Drug News
藥 物 情 報

Issue Number 178

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in August 2024 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

Australia: Azithromycin and rare risk of cardiovascular death

On 1 August 2024, the Therapeutic Goods Administration (TGA) announced that an updated warning about the risk of sudden cardiovascular death has been added to the Product Information (PI) and Consumer Medicine Information (CMI) documents for azithromycin.

Azithromycin already carried a warning of ventricular arrhythmias associated with prolonged QT interval. The update describes an increased short-term risk of cardiovascular death with azithromycin compared to other antibacterial drugs, including amoxicillin. This risk is rare but appears to be greater during the first 5 days of azithromycin use.

The new warning also advises that healthcare professionals should consider a screening electrocardiogram (ECG) in patients at high risk of a prolonged QT, based on their medical history or ongoing medical treatments.

The update was made following a recommendation from the Advisory Committee on Medicines. This was based on the Committee's review of published literature including observational studies, the seriousness of the adverse event and updated warnings by the Food and Drug Administration in the United States.

The Committee noted that the information in the observational studies was insufficient to establish or exclude a causal relationship between acute cardiovascular death and azithromycin use due to inconsistent results between studies.

Healthcare professionals should be aware of this potential adverse event so they can balance the benefits of azithromycin with the rare but serious risk of sudden cardiac death. Consider precautionary ECG screening for patients with a high risk of a prolonged QT.

In Hong Kong, there are 46 registered pharmaceutical products containing azithromycin, and all products are prescription-only medicines. As of the end of 31 August 2024, the Department of Health (DH) had received 8 cases of adverse drug reactions related to azithromycin, but these cases were not related to sudden cardiovascular death. Related news about risks of cardiac death was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 31, with the latest update reported in Drug News Issue No. 41. The DH issued letters to inform local healthcare professionals to draw their attention on 18 May 2012 and 20 May 2013. In February 2015, the Registration Committee of the Pharmacy and Poisons Board decided that the sales pack label and/or package insert of azithromycin products should include the relevant safety information. In light of the above TGA's announcement, with updated warning about the risk of sudden cardiovascular death, the DH issued letters to inform local healthcare professionals to draw their attention on 2 August 2024, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board .

Drug Recall

Batch recall of Augmentin Powder for Syrup 457mg/5ml

On 30 August 2024, the Department of Health (DH) endorsed a licensed drug wholesaler, namely GlaxoSmithKline Ltd (GSK), to recall one batch (batch number: HU7J) of Augmentin Powder for Syrup 457mg/5ml (Hong Kong Registration number: HK-42735), from the market as a precautionary measure due to potential quality issue.

The DH received notification from GSK that the its overseas headquarters has initiated product recall of the above batch due to the potential issue that some of the containers may have an ineffective seal which could lead to humidity exposure and discoloration of the product. As a precautionary measure, GSK is voluntarily recalling the above batch from the market.

The above product, containing amoxicillin and clavulanic acid, is an antibiotic used for the treatment of bacterial infection. According to GSK, the above batch of product have been imported into Hong Kong for distribution to the local private hospitals, private doctors and pharmacies, as well as for re-export to Macao.

As of the end of 31 August 2024, the DH had not received any adverse reaction reports in connection with the above batch of product. A notice was posted in the Drug Office website on 30 August 2024 to alert the public of the product recall. The DH will closely monitor the recall.

Drug Incident

Public urged not to buy or consume slimming product with undeclared controlled and banned drug ingredients

On 6 August 2024, the Department of Health (DH) appealed to the public not to buy or consume a slimming product (labelled as "Z FIT 純中藥減脂丸" with no English name), as it was found to contain undeclared controlled and banned drug ingredients.

Acting upon intelligence, the DH obtained samples of the above product via a social media platform for analysis. Test results from the Government Laboratory revealed that the samples contained sibutramine and frusemide, which are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138). The DH's investigation is continuing.

Sibutramine was once used as an appetite suppressant. Since November 2010, pharmaceutical products containing sibutramine have been banned in Hong Kong because of an increased cardiovascular risk. Frusemide is a diuretic used in the treatment of high blood pressure, heart failure and oedema. Common adverse effects include feeling thirsty, dizziness, headaches and fast or irregular heartbeat.

A press release was posted in the Drug Office website on 6 August 2024 to alert the public of the drug incident.

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 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 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. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $50,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

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.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.

Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/

Useful Contact

Drug Complaint:

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Adverse Drug Reaction (ADR) Reporting:

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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.