anhiba Suppositories 50 mg for Pediatric Use	Change		
			Anhiba Suppositories 100 mg for Pediatric Use	Change		
			Anhiba Suppositories 200 mg for Pediatric Use	Change		
			(Abbott Japan Co., Ltd.)			
			Pyretinol	Change		
			(Iwaki Seiyaku Co., Ltd.)			
			Acetaminophen Tablets 200 mg "Isei"	Change		
			(Isei Co., Inc.)			
			Cocarl Dry Syrup 20% for Pediatric	Change		
			Cocarl Dry Syrup 40%	Change		
			Cocarl Tablets 200 mg	Change		
			(Sanwa Kagaku Kenkyusho Co., Ltd.)			
			Paraceta Suppositories 100	Change		
			Paraceta Suppositories 200	Change		
			(Sioe Pharmaceutical Co., Ltd.)			
			Acetaminophen Tablets 200 mg (TYK)	Change		
			Acetaminophen Suppositories 100	Change		
			Acetaminophen Suppositories 200	Change		
			Acetaminophen Fine Granules 20% (TYK)	Change		
			(Taisho Pharmaceutical Co., Ltd.)			
			Calsil Fine Granules 20%	Change		
			Calsil Tablets 200	Change		
			Calsil Syrup 2% for Pediatric Use	Change		
			Calsil Suppositories 200 for Pediatric Use	Change		
			Calsil Suppositories 100 for Pediatric Use	Change		
			(Taiyo Yakuhin Co., Ltd.)			
			Atmiphen Tablets 200	Change		
			Atmiphen Dry Syrup 20%	Change		
			(Takata Seiyaku Co., Ltd.)			
			Acetaminophen Tablets 200 "Tatsumi"	Change		
			Acetaminophen Fine Granules 20% "Tatsumi"	Change		
			(Tatsumi Kagaku Co., Ltd.)			
			Anyrume Tablets 200 mg	Change		
			Anyrume Tablets 300 mg	Change		
			Anyrume S	Change		
			Anyrume S Suppositories 200	Change		
			Anyrume Fine Granules	Change		
			(Choseido Pharmaceutical Co., Ltd.)			
			Atenemen 20% Fine Granules	Change		
			Atenemen Tablets 200 mg	Change		
			Atenemen Suppositories 100 mg	Change		
			Atenemen Suppositories 200 mg	Change		
			(Tsuruhara Pharmaceutical Co., Ltd.)			
Acetaminophen "Hachi"	Change					
(Oriental Pharmaceutical and Synthetic Chemical Co., Ltd.)						
Sarutu Fine Granules 20%	Change					
Sarutu Tablets 200 mg	Change					
Sarutu Syrup for Pediatric 2%	Change					
Sarutu Dry Syrup for Pediatric 20%	Change					
(Towa Pharmaceutical Co., Ltd.)						
Aphlogis Suppositories 100	Change					
Aphlogis Suppositories 200	Change					

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			(Nissin Pharmaceutical Co., Ltd.)			
			Acetaminophen Tablets 200 mg "NP"	Change		
			Acetaminophen Fine Granules 20%	Change		
			(Nipro Pharma Corporation)			
			Alpiny Suppositories 50	Change		
			Alpiny Suppositories 100	Change		
			Alpiny Suppositories 200	Change		
			(Hisamitsu Pharmaceutical Co., Inc.)			
			Aspain	Change		
			(Maruishi Pharmaceutical Co., Ltd.)			
			Napa	Change		
			Napa Dry Syrup 20%	Change		
			(Merck Seiyaku Ltd.)			
			Acetaminophen "Yoshida"	Change		
			(Yoshida Pharmaceutical Co., Ltd.)			
6-1	Oct. 19, 2007	54	Claritin Tablets 10 mg Claritin RediTabs 10 mg Claritin Dry Syrup 1% (Schering-plough K.K.)	Change Change Approval	Loratadine	Drugs with a new dosage and in a new dosage form, or dry syrup, for use in pediatric patients.
6-1	Jan. 25, 2008	55	Singulair Tablets 5 mg Singulair Tablets 10 (Banyu Pharmaceutical Co., Ltd.) Kipres Tablets 5 mg Kipres Tablets 10 (Kyorin Pharmaceutical Co., Ltd.)	Approval Change Approval Change	Montelukast sodium	Drugs with a new indication and dosage and in a new dosage form for the treatment of allergic rhinitis.
