

Table 1. Products Approved in FY 2009: New Drugs

| Category | Approval Date | | Brand Name (Applicant Company) | Approval/ Partial Change | Active Ingredient(s) (underlined: new active ingredient) | Notes |
|----------|---------------|----|---|--|--|--|
| 1 | Apr. 22, 2009 | 1 | Niflec (Ajinomoto Co., Inc.) | Change | N/A for this combination drug | A drug with a new additional indication and a new dosage for cleansing of gastrointestinal tract for pretreatment of barium enema X-ray examination. |
| | | | Gasmotin Tablets 2.5 mg Gasmotin Tablets 5 mg Gasmotin Powder (Dainippon Sumitomo Pharma Co., Ltd.) | Change Change Change | Mosapride citrate hydrate | Drugs with a new additional indication and a new dosage for adjunctive treatment to pretreatment with orally gastrointestinal lavage solution for barium enema X-ray examination. |
| 1 | Jul. 7, 2009 | 2 | Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Capsules 5 mg (Astellas Pharma Inc.) | Change Change Change | Tacrolimus hydrate | Drugs with a new additional indication and a new dosage for the treatment of refractory (steroid- resistant/steroid-dependent) active ulcerative colitis (limited to moderate-to-severe cases). |
| 1 | Oct. 16, 2009 | 3 | Emend Capsules 80 mg Emend Capsules 125 mg Emend Capsules Set (Ono Pharmaceutical Co., Ltd.) | Approval Approval Approval | <u>Aprepitant</u> | Drugs with a new active ingredient indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.). |
| 1 | Oct. 16, 2009 | 4 | Feron for Injection 6 MIU Feron for Injection 3 MIU Feron for Injection 1 MIU (Toray Industries, Inc.) | Change | Interferon beta | Drugs with a new additional indication and a new dosage for the improvement of viraemia in chronic hepatitis C on concomitant administration with ribavirin. |
| | | | Rebetol Capsule 200 mg (Schering-Plough K.K.) | Change | Ribavirin | A drug with a new additional indication and a new dosage for the improvement of viraemia in chronic hepatitis C on concomitant administration with interferon beta. |
| 1 | Oct. 16, 2009 | 5 | Asacol Tablets 400 mg (Zeria Pharmaceutical Co., Ltd.) | Approval | Mesalazine | A drug in a new dosage form and with a new dosage indicated for the treatment of ulcerative colitis (excluding severe case). |
| 1 | Jan. 20, 2010 | 6 | Aloxi I.V. Injection 0.75 mg (Taiho Pharmaceutical Co., Ltd.) | Approval | <u>Palonosetron hydrochloride</u> | A drug with a new active ingredient indicated for the treatment of digestive symptoms (nausea and vomiting, including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.). |
| 1 | Jan. 20, 2010 | 7 | Epoetin Alfa BS Injection 750 syringe [JCR] Epoetin Alfa BS Injection 1500 syringe [JCR] Epoetin Alfa BS Injection 3000 syringe [JCR] Epoetin Alfa BS Injection 750 [JCR] Epoetin Alfa BS Injection 1500 [JCR] Epoetin Alfa BS Injection 3000 [JCR] (JCR Pharmaceuticals Co., Ltd.) | Approval Approval Approval Approval Approval Approval | <u>Epoetin kappa (genetical recombination) [epoetin alfa biosimilar 1]</u> | Follow-on biologics indicated for the treatment of renal anemia in patients on dialysis and anemia of prematurity. |
| 1 | Mar. 12, 2010 | 8 | Protecadin Tablet 5 Protecadin Tablet 10 (Taiho Pharmaceutical Co., Ltd.) | Change Change | Lafutidine | Drugs with a new additional indication for the treatment of reflux esophagitis. |
| 2 | Apr. 22, 2009 | 9 | Micombi Combination Tablets AP (Nippon Boehringer Ingelheim Co., Ltd.) | Approval | Telmisartan/ hydrochlorothiazide | New combination drugs indicated for the treatment of hypertension. |
| | | 10 | Micombi Combination Tablets BP (Nippon Boehringer Ingelheim Co., Ltd.) | Approval | | |
| 2 | Jul. 7, 2009 | 11 | Caduet Combination Tablets 1ban Caduet Combination Tablets 2ban Caduet Combination Tablets 3ban Caduet Combination Tablets 4ban (Pfizer Japan Inc.) | Approval Approval Approval Approval | Amlodipine besilate/atorvastatin calcium hydrate | New combination drugs indicated for the treatment of comorbidity of hypertension or angina pectoris and hypercholesterolemia or familial hypercholesterolemia. |
| 2 | Jul. 7, 2009 | 12 | Rasilez Tablets 150 mg (Novartis Pharma K.K.) | Approval | <u>Aliskiren fumarate</u> | A drug with a new active ingredient indicated for the treatment of hypertension. |
