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. 280 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Safety Measures for Pediatric Pneumococcal Conjugate Vaccine and Haemophilius Influenzae Type b (Hib) Vaccine

Some fatal cases have been reported in infants who simultaneously received multiple vaccinations including pediatric pneumococcal conjugate vaccine and Haemophilius Influenzae Type b (Hib) vaccine. MHLW temporarily suspended use of these vaccines on March 4, 2011 and held expert meetings on March 8, 24 and, 31 to review the causality between the vaccinations and the infant deaths as well as the safety of these vaccines when they are given simultaneously. Accordingly, it was considered that there were no safety concerns, and vaccination was resumed on April 1. The review process that led up to the resumption of vaccinations and details of safety measures are described in section 1 of the Full text document.

2. Manuals for Management of Individual Serious Adverse Drug Reactions

MHLW has been developing “Manuals for Management of Individual Serious Adverse Drug Reactions” with the cooperation of experts from relevant academic societies since FY 2005 as part of the “Initiative of Comprehensive Action for Serious Adverse Drug Reactions.” The manuals for management of adverse drug reactions including “Acute pyelonephritis” have been completed and are available on the MHLW website. This section presents the aim of the initiative, as well as information about the Manuals.

3. Important Safety Information

This section 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 April 20, 2011.

1. Olopatadine Hydrochloride (oral dosage form)
2. Fludarabine Phosphate
3. Miriplatin Hydrate, Iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil (MIRIPLA suspension vehicle)

4. Revision of Precautions (No. 226)

Revisions of Precautions for the following pharmaceuticals are included in Section 4 of the Full text document.

Ketotifen Fumarate (Oral dosage form), Alprazolam, Pramipexole Hydrochloride Hydrate, Aliskiren Fumarate, Infliximab (Genetical Recombination), Pemetrexed Sodium Hydrate, Micafungin Sodium, Darunavir Ethanolate (300 mg), Darunavir Ethanolate (400 mg), Ribavirin (Tablet), Peginterferon Alfa-2a (Genetical Recombination), Peginterferon Alfa-2b (Genetical Recombination), Ketotifen Fumarate (Oral dosage form) (OTC-drug)

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

A list of products subject to Early Post-marketing Phase Vigilance as of June 1, 2011 is included in Section 5 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).