6-1	Jan. 25, 2008	56	Talymus Ophthalmic Suspension 0.1% (Senju Pharmaceutical Co., Ltd.)	Approval	Tacrolimus hydrate	A drug with a new route of administration indicated for the treatment of vernal conjunctivitis (in the case where anti-allergic drugs are not sufficiently effective). [Orphan drug]
6-2	Apr. 18, 2007	57	Myozyme 50 mg for Intravenous Infusion (Genzyme Japan K.K.)	Approval	<u>Alglucosidase alfa</u> (<u>genetical</u> <u>recombination</u>)	A drug containing a new active ingredient indicated for the treatment of type 2 glycogenosis. [Orphan drug]
6-2	Apr. 18, 2007	58	Actonel Tablets 17.5 mg (Takeda Pharmaceutical Co., Ltd.) Benet Tablets 17.5 mg (Ajinomoto Co., Inc.)	Change Change	Risedronate sodium hydrate	Drugs with a new dosage and in a new dosage form indicated for the treatment of osteoporosis (once-weekly dosing).
6-2	May 24, 2007	59	Glufast Tablets 5 mg Glufast Tablets 10 mg (Kissei Pharmaceutical Co., Ltd.)	Change	Mitiglinide calcium hydrate	Drugs with a new indication for use in combination with α -glucosidase inhibitors to reduce glycemic excursions in patients with type 2 diabetes mellitus in whom diet and exercise therapy is not sufficiently effective.
6-2	Aug. 23, 2007	60	NovoRapid 300 NovoRapid 300 FlexPen NovoRapid 100 U/mL Vial NovoRapid 30 Mix NovoRapid 30 Mix FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval Approval Approval Approval	<u>Insulin aspart</u> (<u>genetical</u> <u>recombination</u>)	Drugs containing a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated. A change has been made to the manufacturing process of the drug substance. Pharmaceutical formulations, manufacturing processes, indications, and dosage are the same as those in the approved formulations.
6-2	Oct. 04, 2007	61	Elaprased 6 mg for Intravenous Infusion (Genzyme Japan K.K.)	Approval	<u>Idursulfase</u> (<u>genetical</u> <u>recombination</u>)	Drugs containing a new active ingredient indicated for the treatment of mucopolysaccharidosis II. [Orphan drug]
6-2	Oct. 19, 2007	62	Levemir 300 Levemir 300 FlexPen (Novo Nordisk Pharma Ltd.)	Approval Approval	<u>Insulin detemir</u> (<u>genetical</u> <u>recombination</u>)	Drugs containing a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated.
6-2	Nov. 13, 2007	63	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 indication for reducing glycemic excursions in patients with type 2 diabetes mellitus (in the case where therapy with biguanides in addition to diet and exercise therapy is not sufficiently effective).

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6-2	Jan. 25, 2008	64	Nobelzin Capsules 25 mg Nobelzin Capsules 50 mg (Nobelpharma Co., Ltd.)	Approval Approval	<u>Zinc acetate dihydrate</u>	Drugs containing a new active ingredient indicated for the treatment of Wilson's disease (hepatolenticular degeneration). [Orphan drug]
6-2	Mar. 28, 2008	65	Naglazyme 5 mg for Intravenous Infusion (AnGes MG, Inc.)	Approval	<u>Galsulfase (genetical recombination)</u>	A drug containing a new active ingredient indicated for the treatment of mucopolysaccharidosis VI. [Orphan drug]
In vivo Diagnostics	May 24, 2007	66	Magnevist Magnevist Syringe (Nihon Schering K.K.)	Change	Meglumine gadopentetate	A drug with a new dosage for use in magnetic resonance computerized tomography imaging of the brain/spinal cord and body/extremities.
In vivo Diagnostics	Oct. 19, 2007	67	EOB Primovist Injection Syringe (Bayer Yakuhin Ltd.)	Approval	<u>Gadoxetate sodium</u>	A drug containing a new active ingredient indicated for use in magnetic resonance computerized tomography imaging of liver tumors.
Oncology drugs	Apr. 18, 2007	68	Avastin 100 mg/4 mL for Intravenous Infusion Avastin 400 mg/16 mL for Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	<u>Bevacizumab (genetical recombination)</u>	Drugs containing a new active ingredient indicated for the treatment of unresectable advanced/relapsed colorectal cancer. [Priority review]
Oncology drugs	Jul. 31, 2007	69	Metastron Injectable (GE Healthcare Ltd.)	Approval	<u>Strontium (⁸⁹Sr) chloride</u>	A drug containing a new active ingredient indicated for pain relief in bone scintigraphy-positive metastatic lesions in patients with solid cancers.
