Pharmaceuticals and Medical Devices Safety Information

No. 310 February 2014

Executive Summary

Published by
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency
Office of Safety I

For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 310, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Thrombosis with YAZ Combination Tablets for Dysmenorrhea

Fatal cases of thrombosis, in which a causal relationship with YAZ cannot be ruled out, have been reported. The MHLW instructed the Marketing authorization holders (MAHs) to revise Precautions in the package inserts and to distribute the Dear Healthcare Professional Letters of Rapid Safety Communications (Blue Letter) on January 17, 2014.
Section 1 of the full text will provide information included in the Blue Letter.

2. Rivaroxaban and Interstitial Pneumonia

Several cases of interstitial pneumonia, including a fatal case in which a causal relationship with revaroxaban cannot be ruled out, have been reported. The MHLW instructed MAHs to revise Precautions on February 6, 2014.
Section 2 of the full text will provide information on the revision of Precautions.

3. Direct Patient Reporting System for Adverse Drug Reactions

The PMDA is conducting a pilot project of the Direct Patient Reporting System for Adverse Drug Reactions and started to make submitted reports publicly available.
Section 3 of the full text will provide information on these reports and an outline of the Direct Patient Reporting System.

4. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated January 7, January17, and February 6, 2014, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 4 of the full text.

1. Atazanavir Sulfate
2. Crizotinib
3. Clopidogrel Sulfate-containing Products
4. Sodium Valproate
5. Drospirenone/Ethinylestradiol Betadex
6. Rivaroxaban

5. Revision of Precautions (No. 253)

Revisions of Precautions for the following pharmaceuticals:
Rufinamide, Lixisenatide, Liraglutide (Genetical Recombination), Acarbose, Anagliptin, Alogliptin Benzoate, Sitagliptin Phosphate Hydrate, Pioglitazone Hydrochloride, Miglitol, Linagliptin, Alogliptin Benzoate/Pioglitazone Hydrochloride, Saxagliptin Hydrate, Voglibose (products with an indication to treat abnormal glucose tolerance), Voglibose (products without an indication to treat abnormal glucose tolerance), Amphotericin B (Liposomal formulation), Chlormadinone Acetate/Mestranol, Norethisterone/Ethinylestradiol (products with an indication to treat dysmenorrhea), Norethisterone/Mestranol, Norgestrel/Ethinylestradiol, Desogestrel/Ethinylestradiol, Norethisterone/Ethinylestradiol (products with an indication for contraception), Levonorgestrel/Ethinylestradiol

6. List of Products Subject to Early Post-marketing Phase Vigilance

(as of February 2014)

A list of products subject to Early Post-marketing Phase Vigilance as of February 1, 2014 will be provided in section 6 of the full text.