Pharmaceuticals and Medical Devices Safety Information

No. 292 July 2012

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 292, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Launch of a pilot program of “Direct Patient Reporting System for Adverse Drug Reactions”

In March 2012, PMDA started a pilot program of direct patient reporting for adverse drug reactions. This web-based system allows patients or their families to report suspected adverse drug reactions. We present an overview of the system and ask for your cooperation.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated June 5, 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. Ivermectin
2. Telaprevir
3. Garenoxacin Mesilate Hydrate

3. Revision of Precautions (No. 237)

Revisions of Precautions etc. for the following pharmaceuticals:
Escitalopram Oxalate, Aliskiren Fumarate, Ropinirole Hydrochloride, Trazodone Hydrochloride, Azosemide, Hydralazine Hydrochloride, Darunavir Ethanolate.

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

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