Pharmaceuticals and Medical Devices Safety Information

No. 295 October 2012

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

1. Serious Hypocalcaemia Associated with Denosumab (Genetical Recombination)

Since the launch on April 17, 2012, denosumab (genetical recombination) has been administered to approximately 7300 patients as of August 31, 2012, and 32 cases of serious hypocalcaemia, including 2 deaths, have been reported (as of August 31, 2012). In light of such information, MHLW/PMDA instructed the marketing authorization holder to distribute the Dear Healthcare Professional Letters of Rapid Safety Communications (Blue Letter) on September 11, 2012 and took additional safety measures. The information 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 September 11 and 25, 2012, 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. Denosumab (Genetical Recombination)
2. Tetracosactide Acetate (0.5 mg preparation)
3. Levocabastine Hydrochloride

3. Revision of Precautions (No. 240)

Revisions of Precautions etc. for the following pharmaceuticals:
Diclofenac Sodium (ophthalmic solution), Diclofenac Sodium (dermatologic preparation), Lithium Carbonate, Cibenzoline Succinate, Aliskiren Fumarate, Propylthiouracil, Tegafur/Gimeracil/Oteracil Potassium, Telaprevir, Tocilizumab (Genetical Recombination), Preparations Containing Diclofenac Sodium (dermatologic preparation) (over-the-counter drug)

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of October 2012)

A list of products subject to Early Post-marketing Phase Vigilance as of October 1, 2012 will be provided in section 4 of the full text.