Pharmaceuticals and Medical Devices Safety Information

No. 285 November 2011

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

1. Safety Measures against Nephrogenic Systemic Fibrosis Associated with Gadolinium Contrast Media

MHLW issued a notification about gadolinium contrast media in April and October 2009 and required marketing authorization holders (MAHs) to revise the "Precautions" section of the package insert to issue alerts for nephrogenic systemic fibrosis (NSF) associated with the drug. Based on review results of reported adverse reaction and situations overseas, MHLW issued an additional notification on September 20, 2011 and required MAHs to revise the "Precautions" section.

2. Carbamazepine-induced Serious Drug Eruption and Genetic Polymorphism

A number of cases of serious drug eruption such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) associated with carbamazepine have been reported. The causality between carbamazepine-induced serious drug eruption and HLA genetic polymorphism in Han Chinese is already included in the package insert of carbamazepine. This time MHLW reviewed the cases reported in Japanese patients and required MAHs to provide the information in the package insert.

3. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated October 25, 2011, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 3 of the full text of PMDSI No.285.

1. Anastrozole
2. Temozolomide
3. Ritodrine

4. Revision of Precautions (No. 231)

Revisions of Precautions etc. for the following pharmaceuticals:
Atomoxetine Hydrochloride, Dasatinib Hydrate, Varenicline Tartrate, Zoledronic Acid Hydrate, Pamidronate Disodium Hydrate, Alendronate Sodium Hydrate (oral dosage form), Etidronate Disodium, Sodium Risedronate Hydrate, Alendronate Sodium Hydrate (injectable dosage form), Minodronic Acid Hydrate

5. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2011)

A list of products subject to Early Post-marketing Phase Vigilance as of November 1, 2011 will be provided in section 5 of the full text of PMDSI No.285.