| 2 | Oct. 16, 2009 | 13 | Adcirca Tablets 20 mg (Eli Lilly Japan K.K.) | Approval | Tadalafil | A drug with a new indication and a new dosage for the treatment of pulmonary arterial hypertension. |
| 2 | Jan. 20, 2010 | 14 | Exforge Combination Tablets (Novartis Pharma K.K.) | Approval | Valsartan/amlodipine besylate | A new combination drug indicated for the treatment of hypertension. |
| 2 | Jan. 20, 2010 | 15 | Rezaltas Combination Tablets LD Rezaltas Combination Tablets HD (Daiichi Sankyo Co., Ltd.) | Approval Approval | Olmesartan medoxomil/ azelnidipine | New combination drugs indicated for the treatment of hypertension. |

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| 3-1 | Apr. 22, 2009 | 16 | Risperdal Consta Intramuscular Injection 25 mg Risperdal Consta Intramuscular Injection 37.5 mg Risperdal Consta Intramuscular Injection 50 mg (Janssen Pharmaceutical K.K.) | Approval Approval Approval | Risperidone | Drugs with a new route of administration indicated for the treatment of schizophrenia. |
| 3-1 | Apr. 22, 2009 | 17 | Strattera Capsules 5 mg Strattera Capsules 10 mg Strattera Capsules 25 mg (Eli Lilly Japan K.K.) | Approval Approval Approval | <u>Atomoxetine hydrochloride</u> | Drugs with a new active ingredient indicated for the treatment of attention-deficit/hyperactivity disorder (AD/HD) in children. [Expedited review] |
| 3-1 | Apr. 22, 2009 | 18 | Clozaril Tablets 25 mg Clozaril Tablets 100 mg (Novartis Pharma K.K.) | Approval Approval | <u>Clozapine</u> | Drugs with a new active ingredient indicated for the treatment of treatment-resistant schizophrenia. |
| 3-1 | Jul. 7, 2009 | 19 | Remeron Tablets 15 mg (Schering-Plough K.K.) Reflex Tablets 15 mg (Meiji Seika Kaisha, Ltd.) | Approval Approval | <u>Mirtazapine</u> | Drugs with a new active ingredient indicated for the treatment of depression. |
| 3-1 | Oct. 16, 2009 | 20 | Paxil Tablets 10 mg Paxil Tablets 20 mg (GlaxoSmithKline K.K.) | Change Change | Paroxetine hydrochloride hydrate | Drugs with a new additional indication and a new dosage for the treatment of social anxiety disorder. |
| 3-1 | Oct. 16, 2009 | 21 | Prograf Capsules 0.5 mg Prograf Capsules 1 mg Prograf Granules 0.2 mg Prograf Granules 1 mg (Astellas Pharma Inc.) | Change Change Change Change | Tacrolimus hydrate | Drugs with a revised indication for the treatment of myasthenia gravis (limitation of patients to be treated was abolished.) [Orphan drug] |
| 3-1 | Jan. 20, 2010 | 22 | Bi-Sifrol Tablets 0.125 mg Bi-Sifrol Tablets 0.5 mg (Nippon Boehringer Ingelheim Co., Ltd.) | Change Change | Pramipexole hydrochloride hydrate | Drugs with a new additional indication and a new dosage for the treatment of moderate to severe idiopathic restless legs syndrome. |
| 3-1 | Jan. 20, 2010 | 23 | Cymbalta Capsules 20 mg Cymbalta Capsules 30 mg (Shionogi & Co., Ltd.) | Approval Approval | <u>Duloxetine hydrochloride</u> | Drugs with a new active ingredient indicated for the treatment of depression. |
| 3-1 | Jan. 20, 2010 | 24 | Kenketsu Venilon-I for Intravenous Injection 500 mg (Kaketsuken [The Chemo-Sero-Therapeutic Research Institute]) | Change | Freeze-dried sulfonated human normal immunoglobulin | A drug with a new additional indication and a new dosage for the improvement of neurological disorder in patients with Churg-Strauss syndrome or allergic granulomatous angiitis (for use only when steroids are not sufficiently effective). [Orphan drug] |
| 3-2 | Jul. 7, 2009 | 25 | Lumigan Ophthalmic Solution 0.03% (Senju Pharmaceutical Co., Ltd.) | Approval | <u>Bimatoprost</u> | A drug with a new active ingredient indicated for the treatment of glaucoma and ocular hypertension. |
| 3-2 | Aug. 20, 2009 | 26 | DisCoVisc 1.0 Ophthalmic Viscoelastic Substance (Alcon Japan Ltd.) | Approval | Sodium hyaluronate, chondroitin sulfate sodium | A drug in a new dosage form indicated for adjunctive treatment for crystalline lens reconstruction. |
| 3-2 | Jan. 20, 2010 | 27 | Bridion Intravenous 200 mg Bridion Intravenous 500 mg (Schering-Plough K.K.) | Approval Approval | <u>Sugammadex sodium</u> | Drugs with a new active ingredient indicated for the recovery from neuromuscular blockade induced by rocuronium bromide or vecuronium bromide. |
