Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 297, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Surveillance on Dissemination and Utilization of Safety Information in Medical Institutions

PMDA has been conducting surveillance from fiscal year 2010 to grasp the status of dissemination and utilization of safety information in medical institutions and to determine appropriate methods for the dissemination and utilization of the information. The results of the surveillance conducted in fiscal year 2011 will be presented in section 1 of the full text.

2. Precautions for Using Gastrointestinal Stents

Section 2 of the full text will report cases of gastrointestinal (GI) perforation caused by GI stents. GI stents including esophageal, gastroduodenal, or colonic stents are placed to relieve GI obstructions/strictures caused by progression of cancer, etc. and to maintain patency of the GI tracts. MHLW/PMDA requires healthcare professionals to take extreme caution when using these stents.

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

A list of products subject to Early Post-marketing Phase Vigilance as of December 1, 2012 will be provided in section 3 of the full text.