

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

1. Precautions in Handling of Reusable Resuscitator

This section reports medical accidents involving insufficient ventilation in patients treated with reusable resuscitators assembled in the wrong way. Precautions when handling reusable resuscitators will be presented in section 1 of the full text.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated March 26, 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. Recombinant Adsorbed Bivalent Human Papillomavirus-like Particle Vaccine (derived from Trichoplusia ni cells)
2. Telaprevir

3. Revision of Precautions (No. 245)

Revisions of Precautions etc. for the following pharmaceuticals:
Gabapentin, Carbamazepine, Gabapentin Enacarbil, Hydrochlorothiazide, Candesartan
Cilexetil/Hydrochlorothiazide, Telmisartan/Hydrochlorothiazide,
Valsartan/Hydrochlorothiazide, Losartan Potassium/Hydrochlorothiazide, Dihydrocodeine
Phosphate/dl-Methylephedrine Hydrochloride/Chlorpheniramine Maleate, Platycodon

Fluidextract/Glycyrrhiza Extract/Plantago Herb Extract/Peony Root Extract/Dihydrocodeine Phosphate, Dihydrocodeine Phosphate/Ephedrine Hydrochloride/Ammonium Chloride, Diprophylline/Dihydrocodeine Phosphate/dl-Methylephedrine Hydrochloride/Diphenhydramine Salicylate/Acetaminophen/Bromovalerylurea, Cherry Bark Extract/Codeine Phosphate Hydrate, Codeine Phosphate Hydrate, Dihydrocodeine Phosphate, Denosumab (Genetical Recombination), Sorafenib Tosilate, Panitumumab (Genetical Recombination), Doripenem Hydrate, Interferon Beta-1b (Genetical Recombination), Escitalopram Oxalate, Sertraline Hydrochloride, Duloxetine Hydrochloride, Fluvoxamine Maleate, Mirtazapine, Milnacipran Hydrochloride

Prevision of Precautions etc. for the following medical devices:

Implantable Cardiac Pacemaker, Biventricular Pacing Pulse Generator without Defibrillator Function

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of May 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of May 1, 2013 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.
