Pharmaceuticals and Medical Devices Safety Information

No. 314 July 2014

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This *Pharmaceuticals and Medical Devices Safety Information (PMDSI)* is issued based on safety information collected by the Ministry of Health, Labour and Welfare (MHLW). It is intended to facilitate safer use of pharmaceuticals and medical devices by healthcare providers.
The PMDSI is available on the Pharmaceuticals and Medical Devices Agency (PMDA) Medical Product Information web page (http://www.pmda.go.jp/english/index.html) and on the MHLW website (http://www.mhlw.go.jp/, only available in Japanese language).

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Pharmaceuticals and Medical Devices Safety Information

No. 314 July 2014

Ministry of Health, Labour and Welfare & Pharmaceutical and Food Safety Bureau, Japan

[Outline of Information]

D: Distribution of Dear Healthcare Professional Letters *P*: Revision of Precautions *C*: Case Reports

PMDA medi-navi
(Pharmaceuticals and Medical Devices Information E-mail Alert Service)

The PMDA is providing the "PMDA medi-navi" a Pharmaceuticals and Medical Devices Information E-mail Alert Service (only available in Japanese language), when important safety information regarding pharmaceuticals and medical devices including Dear Healthcare Professional Letters or Revision of Precautions is issued. This e-mail service will enable you to obtain safety information faster and more efficiently, free of charge. Please feel free to use this service for your faster information collection.
See our website for details of the service. → http://www.info.pmda.go.jp/info/idx-push.html

Reporting of safety information such as adverse reactions to the Minister of Health, Labour and Welfare is a duty of medical and pharmaceutical providers.

If medical and pharmaceutical providers such as physicians, dentists, and pharmacists detect adverse reactions, infections associated with drugs or medical devices, or medical device adverse events, it is mandatory for such providers to report them to the Minister of Health, Labour and Welfare directly or through the marketing authorization holder. As medical and pharmaceutical providers, drugstore and pharmacy personnel are also required to report safety issues related to drugs and medical devices.

Abbreviations

ACEI	Angiotensin-converting enzyme inhibitor
ADRs	Adverse drug reactions
ARB	Angiotensin II receptor blocker
EPPV	Early Post-marketing Phase Vigilance
MAH	Marketing authorization holder
MHLW	Ministry of Health, Labour and Welfare
OTC	Over-the-counter
PFSB	Pharmaceutical and Food Safety Bureau
PMDA	Pharmaceuticals and Medical Devices Agency
PMDSI	Pharmaceuticals and Medical Devices Safety Information

1

Revision of the Report Form in the Drugs and Medical Devices Safety Information Reporting System

1. Summary of the reporting system

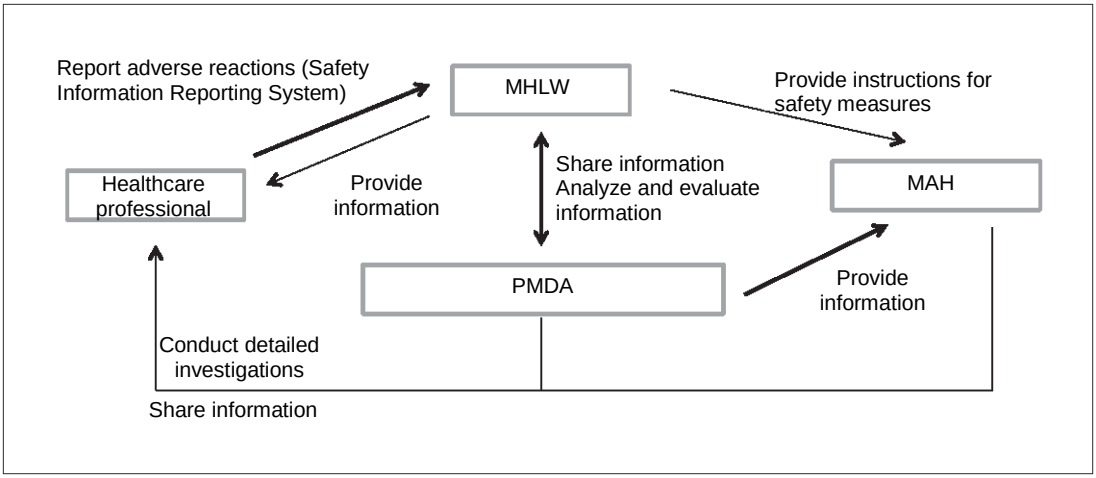
Adverse reactions, infections, and malfunctions associated with drugs or medical devices have been reported by medical institutions under the Drugs and Medical Devices Safety Information Reporting System (the Safety Information Reporting System; Figure 1) in accordance with Article 77-4-2, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145, 1960).* Cooperation by healthcare professionals have been gained as the Safety Information Reporting System.[1]