| 3-2 | Jan. 20, 2010 | 28 | Xalacom Combination Eye Drops (Pfizer Japan Inc.) | Approval | Latanoprost/timolol maleate | A new combination drug indicated for the treatment of glaucoma and ocular hypertension. |
| 3-2 | Jan. 20, 2010 | 29 | Durotep MT Patch 2.1 mg Durotep MT Patch 4.2 mg Durotep MT Patch 8.4 mg Durotep MT Patch 12.6 mg Durotep MT Patch 16.8 mg (Janssen Pharmaceutical K.K.) | Change Change Change Change Change | Fentanyl | Drugs with a new indication for analgesia of moderate to severe chronic pain which cannot be managed by treatments with non-opioid analgesics and weak opioid analgesics (for use only in patients who switch from an opioid analgesic). |
| 3-2 | Mar. 12, 2010 | 30 | Dormicum Injection 10 mg (Astellas Pharma Inc.) | Change | Midazolam | A drug with a new additional pediatric dosage indicated for anesthetic premedication and for sedation during artificial respiration in patients under intensive care. |
| 4 | Apr. 22, 2009 | 31 | Orapenem Fine Granules 10% for Pediatric (Meiji Seika Kaisha, Ltd.) | Approval | <u>Tebipenem pivoxil</u> | A drug with a new active ingredient indicated for the treatment of pneumonia, otitis media, and sinusitis. |
| 4 | Apr. 22, 2009 | 32 | Cravit Tablets 250 mg Cravit Tablets 500 mg (Daiichi Sankyo Co., Ltd.) | Approval Approval | Levofloxacin hydrate | Drugs in an additional dosage form and with a revised dosage of once-daily administration for conventional indications. |
| | | 33 | Cravit Fine Granules 10% (Daiichi Sankyo Co., Ltd.) | Approval | | |

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| 4 | May 20, 2009 | 34 | Valixa Tablets 450 mg (Mitsubishi Tanabe Pharma Corporation) | Change | Valganciclovir hydrochloride | A drug with a new additional indication for the treatment of cytomegalovirus infection in organ transplantation (including hematogenic stem cell transplantation), malignant tumor, etc. |
| 4 | Jun. 17, 2009 | 35 | AmBisome 50 mg for Intravenous Drip Infusion (Dainippon Sumitomo Pharma Co., Ltd.) | Change | Amphotericin B | A drug with new additional indications and a new dosage for the treatment of fungal infections caused by Mucor species, Absidia species, Rhizopus species, Rhizomucor species, Cladosporium species, Cladophialophora species, Fonsecaea species, Phialophora species, Exophiala species, Coccidioides species, Histoplasma species, and Blastomyces species and visceral leishmaniasis. |
| 4 | Oct. 16, 2009 | 36 | Vancomycin Ophthalmic Ointment 1% (Toa Pharmaceutical Co., Ltd.) | Approval | Vancomycin hydrochloride | A drug with a new route of administration indicated for the treatment of conjunctivitis, blepharitis, meibomianitis, and dacryocystitis caused by vancomycin-sensitive methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant Staphylococcus epidermidis (MRSE). [Orphan drug] |
| 4 | Oct. 16, 2009 | 37 | Ozex Fine Granules 15% for Pediatric (Toyama Chemical Co., Ltd.) | Approval | Tosufloxacin tosilate hydrate | A drug with new additional indications and a new dosage and in a new dosage form for the treatment of pneumonia, cholera, otitis media, and anthrax in children. |
| 4 | Dec. 18, 2009 | 38 | Tamiflu Dry Syrup 3% Tamiflu Capsule 75 (Chugai Pharmaceutical Co., Ltd.) | Change Change | Oseltamivir phosphate | Drugs with a new additional indication and a new dosage for prophylaxis of influenza A or B virus infections. |
| 4 | Jan. 13, 2010 | 39 | Rapiacta 300 mg Bag for Intravenous Drip Infusion Rapiacta 150 mg Vial for Intravenous Drip Infusion (Shionogi & Co., Ltd.) | Approval Approval | <u>Peramivir hydrate</u> | Drugs with a new active ingredient indicated for the treatment of influenza A or B virus infections. |
| 4 | Jan. 20, 2010 | 40 | Meropen for Intravenous Drip Infusion Vial 0.25 g Meropen for Intravenous Drip Infusion Vial 0.5 g Meropen for Intravenous Drip Infusion Kit 0.5 g (Dainippon Sumitomo Pharma Co., Ltd.) | Change Change Change | Meropenem hydrate | Drugs with a new additional indication and a new dosage for the treatment of febrile neutropenia. |
| 5 | Jul. 7, 2009 | 41 | Avolve Capsules 0.5 mg (GlaxoSmithKline K.K.) | Approval | <u>Dutasteride</u> | A drug with a new active ingredient indicated for the treatment of benign prostatic hyperplasia. |
