

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

## **1. Severe Haemorrhages Associated with Suspected Interaction between Antirheumatic Igratimod and Warfarin**

A fatal case of pulmonary alveolar haemorrhage associated with a suspected interaction between iguratimod and warfarin has been reported. MHLW/PMDA instructed the marketing authorization holders of iguratimod to contraindicate the concomitant use of iguratimod with warfarin and to distribute the Dear Healthcare Professional Letters of Rapid Safety Communications (Blue Letter) on May 17, 2013. Details will be presented in section 1 of the full text.

## **2. Revision of Precautions for the Effect of Battery Chargers for Electric Cars on Implantable Cardiac Pacemakers**

Based on the results of a verification test on the effect of electromagnetic waves from battery chargers for electric cars on implantable cardiac pacemakers, a precaution was issued for patients and healthcare professionals. A summary of the verification test and relevant safety measures will be presented in section 2 of the full text.

### 3. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated April 23 and May 17, 2013, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 3 of the full text.

1. Ambrisentan
2. Tranexamic Acid
3. Iguratimod

### 4. Revision of Precautions (No. 246)

Revisions of Precautions etc. for the following pharmaceuticals:

Tolvaptan, Tiotropium Bromide Hydrate, Esomeprazole Magnesium Hydrate, Dabigatran Etexilate Methanesulfonate, Nilotinib Hydrochloride Hydrate, Amoxicillin Hydrate, Potassium Clavulanate/Amoxicillin Hydrate, Clarithromycin, Lansoprazole/Amoxicillin Hydrate/Clarithromycin, Lansoprazole/Amoxicillin Hydrate/Metronidazole, Terbinafine Hydrochloride (oral dosage form), Preparations Containing Tranexamic Acid (mainly containing vitamins), Warfarin Potassium

Prevision of Precautions etc. for the following medical devices:

Magnetic Resonance Imaging System

### 5. List of Products Subject to Early Post-marketing Phase Vigilance (as of June 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of June 1, 2013 will be provided in section 5 of the full text.

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