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

McNeil Consumer Healthcare in United States announces voluntary recall of certain Over-The-Counter (OTC) products in the Americas, United Arab Emirates, and Fiji

15 January 2010 - In consultation with the US Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., voluntarily recalled certain lots of Over-The-Counter (OTC) products in the Americas, the United Arab Emirates, and Fiji. The company initiated this recall following an investigation of consumer reports of an unusual moldy, musty, or mildew-like odor that, in a small number of cases, were associated with temporary and non-serious gastrointestinal events. These included nausea, stomach pain, vomiting, or diarrhea.

Based on this investigation, McNeil Consumer Healthcare had determined that the reported uncharacteristic smell was caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). This can result from the breakdown of a chemical that is sometimes applied to wood used to build wood pallets that transport and store product packaging materials. In December 2009, McNeil Consumer Healthcare also recalled all lots of Tylenol Arthritis Pain 100 count with Ez-Open Cap related to this issue.

In Hong Kong, the US McNeil products are not available in the market. There are only 4 registered "Tylenol" products which are manufactured by Shanghai Johnson & Johnson in China and the importer has stopped importation of all these 4 products since September 2009.

US Food and Drug Administration warned consumers about counterfeit Alli

15 January 2010 - The US FDA warned consumers about a counterfeit and potentially harmful version of Alli 60 mg capsules (120 count refill kit). Preliminary laboratory tests conducted by GlaxoSmithKline (GSK) revealed that the counterfeit version did not contain orlistat, the active ingredient in the product. Instead, the counterfeit product contained the controlled substance sibutramine. GSK had determined that the counterfeit product had been sold over the internet. However, there was no evidence at this time that the counterfeit Alli product had been sold through other channels, such as retail stores.

In Hong Kong, Alli is registered by GlaxoSmithKline Limited. The company confirms that the product has not been marketed yet since approval of registration in November last year, and its registered pack sizes are 21's, 42's and 84's.

Follow-up to the October 2008 Updated Early Communication about an ongoing safety review of tiotropium (marketed as Spiriva HandiHaler) by US Food and Drug Administration

21 January 2010 - US FDA announced that data from a recent review of the Spiriva HandiHaler did not support an increased risk of stroke, heart attack, or death in patients using the medicine. Spiriva HandiHaler is used as long-acting respiratory treatment for chronic obstructive pulmonary disease (COPD). A March 2008 FDA early communication had described data submitted by the manufacturer of Spiriva HandiHaler as suggesting a small increased risk of stroke in patients treated with tiotropium. In October 2008, an updated early communication

highlighted two additional publications suggesting an increased risk of stroke, heart attack, and death in patients using tiotropium. In November 2009, the FDA Pulmonary – Allergy Drugs Advisory Committee reviewed the data of a study that compared Spiriva HandiHaler with a placebo in 5,992 COPD patients and concluded that findings from the study resolved the potential safety concerns for Spiriva Handihaler.

In Hong Kong, Spiriva is registered by Boeringher Ingelheim (HK) Ltd. The Department of Health remains vigilant to any other findings about tiotropium.

Update on sibutramine

21 January 2010 - The European Medicines Agency had finalised a safety review of Sibutramine Cardiovascular Outcome Trial (SCOUT) had showed an increased risk of serious, non-fatal cardiovascular events, such as stroke or heart attack, with sibutramine compared with placebo. The Agency concluded that the risks of these medicines are greater than their benefits and recommended the suspension of marketing authorisations for these medicines across the European Union. Based on the same review findings, US Food and Drug Administration and Therapeutic Goods Administration in Australia requested the manufacturer to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease, including: history of coronary artery disease, stroke or transient ischemic attack, heart arrhythmias, congestive heart failure, peripheral arterial disease and uncontrolled hypertension (e.g., > 145/90 mmHg).

Sibutramine products are registered in Hong Kong. Department of Health (DH) has issued a press release and notified healthcare professionals regarding the safety information about sibutramine. The Registration Committee of the Pharmacy and Poisons Board has reviewed the available data as regards the safety of sibutramine, including the above information, at its recent meeting. In view of the final results of SCOUT are yet to be published, the Committee has decided that this drug should continue to be available until more data is available for a comprehensive appraisal of the safety of the drug. Medicines containing sibutramine should not be used in patients with a history of coronary heart disease, congestive heart failure, arrhythmias, or stroke. The existing package inserts of the concerned products have already contained the above safety information.

Update of prescribing information for Velcade (bortezomib) in United States

26 January 2010 - Takeda Oncology and US Food and Drug Administration notified healthcare professionals about revisions to the prescribing information for Velcade pertaining to patients with hepatic impairment at the start of Velcade therapy. The changes also included new safety information on dose adjustment for patients with moderate to severe hepatic impairment; these patients should be treated with Velcade at reduced starting doses and closely monitored for toxicities. Velcade is indicated for the treatment of patients with multiple myeloma. Velcade also is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

In Hong Kong, Velcade is registered by Johnson & Johnson (Hong Kong) Ltd. The company has revised the package insert of Velcade to include this safety information.

