Pharmaceuticals and Medical Devices Safety Information

No. 294 September 2012

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 294, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Proper Use of Contact Lenses and Prevention of Eye Disorders

Corrective contact lenses and non-corrective, decorative/cosmetic contact lenses are regulated as “specially controlled medical devices” in accordance with the Pharmaceutical Affairs Law to ensure their safety and quality. This section reports cases of eye disorders associated with contact lenses. Healthcare providers are requested to warn users thoroughly on the proper use of contact lenses.

2. Summary of Report on Adverse Reactions to the Influenza Vaccine in the 2011 Season

A summary of adverse reactions to the influenza vaccines reported from October 1, 2011 to March 31, 2012 are presented. Adverse reaction reports associated with the influenza vaccines, which had been collected up to March 31, 2012, were identified and reviewed. Based on the results, MHLW instructed the associated marketing authorization holders (MAHs) to revise the Precaution section of package inserts on July 10, 2012. The safety measures are also presented in this section of the full text.

3. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated August 7, 2012, 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.

1. Oxaliplatin

4. Revision of Precautions (No. 239)

Revisions of Precautions etc. for the following pharmaceuticals:
Suxamethonium Chloride Hydrate, Pamidronate Disodium Hydrate, Ropinirole Hydrochloride (extended release tablets), Diazoxide, Zoledronic Acid Hydrate, Nelarabine, Varenicline Tartrate

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

A list of products subject to Early Post-marketing Phase Vigilance as of September 1, 2012 will be provided in section 5 of the full text.