Reported information has been analyzed and evaluated from a specialist's point of view to take necessary safety measures and has been widely provided to healthcare professionals to secure post-marketing safety measures for drugs and medical devices.

*Article 77-4-2, Paragraph 2 of the Pharmaceutical Affairs Act

Proprietors of pharmacies, hospitals, clinics or veterinary clinics, physicians, dentists, pharmacists, registered salespersons, veterinarians or other healthcare professionals must report these cases to the Ministry of Health, Labour and Welfare (MHLW), when they become aware of cases of disease, disabilities or deaths possibly caused by adverse reactions or other reasons related to drugs or medical devices, or cases of infection possibly caused by the use of drugs or medical devices, and they consider that reporting of those cases is necessary to prevent the onset or spread of hazards to public health.

Figure 1. Information flow in the Safety Information Reporting System



2. Revision of the reporting form

Along with the enforcement of the Act for partial amendment of the Pharmaceutical Affairs Act and the Pharmacists Act (Act No. 103, 2013; the Amended Act) as of June 12, 2014, the Drug Safety Information Report Form was revised as described below.[2] Ambiguous parts in the previous report form have been modified by changing the arrangement and adding descriptions on the information required for reporting.

2-1 Revision about guidance-mandatory drugs and over-the-counter drugs

The Amended Act designates products in the early post-switch phase (products recently switched from ethical drugs to over-the-counter (OTC) drugs with no established risks as the OTC drugs yet) and powerful drugs as guidance-mandatory drugs and requires pharmacists to provide the product information and instructions for use to the consumer in a face-to-face consultation, since such products are different in character from other OTC drugs (first-class OTC drugs to third-class OTC drugs). OTC drugs (first-class OTC drugs to third-class OTC drugs) are allowed to be sold online under appropriate rules.[3]

In line with the enforcement of the Amended Act, aiming to capture information on the suspected drugs and their usages more accurately, choice of "guidance-mandatory drugs" is added to distinguish guidance-mandatory drugs from OTC drugs, and "purchase route" of OTC drugs is newly added to the field of suspected drugs as options in the report form.

2-2 Revision about reporting related to the Relief Systems for Sufferers

Relief Systems for Sufferers of adverse health effects (Table 1) are available to compensate for adverse health effects of certain severity (ex. requiring inpatient treatment) caused by adverse reactions and infections associated with drugs including OTC drugs.

The number of applications for the Relief System and payment of relief benefits has been increasing in recent years. However, according to the survey conducted in 2012, the Relief System for Sufferers from Drug Adverse Reactions is recognized by only 20.7% of the public in Japan; 5.3% of those surveyed answered they knew the system and 15.4% answered they have heard about the system.[4] Some people may not claim compensation for the adverse health effects associated with adverse drug reactions (ADRs) they have suffered because they don't know about the Relief System.

A field related to the Relief Systems for Sufferers was newly added to the report form together with multiple choices such as "to be filed as an application by the patient" and "patient informed of the system" to increase the public recognition of the systems and survey the intentions of ADR sufferers to claim compensation in the future.

Table 1. Relief Systems for Sufferers

System	Subjects	Contact
Relief System for Sufferers from Drug Adverse Reactions	Drugs (excluding some drugs such as anti-cancer drugs)	Pharmaceuticals and Medical Devices Agency (PMDA) 0120-149-931 (toll-free) http://www.pmda.go.jp/kenkouhigai.html
Relief System for Infections Derived from Biological Products	Biological products	

*Relief System for Injury to Health with Vaccination is available for vaccination products regulated by the Preventive Vaccination Law. Contact the municipality for more information.

