Pharmaceuticals and Medical Devices Safety Information

No. 296 November 2012

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. 296, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Summary of Payment/Non-payment of Adverse Drug Reaction Relief Benefits and Drugs with Many Cases of Improper Use

Under the Relief System for Sufferers from Adverse Drug Reactions, relief benefits have not been approved in some cases due to improper use of drugs. MHLW/PMDA presents here drugs with many cases of improper use and encourages proper use of drugs.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated October 30, 2012, 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. Imatinib Mesilate
2. Ceftriaxone Sodium Hydrate
3. Mexiletine Hydrochloride

3. Revision of Precautions (No. 241)

Revisions of Precautions etc. for the following pharmaceuticals:
Inactivated Poliomyelitis Vaccine, Acetaminophen, Isopropylantipyrine/Acetaminophen/Allylisopropylacetylurea/Anhydrous Caffeine, Tramadol Hydrochloride/Acetaminophen, Salicylamide/Acetaminophen/Anhydrous Caffeine/Chlorpheniramine Maleate, Diprophylline/Dihydrocodeine Phosphate/*dl*-Methylephedrine Hydrochloride/Diphenhydramine Salicylate/Acetaminophen/Bromovalerylurea, Spironolactone, Dabigatran Etexilate Methanesulfonate, Rotavirus Vaccine, Live, Oral, Pentavalent

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2012)

A list of products subject to Early Post-marketing Phase Vigilance as of November 1, 2012 will be provided in section 4 of the full text.

This English version of PMDSI is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA shall not be responsible for any consequence resulting from use of this English version.