Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 284, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Safety Measures against Disturbed Consciousness Associated with the Use of Smoking Cessation Aid CHAMPIX Tablets

An alert for dizziness and somnolence associated with the use of smoking cessation aid CHAMPIX Tablets (hereinafter referred to as “CHAMPIX”) have been included in the package insert since the product’s launch. In addition, MHLW required the marketing authorization holder of CHAMPIX to revise the package insert to emphasize alerts for disturbed consciousness associated with CHAMPIX because cases of disturbed consciousness (e.g., decreased level of consciousness and loss of consciousness), some of which resulted in automobile accidents, have been reported in CHAMPIX users in the post-marketing setting. However, automobile accidents involving CHAMPIX users were still reported after the revision of the package insert. Accordingly, additional information should be provided to healthcare professionals and the product users to promote proper use of CHAMPIX.

2. The Guidelines for Provision of Dear Healthcare professional Letters of Emergent/Rapid Safety Communications

The circumstances of provision of the important safety information concerning pharmaceuticals and medical devices to healthcare professionals have changed. Accordingly, guidelines for distribution of Dear Healthcare Professional Letters of Emergent Safety Communications (Yellow Letter) and Dear Healthcare Professional Letters of Rapid Safety Communications (Blue Letter) were developed to facilitate more proper provision of safety information and enforced as of October 1, 2011.

3. Summary of the Report on Adverse Reactions to the Influenza A (H1N1) Vaccine in the 2010 Season

A joint meeting of the Subcommittee on Drug Safety of Committee on Drug Safety and the Influenza A (H1N1) Vaccine Adverse Reaction Review Committee was held on July 13, 2011, and a summary of adverse reactions to the influenza A (H1N1) vaccines that occurred up until May 31, 2011 was reported. In addition, after organizing and reviewing the adverse reactions to the influenza vaccines, which have been collected up to March 31, 2011, MHLW issued a notification on August 9, 2011 and required marketing authorization holders to revise the Precautions section of package inserts.

4. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated September 20, 2011, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 4 of the full text of PMDSI No.284.

5. Revision of Precautions (No. 230)

Revisions of Precautions etc. for the following pharmaceuticals:
Gadoxetate Sodium, Gadodiamide Hydrate, Gadoteridol, Meglumine Gadoterate, Gadopentetate Dimeglumine, Carbamazepine, Dabigatran Etexilate Methanesulfonate, Fondaparinux Sodium, Clopidogrel Sulfate, Sodium Hyaluronate Crosslinked Polymer/Sodium Hyaluronate Crosslinked Polymer Crosslinked with Vinylsulfone, Capecitabine, Garenoxacin Mesilate Hydrate

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

A list of products subject to Early Post-marketing Phase Vigilance as of October 1, 2011 will be provided in section 6 of the full text of PMDSI No.284.

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).