2-3 Report form for cosmetics and quasi-drugs

The report form for drugs has also been used to report possible adverse reactions to cosmetics and quasi-drugs. “Cosmetics/Quasi-drugs Safety Information Report Form” is now available separately from the report form for drugs.

After the consecutive reports on leukoderma associated with medicinal cosmetics, as of April 2014, marketing authorization holders (MAHs) are required to report individual cases of adverse reactions of “cases that require at least 30 days for treatment” as well as of serious adverse reactions (the same definition of adverse reactions to drugs applies) to monitor adverse reactions more broadly compared with drugs.[5] “Cases that require at least 30 days for treatment” was newly added to the criteria for seriousness assessment in the adverse reaction section in the reporting form.

When healthcare professionals notice about any serious adverse reactions suspected by the use of cosmetics or quasi-drugs, and any patients requiring a long-term treatment for adverse reactions, you are required to report these cases using the Cosmetics/Quasi-drugs Safety Information Report Form even if the contact information of the MAH is unknown.

3. Closing comments

The Safety Information Reporting System is important because it enables the MHLW to collect occurrences of adverse reactions promptly and detect adverse reactions that have not yet been grasped by MAHs by direct adverse reactions reporting from healthcare professionals to the MHLW. Your continued cooperation would be appreciated.

Healthcare professionals are encouraged to provide the information on the Relief System to the patient suffering from adverse health effects if the reported adverse reactions or infections are possibly applicable for the relief benefits.

1 Revision of operating procedure for reporting of adverse reactions, infections and malfunctions associated with drugs and medical devices from medical institutions (Pharmaceutical and Food Safety Bureau (PFSB) Notification No. 0729-2, by the Director of PFSB (provisionally translated title), dated July 29, 2010). The report form for drugs has also been used to report possible adverse reactions with cosmetics and quasi-drugs. As described in 2-3, a separate report form is now available.

2 Revision of the Report Form in the Drugs and Medical Devices Safety Information Reporting System (PFSB Notification No. 0612-1, by the Director of PFSB, dated June 12, 2014).

3 Pharmaceutical product sales system
http://www.mhlw.go.jp/bunya/iyakuhin/ippanyou/131218-1.html
(only available in Japanese language)

4 2012 Awareness Survey on the Relief System for Sufferers from ADRs
http://www.pmda.go.jp/kenkouhigai/ninchi/h24_ninchi_gaiyo.html
(only available in Japanese language)

5 “1. Revised Adverse Reaction Reporting System for Quasi-drugs and Cosmetics” Pharmaceutical and Medical Device Safety Information No. 311 (March 2014)
http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-311.pdf

<References>

- Dear healthcare professionals (request for adverse reaction/infection/malfunction reporting)
  http://www.info.pmda.go.jp/info/houkoku.html (only available in Japanese language)
  (The report form can be downloaded from the website. Reports may be sent by mail, fax, e-mail or through the e-Gov. electronic application system.)
- Relief systems
  http://www.pmda.go.jp/kenkouhigai.html (only available in Japanese language)
  (Booklet and leaflets describing a clear explanation of the Relief Systems can be downloaded from the website.)

2

Revision of Precautions (No. 257)

This section presents details of revisions to the Precautions section of package inserts and brand names of drugs that have been revised in accordance with the Notifications dated June 3, 2014.

1 Antihypertensives

(1) Azilsartan
(2) Azilsartan/Amlodipine Besilate
(3) Irbesartan
(4) Irbesartan/Amlodipine Besilate
(5) Irbesartan/Trichlormethiazide
(6) Olmesartan Medoxomil
(7) Olmesartan Medoxomil/Azelnidipine
(8) Candesartan Cilexetil
(9) Candesartan Cilexetil/Amlodipine Besilate
(10) Candesartan Cilexetil/Hydrochlorothiazide
(11) Valsartan
(12) Valsartan/Amlodipine Besilate
(13) Valsartan/Cilnidipine
(14) Valsartan/Hydrochlorothiazide
(15) Losartan Potassium/Hydrochlorothiazide