| 5 | Jul. 7, 2009 | 42 | Gonalef 75 Gonalef Pen 300 Gonalef Pen 450 Gonalef Pen 900 (Merck Serono Co., Ltd.) | Change Change Change Change | Follitropin alfa (genetical recombination) | Drugs with a new additional indication and a new dosage for induction of ovulation in patients with anovulation and infrequent ovulation associated with hypothalamic-pituitary dysfunction or polycystic ovarian syndrome. |
| 5 | Nov. 6, 2009 | 43 | Rinderon Injection 2 mg (0.4%) Rinderon Injection 4 mg (0.4%) (Shionogi & Co., Ltd.) | Change Change | Betamethasone sodium phosphate | Drugs with a new additional indication and a new dosage for prevention of neonatal respiratory distress syndrome by way of enhancing fetal lung maturation by maternal administration for use in cases where premature birth is expected. |
| 5 | Dec. 18, 2009 | 44 | Uritos Tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.) Staybla Tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.) | Change Change | Imidafenacin | Drugs with a new dosage indicated for the treatment of urgency of urination, pollakiuria, and urge urinary incontinence associated with overactive bladder. |
| 5 | Dec. 18, 2009 | 45 | Bup-4 Tablet 10 Bup-4 Tablet 20 Bup-4 Fine Granule 2% (Taiho Pharmaceutical Co., Ltd.) | Change Change Change | Propiverine hydrochloride | Drugs with a new additional indication for the treatment of urgency of urination, pollakiuria, and urge urinary incontinence associated with overactive bladder. |
| 6-1 | Apr. 22, 2009 | 46 | Allermist 27.5 µg 56 metered Nasal Spray (GlaxoSmithKline K.K.) | Approval | <u>Fluticasone furoate</u> | A drug with a new active ingredient indicated for the treatment of allergic rhinitis. |
| 6-1 | Apr. 22, 2009 | 47 | Zyrtec Dry Syrup 1.25% Zyrtec Tablet 5 (UCB Japan Co., Ltd.) | Change Change | Cetirizine hydrochloride | Drugs with a new additional pediatric dosage indicated for the treatment of allergic rhinitis, urticaria, and itching associated with skin disease (eczema/dermatitis and pruritus cutaneous). |
| 6-1 | Jun. 17, 2009 | 48 | Celecox Tablets 100 mg Celecox Tablets 200 mg (Astellas Pharma Inc.) | Change Change | Celecoxib | Drugs with new additional indications for the treatment of lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tenosynovitis. |

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| 6-1 | Jul. 7, 2009 | 49 | Enbrel 25 mg for S.C. Injection (Wyeth K.K.) | Change | Etanercept (genetical recombination) | A drug with a new indication and a new dosage for the treatment of polyarticular-course juvenile idiopathic arthritis (for use only in patients who have not sufficiently responded to conventional treatments). |
| 6-1 | Jul. 7, 2009 | 50 | Asmanex Twisthaler 100 µg 60 doses Asmanex Twisthaler 200 µg 60 doses (Schering-Plough K.K.) | Approval Approval | Mometasone furoate | Drugs with a new route of administration indicated for the treatment of bronchial asthma. |
| 6-1 | Jul. 7, 2009 | 51 | Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation) | Change | Infliximab (genetical recombination) | A drug with a new indication and a new dosage for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments. [Expedited review] |
| 6-1 | Oct. 16, 2009 | 52 | Erizas Capsule for Nasal Spray 400 µg (Nippon Shinyaku Co., Ltd.) | Approval | <u>Dexamethasone cipeclate</u> | A drug with a new active ingredient indicated for the treatment of allergic rhinitis. |
| 6-1 | Oct. 16, 2009 | 53 | Symbicort Turbuhaler 30 doses Symbicort Turbuhaler 60 doses (AstraZeneca K.K.) | Approval Approval | Budesonide/formoterol fumarate hydrate | New combination drugs indicated for the treatment of bronchial asthma (when a combination treatment of an inhaled steroid and a long-acting beta ₂ agonist is needed). |
| 6-1 | Nov. 6, 2009 | 54 | Mohrus Tape 20 mg Mohrus Tape L 40 mg (Hisamitsu Pharmaceutical Co., Inc.) | Change Change | Ketoprofen | Drugs with a new additional indication for relief of local pain associated with rheumatoid arthritis. |
| 6-1 | Jan. 20, 2010 | 55 | Spiriva 2.5 µg Respimat 60 puffs (Nippon Boehringer Ingelheim Co., Ltd.) | Approval | Tiotropium bromide hydrate | A drug in a new dosage form and with a new dosage as a kit product consisting of Respimat inhaler and a cartridge (solution). |
