Pharmaceuticals and Medical Devices Safety Information

No. 306 October 2013

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 306, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Adverse Reactions to Influenza Vaccine in the 2012 Season

Adverse reactions to influenza vaccine reported between October 1, 2012 and March 31, 2013 will be summarized in the full text. Adverse reactions included in the full text were presented on June 14, 2013 at a joint meeting of Committee on Adverse Reactions of Immunization and Vaccine Department in the Health Science Council (the second meeting) and Subcommittee on Drug Safety of Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the second meeting).

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated September 17, 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. Propylthiouracil
2. Bortezomib
3. Minocycline Hydrochloride (oral dosage form, injectable dosage form)
4. Losartan Potassium

3. Revision of Precautions (No. 250)

Revisions of Precautions for the following pharmaceuticals:
Celecoxib, Sertraline Hydrochloride, Fondaparinux Sodium, Zoledronic Acid Hydrate, Erlotinib Hydrochloride

Revisions of Precautions for the following medical devices:
Tracheostomy Masks

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of October 2013)

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