Brand Name

(1) Azilva Tablets 20 mg, 40 mg (Takeda Pharmaceutical Company Limited)
(2) Zacras Combination Tablets LD, HD (Takeda Pharmaceutical Company Limited)
(3) Avapro Tablets 50 mg, 100 mg, 200 mg (Sumitomo Dainippon Pharma Co., Ltd.), Irbetan Tablets 50 mg, 100 mg, 200 mg (Shionogi & Co., Ltd.)
(4) Aimix Combination Tablets LD, HD (Sumitomo Dainippon Pharma Co., Ltd.)
(5) Irtra Combination Tablets LD, HD (Shionogi & Co., Ltd.)
(6) Olmetec Tablets 5 mg, 10 mg, 20 mg, 40 mg (Daiichi Sankyo Company, Limited)
(7) Rezaltas Combination Tablets LD, HD (Daiichi Sankyo Company, Limited)
(8) Blopress Tablets 2 mg, 4 mg, 8 mg, 12 mg (Takeda Pharmaceutical Company Limited), and the others
(9) Unisia Combination Tablets LD, HD (Takeda Pharmaceutical Company Limited)
(10) Ecard Combination Tablets LD, HD (Takeda Pharmaceutical Company Limited)
(11) Diovan Tablets 20 mg, 40 mg, 80 mg, 160 mg, Diovan OD Tablets 20 mg, 40 mg, 80 mg, 160 mg (Novartis Pharma K.K.), and the others

(12) Exforge Combination Tablets (Novartis Pharma K.K.)
(13) Atedio Combination Tablets (Ajinomoto Pharmaceuticals Co., Ltd.)
(14) Co-dio Combination Tablets MD, EX (Novartis Pharma K.K.)
(15) Preminent Tablets LD, HD (MSD K.K.), and the others

Interactions (precautions for concomitant use)

Angiotensin-converting enzyme inhibitors (ACEIs) [Clinical symptoms and measures: Renal impairment, hyperkalaemia, and/or hypotension may occur. Patients should be carefully monitored for renal function, serum potassium level, and blood pressure. Mechanism and risk factors: Concomitant use with ACEIs may increase an effect of renin-angiotensin system blockade.]

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2 **Antihypertensives**

(1) Alacepril
(2) Imidapril Hydrochloride
(3) Enalapril Maleate
(4) Captopril
(5) Quinapril Hydrochloride
(6) Cilazapril Hydrate
(7) Temocapril Hydrochloride
(8) Delapril Hydrochloride
(9) Trandolapril
(10) Benazepril Hydrochloride
(11) Perindopril Erbumine
(12) Lisinopril Hydrate

Brand Name

(1) Cetapril Tablets 12.5 mg, 25 mg, 50 mg (Sumitomo Dainippon Pharma Co., Ltd.), and the others
(2) Tanatril Tablets 2.5 mg, 5 mg, 10 mg (Mitsubishi Tanabe Pharma Corporation), and the others
(3) Renivace Tablets 2.5, 5, 10 (MSD K.K.), and the others
(4) Captoril Tablets 12.5 mg, 25 mg, Captoril Fine Granules 5%, Captoril-R Capsules 18.75 mg (Daiichi Sankyo Espha Co., Ltd.), and the others
(5) Conan Tablets 5 mg, 10 mg, 20 mg (Mitsubishi Tanabe Pharma Corporation)
(6) Inhibace Tablets 0.25, 0.5, 1 (Chugai Pharmaceutical Co., Ltd.), and the others
(7) Acecol Tablets 1 mg, 2 mg, 4 mg (Daiichi Sankyo Company, Limited), and the others
(8) Adecut Tablets 7.5 mg, 15 mg, 30 mg (Takeda Pharmaceutical Company Limited)
(9) Preran Tablets 0.5 mg, 1 mg (Sanofi K.K.), Odric Tablets 0.5 mg, 1 mg (Nippon Shinyaku Co., Ltd.), and the others
(10) Cibacen Tablets 2.5 mg, 5 mg, 10 mg (Novartis Pharma K.K.), and the others
(11) Coversyl Tablets 2 mg, 4 mg (Kyowa Hakko Kirin Co., Ltd.), and the others
(12) Zestril Tablets 5 mg, 10 mg, 20 mg (AstraZeneca K.K.), Longes Tablets 5 mg, 10 mg, 20 mg (Shionogi & Co., Ltd.), and the others

