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. 277 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Safety Measures for Gemtuzumab Ozogamicin (Genetical Recombination)

On June 21, 2010, it was published that gemtuzumab ozogamicin (Genetical Recombination), a therapeutic agent for acute myeloid leukaemia, was voluntarily withdrawn from the U.S. market. On the basis of the above, the MHLW reviewed the safety measures for gemtuzumab ozogamicin to be taken in Japan, and an expert discussion was held at the meeting of the Subcommittee of the Drug Safety, part of the Committee on Drug Safety, under the Pharmaceutical Affairs and Food Sanitation Council, on November 2, 2010. As a result, additional safety measures for the use of this drug have been taken. 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 January 11, 2011.

1. Imatinib Mesilate, Nilotinib Hydrochloride Hydrate
2. Sunitinib Malate
3. Pilsicainide Hydrochloride Hydrate

3. Revision of Precautions (No. 223)

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

Ciclosporin, Mianserin Hydrochloride, Trichlormethiazide, Hydrochlorothiazide, Benzylhydrochlorothiazide, Indapamide, Benzylhydrochlorothiazide/Reserpine/Carbazochrome, Meticrane, Mefruside, Tripamide, Losartan Potassium/Hydrochlorothiazide, Agalsidase Alfa (Genetical Recombination), Sitagliptin Phosphate Hydrate, Temozolomide, Miriplatin Hydrate, Entecavir Hydrate, Freeze-dried, Cell Culture-derived Japanese Encephalitis Vaccine (Inactivated), Perflubutane, Iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil, and Remifentanil Hydrochloride

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

A list of products subject to Early Post-marketing Phase Vigilance as of February 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).