Drug News
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Issue Number 142

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in August 2021 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: Health Canada updates Pfizer-BioNTech COVID-19 vaccine label to reflect very rare reports of Bell's Palsy

On 6 August 2021, Health Canada announced for having updated the product information for the Pfizer-BioNTech COVID-19 vaccine to describe very rare reports of Bell's Palsy (typically temporary weakness or paralysis on one side of the face) following vaccination. Cases were reported in a small number of people in Canada and internationally.

Bell's Palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear suddenly and generally start to improve after a few weeks. The exact cause is unknown. It is believed to be the result of swelling and inflammation of the nerve that controls muscles on one side of your face.

Health Canada reassured Canadians that COVID-19 vaccines continue to be safe and effective at protecting them against COVID-19. The benefits of COVID-19 vaccines continue to outweigh their potential risks, as scientific evidence shows that they reduce deaths and hospitalizations due to COVID-19.

Health Canada would continue to work with manufacturers, as well as domestic and international partners, to gain a better understanding of the potential relationship between COVID-19 vaccines and adverse events. The Department would take further action if necessary.

Those who experience any combination of the following symptoms after vaccination are to seek medical attention: uncoordinated movement of the muscles that control facial expression; loss of feeling in the face; headache; tearing from the eye; drooling; lost sense of taste on the front two-thirds of the tongue; hypersensitivity to sound in one ear; or inability to close an eye on one side of the face.

Healthcare professionals should be alert to the signs and symptoms of side effects following vaccination with COVID-19 vaccines and report any event potentially related to a vaccine to their local public health unit.

In Hong Kong, the above product is not registered pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). Acute peripheral facial paralysis (or palsy) is listed as a rare adverse reaction in the package insert of Comirnaty. The Department of Health (DH) will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Canada: Summary Safety Review: Veklury (remdesivir): Assessing the potential risk of sinus bradycardia

On 18 August 2021, Health Canada announced that it had reviewed the potential risk of sinus bradycardia with the use of Veklury following the submission of international case reports of sinus bradycardia from the manufacturer.

Sinus bradycardia occurs when the heart beats slower than normal. Sinus bradycardia can very rarely cause symptoms, such as dizziness, tiredness, shortness of breath, and chest discomfort.

Health Canada reviewed the available information from searches of the Canada Vigilance database,

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international databases, published literature, clinical trials, and information received from the manufacturer. At the time of the review, Health Canada had not received any Canadian reports of sinus bradycardia related to Veklury use. However, there was 1 Canadian case from the published literature. Health Canada assessed 47 (46 international and 1 Canadian) case reports of sinus bradycardia in patients receiving Veklury. Thirty of the international cases were from the Canada Vigilance database. Of the 47 case reports, 39 cases were found to be possibly linked to the use of Veklury, 6 cases were unlikely to be linked, and 2 cases did not have enough information to be further assessed. In all 39 cases assessed as possibly linked, existing medical conditions and/or COVID-19 illness may have contributed to sinus bradycardia.

Health Canada also looked at additional information available from 11 articles in published scientific literature and 7 studies provided by the manufacturer on the risk of sinus bradycardia with Veklury use. In general, there was limited information from these sources suggesting that treatment of COVID-19 patients with Veklury could lead to sinus bradycardia.

Health Canada's review of the available information concluded that a link between the use of Veklury and the risk of sinus bradycardia is possible. Health Canada would work with the manufacturer of Veklury to update the Canadian product safety information to inform healthcare professionals and patients about the potential risk of sinus bradycardia.

In Hong Kong, there is one registered pharmaceutical product containing remdesivir, namely Veklury Powder for Concentrate for Solution for Infusion 100mg (HK-66766). The product is registered by Gilead Sciences Hong Kong Limited, and is a prescription-only medicine. The product is indicated for SARS-CoV-2 Infection and is conditionally approved with very limited safety, efficacy, and quality data for public health emergency to satisfy local unmet medical need and the registration status is subjected to be reviewed by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee).

As of the end of August 2021, the DH has received one case of adverse drug reaction related to remdesivir, but this case is not related to sinus bradycardia.

Related news was previously issued by European Medicines Agency, and was reported on Drug News Issue Nos. 136 & 140. The DH issued letters to inform local healthcare professionals to draw their attention on 15 Jun 2021. As previously reported, the matter will be discussed by the Committee.

Drug Recall

Batch Recall of Cephanmycin Capsules 250mg (Yung Shin)

On 18 August 2021, the DH endorsed a licensed drug wholesaler, namely Yung Shin Co. Ltd (the wholesaler) to recall one batch (batch number: CCC M001) of Cephanmycin Capsules 250mg (Hong Kong Registration number HK-34698) from the market as a precautionary measure due to one bottle of the product was found to contain capsules in different colour.

The DH received notification from the wholesaler that a local pharmacy had reported to them that a few yellow capsules were found in a recently received bottle of the concerned product which should contain green/white capsules. Preliminary investigation of the overseas manufacturer revealed that the yellow capsules might come from another product that belongs to the same class of antibiotic manufactured by them. As a precautionary measure, the wholesaler voluntarily recalled the affected batch.

Cephanmycin Capsules 250mg (YUNG SHIN) is packaged in a plastic bottle containing 1000 capsules with active ingredient of cephalexin, an antibiotic. The product is a prescription medicine for treatment of various infections. According to the wholesaler, only a small quantity of affected batch has been imported into Hong Kong and supplied to the one private doctor and four community pharmacies. The investigation of the root cause of mix-up is continuing.

As of the end of August 2021, the DH has not received any adverse reaction reports in connection with the affected product. A notice was posted on

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the Drug Office website on 18 August 2021 to alert the public of the product recall. The DH noted that the recall was completed.

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.

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/reListRPP_index.html.

Useful Contact

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Adverse Drug Reaction (ADR) Reporting:
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Link: http://www.drugoffice.gov.hk/adr.html
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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.