Drug News
藥 物 情 報

Issue Number 55

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in May 2014 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

Canada: Association of Temodal® (temozolomide) with the risk of hepatic injury

On 7 May 2014, Merck Canada Inc., in consultation with Health Canada, informed healthcare professionals of new warnings for Temodal® (temozolomide) regarding cases of hepatic injury, including fatal hepatic failure reported post-marketing. Cases of hepatic injury, including fatal hepatic failure, have been reported in patients receiving temozolomide. Liver toxicity may occur several weeks after initiation of treatment or after temozolomide discontinuation. Liver function tests should be performed prior to treatment initiation; after each treatment cycle; midway during the treatment cycle for patients on a 42 day treatment cycle. For patients with significant liver function abnormalities, the benefits and risks of continuing treatment should be carefully considered. The local Temodal® (temozolomide) Product Monograph had been revised to include updated information on the risk of hepatic injury and specific recommendations for monitoring of liver function.

In Hong Kong, there are six registered pharmaceutical products containing the antineoplastic agent temozolomide, and they are prescription only medicines. So far, the Department of Health (DH) had not received any adverse drug reaction report in connection with the drug. In view of Health Canada's announcement, a letter to healthcare professionals to draw their attention and urge them to report any Adverse Drug Reaction (ADR) related to the drug was issued on 8 March 2014, and the matter will be discussed in the meeting of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certificate of Clinical Trial/Medicine Test) Committee (the Registration Committee) of the Pharmacy and Poisons Board.

EU: Review of hydroxyzine-containing medicines started

On 8 May 2014, the European Medicines Agency (EMA) had started a review of hydroxyzine-containing medicines, which have been approved in most EU countries for a variety of uses including anxiety disorders, as premedication before surgery, for relief of pruritus (itching), and for sleep disorders. The review was requested by the Hungarian medicines agency (GYEMSZI-OGYI) over concerns about the side effects of these medicines on the heart. This followed an examination of the benefits and risks by a marketing authorisation holder for hydroxyzine. Data from drug safety monitoring (pharmacovigilance) and published experimental studies identified a potentially increased risk of alterations of the electrical activity of the heart and arrhythmias. As hydroxyzine-containing medicines are approved in other EU countries, the Hungarian agency decided to trigger an EU-wide review.

The EMA would review the available data on the benefits and risks of hydroxyzine-containing medicines in all authorised indications, and issue an opinion on the marketing authorisations of these medicines across the EU.

In Hong Kong, there are 16 registered pharmaceutical products containing hydroxyzine. All are prescription only medicines. So far, the DH had not received any adverse drug reaction report in connection with the drug. The DH will keep vigilant against any new safety updates with respect to the drug.

EU: Review of Corlentor/Procoralan started

On 8 May 2014, the EMA had started a review of the medicine Corlentor/Procoralan (ivabradine). Corlentor/Procoralan is used to treat the symptoms of adults with long-term stable angina or long-term heart failure. The review follows preliminary results from the SIGNIFY study, which was evaluating whether treatment with Corlentor/ Procoralan in patients with coronary heart disease reduces the rate of cardiovascular events (such as heart attack) when compared with placebo (a dummy treatment). Patients in the study received up to 10 mg twice daily, which is higher than the currently authorised maximum daily dose (7.5 mg twice daily), and the results showed a small but significant increase in the combined risk of cardiovascular death or non-fatal heart attack with the medicine in a subgroup of patients who had symptomatic angina.

The EMA would evaluate the impact of the data from the SIGNIFY study on the balance of benefits and risks of Corlentor/Procoralan and issue an opinion on whether the marketing authorisation should be maintained, varied, suspended or withdrawn across the EU.

In Hong Kong, there are two registered pharmaceutical products containing ivabradine, namely Coralan Tab 7.5mg (HK-55438) and Coralan Tab 5mg (HK-55439), and are registered by Servier HK Ltd. Both are prescription only medicines. So far, the DH had not received any adverse drug reaction report in connection with the drug. The DH will keep vigilant against any new safety updates with respect to the drug.

Singapore / Canada: Risk of Stevens-Johnson syndrome and toxic epidermal necrolysis in patients treated with Vectibix™ (panitumumab)

It was noted from the Health Sciences Authority (HSA) website on 9 May 2014 that GlaxoSmithKline (GSK) informed healthcare professionals of the risk of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) in patients treated with Vectibix™ (panitumumab). Based on data from a regular safety review, rare (≥1/10,000 to <1/1000 patients) cases of SJS and TEN have been reported in patients treated with Vectibix™. Healthcare professionals are advised to withhold or discontinue the use of Vectibix™ in their patients if SJS or TEN are suspected.

On 27 May 2014, Amgen Canada Inc., in consultation with Health Canada, also informed healthcare professionals of important updates to safety information regarding the risk of SJS and TEN associated with the use of Vectibix®. The local Product Monograph of Vectibix® was updated to include the risk of SJS and TEN.

In Hong Kong, Vectibix Concentrate for Solution for Infusion 20mg/ml (HK-61371) is registered by GSK Ltd. and is a prescription only medicine. So far, the DH had not received any adverse drug reaction report in connection with the drug. In view of the HSA's announcement, a letter to healthcare professional to draw their attention and urge them to report any ADR related to the drug was issued by DH on 9 May 2014, and the matter will be discussed in the meeting of the Registration Committee.

