Drug News
藥 物 情 報

Issue No. 16 : February 2011

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

Worldwide Recall of Triad alcohol prep pads, alcohol swabs, and alcohol swabsticks due to potential microbial contamination

January 2011- The Triad Group, a manufacturer of over-the-counter products, initiated a worldwide recall of its alcohol prep products, including alcohol prep pads, alcohol swabs and alcohol swabsticks, due to potential contamination with a bacterium, Bacillus cereus. The contamination may lead to life-threatening infections, especially in at risk populations, e.g. immune suppressed and surgical patients. These products had been packaged in individual packets or co-packaged with other medicines for distribution nationwide.

Following the Triad Group's recall, pharmaceutical companies from various countries also issued press releases to alert consumers who had purchased products co-packed with related alcohol preparations. They were advised to use the alcohol preparations which are not involved with the Triad Group recall for skin cleansing when using the product concerned. The details of the affected products were listed in the table below.

	Announce-ment date	Countries	Pharmaceutical companies	Affected products	Situation in Hong Kong
1	17 January 2011	US	Genentech, Inc.	a) Boniva Injection, b) Fuzeon, c) Nutropin A.Q. Pen, d) Pegasys, e) TNKase	Out of these products, only Fuzeon (enfuvirtide) is registered and co-packaged with alcohol swabs. The alcohol swabs co-packaged in the product are manufactured by Buttner-Frank GmbH in Germany and thus not affected by recall action of US.
2	21 January 2011	US	Bayer Health-Care Pharmaceuti-cals	Betaseron	The product is registered by Bayer HealthCare Ltd under the brand name of Betaferon (interferon beta). The company confirmed that alcohol swab co-packaged in the product is not manufactured by Triad Group.

	Announce-ment date	Countries	Pharmaceutical companies	Affected products	Situation in Hong Kong
3	27 January 2011	US	Pfizer and Progenics	Relistor Kit	Relistor (methylnaltrexone bromide) in single vial is registered by Wyeth (HK) Limited. The company confirmed that the product has not been marketed in Hong Kong.
4	29 January 2011	US	GlaxoSmith-Kline	Arixtra Starter Kit	Arixtra (fondaparinux) is registered by GlaxoSmith-Kline Limited in pre-filled syringe. The company confirmed that the product has not been marketed in Hong Kong and neither alcohol prep pads, alcohol swabs, nor alcohol swabsticks are contained in the product.
5	7 February 2011	Canada	Merck Canada Inc.	Pegetron Redipen	Please refer to the situation in Hong Kong mentioned below.
6	12 February 2011	UK	MSD/(Schering Plough)	ViraferonPeg pre-filled pens, IntronA products	

Situation in Hong Kong regarding the above-mentioned announcement 5 & 6

In Hong Kong, Schering-Plough had notified the Department of Health (DH) on 25 January 2011 that the following interferon alpha products (the collated products of the above-mentioned Pegetron Redipen, ViraferonPeg and IntronA products) registered by the company were to be withdrawn temporarily from the local market as they are co-packaged with one of the incriminated swabs: Intron A inj 18miu/1.2ml multidose pen (HK-46113), Peg-Intron Redipen for inj 50mcg/0.5ml (HK-55115), Peg-Intron Redipen for inj 120mcg/0.5ml (HK-55117), Peg -Intron Redipen for inj 100mcg/0.5ml (HK-55118), and Peg-Intron Redipen for inj 80mcg/0.5ml (HK-55119).

Intron A is used for the treatment of chronic hepatitis B, chronic hepatitis C and leukemia, while Peg-Intron Redipen is used for the treatment of chronic hepatitis C. They are prescription drugs and are usually distributed to public and private hospitals, private doctors and pharmacies.

DH advised patients and healthcare providers to discard Triad Group's alcohol swab preparations supplied together with the above-mentioned injections and use alternate alcohol preparations for pre-injection cleansing, whereas the drugs can still be used in accordance with instructions on the package inserts or as directed by healthcare providers. DH issued letters to healthcare professionals to inform them about this matter on 25 January 2011 and a press statement was issued on the same day to inform the public of the matter.