Pharmacy level recall of Intron A 18, 30 and 60 million IU solution for injection (Recombinant interferon alfa-2b) by Schering-Plough Ltd in United Kingdom

28 January 2010 - Schering-Plough Ltd recalled certain batches of Intron A 18 million IU (9IOL10504, 9IOL10609), 30 million IU (9IOK40308, 9IOK40328) and 60 million IU (9IOM70212, 9IOM70316) solutions for injection (Recombinant interferon alfa-2b) which had a shelf-life of 18 months as a precautionary measure because the stability of the products after 15 months could not be assured. All new batches were supplied through normal wholesaler channels with a 15-month shelf-life.

In Hong Kong, Intron A is registered by Schering-Plough. The company confirmed that only the 18 million IU solution, which shelf-life is 15 months, is available in Hong Kong. The affected batches have not been imported into Hong Kong.

Safety Update

Important safety information on use of Zyprexa (olanzapine) in adolescents announced by US Food and Drug Administration

29 January 2010 - Lilly and US Food and Drug Administration notified healthcare professionals of recent extension of approval of Zyprexa to use in adolescents (ages 13-17) for treatment of schizophrenia and bipolar I disorder [manic or mixed episodes], but that in deciding its use for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and hyperlipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

In Hong Kong, Zyprexa is registered by Eli Lilly Asia Inc (HK Branch) and it is not recommended for use in children and adolescents under 18 years of age.

Reports of the risk of non-cirrhotic portal hypertension associated with Videx/Videx EC (didanosine) by US Food and Drug Administration

29 January 2010 - US Food and Drug Administration (FDA) notified healthcare professionals and patients about a rare, but serious, complication in the liver known as non-cirrhotic portal hypertension in patients using Videx or Videx EC (didanosine), a medication used to treat human immunodeficiency virus (HIV) infection. Based on the number of well-documented cases and exclusion of other causes of portal hypertension such as alcohol-related cirrhosis or hepatitis C, FDA concludes there is an association between use of didanosine and development of non-cirrhotic portal hypertension. Because of the potential severity of portal hypertension, including death from hemorrhaging esophageal varices, FDA has revised the drug label to assure safe use of the medication. FDA believes the clinical benefits of didanosine for certain patients with HIV continue to outweigh its potential risks.

In Hong Kong, Videx is registered by Bristol-Myers Squibb Pharma (HK) Ltd. The package insert of the product has been revised to include the above safety information.

Drug Incident

Public urged not to consume proprietary Chinese medicine "Ba Bao Xiao Ke Dan" with undeclared western drug ingredient

On 28 January 2010, the Department of Health (DH) called on members of the public not to buy or use a proprietary Chinese medicine named "Ba Bao Xiao Ke Dan 八寶消渴丹", because it was found to have contained an undeclared western medicine, glibenclamide, which may cause serious side effects.

The appeal was made following an investigation by DH on a report from the Hospital Authority concerning a person feeling unwell after consuming such product. An 84-year-old man was found unconscious owing to low blood sugar on 20 January 2010 and was admitted to Caritas Medical Centre. He was discharged after medical treatment.

Laboratory result confirmed that glibenclamide was present in the samples. Glibenclamide is a sugar-lowering drug used for treatment of diabetes. Improper use of glibenclamide may cause a significant fall in blood sugar level with serious health consequence or even death. Products containing glibenclamide can be sold only on a doctor's prescription and under the supervision of a pharmacist.

The manufacturer, Pang Sau Tong (Hong Kong) Company Limited, has been instructed to immediately recall the product from the market.

Public urged not to consume virility product "Man Power" with undeclared western drug ingredient

On 8 February 2010, the Department of Health appealed to people not to buy or use a product named "Man Power 威力勁" for managing sexual dysfunction as it was found to have contained an undeclared western drug ingredient tadalafil which may cause serious side effects.

The appeal was made following laboratory tests on

the product sample which showed the presence of tadalafil. It was found that the product, which was not a registered pharmaceutical product in Hong Kong, was put up for sale at an Internet website.

Tadalafil is a western medicine ingredient usually used for treating male sexual dysfunction. Its side effects include low blood pressure, headache, vomiting, dizziness, and transient vision disturbance. 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 tadalafil may pose serious health risks, especially for patients with heart problems. Products containing tadalafil can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

People with sexual dysfunction were urged to consult healthcare professionals for advice if necessary.

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.

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 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.

Cautioned against self medication with "Tai Er Si Yi Wei A Suan Jiao Wan"

On 12 February 2010, the Department of Health called on the public not to buy or consume a product called "Tai Er Si Yi Wei A Suan Jiao Wan 泰爾絲異維 A 酸膠丸" as it claimed to contain a western medicine, isotretinoin, that may cause serious side effects. The product, which was not a registered pharmaceutical product in Hong Kong, was found for sale at an internet auction site.

Isotretinoin is a western medicine. When taken orally, it is used for treating severe acne that has not responded to other measures. The medicine is not indicated for uncomplicated adolescent acne. Its common side effects include dryness of skin with scaling and redness, conjunctivitis, dry sore mouth, visual disturbance, hair thinning and mood changes. It may cause fetal malformation and spontaneous abortion and should not be used during pregnancy. Pregnancy should be avoided for one month after treatment has been stopped. Products containing isotretinoin can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

Those with skin problem should consult medical professionals for appropriate advice and treatment.

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