Pharmaceuticals and Medical Devices Safety Information

No. 304 August 2013

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. 304, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Surveillance on Availability, Dissemination, and Utilization of Drug Safety Information in Medical institutions and Pharmacies

The PMDA has been conducting surveillance starting from fiscal year 2010 in order to grasp the status of dissemination and utilization of safety information and to determine appropriate ways of dissemination and utilization of the information in medical institutions.

Appropriate dissemination and utilization of the most current drug safety information in clinical practice is important to secure appropriate use of medical products including drugs. The PMDA website and medi-navi (an e-mail alert service) are useful information sources to ensure access to drug safety information in a prompter manner. My Drug List for Safety Update, which is an additional service for the PMDA medi-navi subscribers, can be a powerful tool for information management of drugs prescribed exclusively for extramural dispensing and bring-in drugs which are not dispensed in the hospital. Use of these information sources provided by the PMDA is strongly recommended.

Details of the surveillance in FY 2012 will be provided 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 July 9, 2013, 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. Golimumab (Genetical Recombination)

3. Revision of Precautions (No. 248)

Revisions of Precautions etc. for the following pharmaceuticals:
Paliperidone, Sulbactam Sodium/Ampicillin Sodium, Sitafloxacin Hydrate, Peramivir Hydrate, Itraconazole, and Albendazole

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

(as of August 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of August 1, 2013 will be provided in section 4 of the full text.