Drug News
藥 物 情 報

Issue Number 145

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

Singapore: Alecensa (alectinib) - Warning and precaution and specific dose modification guidance for management of haemolytic anaemia

On 11 November 2021, Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter had been issued by F. Hoffmann-La Roche to inform healthcare professionals of the specific dose modification guidance for the management of haemolytic anaemia associated with the use of Alecensa (alectinib). This is in response to a recent cumulative analysis of haemolytic anaemia cases which showed that dose modification of Alecensa led to improvement of the majority of haemolytic anaemia events with reported outcome. Healthcare professionals are advised to withhold Alecensa and initiate appropriate laboratory testing, if the haemoglobin concentration is below 10 g/dl and haemolytic anaemia is suspected. If haemolytic anaemia is confirmed, healthcare professionals are advised to withhold Alecensa treatment until event resolution and resume at a reduced dose, or permanently discontinue Alecensa. The local package insert for Alecensa is being updated with the recommendations.

In Hong Kong, Alecensa Capsules 150mg (HK-64854) is an alectinib-containing pharmaceutical product registered by Roche Hong Kong Limited (Roche) and is a prescription-only medicine. As of the end of November 2021, the Department of Health (DH) has received 15 cases of adverse drug reaction related to alectinib but none of them are related to haemolytic anaemia. As confirmed with Roche, letters to inform local healthcare professionals have been issued by Roche. The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

Drug Recall

Recall of Dotarem Injection 377mg/ml (10 ml vial)

On 12 November 2021 and 22 November 2021, the Department of Health (DH) endorsed a licensed drug wholesaler, Guerbet Asia Pacific Limited (Guerbet), to recall a total of 5 batches of Dotarem Inj 377mg/ml (10ml vial) (HK-41578) (batch number: 21GD054A, 20GD075A, 20GD075B, 20GD075C, 20GD080A) from the market as a precautionary measure due to potential quality defects of the product.

The DH received notifications from Guerbet on 12 November 2021 and 22 November 2021 that the overseas manufacturer of the above product has noticed leakage of content in some finished products. The overseas manufacturer's assessment showed that the leakage is caused by defects of certain lots of glass containers of the above product. As a result, the manufacturer decided to recall related affected batches of finished products as quality of them may be affected. According to Guerbet, the above affected batches have been imported and supplied in Hong Kong. As a precautionary measure, Guerbet is voluntarily recalling these batches from the market.

The above product is a diagnostic imaging agent as well as a prescription medicine used in magnetic resonance imaging (MRI) for diagnosis of diseases such as cerebral and spinal diseases. The DH noted that the concerned product is not a radioactive substance and would only be administered to patient

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receiving MRI at hospitals or clinics. According to Guerbet, the affected batches have been supplied to private hospitals and private doctors in Hong Kong as well as exported to Thailand (batch number: 21GD054A) and eight Asian countries (batch number: 20GD075A, 20GD075B, 20GD075C and 20GD080A). Guerbet has informed these parties about the recall.

As of the end of November 2021, the DH has not received any adverse reaction reports in connection with the affected batches of the above product. Notices were posted on the Drug Office website on 12 November 2021 and 22 November 2021 to alert the public of the product recall. The DH will closely monitor the recall.

Recall of Famotidina Cinfa Tablet 20mg

On 24 November 2021, the Department of Health (DH) endorsed a licensed drug wholesaler, Reich Pharm Limited (Reich), to recall all batches of Famotidina Cinfa Tablet 20mg (Hong Kong Registration number HK-51630) from the market because the product's label does not match with the registered one.

In the course of routine market surveillance by the DH, it was found that the label of the above product on minor information was different from the registered label, which rendered the product unregistered. Since supply of unregistered pharmaceutical product contravenes the Pharmacy and Poisons Regulations (Cap. 138A), Reich voluntarily recalls the product from the market. DH's investigation is continuing.

The above product, containing famotidine, is an over-the-counter product used for treatment and prevention of stomach ulcer. According to Reich, the product has been supplied to local community pharmacies only.

As of the end of November 2021, the DH has not received any adverse drug reaction reports related to the affected product. A notice was posted on the Drug Office website on 24 November 2021 to alert the public of the product recall. The DH will closely monitor the recall.

Drug Incident

Public urged not to buy or consume oral product "Hemohim" containing undeclared controlled substance

On 1 November 2021 and 2 November 2021, the Department of Health (DH) appealed to the public not to buy or consume an oral product named "Hemohim" as it was found to contain an undeclared controlled substance.

Following up on the DH's announcement dated 1 November 2021 on the investigation of suspected poisoning cases related to the consumption of the above product, it was found that the products were distributed by Atomy Asia Pacific Limited (Atomy). A sample of the above product was obtained from a premise of Atomy at Cheung Sha Wan for analysis and test result from the Government Laboratory was received on 2 November 2021, which revealed that the sample of "Hemohim" contained methoxsalen.

Methoxsalen is a Part 1 poisons and prescription medicine under the Pharmacy and Poisons Ordinance (Cap 138). It can only be sold at pharmacies under the supervision of a registered pharmacist and upon doctor's prescription. Methoxsalen can be used to treat diseases such as psoriasis and vitiligo. Common adverse effects include nausea, headache, dizziness, fatigue, depression and skin reaction to sunlight.

According to the information provided by Atomy, the above product was manufactured in Korea and imported for local distribution through its company website. The DH's investigation is continuing and will take enforcement action when necessary. Upon completion of its investigations, the DH will seek advice from the Department of Justice on prosecution matters.

Press releases were posted on the Department of Health websites on 1 November 2021 and 2 November 2021 to alert the public of the drug incident.

Man arrested for suspected illegal sale of unregistered pharmaceutical product with undeclared drug ingredient

On 10 November 2021, the Department of Health (DH) conducted an operation against the sale of an unregistered pharmaceutical product, namely Neo Hair Lotion, which was found to contain an

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undeclared drug ingredient. During the operation, a 40-year-old man was arrested by the Police for suspected illegal sale and possession of an unregistered pharmaceutical product and a Part 1 poison.

During the DH's market surveillance, a sample of the above product was purchased via the Internet for analysis. Test results from the Government Laboratory revealed that the sample contained minoxidil. The DH's investigation is continuing and advice will be sought from the Department of Justice on prosecution matters upon completion of the investigation.

Minoxidil is a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138). It can only be sold at pharmacies under the supervision of a registered pharmacist. Minoxidil is commonly used for the treatment of hair loss, with side effects including scalp irritation and itchiness.

Press release was posted on the Drug Office website on 10 November 2021 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.

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.