Canada: Risk of serotonin syndrome associated with serotonin blocking drugs used to treat nausea and vomiting

On 14 May 2014, Health Canada has completed a safety review of the serotonin blocking drugs dolasetron (Anzemet), granisetron (Kytril and generics), ondansetron (Zofran and generics) and palonosetron (Aloxi), which are used for treating nausea and vomiting. This review identified a potential risk of serotonin syndrome. Serotonin syndrome occurs when serotonin, a chemical normally found in the body, accumulates to high levels. This usually happens with combinations of certain serotonin drugs, but may also occur with a single drug.

It is very important to diagnose serotonin syndrome early as it can be fatal if not treated. Symptoms of serotonin syndrome may include agitation, confusion, fast heartbeat, muscle twitching or stiffness, fever, loss of consciousness or coma. As serotonin syndrome can be misdiagnosed, it is important that patients who experience any of these symptoms should talk to a healthcare practitioner immediately.

The Canadian Product Monographs for Aloxi, Kytril and Zofran now contain this new safety

information. Anzemet has been withdrawn from the Canadian market by the manufacturer. Manufacturers of generic versions of these drugs will also update their Product Monographs.

In Hong Kong, there are 12 registered pharmaceutical products containing granisetron; 21 containing ondansetron; 3 containing palonosetron; and there is nil registered pharmaceutical product containing dolasetron. All of them are prescription only medicines. So far, the DH has received one adverse drug reaction report related to seizure suspected to be associated with the use of Zofran (ondansetron) and has not received any relevant adverse drug reaction report in connection with granisetron and palonosetron. In view of Health Canada's announcement, a letter to healthcare professionals to draw their attention and urge them to report any ADR related to the drug was issued on 15 May 2014, and the matter will be discussed in the meeting of the Registration Committee.

Drug Recall

Recall of B-Comfor Tablet (HK-04902)

On 14 May 2014, DH endorsed a licensed drug wholesaler, Wah Kin Pharmaceutical Products Co. Ltd. (Wah Kin), to conduct a voluntary recall of two batches (batch numbers: M111001 and M130101) of B-Comfor Tablet [both 1000 tablets (1000's) and 100 tablets pack size (100's)] from the market due to a quality issue. B-Comfor Tablet is an over-the-counter pharmaceutical product containing vitamin-B complex used as a nutritional supplement.

Under the DH's market surveillance, sample of B-Comfor Tablet with batch number M111001 was taken for analysis. Upon the Government Laboratory's testing, the content of one of the active ingredients of the product, namely, Vitamin B1 (thiamine hydrochloride), was found to be lower than that specified on the label. The quality defect may affect the efficacy of the product. As a precautionary measure, Wah Kin is voluntarily recalling both batches of the product currently available on the market.

According to Wah Kin, a total of 2010 bottles of 1000's and 5000 bottles of 100's of B-Comfor Tablet were imported from Shanghai Sine Huanghe Pharmaceutical Co., Ltd. of China since November 2011. They were all supplied to pharmacies, medicine shops and private doctors in Hong Kong. As on 14 May 2014, DH had not received any adverse drug reaction reports in connection with the product and DH had closely monitored the recall. A notice was released on the Drug Office's website on the same day to alert the public of the recall.

Recall of Streptomycin Sulphate Reig Jofre Powder for Solution for Injection 1g

On 14 May 2014, DH instructed a licensed drug wholesaler, Hind Wing Co. Ltd. (Hind Wing), to recall one batch (batch number: 1405312) of Streptomycin Sulphate Reig Jofre Powder for Solution for Injection 1g (Streptomycin Injection) (registration number: HK-62354) from the market because unapproved package insert was used in the product. Streptomycin Injection is an antibiotic indicated for the treatment of tuberculosis. They can only be sold in pharmacy according to doctor's prescription and under the supervision of registered pharmacist.

The case was reported by a DH clinic when checking the recently received Streptomycin Injection (batch number: 1405312) bearing the package insert which was different from the registered one. Hind Wing has provided certificate of analysis of the affected batch showing the quality requirement is met. However, the unapproved package insert in the product rendered as unregistered pharmaceutical product under the Pharmacy and Poisons Regulations (Cap 138A).

According to Hind Wing, 6000 doses of Streptomycin Injection were imported to Hong Kong in March 2014. Among the imported stock, about 2200 doses have been supplied to DH clinics, a public hospital and local pharmacies. As on 14 May 2014, DH had not received any adverse drug reaction reports in connection with the product and DH had closely monitored the recall. A notice was released on the Drug Office's website on the same day to alert the public of the recall.

Drug Recall

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part I poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part I poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence.

All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". The products mentioned in the above incidents were not registered pharmaceutical products under the Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. Members of the public were exhorted not to use products of unknown or doubtful composition. They should stop using the aforementioned products immediately if they had them in their possession and to consult healthcare professionals if they felt unwell after taking the products. The products should be destroyed or disposed properly, or submitted to the Department's Drug Office during office hours.

Useful Contact

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2186 9845

E-mail: adr@dh.gov.hk

Link: http://www.drugoffice.gov.hk/adr.html

Post: ***Pharmacovigilance Unit,***
Drug Office, Department of Health,
Rm 1856, 18/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong

The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.