Pharmaceuticals and Medical Devices Safety Information

No. 307 November 2013

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. 307, interested readers are advised to consult the PMDA's Medical Product Information web page for upcoming information. The contents of this month's PMDSI are outlined below.

1. Summary of the Relief System for Sufferers from Adverse Drug Reactions and the Cases of Non-payment of Relief Benefits Due to Improper Use of Drugs

Recently, the number of applications for the Relief System for Sufferers from Adverse Drug Reactions has been increasing. However, it has been pointed out that the system is still not well-known to the healthcare professionals and public. The summary of the Relief System will be provided in section 1 of the full text.

The cases of non-payment of relief benefits will also be presented in the full text, since relief benefits have not been approved in some cases due to the improper use of drugs. MHLW/PMDA encourages the 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 22, 2013, 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. Axitinib
2. Bevacizumab (Genetical Recombination)

3. Revision of Precautions (No. 251)

Revisions of Precautions for the following pharmaceuticals:
Clobazam, Olmesartan Medoxomil, Olmesartan Medoxomil/Azelnidipine, Omega-3 fatty acid ethyl ester, Apixaban, Ethyl Icosapentate, Gemcitabine Hydrochloride, Oxaliplatin, Cisplatin (Non-intra-arterial injection), Regorafenib Hydrate, Ethyl Icosapentate (OTC drugs)

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

(as of November 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of November 1, 2013 will be provided in section 4 of the full text.