Pharmaceuticals and Medical Devices Safety Information

No. 279 May 2011

Executive Summary

Published by
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 279 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Project of Japan Drug Information Institute in Pregnancy

MHLW established Japan Drug Information Institute in Pregnancy (JDIIP) at the National Center for Child Health and Development (NCCHD) in October 2005 to provide consultation services and perform research activities. Four hospitals that joined the Project in FY2011 to strengthen the system are introduced together with the outline and current status of the project. The details are described in Section 1 of the Full text document.

2. Safety Measures related to Lenalidomide Hydrate

Lenalidomide hydrate was originally approved for concomitant use with dexamethasone for the indication for treatment of patients with relapsed or refractory multiple myeloma in June 2010. In August 2010, the additional indication for treatment of patients with myelodysplastic syndrome associated with a chromosome 5q deletion was approved.

During the Early Post-marketing Phase Vigilance (EPPV) in Japan (July 20, 2010 to February 19, 2011), a number of adverse drug reaction (ADR) reports concerning infection and hepatic dysfunction were gathered. In January 2011, arterial thromboembolism such as cerebral infarction was added to the European Summaries of Product Characteristics.

Based on the above, the safety measures related to infection, hepatic dysfunction and cerebral infarction associated with lenalidomide hydrate were reviewed. The details are described in Section 2 of the Full text document.

3. 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 March 22, 2011.

1. Aripiprazole
2. Freeze-dried Live Attenuated Mumps Vaccine
3. Anti-human Thymocyte Immunoglobulin, Rabbit
4. Tacrolimus Hydrate (oral dosage form, injectable dosage form)
5. Tolvaptan
6. Pioglitazone Hydrochloride, Pioglitazone Hydrochloride/Glimepiride, Pioglitazone Hydrochloride/Metformin Hydrochloride

4. Revision of Precautions (No. 225)

Revisions of Precautions for the following pharmaceuticals are included in Section 4 of the Full text document.

Sanilvudine, Acetaminophen (preparations without the indications for osteoarthritis), Isopropylantipyrine/Acetaminophen/Allylisopropylacetylurea/Anhydrous Caffeine, Oxypertine, Olanzapine, Carpipramine Hydrochloride Hydrate, Carpipramine Maleate, Quetiapine Fumarate, Clocapramine Hydrochloride Hydrate, Clozapine, Chlorpromazine Hydrochloride, Chlorpromazine Hydrochloride/Promethazine Hydrochloride/Phenobarbital, Chlorpromazine Hibenzate, Chlorpromazine Phenolphthalinate, Spiperone, Sultopride Hydrochloride, Sulpiride, Zotepine, Timiperone, Trifluoperazine Maleate, Nemonapride, Paliperidone, Pipamperone Hydrochloride, Pimozide, Fluphenazine Decanoate, Fluphenazine Maleate, Prochlorperazine Maleate, Prochlorperazine Mesilate, Blonanserin, Propericiazine, Bromperidol, Perphenazine, Perphenazine Hydrochloride, Perphenazine Fendizoate, Perphenazine Maleate, Perospirone Hydrochloride Hydrate, Mosapramine Hydrochloride, Moperone Hydrochloride, Risperidone, Levomepromazine Hydrochloride, Levomepromazine Maleate, Trazodone Hydrochloride, Haloperidol, Haloperidol Decanoate, Salicylamide/Acetaminophen/Anhydrous Caffeine/Chlorpheniramine Maleate (for adults), Salicylamide/Acetaminophen/Anhydrous Caffeine/Promethazine Methylenedisalicylate (for adults), Salicylamide/Acetaminophen/Anhydrous Caffeine/Chlorpheniramine Maleate (for pediatrics), Salicylamide/Acetaminophen/Anhydrous Caffeine/Promethazine Methylenedisalicylate (for pediatrics), Amiodarone Hydrochloride (injectable dosage form), Olmesartan Medoxomil, Olmesartan Medoxomil/Azelnidipine, Beraprost Sodium, Diprophylline/Dihydrocodeine Phosphate/*dl*-Methylephedrine Hydrochloride/Diphenhydramine Salicylate/Acetaminophen/Bromovalerylurea, Ephedra Herb Extract/Caffeine and Sodium Benzoate/Magnesium Oxide/Acetaminophen/Scopolia Extract, Tiotropium Bromide Hydrate, Minocycline Hydrochloride (dental), Azathioprine, Everolimus (0.25 mg, 0.5 mg, 0.75 mg), Gusperimus Hydrochloride, Ciclosporin (oral dosage form, injectable dosage form), Mycophenolate Mofetil, Mizoribine, Everolimus (5 mg), Efavirenz, Saquinavir Mesilate, Nevirapine, Peramivir Hydrate, Laninamivir Octanoate Hydrate, Itraconazole, Basiliximab (Genetical Recombination), Muromonab-CD3, Monobasic Sodium Phosphate Monohydrate/Sodium Dihydrogen Phosphate Anhydrous, Pneumococcal polysaccharide conjugate vaccine (diphtheria toxoid conjugate), Haemophilus type b conjuegate vaccine(tetanus toxoid conjugate), Nanpao (OTC-drug)

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

A list of products subject to Early Post-marketing Phase Vigilance as of May 1, 2011 is included in Section 5 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).