| 6-1 | Jan. 20, 2010 | 56 | Remicade for I.V. Infusion 100 (Mitsubishi Tanabe Pharma Corporation) | Change | Infliximab (genetical recombination) | A drug with new additional indications and a new dosage for the treatment of plaque psoriasis, psoriatic arthritis, pustular psoriasis, and erythrodermic psoriasis in patients who have not responded sufficiently to conventional treatments. |
| 6-1 | Jan. 20, 2010 | 57 | Humira 40 mg for S.C. Injection Syringe 0.8 mL (Abbott Japan Co., Ltd.) | Change | Adalimumab (genetical recombination) | A drug with new additional indications and a new dosage for the treatment of plaque psoriasis and psoriatic arthritis in patients who have not responded sufficiently to conventional treatments. |
| 6-1 | Feb. 5, 2010 | 58 | Enbrel 10 mg for S.C. Injection Enbrel 25 mg Syringe 0.5 mL for S.C. Injection (Wyeth K.K.) | Change Change | Etanercept (genetical recombination) | Drugs with a new dosage indicated for the treatment of rheumatoid arthritis (for use only in patients who have not sufficiently responded to conventional treatments). |
| | | 59 | Enbrel 25 mg for S.C. Injection Enbrel 50 mg Syringe 1.0 mL for S.C. Injection (Wyeth K.K.) | Change Approval | | |
| 6-2 | Apr. 22, 2009 | 60 | Norditropin S Injection 5 mg Norditropin S Injection 10 mg Norditropin NordiFlex Injection 5 mg Norditropin NordiFlex Injection 10 mg Norditropin NordiFlex Injection 15 mg (Novo Nordisk Pharma Ltd.) | Change Change Change Change Change | Somatropin (genetical recombination) | Drugs with a new additional indication and a new dosage for the treatment of adult growth hormone deficiency (for use only in severe cases). |
| 6-2 | Apr. 22, 2009 | 61 | Apidra Inj. Cart Apidra Inj. OptiClik Apidra Inj. SoloStar Apidra Inj. 100 U/mL (Sanofi-Aventis K.K.) | Approval Approval Approval Approval | <u>Insulin glulisine (genetical recombination)</u> | Drugs with a new active ingredient indicated for the treatment of diabetes mellitus where insulin therapy is indicated. |
| 6-2 | May 20, 2009 | 62 | Melbin Tablets 250 mg (Dainippon Sumitomo Pharma Co., Ltd.) Glycoran Tablets 250 mg (Nippon Shinyaku Co., Ltd.) | Change Change | Metformin hydrochloride | Drugs with a new indication and a new dosage for the treatment of type 2 diabetes mellitus in patients who have not responded sufficiently to either (1) diet and exercise therapies alone or (2) sulfonylurea along with diet and exercise therapies. |
| 6-2 | Jun. 17, 2009 | 63 | Norditropin S Injection 5 mg Norditropin S Injection 10 mg Norditropin NordiFlex Injection 5 mg Norditropin NordiFlex Injection 10 mg Norditropin NordiFlex Injection 15 mg (Novo Nordisk Pharma Ltd.) | Change Change Change Change Change | Somatropin (genetical recombination) | Drugs with a new additional indication and a new dosage for the treatment of dwarfism with no epiphyseal closure in patients born small for gestational age (SGA). |
| 6-2 | Jul. 7, 2009 | 64 | Growject for Injection 1.33 mg Growject for Injection 8 mg Growject BC for Injection 8 mg (JCR Pharmaceuticals Co., Ltd.) | Change Change Change | Somatropin (genetical recombination) | Drugs with a new additional indication and a new dosage for the treatment of adult growth hormone deficiency (for use only in severe cases). |

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| 6-2 | Aug. 20, 2009 | 65 | NovoRapid 70 Mix Penfill NovoRapid 70 Mix FlexPen (Novo Nordisk Pharma Ltd.) | Approval Approval | Insulin aspart (genetical recombination) | Drugs with a new dosage indicated for the treatment of diabetes mellitus where insulin therapy is indicated. |
| 6-2 | Aug. 20, 2009 | 66 | Humalog Mix 50 Cart Humalog Mix 50 Kit Humalog Mix 50 MirioPen (Eli Lilly Japan K.K.) | Change Change Change | Insulin lispro (genetical recombination) | Drugs with a new dosage indicated for the treatment of diabetes mellitus where insulin therapy is indicated. |
| 6-2 | Sep. 18, 2009 | 67 | NovoRapid 50 Mix Penfill NovoRapid 50 Mix FlexPen (Novo Nordisk Pharma Ltd.) | Approval Approval | Insulin aspart (genetical recombination) | Drugs with a new dosage and in an additional dosage form indicated for the treatment of diabetes mellitus where insulin therapy is indicated. |
