Pharmaceuticals and Medical Devices Safety Information

No. 293 August 2012

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 293, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Serious Adverse Reactions Associated with Over-the-counter Drugs

Adverse reactions reported by marketing authorization holders or healthcare professionals include some serious adverse reactions associated with over-the-counter drugs. Reports of serious adverse reactions resulting from the use of over-the-counter drugs from 2007 to 2011 are presented.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated July 10, 2012, 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. Pregabalin
2. Methotrexate (tablet 2 mg, capsule)
3. Influenza HA Vaccine

3. Revision of Precautions (No. 238)

Revisions of Precautions etc. for the following pharmaceuticals:
Metformin Hydrochloride, Eltrombopag Olamine, Denosumab (Genetical Recombination), Temsirolimus, Nilotinib Hydrochloride Hydrate, Voriconazole, Sitafloxacin Hydrate, Ciprofloxacin, Ciprofloxacin Hydrochloride, Adefovir Pivoxil, Famciclovir

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

A list of products subject to Early Post-marketing Phase Vigilance as of August 1, 2012 will be provided in section 4 of the full text.