Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 311, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Revised Adverse Reaction Reporting System for Quasi-drugs and Cosmetics

The marketing authorization holders of quasi-drugs and cosmetics have reported research reports to the PMDA via an adverse reaction reporting system until now. From April 1, 2014, the system will be improved to receive individual case safety reports of quasi-drugs and cosmetics too, so that the MHLW/PMDA can identify hazardous health effects. This change follows recent cases of skin disorders from the use of cosmetics or quasi-drugs in Japan. A summary of the revised system will be presented in section 1 of the full text.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated February 18, 2014, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 2 of the full text.

1. Salazosulfapyridine
2. Sulfamethoxazole/Trimethoprim
3. Felbinac (for ethical use)
4. Regorafenib Hydrate

3. Revision of Precautions (No. 254)

Revisions of Precautions for the following pharmaceuticals:
Mianserin Hydrochloride, Bixalomer, Minodronic Acid Hydrate, Yokukansan (for ethical use), Felbinac-containing Products (OTC drugs), Yokukansan (OTC drugs)

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

(as of March 2014)

A list of products subject to Early Post-marketing Phase Vigilance as of March 1, 2014 will be provided in section 4 of the full text.