| 6-2 | Oct. 16, 2009 | 68 | Januvia Tablets 25 mg Januvia Tablets 50 mg Januvia Tablets 100 mg (Banyu Pharmaceutical Co., Ltd.) Glactiv Tablets 25 mg Glactiv Tablets 50 mg Glactiv Tablets 100 mg (Ono Pharmaceutical Co., Ltd.) | Approval Approval Approval Approval Approval Approval | <u>Sitagliptin phosphate hydrate</u> | Drugs with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who do not sufficiently respond to any one of the following treatments): 1. Dietary therapy and/or exercise therapy only 2. Use of sulfonylureas in addition to dietary therapy and/or exercise therapy 3. Use of thiazolidinediones in addition to dietary therapy and/or exercise therapy 4. Use of biguanides in addition to dietary therapy and/or exercise therapy |
| 6-2 | Oct. 16, 2009 | 69 | Basen Tablets 0.2 Basen OD Tablets 0.2 (Takeda Pharmaceutical Company Limited) | Change Change | Voglibose | Drugs with a new additional indication and a new dosage for prevention of type 2 diabetes mellitus in patients with impaired glucose tolerance (only for whom glycemic control is not sufficient by diet and/or exercise). |
| 6-2 | Nov. 6, 2009 | 70 | Seibule Tablets 25 mg Seibule Tablets 50 mg Seibule Tablets 75 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) | Change Change Change | Miglitol | Drugs with a new additional indication for improvement of postprandial hyperglycemia in patients with diabetes mellitus (for use only in patients who have not responded sufficiently to treatment with biguanides in conjunction with dietary and exercise regimens). |
| 6-2 | Jan. 20, 2010 | 71 | Equa Tablets 50 mg (Novartis Pharma K.K.) | Approval | <u>Vildagliptin</u> | A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies). |
| 6-2 | Jan. 20, 2010 | 72 | Metgluco Tablets 250 mg (Dainippon Sumitomo Pharma Co., Ltd.) | Approval | Metformin hydrochloride | A drug with a new dosage exceeding the maximum dosage (750 mg/day) of the conventional formulation indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies). |
| 6-2 | Jan. 20, 2010 | 73 | Victoza Subcutaneous Injection 18 mg (Novo Nordisk Pharma Ltd.) | Approval | <u>Liraglutide (genetical recombination)</u> | A drug with a new active ingredient indicated for the treatment of type 2 diabetes mellitus (for use only in patients who have not responded sufficiently to either [1] diet and exercise therapies alone or [2] sulfonylurea along with diet and exercise therapies). |
| AIDS drugs | Aug. 20, 2009 | 74 | Prezista Tablets 400 mg (Janssen Pharmaceutical K.K.) | Approval | Darunavir ethanolate | A drug with a new dosage indicated for the treatment of HIV infection. [Orphan drug] |
| Blood products | Oct. 16, 2009 | 75 | BeneFIX Intravenous 250 BeneFIX Intravenous 500 BeneFIX Intravenous 1000 BeneFIX Intravenous 2000 (Wyeth K.K.) | Approval Approval Approval Approval | <u>Nonacoq alfa (genetical recombination)</u> | Drugs with a new active ingredient indicated for inhibition of bleeding tendency in patients with hemophilia B (congenital blood coagulation factor IX deficiency). [Orphan drug] |
| Blood products | Mar. 12, 2010 | 76 | NovoSeven for Injection 1.2 mg NovoSeven for Injection 4.8 mg (Novo Nordisk Pharma Ltd.) | Change Change | Eptacog alfa (activated) (genetical recombination) | Drugs with a new additional indication and a new dosage for inhibition of bleeding tendency in patients with congenital factor VII deficiency. |
| | | 77 | NovoSeven HI for Intravenous Injection 1 mg NovoSeven HI for Intravenous Injection 2 mg NovoSeven HI for Intravenous Injection 5 mg (Novo Nordisk Pharma Ltd.) | Change Change Change | | |
| Oncology drugs | Apr. 22, 2009 | 78 | Doxil Injection 20 mg (Janssen Pharmaceutical K.K.) | Change | Doxorubicin hydrochloride | A drug with a new indication and a new dosage for the treatment of ovarian cancer which has progressed after cancer chemotherapy. [Expedited review] |
| Oncology drugs | Apr. 22, 2009 | 79 | Tykerb Tablets 250 mg (GlaxoSmithKline K.K.) | Approval | <u>Lapatinib tosilate hydrate</u> | A drug with a new active ingredient indicated for the treatment of inoperable or recurrent breast cancer with HER2 overexpression. [Priority review] |

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| Oncology drugs | May 20, 2009 | 80 | Nexavar Tablets 200 mg (Bayer Yakuhin, Ltd.) | Change | Sorafenib tosilate | A drug with a new additional indication for the treatment of unresectable hepatocellular carcinoma. [Priority review] |