Interactions (precautions for concomitant use)

Angiotensin II receptor blockers (ARBs) [Clinical symptoms and measures: Renal impairment, hyperkalaemia, and/or hypotension may occur. Patients should be carefully monitored for renal function, serum potassium level, and blood pressure. Mechanism and risk factors: Concomitant use with ARBs may increase an effect of renin-angiotensin system blockade.]

3 Antihypertensives

(1) Telmisartan
(2) Telmisartan/Amlodipine Besilate
(3) Telmisartan/Hydrochlorothiazide

Brand Name

(1) Micardis Tablets 20 mg, 40 mg, 80 mg (Nippon Boehringer Ingelheim Co., Ltd.)
(2) Micamlo Combination Tablets AP, BP (Nippon Boehringer Ingelheim Co., Ltd.)
(3) Micombi Combination Tablets AP, BP (Nippon Boehringer Ingelheim Co., Ltd.)

Interactions (precautions for concomitant use)

ACEIs [Clinical symptoms and measures: Renal impairment (including acute renal failure), hyperkalaemia, and/or hypotension may occur. Patients should be carefully monitored for renal function, serum potassium level, and blood pressure. Mechanism and risk factors: Concomitant use with ACEIs may increase an effect of renin-angiotensin system blockade.]

4 Antihypertensives

Losartan Potassium

Brand Name

Nu-lotan Tablets 25 mg, 50 mg, 100 mg (MSD K.K.), and the others

Important Precautions

Increased serum potassium and creatinine levels are likely to occur in patients with diabetic nephropathy in type 2 diabetes mellitus. Patients should be carefully monitored through periodic monitoring (every 2 weeks in an early phase of the treatment and approximately once monthly in a subsequent stable phase) for serum potassium and creatinine levels during administration of this drug. If any abnormalities are observed in serum potassium and/or creatinine levels, appropriate measures should be taken. Careful attention should be paid especially to the concomitant use with ACEIs because increased risks of acute renal failure and/or hyperkalaemia have been reported in concomitant use of this drug and ACEIs.

Interactions (precautions for concomitant use)

ACEIs [Clinical symptoms and measures: Renal impairment, hyperkalaemia, and/or hypotension may occur. Patients should be carefully monitored for renal function, serum potassium level, and blood pressure. Mechanism and risk factors: Concomitant use with ACEIs may increase an effect of renin-angiotensin system blockade.]

5 Hyperlipidaemia agents

Rosuvastatin Calcium

Brand Name

Crestor Tablets 2.5 mg, 5 mg (AstraZeneca K.K.)

Adverse Reactions (clinically significant adverse reactions)

Erythema multiforme: Erythema multiforme may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

Peripheral nerve disorder: Peripheral nerve disorders including sensory disturbance (such as hypoaesthesia or numbness), pain or muscular weakness may occur in limbs. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

6 Urogenital and anal organ agents-Miscellaneous

Imidafenacin

Brand Name	Uritos Tablets 0.1 mg, Uritos OD Tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.), Staybla Tablets 0.1 mg, Staybla OD Tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.)
Adverse Reactions (clinically significant adverse reactions)	**Hepatic dysfunction:** Hepatic dysfunction with elevations of aspartate aminotransferase (AST or glutamate oxaloacetate transaminase [GOT]), alanine aminotransferase (ALT or glutamate pyruvate transaminase [GPT]), or bilirubin may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken immediately.

7 Blood and body fluid agents-Miscellaneous

Nartograstim (Genetical Recombination)

Brand Name	Neu-up Injections 25 μg, 50 μg, 100 μg, 250 μg (Yakult Honsha Co., Ltd.)
Adverse Reactions (clinically significant adverse reactions)	**Capillary leak syndrome:** Cases of capillary leak syndrome have been reported in patients treated with other granulocytic colony-stimulating factor. Patients should be carefully monitored, and hypotension, hypoalbuminaemia, oedema, pulmonary oedema, pleural effusion, ascites, haemoconcentration, and other signs and symptoms are observed, appropriate measures such as discontinuation of administration should be taken.

