

PMDA Updates

January, 2011

< News >

1. Public relations for “Relief System for Adverse Drug Reactions”

PMDA is aiming to reinforce its publicity activities on “Relief System for Adverse Drug Reactions”. The agency launched a public relations campaign via multiple media including newspaper advertisements, big posters on railroad stations and Internet / professional publications advertising. The campaign will run until the end of March.

< Safety Information >

● Pharmaceuticals and Medical Devices Safety Information No.275, December 2010

The articles in this issue describe the following information.

- Safety Measures for Use of the Antidiabetic Drugs with New Action Mechanisms (DPP-4 inhibitors and GLP-1 receptor agonists)
- Important Safety Information [Kanpo medicines: (Keigairengyoto, Nijutsuto, Ryutanshakanto)]
- Revision of Precautions section of package inserts [Aliskiren Fumarate (and 8 others)]
- List of Products Subject to Early Post-marketing Phase Vigilance

For more details: <http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-275.pdf>

Medical Information for Risk Assessment Initiative “MIHARI”

As one of the activities for reinforcement and enhancement of the system for safety information collection and evaluation of medical products in the PMDA 2nd midterm plan (2009-13), the project on the use of electronic medical records, etc. for safety measures was launched. This project is the "Medical Information for Risk Assessment Initiative" and also called "MIHARI project". "MIHARI" means "monitoring" in Japanese. PMDA Expert Committee on the use of electronic medical records, etc. was also established as an advisory board for the "MIHARI project" in 2009

For more information: http://www.pmda.go.jp/english/service/mihari_project.html

< Events >

1. Conferences/meetings PMDA participates in

Date	Title	Location
March 2-4	LSIF RHSC Meeting	Washington DC
March 16-17	HBD East 2011 Think Tank Meeting	Tokyo
March 28 – 30	DIA EURO Meeting	Geneva