Pharmaceuticals and Medical Devices Safety Information

No. 286 December 2011

Executive Summary

Published by
Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency
Office of Safety Ⅰ

For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 286, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Cases of Non-payment under the Relief System for Sufferers from Adverse Drug Reactions and Proper Use of Drugs

Recently, the number of application for the Relief System for Sufferers from Adverse Drug Reactions and Diseases Infected from Biological Products has been increasing. However, relief benefits have not been approved in some cases due to improper use of drugs. Thus MHLW/PMDA encourages proper use of drugs. In this section, the cases of non-payment of relief benefits are presented.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated November 29, 2011, 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 of PMDSI No.286.

1. Epoprostenol Sodium

3. Revision of Precautions (No. 232)

Revisions of Precautions etc. for the following pharmaceuticals:
Solifenacin Succinate, Nitrazepam, Fluticasone Furoate, Fluticasone Propionate (nasal solution), Acetazolamide, Acetazolamide Sodium, Isoniazid, Isoniazid Sodium Methanesulfonate Hydrate, Remifentanil Hydrochloride

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2011)

A list of products subject to Early Post-marketing Phase Vigilance as of December 1, 2011 will be provided in section 4 of the full text of PMDSI No.286.