Pharmaceuticals and Medical Devices Safety Information

No. 309 January 2014

Executive Summary

Published by
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency
Office of Safety I

For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 309, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Precautions for Use of Puncture Site Closure Devices

Cases of serious malfunctions have been reported regarding puncture site closure devices that are used for hemostasis at the site of catheterization (site of femoral artery puncture) for percutaneous transluminal angioplasty or other procedures. This section provides information on the malfunctions reported in Japan, as well as precautions for patient care and other procedures during and after using closure devices.

2. List of Products Subject to Early Post-marketing Phase Vigilance

(as of January 2014)

A list of products subject to Early Post-marketing Phase Vigilance as of January 1, 2014 will be provided in section 2 of the full text.

Reference: Drugs and Medical Devices Safety Information Reporting System

Healthcare professionals are encouraged to report to the MHLW about adverse reactions or device malfunctions of not only drugs and medical devices but also quasi-drugs and cosmetics.