Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 283 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Safety Measures against Bladder Cancer Associated with Diabetes Medication "Pioglitazone Hydrochloride-Containing Products"

The French regulatory authority (Afssaps) suspended new prescriptions of the type 2 diabetes treatment pioglitazone hydrochloride-containing products on June 9, 2011, based on new results from the French epidemiological study which suggested an increased risk of bladder cancer for patients treated with the drug. The European Medicines Agency and the U.S. Food and Drug Administration started to review pioglitazone hydrochloride based on results from the new study. MHLW has also reviewed the new study data together with existing information and has taken safety measures including the revision of package inserts. The details are described in section 1 of the full text document.

2. Important Safety Information

Section 2 of the full text document presents the contents of the revisions and case summaries that served as the basis for these revisions to important adverse reactions included under the Precautions section of package inserts of drugs that have been revised in accordance with the Notification dated August 9 and 12, 2011.

1. Influenza HA Vaccine
2. Thalidomide
3. Doxorubicin Hydrochloride
4. Dabigatran Etexilate Methanesulfonate

3. Revision of Precautions (No. 229)

Revisions of Precautions for the following pharmaceuticals are included in Section 3 of the full text document.

Modafinil, Shakuyakukanzoto, Esmolol Hydrochloride, Bosentan Hydrate, Clomifene Citrate, Methotrexate, Azithromycin Hydrate (tablet 250 mg, 600 mg, capsule for pediatrics, fine granule for pediatrics, injectable dosage form), Azithromycin Hydrate (dry syrup for adults), Clarithromycin, Lansoprazole/Amoxicillin Hydrate/Clarithromycin, Ofloxacin (oral dosage form), Levofloxacin Hydrate (oral dosage form) (low-dose), Levofloxacin Hydrate (oral dosage form) (high-dose), Levofloxacin Hydrate (injectable dosage form), Maraviroc, Sulfamethoxazole/Trimethoprim, Eptacog Alfa (Activated) (Genetical Recombination), Shakuyakukanzoto (OTC-drug)

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

A list of products subject to Early Post-marketing Phase Vigilance as of September 1, 2011 is included in Section 4 of the Full text document.

PMDSI is also available on the Pharmaceuticals and Medical Devices Agency website (http://www.pmda.go.jp/english/index.html) and on the MHLW website (http://www.mhlw.go.jp/, Japanese only).