US - Update on Fluzone Influenza Vaccine and reports of febrile seizures in children

21 January 2011- US FDA and the Centers for Disease Control and Prevention (CDC) detected an increase in the number of reports of febrile seizures following vaccination with Fluzone (a trivalent inactivated influenza vaccine or TIV, manufactured by Sanofi Pasteur, Inc.) to the Vaccine Adverse Event Reporting System (VAERS). In US, Fluzone is the only influenza vaccine recommended for use for the 2010-2011 flu season in infants and children of 6-23 months of age. Data from VAERS were preliminary and further investigations were under way to assess whether there could be an association between influenza vaccination and febrile seizures, or if other factors could be involved. According to the FDA and CDC, these reported febrile seizures were primarily in children younger than 2 years of age. There was no increase in VAERS reports of febrile seizures in people older than 2 years of age following vaccination with TIV, and also no increase after vaccination with live attenuated influenza vaccine (FluMist, the nasal spray vaccine). In the cases reported, all children recovered and no lasting effects have been seen. Recommendations for the use of flu vaccine in children have not been changed.

In Hong Kong, Fluzone Influenza Virus Vaccine is a prescription pharmaceutical product registered by Sanofi-Aventis Hong Kong Ltd. The influenza vaccine used in the local public vaccination programme is Vaxigrip Purified Vaccine manufactured by Sanofi Pasteur S. A. of France. So far, DH has not detected any increasing trend of febrile convulsion related to Fluzone vaccination. Similar news regarding the investigation of another trivalent seasonal flu vaccine Fluvax and febrile convulsion in Australia and UK have been reported in Issue No. 7, No. 9 and No. 15 of Drug News. DH remains vigilant to any updates about this issue.

EU - Benefit-risk review of Multaq (dronedarone)

22 January 2011- While US FDA had alerted healthcare professionals about the risk of serious liver injury in patients taking Multaq, an anti-arrhythmic medicine, on 15 January, the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency (EMA) also assessed all relevant available data and, during the January 2011 meeting, concluded that there was a need for urgent regulatory action to help manage the possible risk of severe liver complications with the medicine. The CHMP recommended to introduce warnings and precautions into the medicine's prescribing information so as to ensure patients' liver function is tested before initiation of treatment and closely monitored during treatment, and that treatment should be stopped if there are signs of potential liver damage.

In Hong Kong, Multaq (dronedarone) is a prescription drug registered by Sanofi-Aventis HK Ltd. Similar alert from US FDA was published in No. 15 of Drug News. The drug is an anti-arrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients due to atrial fibrillation or atrial flutter. Its package insert has been revised to include the relevant warning messages. DH had also sent letters to healthcare professionals to alert them about the issue on 15 January 2011.

EU -Review of the manufacture of Baxter's peritoneal dialysis solutions for the potential presence of endotoxins in some batches

22 January 2011- Further to the report of the detection of endotoxins in Baxter peritoneal dialysis (PD) solutions (Dianeal, Extraneal and Nutrineal) manufactured in its Castlebar plant in Ireland, which had been reported in Issue No. 15 of Drug News, the Baxter informed EMA that

the problem has not been solved and it could not guarantee the production of endotoxin-free solutions from a production line at the plant in the short-term. As a consequence, the EMA's CHMP, at the request of the European Commission, started a full review of the manufacture of Baxter's dialysis solutions at the affected plant. The CHMP considered importing alternative solutions manufactured in other parts of the world into the European Union. In the meantime, as there is no replacement for these treatments, batches of PD solutions manufactured in Castlebar would have to be released to meet patients' needs. The CHMP recommended introducing further safeguards to minimize the risks for patients. Healthcare professionals were advised to be vigilant when prescribing the solutions.

In Hong Kong, two Nutrineal products of Baxter Healthcare Ltd are registered, one is manufactured in Ireland (HK-45278) whereas the other is manufactured in Singapore (HK-51751). The company has confirmed that only Nutrineal manufactured in Singapore is marketed in Hong Kong.

