Drug News
藥 物 情 報

Issue No. 3 : January 2010

This is a monthly digest of local and overseas drug safety news and information released in the previous month. For the latest news and information, please refer to public announcements or the website of the Pharmaceutical Service of the Department of Health (http://www.psdh.gov.hk).

Safety Update

Health Canada issued reports of pure red cell aplasia in patients treated with Myfortic (mycophenolate sodium)

23 December 2009 - Novartis Pharmaceuticals Canada Inc. informed healthcare professionals of important new safety information regarding reports of pure red cell aplasia (PRCA) in patients treated with Myfortic (mycophenolate sodium) in combination with other immunosuppressive agents. Cases of PRCA had been reported worldwide in patients treated with Myfortic in combination with other immunosuppressive agents. Myfortic is an immunosuppressive agent indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplant.

In Hong Kong, Myfortic is registered by Novartis Pharmaceuticals (HK) Ltd. The package insert of the product has been revised to include the above safety information.

Recall of BiCNU (carmustine for injection) due to risk of infection announced by Health Canada

5 January 2010 - Bristol-Myers Squibb Canada had initiated a voluntary recall of the BiCNU (carmustine for injection) Combo kit Lot number 8K4218A (vial Lot number 1486494C) in Canada. This recall was being conducted as a precautionary measure due to a sterility assurance concern. A vial of BiCNU has been found to be contaminated with the microorganism *Bacillus Circulans*. This was recently identified during a product investigation due to an out-of-specification sterility test result reported during routine in-country release testing in one of the distribution markets. BiCNU (carmustine for injection) 100 mg vial is indicated as adjuvant therapy to surgery and radiotherapy or in combination therapy with other chemotherapeutic agents in the following: primary brain tumors, malignant lymphomas, multiple myeloma, malignant melanoma (disseminated) and gastrointestinal carcinoma.

In Hong Kong, BiCNU is registered by Bristol-Myer Squibb Pharma (HK) Ltd. The company confirmed that the affected lot had not been imported into Hong Kong.

Department of Health (DH) has contacted Health Canada and confirmed that no other batch of the product was affected. DH has also issued press release and alerted healthcare professionals to be vigilant to the possibility of infection in patients being treated with the product. Samples of the product have been obtained by the DH for microbiological testing and no microbial growth was found.

Recall of Influenza A (H1N1) 2009 Monovalent Vaccine by Sanofi Pastuer in United States

23 December 2009 - Sanofi Pasteur, Inc. in US notified the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) that routine testing of its pediatric Influenza A (H1N1) 2009 Monovalent Vaccine in 0.25mL syringes had identified four distributed lots with lower antigen content than the specification limit. Sanofi Pasteur had initiated a voluntary recall of 4 lots of Influenza A (H1N1) 2009 Monovalent Vaccine, pediatric dose (0.25mL) pre-filled syringes. These lots were shipped in November and are intended for children 6 through 35 months of age. No other distributed lots of Influenza A (H1N1) 2009 Monovalent Vaccine are affected. The FDA and the CDC had determined that there are no safety concerns with any of these lots.

Safety Update

In Hong Kong, Influenza A (H1N1) Vaccine is registered by Sanofi-Aventis Hong Kong Ltd under the name "Panenza". The company confirmed that the vaccine available in Hong Kong is supplied in vials only, but not in pre-filled syringes as in US. In addition, the US vaccine is manufactured by the Sanofi-Pastuer plant in US, while the vaccine being used in Hong Kong is manufactured by its plant in France. The recall in US was not related to the vaccine available in Hong Kong.

Drug Incident

Public urged not to consume virility product "Vegetal Vigra" with undeclared western drug ingredients

On 8 January 2010, a 33-year-old man was arrested in a joint operation between the Department of Health and the police as part of a follow-up investigation into the sale of an unregistered product for managing sexual dysfunction which was found earlier to contain undeclared western medicine.

The man was suspected of selling the product named "Vegetal Vigra" on the Internet. Three boxes of the product were seized from the man at the time of arrest. Another thirteen boxes of "Vegetal Vigra" and four boxes of two other slimming products were also found in a home search. The investigation revealed that the products were obtained from the Mainland.

In December 2009, the department obtained "Vegetal Vigra" from an Internet auction website during the department's surveillance operation. The department issued a warning on December 18, 2009 reminding people not to take the product as laboratory tests on the product showed the presence of sildenafil and tadalafil.

Both sildenafil and tadalafil were Western medicines usually used for treating male sexual dysfunction. Their side effects included low blood pressure, headache, vomiting, dizziness, and transient vision disturbances. It may interact with nitrates found in some prescription drugs (such as nitroglycerin for treatment of angina) and may lower blood pressure of patients to dangerous levels. Improper use of sildenafil and tadalafil may pose serious health risks, especially for patients with heart problems. Products containing sildenafil and tadalafil can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

The aforementioned product was not a registered pharmaceutical product in Hong Kong. A product containing any western drug ingredient must be registered before it can be sold in Hong Kong. Under the Pharmacy and Poisons Ordinance, possession or sale of unregistered pharmaceutical product is an offence liable to the maximum penalties of a $100,000 fine and two year's imprisonment.

The Department of Health exhorted members of the public not to sell products of unknown or doubtful composition. Members of the public should stop using the aforementioned product and they should see doctors if they feel unwell after taking it. They should destroy and dispose the aforementioned product or submit it to the Department's Pharmaceutical Service during office hours.

People with sexual dysfunction should consult healthcare professionals for advice if necessary.

Useful Contact

Drug Complaint:
Tel: 2572 2068
Fax: 2147 0457 & 2123 1996
E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:
You are encouraged to report any suspected or confirmed ADR cases to our office by:
Fax: 2572 4570
E-mail: adr@dh.gov.hk
Post:
ADR Monitoring Unit
Pharmaceutical Service,
Department of Health,
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon