Drug News
藥 物 情 報

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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

Important safety information regarding the use of sleep aid drugs and the risk of complex sleep-related behaviours announced by Health Canada

7 October 2009 — Health Canada informed consumers and health professionals of recent changes to the labelling information of prescription sleep aid medications used in the short-term treatment of insomnia. The new labelling describes reports of complex sleep-related behaviours that have occurred while patients using these drugs were not fully awake, such as talking, walking, cooking, eating, and driving. The sleep-aid medications with potential risk of complex sleep-related behaviours include flurazepam, nitrazepam, temazepam, triazolam, zopiclone, zolpidem, and zaleplon.

In Hong Kong, existing label or package insert of the products concerned have already covered similar warning regarding complex sleep-related behaviours.

New safety information regarding Intelence (etravirine) and severe skin and hypersensitivity reactions announced by Health Canada

19 October 2009 — Tibotec, a division of Janssen-Ortho Inc., in collaboration with Health Canada, issued safety information regarding severe skin reactions in patients receiving combination therapy involving Intelence (etravirine) tablets. There had been post-marketing reports of severe hypersensitivity reactions, sometimes accompanied by hepatic failure, and a report of fatality due to toxic epidermal necrolysis. Tibotec worked with Health Canada to incorporate this new safety information in the Canadian Product Monograph for Intelence.

In Hong Kong, Intelence is registered by Johnson and Johnson (Hong Kong) Ltd. It is used in combination with other antiretroviral agents indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. The above issue was raised by US Food and Drug Administration in August this year and the corresponding safety information has been added in product's package insert in Hong Kong.

Health Canada issued important safety information on ceftriaxone

20 October 2009 — Health Canada informed hospitals and medical professionals of updated prescribing information for ceftriaxone when used with calcium-containing solutions via the intravenous (IV) route. This new safety information was based on the results of 2 recent *in vitro* studies, which showed an increased risk of ceftriaxone-calcium precipitates in neonatal plasma.

In Hong Kong, a caution statement "The product should not be added to solutions containing calcium" has already been added on the product labels and/or package inserts of ceftriaxone products.

Health Canada informed the public and healthcare professionals of important new safety information regarding the use of Rituxan (rituximab) and progressive multifocal leukoencephalopathy (PML)

23 October 2009 — Health Canada informed that a third case of progressive multifocal leukoencephalopathy (PML) was reported in a patient with rheumatoid arthritis treated with Rituxan. While the potential mechanism of Rituxan in the development of PML was unclear, a contributory role was possible. Physicians should consider PML in any patient being treated with Rituxan who presents with new onset of neurologic manifestations (i.e. cognitive impairment, motor deficit, speech and vision impairment) and should immediately refer the patients for neurological assessment.

In Hong Kong, rituximab is registered as Mabthera by Roche Hong Kong Ltd. A warning regarding the risk of PML in patients with rheumatoid arthritis has been included in the package insert of the product. Recently, Roche has also issued a letter to all doctors who have prescribed Mabthera to patients with rheumatoid arthritis to inform them regarding the above risk.

Cases of altered kidney function, including acute renal failure and renal insufficiency, in patients using Byetta reported by the US Food and Drug Administration

2 November 2009 — The US Food and Drug Administration (FDA) acted on new safety information about possible kidney function problems, including kidney failure, in patients taking Byetta (exenatide), a drug used to treat Type 2 diabetes. From April 2005 through October 2008, the FDA received 78 reports of problems with kidney function in patients using Byetta. Some cases occurred in patients with pre-existing kidney disease or in patients with one or more risk factors for developing kidney problems. The FDA worked with the manufacturer to update the drug's prescribing information.

In Hong Kong, Byetta is registered by Eli Lilly Asia Inc (HK Branch). Similar changes have been made in the HK package insert of Byetta as recommended by US FDA, including that Byetta should not be used in patients with severe renal impairment (creatinine clearance <30 ml/min) or end-stage renal disease and caution should be applied when initiating or increasing doses of Byetta from 5 mcg to 10 mcg in patients with moderate renal impairment (creatinine clearance 30 to 50 ml/min).

The Medicines and Healthcare Products Regulatory Agency (MHRA) in UK communicated updates to product safety information of all statins

3 November 2009 — A Europe-wide review of clinical trial data, adverse drug reaction reports and published literature on statins has concluded that any of the following adverse reactions may be associated with statins use: sleep disturbances, memory loss, sexual dysfunction, depression and interstitial lung disease (leading to breathing problems). MHRA stated that the product information for all statins will be updated with warnings on all of these side effects.