8 Blood and body fluid agents-Miscellaneous

(1) Filgrastim (Genetical Recombination)
(2) Filgrastim (Genetical Recombination) (Filgrastim Biosimilar 1)
(3) Filgrastim (Genetical Recombination) (Filgrastim Biosimilar 2)
(4) Filgrastim (Genetical Recombination) (Filgrastim Biosimilar 3)
(5) Lenograstim (Genetical Recombination)

Brand Name	(1) Gran Injections 75 μg, 150 μg, M300 μg, Gran Syringe 75 μg, 150 μg, M300 μg (Kyowa Hakko Kirin Co., Ltd.) (5) Neutrogin Injections 50 μg, 100 μg, 250 μg (Chugai Pharmaceutical Co., Ltd.)
Adverse Reactions (clinically significant adverse reactions)	**Capillary leak syndrome:** Cases of capillary leak syndrome have been reported in patients treated with this drug. Patients should be carefully monitored, and hypotension, hypoalbuminaemia, oedema, pulmonary oedema, pleural effusion, ascites, haemoconcentration, and other signs and symptoms are observed, appropriate measures such as discontinuation of administration should be taken.

3

List of Products Subject to Early Post-marketing Phase Vigilance

Early Post-marketing Phase Vigilance (EPPV) was established in 2001. This unique system for new drugs refers to any safety assurance activities that are conducted within a period of 6 months just after marketing of a new drug. It is imposed that its MAH is responsible for collecting the ADRs from all of the medical institutions where the drugs are used and taking safety measures. The aim of the EPPV is to promote the rational proper use of drugs in medical treatments, and to promptly take actions for prevention of the serious ADRs. EPPV is specified as a condition of approval.

(As of July 1, 2014)

◎: Newly-posted products, or products changed from the last Bulletin

	Nonproprietary name Brand name on	Name of the MAH	Date of EPPV initiate
◎	sorafenib tosilate Nexavar Tablets 200 mg*1	Bayer Yakuhin, Ltd.	June 20, 2014
◎	pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein) Prevenar 13 Suspension Liquid Injections*2	Pfizer Japan Inc.	June 20, 2014
◎	azilsartan/amlodipine besilate Zacras Combination Tablets LD & HD	Takeda Pharmaceutical Company Limited	June 18, 2014
◎	natalizumab (genetical recombination) Tysabri. for I.V. Infusions 300 mg	Biogen Idec Japan Ltd.	June 4, 2014
◎	prasugrel hydrochloride Efient Tablets 3.75 mg, 5 mg	Daiichi Sankyo Company, Limited	May 27, 2014
◎	betaine Cystadane	ReqMed Company, Ltd.	May 27, 2014
◎	trifluridine/tipiracil hydrochloride Lonsurf Combination Tablets T15, T20	Taiho Pharmaceutical Co., Ltd.	May 26, 2014
◎	denosumab (genetical recombination) Ranmark Subcutaneous Injections 120 mg*3	Daiichi Sankyo Company, Limited	May 23, 2014
◎	enzalutamide Xtandi Capsules 40 mg	Astellas Pharma Inc.	May 23, 2014
◎	valsartan/cilnidipine Atedio Combination Tablets	Ajinomoto Pharmaceuticals Co., Ltd	May 23, 2014
◎	tofogliflozin hydrate (1) Deberza Tablets 20 mg (2) Apleway Tablets 20 mg	(1) Kowa Company, Ltd. (2) Sanofi K.K.	May 23, 2014
◎	luseogliflozin hydrate Lusefi Tablets 2.5 mg, 5 mg	Taisho Pharmaceutical Co., Ltd.	May 23, 2014
◎	dapagliflozin propylene glycolate hydrate Forxiga Tablets 5 mg, 10 mg	Bristol-Myers K.K.	May 23, 2014

