Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 281 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Revision of Package Inserts of Subcutaneous Port and Catheter

A subcutaneous port and catheter is an implantable medical device used for delivering drugs, etc into a blood vessel.

Catheter disconnection from the port as well as catheter fracture and breakage on the port connector or between the first rib and the clavicle have been reported in patients using these devices. Accordingly, MHLW required the marketing authorization holders (MAHs) to revise the Warnings and other sections of the package inserts. The details are described in section 1 of the Full text document.

2. Important Safety Information

This section presents the contents of the revisions and case summaries that served as the basis for these revisions to important adverse reactions included under the “Precautions” section of package inserts of drugs that have been revised in accordance with the Notification dated May 31, 2011.

1. Freeze-dried Live Attenuated Measles Vaccine, Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine
2. Cisplatin (intra-arterial injection)
3. Sitagliptin Phosphate Hydrate
4. Sorafenib Tosilate
5. Metformin Hydrochloride (for products with “Dosage and Administration” of maximum daily dose of 2250 mg)

3. Revision of Precautions (No. 227)

Revisions of Precautions for the following pharmaceuticals are included in Section 3 of the Full text document.

Cortisone Acetate, Dexamethasone (Oral dosage form), Dexamethasone Metasulfobenzoate Sodium (Injectable dosage form), Dexamethasone Sodium Phosphate (Injectable dosage form), Triamcinolone, Triamcinolone Acetonide (Injectable dosage form for intra-articular/intramuscular/intradermal administration), Hydrocortisone Sodium Phosphate, Fludrocortisone Acetate, Prednisolone (Oral dosage form), Prednisolone Sodium Succinate, Prednisolone Sodium Phosphate, Betamethasone, Betamethasone Acetate/Betamethasone Sodium Phosphate, Betamethasone Sodium Phosphate (Injectable dosage form, Enema), Dexamethasone Palmitate, Hydrocortisone, Hydrocortisone Sodium Succinate, Methylprednisolone, Methylprednisolone Sodium Succinate, Methylprednisolone Acetate, Betamethasone/*d*-Chlorpheniramine Maleate, Mitotane, Linezolid, Freeze-dried, Cell Culture-derived Japanese Encephalitis Vaccine (Inactivated) (ENCEVAC), Freeze-dried, Cell Culture-derived Japanese Encephalitis Vaccine (Inactivated) (JEBIK V), Inulin

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

A list of products subject to Early Post-marketing Phase Vigilance as of July 1, 2011 is included in Section 4 of the Full text document.

PMDSI is also available on the Pharmaceuticals and Medical Devices Agency website (http://www.pmda.go.jp/english/index.html) and on the MHLW website (http://www.mhlw.go.jp/, Japanese only).

This English version of PMDSI is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA shall not be responsible for any consequence resulting from use of this English version.