Drug News
藥 物 情 報

Issue No. 9 : July 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

Voluntary product recall of Cancidas (caspofungin acetate for injection) 50 mg/vial in Canada

15 June 2010 – Health Canada announced that Merck Frosst Canada Ltd. initiated a voluntary recall of Cancidas (caspofungin acetate for injection) 50 mg/vial with lot numbers 0204Y, 1513X and 1734X. This recall was being conducted as a precautionary measure due to a potential for a limited number of cracked vials to be present in these lots. Only the listed lots of Cancidas 50 mg/vial mentioned above were subject to this recall in Canada.

In Hong Kong, Cancidas for Inj 50mg/vial is registered by Merck Sharp & Dohme (Asia) Ltd. The company has confirmed that the affected batches have not been imported into Hong Kong.

Follow-up to the investigation into febrile reactions in young children following 2010 seasonal trivalent influenza vaccination by Therapeutic Goods Administration (TGA) in Australia

5 July 2010 – Further to the report of an increase in febrile reactions related to vaccination in Western Australia (WA) of Australia in the Issue no. 7 of Drug News, the epidemiological analyses so far by the TGA demonstrated an excess of fever and febrile convulsions in children 6 months to 5 years with the use of CSL's 2010 trivalent influenza vaccine (TIV) products Fluvax and Fluvax Junior. However, despite extensive analyses, the TGA opined that the biological basis for the excess cases of fever and febrile convulsions remains unclear. Inspection of the CSL vaccine manufacturing facility had not identified a manufacturing deficiency that was causally linked to the occurrence of a higher than expected rate of febrile convulsions.

The TGA had concluded that the overall risk benefit balance of Fluvax/Fluvax Junior remains positive and it was considered appropriate to reserve the use of TIV to those children under 5. Information about the increase in reports of fever and febrile convulsions in young children during the 2010 southern hemisphere influenza season had been included in the Product information of the two vaccines in Australia .

As reported previously, one of the concerned vaccine (Fluvax) is registered by Luen Cheong Hong Ltd in Hong Kong. The company has confirmed that the Fluvax is solely for the southern hemisphere and has not been imported into Hong Kong. The company was instructed to ensure that the above safety information has been included in the package insert before the vaccine is imported into Hong Kong in future.

New boxed warning for severe liver injury with arthritis drug Arava (leflunomide) added by the U.S. Food and Drug Administration

13 July 2010 - The U.S. Food and Drug Administration (FDA) added information on severe liver injury to the boxed warning of Arava (leflunomide) – a drug used to treat

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rheumatoid arthritis - to highlight the risk of severe liver injury in patients using this drug and how this risk might be reduced. The decision made was based on FDA's 2010 review of adverse event reports of leflunomide which identified 49 cases of severe liver injury, including 14 cases of fatal liver failure, between August 2002 and May 2009.

Arava and other products containing leflunomide are available in Hong Kong. The information on severe liver injury is already present in the package insert of Arava. Department of Health has issued a press release and a "Dear Healthcare Professionals" letter to doctors reminding them to be vigilant to this safety information. In addition, the above issue will be considered in the forthcoming meeting of the Registration Committee of the Pharmacy and Poisons Board.

Drug Recall

Recall of pharmaceutical product – Fucidin for Intravenous Infusion 500mg (HK-37409)

On 13 July 2010, DKSH, a licensed wholesaler of pharmaceutical products informed Department of Health (DH) that manufacturer Leo Pharma was conducitng a voluntary recall of all batches of Fucidin for Intravenous Infusion 500mg from the market in view of its quality defect.

The recall was conducted after the manufactuer received three complaints from the Mainland regarding the presence of glass fragments in some of the vials of the product. No report of patient injury had been received. According to Leo Pharma, the glass fragments identified in the product have a size too large to pass through most needles used for administration. The recall was initiated to eliminate any potential risks to patients

Fucidin for Intravenous Infusion 500mg, containing sodium fusidate, is an antibiotic which is available only on prescription and usually used in hospitals for various infectious diseases. The product was imported from Denmark.

It was revealed that the affected product had been supplied to Hospital Authority hospitals and some private hospitals in Hong Kong. The relevant hospitals had been informed about the recall. On assessment, DH endorsed Leo Pharma's decision and would closely monitor the exercise and developments. DKSH had set up a hotline for public enquiries.

DH has issued a press statement to urge healthcare professionals to stop administering the product to patients. Patients should consult healthcare professionals if in doubt.

Drug Incident

Suspected counterfeit "Po Chai Pills" with undeclared western drug ingredient

On 22 June 2010, the Department of Health (DH) discovered the presence of an undeclared western drug ingredient, diclofenac, in a batch of "Po Chai Pills 保濟丸" (batch number 21214) during DH's routine market surveillance. The problematic product was found to be different from the registered proprietary Chinese medicine Po Chai Pills in packaging and pill color. The case has been referred to the Customs and Excise Department for further investigations as the problematic product was suspected to be a counterfeit product.

Diclofenac is a pain killer. Its side-effects are gastro-intestinal disturbances including gastric pain, nausea, vomiting, peptic ulcer and bleeding. Oral products containing diclofenac can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

Drug Incident

Woman arrested for suspectedly selling slimming product "2007 時尚瘦吧" with undeclared drug ingredients

On 17 June 2010, a 26-year-old woman was arrested in a joint operation of the Police and the Department of Health (DH) for selling a slimming product, "2007 時尚瘦吧", which was found to have contained undeclared western drug ingredients, sibutramine and its analogues, which may cause serious side effects.

Previously, DH had issued a press statement on 17 October 2008 warning members of the public not to take the product because it was found to have contained undeclared western drug ingredients, sibutramine and its analogues. Since 2008, no offering for sale of "2007 時尚瘦吧" has been detected via DH's surveillance exercise on the Internet. The product found on 17 June 2010 was offered for sale on the internet under the name of "綠盒清秀亭" and investigation later revealed that the product was in fact "2007 時尚瘦吧".

Sibutramine is a western medicine used as an appetite suppressant. Its side effects include increased blood pressure and heart rate, psychosis and possibly convulsion. People with heart problems, should not take it. Products containing sibutramine can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist. Sibutramine analogues, being chemically similar to sibutramine, are expected to have the same side effect as sibutramine.

All of the aforementioned products were not registered pharmaceutical products under the Pharmacy and Poisons Ordinance 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.

Members of the public should stop using the aforementioned products that contained undeclared western drug ingredients and they should see doctors if they feel unwell after taking the products. They should destroy, dispose or submit them to the Department's Pharmaceutical Service during office hours.

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