Pharmaceuticals and Medical Devices Safety Information

No. 289 March 2012

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 289, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Reactivation of Hepatitis B Virus Associated with Antineoplastic Agents Everolimus

Alerts against reactivation of hepatitis B virus (HBV) associated with everolimus have been included in the package insert, etc. since marketing authorization. Since fatal case due to reactivation of HBV after being treated with everolimus was reported in Japan, reactivation of HBV associated with the use of immunosuppressive drugs is presented. In addition, the background of safety measures and summary of reported cases are also included to provide information for proper use of everolimus.

2. Use of the “PMDA medi-navi” and “My Drug List for Safety Update”

The PMDA medi-navi (Pharmaceuticals and Medical Devices Information E-mail Alert Service) that provides information in a timely manner when very important safety information regarding pharmaceuticals and medical devices is issued, and its additional feature “My Drug List for Safety Update” are introduced.

3. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated February 14, 2012, 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 of PMDSI No.289.

1. Montelukast Sodium
2. Monobasic Sodium Phosphate Monohydrate/Dibasic Sodium Phosphate anhydrous

4. Revision of Precautions (No. 234)

Revisions of Precautions etc. for the following pharmaceuticals:
Leflunomide, Extract from Inflamed Cutaneous Tissue of Rabbits Inoculated with Vaccine Virus (oral dosage form), Extract from Inflamed Cutaneous Tissue of Rabbits Inoculated with Vaccine Virus (injectable dosage form), FK Powder, HM Powder, KM Powder, NIM Combination Powder, OM Powder Mix, Deferasirox, Ritonavir.

Revisions of Precautions etc. for the following medical devices:
Radiation Therapy Equipment (X-ray/CT combined linear accelerator system, X-ray/CT combined particle radiotherapy equipment, Living tissue radiotherapy system, Linear accelerator system, Stereotactic radiotherapy accelerator system, Stereotactic radiotherapy radionuclide system, Non-linear accelerator system, Particle radiotherapy equipment)

5. List of Products Subject to Early Post-marketing Phase Vigilance (as of March 2012)

A list of products subject to Early Post-marketing Phase Vigilance as of March 1, 2012 will be provided in section 4 of the full text of PMDSI No.289.