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

1. Implementation of the "Risk Management Plan"

Preparation of the Risk Management Plan (RMP) will be introduced for new drugs and biosimilars/follow-on biologics for which approval applications are submitted on or after April 1, 2013. This section of the full text introduces the outline of the system and future actions and encourages healthcare professionals to utilize the Risk Management Plan.

2. Revision of Precautions (No. 244)

Revisions of Precautions etc. for the following pharmaceuticals:
Estradiol (ESTRANA, Julina, DIVIGEL, FEMIEST), Estradiol Benzoate, Estradiol Valerate, Estradiol Dipropionate, Estriol (oral dosage form), Estriol Tripropionate, Conjugated Estrogens, Estradiol/Norethisterone Acetate, Estradiol/Levonorgestrel, Testosterone/Estradiol, Testosterone Enanthate/Estradiol Valerate, Testosterone Enanthate/Testosterone Propionate/Estradiol Valerate, Ethinylestradiol, Norethisterone/Mestranol (preparation with the indication for climacteric disturbance), Propafenone Hydrochloride, Purified Human Menopausal Gonadotrophin, Human Menopausal Gonadotrophin, Human Chorionic Gonadotrophin, Follitropin Beta (Genetical Recombination), Follitropin Alfa (Genetical Recombination), Estriol (injectable dosage form, preparations for vaginal application), Clomifene Citrate, Gonadorelin Acetate (1.2 mg, 2.4 mg), Cyclofenil

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

A list of products subject to Early Post-marketing Phase Vigilance as of March 1, 2013 will be provided in section 3 of the full text.