| Oncology drugs | May 20, 2009 | 81 | Alimta Injection 100 mg Alimta Injection 500 mg (Eli Lilly Japan K.K.) | Approval Change | Pemetrexed sodium hydrate | Drugs with a new additional indication and a new dosage in an additional dosage form (Alimta Injection 100 mg) indicated for the treatment of unresectable advanced or recurrent non-small cell lung cancer. |
| Oncology drugs | Aug. 20, 2009 | 82 | Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg Elplat for Injection 50 mg Elplat for Injection 100 mg (Yakult Honsha Co., Ltd.) | Approval Approval Change Change | Oxaliplatin | Drugs with a new additional indication and a new dosage in an additional dosage form (Elplat I.V. Infusion Solution 50 mg and Elplat I.V. Infusion Solution 100 mg) for post-operative adjuvant chemotherapy for colon cancer. [Priority review] |
| Oncology drugs | Aug. 20, 2009 | 83 | Miripla Suspension Vehicle 4 mL (Dainippon Sumitomo Pharma Co., Ltd.) | Approval | Iodine addition products of the ethyl esters of the fatty acids obtained from poppyseed oil | A drug with a new indication for suspending Miripla for intra-arterial injection 70 mg. |
| Oncology drugs | Sep. 18, 2009 | 84 | Xeloda Tablet 300 (Chugai Pharmaceutical Co., Ltd.) | Change | Capecitabine | A drug with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection. |
| Oncology drugs | Sep. 18, 2009 | 85 | Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.) | Change Change | Bevacizumab (genetical recombination) | Drugs with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection. |
| Oncology drugs | Sep. 18, 2009 | 86 | Elplat for Injection 100 mg Elplat I.V. Infusion Solution 50 mg Elplat I.V. Infusion Solution 100 mg (Yakult Honsha Co., Ltd.) | Change Change Change | Oxaliplatin | Drugs with a new additional indication and a new additional dosage and administration for combination therapy with other anticancer drugs (XELOX + BV regimen) for advanced or recurrent colorectal cancer not suited for curative resection. |
| | | 87 | Elplat for Injection 50 mg (Yakult Honsha Co., Ltd.) | Change | | |
| Oncology drugs | Oct. 16, 2009 | 88 | Miripla for Intra-arterial Injection 70 mg (Dainippon Sumitomo Pharma Co., Ltd.) | Approval | <u>Miriplatin hydrate</u> | A drug with a new active ingredient indicated for lipiodolization in hepatocellular carcinoma. |
| Oncology drugs | Oct. 16, 2009 | 89 | Rasuritek 1.5 mg for I.V. Infusion Rasuritek 7.5 mg for I.V. Infusion (Sanofi-Aventis K.K.) | Approval Approval | <u>Rasburicase (genetical recombination)</u> | Drugs with a new active ingredient indicated for the treatment of hyperuricemia in patients receiving cancer chemotherapy. |
| Oncology drugs | Nov. 6, 2009 | 90 | Fludara Tab. 10 mg (Bayer Yakuhin, Ltd.) | Change | Fludarabine phosphate | A drug with a new additional indication for the treatment of chronic lymphocytic leukemia with anemia or thrombocytopenia. |
| Oncology drugs | Nov. 6, 2009 | 91 | Fludara for IV Inj. 50 mg (Bayer Yakuhin, Ltd.) | Change | Fludarabine phosphate | A drug with new additional indications and a new dosage for the treatment of recurrent or refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. |
| Oncology drugs | Nov. 6, 2009 | 92 | Avastin 100 mg/4 mL Intravenous Infusion Avastin 400 mg/16 mL Intravenous Infusion (Chugai Pharmaceutical Co., Ltd.) | Change Change | Bevacizumab (genetical recombination) | Drugs with a new additional indication and a new dosage for the treatment of unresectable advanced or recurrent non-squamous non-small cell lung cancer. [Priority review] |
| Oncology drugs | Jan. 20, 2010 | 93 | Temodal Injection 100 mg (Schering-Plough K.K.) | Approval | Temozolomide | A drug with a new route of administration indicated for the treatment of malignant glioma. |
| Oncology drugs | Jan. 20, 2010 | 94 | Afinitor Tablets 5 mg (Novartis Pharma K.K.) | Approval | Everolimus | A drug with a new additional indication and a new dosage for the treatment of unresectable or metastatic renal cell carcinoma. [Priority review] |
