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. 298, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Partial Amendment of the "Guidance for Bar Code Labeling on Prescription Drugs" for the Prevention of Medical Accidents

The "Partial Amendment of the 'Guidance for Bar Code Labeling on Prescription Drugs'" has been issued to prevent medical accidents. This section of the full text presents the background for developing bar code labeling on prescription drugs, an outline of the amendment, and the implementation schedule. Healthcare professionals are encouraged to utilize bar codes for medical safety.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated December 4, 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. Temozolomide
2. Telaprevir
3. Pramipexole Hydrochloride Hydrate
4. Mogamulizumab (Genetical Recombination)

3. Revision of Precautions (No. 242)

Revisions of Precautions etc. for the following pharmaceuticals:
Digoxin, Deslanoside, Metildigoxin, Ambrisentan, Gelatin (sponge 2 cm × 6 cm × 0.7 cm, 8 cm × 12.5 cm × 1 cm), Gelatin (sponge 5 cm × 2.5 cm, 10 cm × 7 cm), Pazopanib Hydrochloride, Gelatin (film)

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of January 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of January 1, 2013 will be provided in section 4 of the full text.