Oncology drugs	Aug. 23, 2007	70	TS-1 Capsule 20 TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Change Change	A combination drug of Tegafur, Gimeracil, and Oteracil potassium	Drugs with a new indication for the treatment of biliary cancer in addition to gastric cancer, colorectal cancer, head and neck cancer, non-small cell lung cancer, inoperable or relapsed breast cancer, and pancreatic cancer.
Oncology drugs	Oct. 19, 2007	71	Tarceva Tablets 25 mg Tarceva Tablets 100 mg Tarceva Tablets 150 mg (Chugai Pharmaceutical Co., Ltd.)	Approval Approval Approval	<u>Erlotinib</u>	Drugs containing a new active ingredient indicated for the treatment of unresectable, relapsed/advanced non-small cell lung cancer exacerbated after cancer chemotherapy. [Priority review]
Oncology drugs	Oct. 19, 2007	72	Arranon G Injection 250 mg (GlaxoSmithKline K.K.)	Approval	<u>Nelarabine</u>	A drug containing a new active ingredient indicated for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma. [Orphan drug]
Oncology drugs	Dec. 12, 2007	73	Xeloda Tablets 300 (Chugai Pharmaceutical Co., Ltd.)	Change	Capecitabine	A drug with a new indication and dosage for use as a postoperative adjuvant chemotherapy of colon cancer. A drug with a new dosage for the treatment of inoperable or relapsed breast cancer.
Oncology drugs	Dec. 12, 2007	74	Taxol Injection 30 mg Taxol Injection 100 mg (Bristol-Myers K.K.)	Change Change	Paclitaxel	Drugs with a new dosage indicated for the treatment of breast cancer, with once-weekly dosing continuously for 6 weeks followed by a 2-week withdrawal period.
Oncology drugs	Jan. 25, 2008	75	Nexavar Tablets 200 mg (Bayer Yakuhin Ltd.)	Approval	<u>Sorafenib tosilate</u>	A drug containing a new active ingredient indicated for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review]

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Oncology drugs	Jan. 25, 2008	76	1. Zevalin Yttrium (⁹⁰ Y) Injection Set	Approval	<u>1: Ibritumomab tiuxetan (genetical recombination) Yttrium chloride (90Y)</u> <u>2: Ibritumomab tiuxetan (genetical recombination) Indium chloride (111In)</u>	1: A drug containing a new active ingredient indicated for the treatment of relapsed or refractory, CD20-positive lymphomas of the following: low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. 2: A drug containing a new active ingredient indicated for determining the site of ibritumomab tiuxetan (genetical recombination) accumulation. [Orphan drug]
			2. Zevalin Indium (¹¹¹ In) Injection Set (Bayer Yakuhin Ltd.)	Approval		
			Rituxan Injection 10 mg/mL (Zenyaku Kogyo K.K.)	Change		
Oncology drugs	Feb. 29, 2008	77	Herceptin Injection 60 Herceptin Injection 150 (Chugai Pharmaceutical Co., Ltd.)	Change	Trastuzumab (genetical recombination)	Drugs with a new indication and dosage for use as a postoperative adjuvant chemotherapy in patients with HER2-overexpressing breast cancer. [Priority review]
Blood products	Oct. 19, 2007	78	rHSA Bulk Solution Medway Injection 25% Medway Injection 5% (Mitsubishi Tanabe Pharma Corporation) rHSA Bulk Solution—Bipha Stem Injection 25% Stem Injection 5% (Bipha Corporation)	Approval Approval Approval Approval	<u>Human serum albumin (genetical recombination)</u>	Drugs containing a new active ingredient indicated for the treatment of hypoalbuminemia caused by loss of albumin (due to thermal burn, nephrotic syndrome, etc.) and reduced albumin synthesis (cirrhosis, etc.), and hemorrhagic shock.
Biologicals	Oct. 19, 2007	79	Adsorbed Pandemic Influenza Vaccine (H5N1) "Hokken" (The Kitasato Institute)	Approval	<u>Inactivated influenza virus, H5N1 (whole virion)</u>	A drug containing a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
Biologicals	Oct. 19, 2007	80	Adsorbed Pandemic Influenza Vaccine (H5N1) "Biken" (The Research Foundation for Microbial Diseases of Osaka University)	Approval	<u>Inactivated influenza virus, H5N1 (whole virion)</u>	A drug containing a new active ingredient indicated for the prevention of pandemic influenza (H5N1). [Orphan drug]
AIDS drugs	Nov. 22, 2007	81	Prezista Tablets 300 mg (Janssen Pharmaceutical K.K.)	Approval	<u>Darunavir ethanolate</u>	A drug containing a new active ingredient indicated for the treatment of HIV infection. [Orphan drug]