# Pharmaceuticals and Medical Devices Safety Information

## No. 276 January 2011

## Executive Summary

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Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 276 will be upcoming soon. The contents of this month's PMDSI are outlined below.

## 1. Safety Measures Against Photosensitivity due to Topical Ketoprofen

The MHLW has issued an alert about possible photosensitivity due to topical ketoprofen, a percutaneous anti-inflammatory analgesic, available as an ethical drug or an over-the-counter drug in the section of Precautions in the package insert. European Medicines Agency announced in July 2010 based on its review of the efficacy and safety of topical ketoprofen, that safety measures against photosensitivity should be strengthened and that these drugs should no longer be available over the counter. In light of these circumstances, the MHLW reviewed the necessity of further safety measures against possible photosensitivity due to topical ketoprofen and required the marketing authorization holders (MAHs) to revise the section of Precautions on October 12, 2010. The details are described in Section 1 of the Full text document.

In addition, the necessity of changing the risk categories of OTC topical ketoprofen was discussed based on a review of safety measures against possible photosensitivity. The details are described in Section 1 of the Full text document.

## 2. Research on System for Receiving Adverse Reaction Information from Patients

Under the Japanese adverse reaction reporting system, information on adverse reactions is to be collected from pharmaceutical companies and healthcare providers, such as physicians. The final proposal by the Committee for Investigation of Drug-induced Hepatitis Cases and Appropriate Regulatory Administration to Prevent Recurrence of Yakugai (Drug-induced suffering) (April 28, 2010) advocated the need for a scheme to effectively use adverse reaction information reported by patients. A system for adverse reaction reporting by patients has been introduced in more countries in Europe and in the US in recent years. In Japan, “the Research on System for Receiving Adverse Reaction Information from Patients” was started in FY 2009, supported by Health and Labour Sciences Research Grants to effectively use the adverse

reaction information reported by patients. The summary of the survey and the pilot study are introduced in Section 2 of the Full text document.

## 3. Revision of Precautions (No. 222)

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

Atomoxetine Hydrochloride, Carteolol Hydrochloride (ophthalmic solution), Lanthanum Carbonate Hydrate, Thiamazole, Cilostazol, Sugammadex Sodium, Deferoxamine Mesilate, Capecitabine, Gefitinib, Etravirine, and Yellow fever vaccine

Revisions of Precautions for the following medical device are included in Section 3 of the Full text document.

Inferior Vena Cava Filter

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

A list of products subject to Early Post-marketing Phase Vigilance as of January 1, 2011 is included in Section 4 of the main 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).