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

1. Tolvaptan and Hepatic Dysfunction

The MHLW required the Marketing Authorization Holder (MAH) of Tolvaptan to prepare educational materials for healthcare professionals based on a review of accumulated reports including hepatic dysfunction. Furthermore, the MHLW ordered the MAH to revise the package insert on April 23 and July 9, 2013.

The current package insert has been updated as follows:

- Important Precautions

  Serious hepatic dysfunction may occur from the beginning of the treatment with Tolvaptan. Liver function tests should be performed before starting treatment with Tolvaptan and frequently during at least the first 2 weeks of the treatment. Subsequent tests should be performed as clinically indicated when the treatment needs to continue.
- Clinically significant adverse reactions

  Hepatic dysfunction (frequency unknown): Hepatic dysfunction with elevations of AST (GOT), ALT (GPT), γ-GTP, Al-P, bilirubin, etc. may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of the drug should be discontinued and appropriate measures should be taken.

Details will be provided in section 1 of the full text.

2. Revision of Precautions for Magnetic Resonance Imaging System

Magnetic Resonance Imaging (MRI) scans have been contraindicated in patients with metal-containing medical devices inside their body. Bringing metal-containing medical devices into an MRI room also has been prohibited.

Recently, however, patients with certain implantable or indwelling medical devices have become able to take MRI scans as long as they comply with required conditions and precautions for MRI scans. In addition, some metal-containing medical devices that are allowed to be brought into an MRI room have been launched.

In light of the above, Precautions for Magnetic Resonance Imaging System have been revised. Details will be provided 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 June 4, 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. Interferon beta (Products for administration in combination with ribavirin) and Ribavirin (Capsules)
2. Carboplatin
3. Tegafur/Gimeracil/Oteracil Potassium
4. Tolvaptan
5. Paroxetine Hydrochloride Hydrate
6. Levetiracetam

4. Revision of Precautions (No. 247)

Revisions of Precautions etc. for the following pharmaceuticals:
Loxoprophen sodium hydrate (oral dosage form), Sugammadex Sodium, Nelarabine, Loxoprophen sodium hydrate (oral dosage form) (OTC drugs), Recombinant Absorbed Bivalent Human Papillomavirus-like Particle Vaccine (derived from Trichoplusia ni cells) and Recombinant Adsorbed Quadrivalent Human Papillomavirus Virus-Like Particle Vaccine (Yeast Origin)

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

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