In Hong Kong, this information will be passed to the Registration Committee under the Pharmacy and Poisons Board for consideration.

Drug Recall

Recall of pharmaceutical product – Bandi Enema (HK-48262)

On 22 October 2009, Hengan Pharmacare Company Limited ("Hengan"), a licensed wholesaler of pharmaceutical products, initiated the recall of a product Bandi Enema (batch number 8198) which was found to have contained higher than registered level of glycerin (0.14 instead of 0.1g/ml) and sodium chloride (0.15 instead of 0.05g/ml).

The recall was extended to all batches of the product on 2 November 2009 because further batches of the product were found to have the same quality problem.

Use of the affected batch of product according to the recommended dosage (i.e. 10ml for children and 20ml for adult) should not cause any harmful effect to health.

The product, manufactured in Taiwan, is used to relieve constipation.

The product is a registered over-the-counter pharmaceutical product. Hengan has supplied it to retailers of medicines.

Drug Incident

Warning about slimming product with undeclared drug ingredients

On 13 October 2009, the Department of Health called on people not to buy or use a slimming product called "Show Party 瘦身派", which was found to contain undeclared Western drug ingredients that may cause serious side effects.

The appeal was made following investigations by the department into a report by the Hospital Authority concerning a girl who fell ill after consuming the slimming product bought on the Internet. The 17-year-old girl developed symptoms of acute psychosis including emotional disturbance, paranoid ideas, hallucinations, having suicidal thoughts, and self-harm behaviour after consuming the product. She was admitted to United Christian Hospital on October 4.

Laboratory tests on the product sample showed the presence of undeclared Western drugs, phenolphthalein and sibutramine. Phenolphthalein was once used for treating constipation but has been banned for its cancer-causing effect. 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.

A product containing sibutramine must be registered before it can be sold in Hong Kong. It can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

Public urged to seek medical advice on stopping Neovidan medication

On 29 October 2009, the Department of Health reminded members of the public not to buy or consume a product called "Neovidan" which was found to contain undeclared Western drug ingredients that may cause serious side effects.

The Department advised those who had taken Neovidan for a long time to seek medical advice before stopping medication as there may be serious effects in acute withdrawal.

The appeal followed the department's investigation into a case involving a 66-year-old woman who had taken Neovidan. The woman showed symptoms of fever, tachycardia, diarrhea, vomiting and abdominal pain on 13 October 2009 after withdrawal of Neovidan. She was admitted to United Christian Hospital and diagnosed as Addisonian Crisis (a hormonal disorder) induced by acute withdrawal of steroid.

Neovidan was earlier found to contain Western drug ingredients including prednisolone and mefenamic acid. The department has earlier cautioned against Neovidan. It was revealed in ensuing investigations that the sales outlet concerned had folded.

Prednisolone is a steroid. Taking prednisolone for a long time can cause side effects such as moon face (round face), high blood pressure, high blood sugar and peptic ulcer. Mefenamic acid is a non-steroidal anti-inflammatory drug. The known side effects include gastro-intestinal discomfort, nausea, stomach pain and bleeding.

People who have been using Neovidan are advised to seek medical advice while stopping medication.

A product containing prednisolone or mefenamic acid must be registered before it can be sold in Hong Kong. It can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

Public urged not to consume virility product with undeclared drug ingredients

On 4 November 2009, the Department of Health urged members of the public not to buy or use a product named "Zeng Da Yan Shi Wan" (增大延時丸) as it was found to contain an undeclared drug ingredient which may cause serious side effects

The product was found during an investigation into a case of a 78-year-old man who was admitted to Queen Mary Hospital on September 26 for decreased general condition. Analysis showed that the product contained sildenafil, a drug used for treating male sexual dysfunction. There was no evidence to suggest that the patient's symptoms were related to the product.

The side effects of sildenafil include 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 may pose serious health risks, especially for patients with heart problems.

A product containing sildenafil must be registered before it can be sold in Hong Kong. It can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

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 years' imprisonment.
Members of the public should stop using the aforementioned products and they should see doctors if they feel unwell after taking the products. They should destroy and dispose of the aforementioned products 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.