Singapore- Recall of T3 Actin Tretinoin Cream 0.1%

28 January 2011- The Health Sciences Authority (HSA) of Singapore announced a recall of a batch of T3 Actin Tretinoin Cream 0.1% (batch number 06867005) as the contents of tretinoin were found to be understrength. The product was manufactured by HOE Pharmaceutical Sdn. Bhd. in Malaysia.

In Hong Kong, T3 Actin Cream 0.1% (HK-57658) is a prescription medicine registered by Hoepharma (HK) Limited. It is used for treating acne vulgaris. The company recalled the product from local market on 28 January 2011. DH had closely monitored the recall and a letter has been issued to healthcare professionals to inform them about the recall.

China - Removal of pharmaceutical products containing dextropropoxyphene, the dextro stereoisomer of propoxyphene

28 January 2011-In view of the potential risk of serious or even fatal *heart rhythm abnormalities on patients taking propoxyphene-containing products*, the State Food and Drug Administration (SFDA) of China announced that pharmaceutical products containing dextropropoxyphene (the dextro stereoisomer of propoxyphene) would be gradually withdraw from China market. By 31 July 2011, pharmaceutical products containing dextropropoxyphene should be recalled in accordance with Drug Administration Law and Regulations for Implementation of the Drug Administration Law and they could not be manufactured, sold or used in China. Doctors were advised to help their patients currently on dextropropoxyphene-containing products to gradually withdraw from the medications.

Propoxyphene is an opioid analgesic for alleviating mild to moderate pain. In Hong Kong, there were 21 registered products containing dextropropoxyphene in the local market as at December 2010. Registration Committee of the Pharmacy and Poisons Board decided, at its meeting held on 29 December 2010, to deregister products containing propoxyphene in Hong Kong for public health protection, starting from 10 January 2011. The Committee's decision was made after considering all the available information, including the effects of propoxyphene on human cardiac electrophysiology at therapeutic dose range, the availability of alternative analgesic drugs in Hong Kong and regulatory actions taken by other lead regulatory agencies. The safety information and deregistration of the drug have been reported in Issue No. 14 of Drug News.

Safety Update

Recall of Tegretol Retard (carbamazepine) 200mg Tablets in UK

1 February 2011- The MHRA announced that Sam Pharma Limited recalled some batches of parallel imported Tegretol Retard 200mg Tablets because the patient information leaflet did not include mandatory safety warnings issued by the EMA. The missing warnings are about the emergency of suicidal ideation and behaviour in some patients received anti-epileptics such as carbamazepine. Patients should seek medical advice if signs of suicidal ideation or behavioiur emerge after taking the drug.

In Hong Kong, Tegretol Tab 200mg and Tegretol CR Tab 200mg are prescription medicines registered by Novartis Pharmaceuticals (HK) Ltd. They are used for treatment of epilepsy, trigeminal neuralgia and bipolar disorder. The concerned safety warnings have already been included in the package insert of these products.

Drug Recall

Recall of Apo-Citalopram Tab 20mg

On 21 January 2011, Hind Wing Co. Ltd. (Hind Wing), a licensed drug wholesaler, initiated a recall of Apo-Citalopram Tab 20mg (HK-53084, batch no. JK2403) from the market because its bottle label showed an incorrect ingredient name.

The recall was initiated after the Department of Health (DH) found that the text on the side of the bottle label indicates the incorrect ingredient name as "Citalopram *Hydrochloride*" while the correct label should be "Citalopram *Hydrobromide*". Although the issue would not cause immediate safety, quality and efficacy concern, Hind Wing opted for voluntary recall as a precautionary measure. After assessment, the DH endorsed Hind Wing's decision and closely monitored the recall.

Apo-Citalopram Tab 20mg is registered by Hind Wing and is a prescription-only medicine. It is used for treatment of depression and panic disorder.

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: 2147 0457

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