◎	tenofovir disoproxil fumarate Tenozet Tablets 300 mg	GlaxoSmithKline K.K.	May 16, 2014
◎	turoctocog alfa (genetical recombination) Novoeight Intravenous Infusions 250, 500, 1000, 1500, 2000, 3000	Novo Nordisk Pharma Ltd.	May 12, 2014
◎	ferric citrate hydrate Riona Tablets 250 mg	Japan Tobacco Inc.	May 12, 2014
◎	afatinib maleate Giotrif Tablets 20 mg, 30 mg, 40 mg, 50 mg	Nippon Boehringer Ingelheim Co., Ltd.	May 7, 2014
	trastuzumab emtansine (genetical recombination) Kadcyla Intravenous Infusions 100 mg, 160 mg	Chugai Pharmaceutical Co., Ltd.	April 18, 2014
	riociguat Adempas Tablets 0.5 mg, 1.0 mg, 2.5 mg	Bayer Yakuhin, Ltd.	April 18, 2014
	levocetirizine hydrochloride Xyzal Syrup 0.05%	GlaxoSmithKline K.K.	April 17, 2014
	dolutegravir sodium Tivicay Tablets 50 mg	ViiV Healthcare K.K.	April 17, 2014
	brentuximab vedotin (genetical recombinatin) Adcetris Intravenous Infusions 50 mg	Takeda Pharmaceutical Company Limited	April 17, 2014
	ipragliflozin l-proline Suglat Tablets 25 mg, 50 mg	Astellas Pharma Inc.	April 17, 2014
	tadalafil Zalutia Tablets 2.5 mg, 5 mg	Eli Lilly Japan K.K.	April 17, 2014
	tolvaptan Samsca Tablets 7.5 mg, 15 mg, 30 mg*4	Otsuka Pharmaceutical Co., Ltd.	March 24, 2014
	fluticasone furoate Allermist 56 metered Nasal Spray 27.5μg*5	GlaxoSmithKline K.K.	March 17, 2014
	pazopanib hydrochloride Votrient Tablets 200 mg*6	GlaxoSmithKline K.K.	March 17, 2014
	mogamulizumab (genetical recombination) Poteligeo Injections 20 mg*7	Kyowa Hakko Kirin Co., Ltd.	March 17, 2014
	cinacalcet hydrochloride Regpara Tablets 25 mg, 75 mg*8	Kyowa Hakko Kirin Co., Ltd.	February 21, 2014
	ranibizumab (genetical recombination) Lucentis Solution Intravitreal Injections 2.3 mg/0.23 mL*9	Novartis Pharma K.K.	February 21, 2014
	pH-4 treated acid normal human immunoglobulin (subcutaneous injections) Hizentra 20% S.C. Injections 1 g/5 mL, 2 g/10 mL, 4 g/20 mL	CSL Behring K.K.	January 30, 2014
	ioflupane (^{123}I) Datscan Injectable	Nihon Medi-Physics Co., Ltd.	January 27, 2014
	talaporfin sodium Laserphyrin Injections 100 mg*10	Meiji Seika Pharma Co., Ltd.	January 20, 2014

*1 An additional indication for “the treatment of patients with radically unresectable differentiated thyroid carcinoma”

*2 An additional indication for “the prevention of infection caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in elderly patients”

*3 An additional indication for “the treatment of patients with bone giant cell tumour”

*4 An additional indication for “the control of disease progression in patients with autosomal dominant polycystic kidney who already had increased kidney volume and whose kidney volume was further rapidly increasing.” Samsca Tablets 30 mg was launched in May 29, 2014.

*5 An additional administration for “pediatrics”

*6 An additional indication for “the treatment of patients with radically unresectable or metastatic renal cell carcinoma”

*7 An additional indication for “the treatment of patients with relapsed or refractory CCR4-positive peripheral T-cell lymphoma and patients with relapsed or refractory CCR4-positive cutaneous T-cell lymphoma”

*8 An additional indication for “the treatment of hypercalcaemia in patients with the following diseases: parathyroid carcinoma, and primary hyperparathyroidism for which patients are unable to undergo parathyroidectomy or which relapses after operation”

*9 An additional indication for “the treatment of patients with diabetic macular oedema”

*10 An additional indication for “the treatment of patients with primary malignant brain tumour (only in patients who undergo tumourectomy)”