| Oncology drugs | Feb. 5, 2010 | 95 | Gemzar Injection 200 mg Gemzar Injection 1 g (Eli Lilly Japan K.K.) | Change Change | Gemcitabine hydrochloride | Drugs with a new additional indication and a new dosage for the treatment of inoperable or recurrent breast cancer. |
| Biologicals | Oct. 16, 2009 | 96 | Cervarix (GlaxoSmithKline K.K.) | Approval | <u>HPV-16 L1 VLP and HPV-18 L1 VLP</u> | A drug with a new active ingredient indicated for prevention of cervical cancer (squamous-cell carcinoma and adenocarcinoma) and its precursor lesions (cervical intraepithelial neoplasia [CIN] 2 and 3) associated with human papillomavirus (HPV) types 16 and 18 infection. [Priority review] |

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| Biologicals | Oct. 16, 2009 | 97 | Prevenar Suspension Liquid for S.C. Injection (Wyeth K.K.) | Approval | <u>Pneumococcal polysaccharide (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F)-CRM₁₉₇ conjugate</u> | A drug with a new active ingredient indicated for prophylaxis of pneumococcal invasive disease (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F). [Priority review] |
| Biologicals | Jan. 20, 2010 | 98 | Arepanrix (H1N1) Intramuscular Injection (GlaxoSmithKline K.K.) | Emergency approval | <u>Inactivated split-virus influenza A (A/California/7/2009 [H1N1])</u> | A drug with a new active ingredient indicated for prophylaxis of pandemic (H1N1) influenza. [Emergency approval] |
| Biologicals | Jan. 20, 2010 | 99 | Cell-culture Derived Influenza A (H1N1) Emulsion HA Vaccine "Novartis" for Intramuscular Injection (Novartis Pharma K.K.) | Emergency approval | <u>Pandemic influenza virus surface antigens of A/California/7/2009 (H1N1) like strain</u> | A drug with a new active ingredient indicated for prophylaxis of pandemic (H1N1) influenza. [Emergency approval] |
| <i>In vivo</i> Diagnostics | Sep. 18, 2009 | 100 | Indigocarmine Injection 20 mg "Daiichi Sankyo" (Daiichi Sankyo Co., Ltd.) | Change | Indigocarmine | A drug with a new route of administration, a new indication, and a new dosage for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review] |
| <i>In vivo</i> Diagnostics | Sep. 18, 2009 | 101 | Diagnogreen for Injection 25 mg (Daiichi Sankyo Co., Ltd.) | Change | Indocyanine green | A drug with a new route of administration, a new indication, and a new dosage for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review] |
| <i>In vivo</i> Diagnostics | Mar. 12, 2010 | 102 | FerriSeltz Powder 20% (Otsuka Pharmaceutical Co., Ltd.) | Change | Ferric ammonium citrate | A drug with a new additional indication and a new dosage for negative contrast of digestive tract in cholangiopancreatography. |
| Bio-CMC | Jun. 22, 2009 | 103 | Somatropin BS S.C. Injection 5 mg [Sandoz] Somatropin BS S.C. Injection 10 mg [Sandoz] (Sandoz K.K.) | Approval Approval | Somatropin (genetical recombination) | Follow-on biologics indicated for the treatment of growth disturbance due to growth hormone deficiency before epiphyseal closure and growth disturbance associated with Turner syndrome or chronic renal insufficiency before epiphyseal closure. |
| Radio-pharmaceuticals | Sep. 18, 2009 | 104 | Tin Colloid Tc-99m Kit (Nihon Medi-Physics Co., Ltd.) | Change | Technetium (^{99m} Tc) stannous colloid | A drug with a new route of administration and a new indication for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review] |
| Radio-pharmaceuticals | Sep. 18, 2009 | 105 | Techne Phytate Kit (Fujifilm RI Pharma Co., Ltd.) | Change | Technetium (^{99m} Tc) phytate | A drug with a new route of administration and a new indication for sentinel lymph node mapping in breast cancer and malignant melanoma. [Expedited review] |
| Radio-pharmaceuticals | Nov. 6, 2009 | 106 | MyoMIBG- ¹²³ Injection (Fujifilm RI Pharma Co., Ltd.) | Change | 3-iodobenzylguanidine (¹²³ I) injection | A drug with a new additional indication and a new dosage for diagnosis of neuroblastoma in tumor scintigraphy. |
| Radio-pharmaceuticals | Feb. 5, 2010 | 107 | Cardiolite Injection Daiichi Cardiolite Daiichi (Fujifilm RI Pharma Co., Ltd.) | Change Change | Technetium (^{99m} Tc) hexakis (2-methoxy-isobutyl isonitrile) Tetrakis (2-methoxy-isobutyl isonitrile) copper (I) tetrafluoroborate | Drugs with a new additional indication for diagnostic localization of hyperparathyroidism in parathyroid scintigraphy. |