Drug News
藥 物 情 報

Issue Number 85

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in November 2016 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

UK: Brimonidine gel (Mirvaso): risk of exacerbation of rosacea

On 8 November 2016, the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) advised that some patients may have exacerbation or rebound symptoms of rosacea associated with the use of Brimonidine gel (Mirvaso). It is important to initiate treatment with a small amount of gel and increase the dose gradually, based on tolerability and treatment response.

Brimonidine (Mirvaso) is a topical gel indicated for the symptomatic treatment of facial erythema of rosacea in adults. Symptom exacerbation has been reported very commonly in patients treated with brimonidine gel, including cases of a rebound effect after the therapeutic effect wears off (approximately 8–12 hours after application) and cases in which exacerbation of symptoms (particularly erythema and flushing) occurred during treatment soon after it was applied.

Across all clinical studies, 16% of patients who were receiving brimonidine gel had symptom exacerbation. Most patients recovered on stopping treatment. The potential mechanism is currently unknown.

Following an European Union (EU) - wide review, prescribing advice has been updated in the UK. Patients should start treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment. This will help enable patients to find the best balance between therapeutic and adverse effects.

The MHRA advised healthcare professionals of the following:

- exacerbation of rosacea symptoms occurred in up to 16% of patients treated with brimonidine gel in clinical studies; in most cases, erythema and flushing resolve after stopping treatment
- initiate treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment
- advise patients carefully on how to apply the gel and on the importance of not exceeding the maximum daily dose (which is 1 g of gel in total weight, approximately 5 pea-sized amounts)
- advise patients to stop treatment and consult a doctor if their symptoms worsen during treatment (increased redness or burning)

In Hong Kong, Mirvaso Gel 0.33% (HK-63413) containing brimonidine (as tartrate) is a pharmaceutical product registered by Galderma Hong Kong Limited (Galderma), and is a prescription only medicine. As on 13 February 2017, the Department of Health (DH) has not received any adverse drug reaction (ADR) report related to brimonidine. Galderma has updated the package insert of the product to include erythema and flushing as special warnings with precaution for use. In view of MHRA's new prescribing advice for healthcare professionals, DH issued a letter to inform local healthcare professionals to draw their attention on 9 November 2016. DH will remain vigilant on any safety update of the drug by other overseas drug regulatory authorities.

Safety Update

Taiwan: Recall: METHENIN 滅癬寧

On 10 and 17 November 2016, Taiwan Food and Drug Administration (TFDA) announced recall of METHENIN 滅癬寧 (batch numbers: 5173, 5174, 5175, 5176, 5177, 5178, 5179, 5180, 5181 and 5182) from market by its manufacturer Jen Sheng Pharmaceutical Co., Ltd (Jen Sheng) in Taiwan. Jen Sheng initiated recall of batch 5174 because samples have failed the on-going stability tests. As a precautionary measure, the manufacturer recalled other batches mentioned.

In Hong Kong, Methenin Lotion (HK-42181) is a pharmaceutical product registered by Lanway Ltd (Lanway), and is an over-the-counter medicine. Methenin Lotion, containing Potassium iodide, Iodine, Camphor, Phenol and Salicylic acid is indicated for the external treatment of fungal infection.

DH endorsed Lanway to recall three batches (5174, 5178 and 5181) of Methenin Lotion available in the local market from 16 January 2017 onwards. According to Lanway, the affected product has been supplied to the local pharmacies and medicine stores. A notice was posted on the Drug Office website on 16 January 2017 to alert the public of the drug recall.

Drug Recall

DH endorsed recall of three Fleming antibiotics

On 14 November 2016, DH endorsed a licensed drug wholesaler, Medreich Far East Limited (Medreich), to recall all batches of three antibiotics from the market as their package inserts do not match with the registered ones.

The three pharmaceutical products are Fleming Tablet 1g (HK-52242), Fleming for oral suspension 457mg/5ml (HK-56072) and Fleming for suspension 228.5mg/5ml (HK-56069).

DH received notification from Medreich that the package inserts of the above three products were different from those of the registered versions and this rendered the products unregistered. As the supply of unregistered pharmaceutical products contravenes the Pharmacy and Poisons Regulations (Cap 138A), Medreich voluntarily recalled the products from the market.

The above three products, containing amoxicillin and clavulanic acid, are antibiotics and prescription only medicines used for the treatment of bacterial infections.

According to Medreich, while both Fleming suspensions have been supplied to private hospitals/clinics, local pharmacies and other licensed wholesale dealers, the tablets have also been supplied to the Hospital Authority in addition to the above sectors.

As on 13 February 2017, DH has not received any ADR report in connection with the above products. A notice was posted on the Drug Office website on 14 November 2016 to alert the public of the product recall.

DH endorsed batch recall of L-Cysteine Hydrochloride Injection 50mg/ml

On 16 November 2016, DH endorsed a licensed drug wholesaler Hua Tai Pharmaceutical Co.Ltd. (Hua Tai), to recall three batches of L-Cysteine Hydrochloride Injection 50mg/ml (batch numbers: 2082115, 2082815 and 2090115) from the market because of the potential quality issue.

DH received notification from Hua Tai that the product's manufacturer in the United States of America (USA) was recalling certain batches of product because the sterility of the product may be compromised.

The above product, containing L-Cysteine Hydrochloride, is for nutritional use in infants. The product is not registered in Hong Kong but, according to Hua Tai, a total of 1,600 vials of the above batches of product have been imported for the use of particular patients in a hospital under the Hospital Authority. Hua Tai has already notified

Drug Recall

the hospital involved.

As on 13 February 2017, DH has not received any ADR report in connection with the above batches of the product. A notice was posted on the Drug Office website on 16 November 2016 to alert the public of the product recall.

DH endorsed recall of 3 pharmaceutical products: Alfex-180 Tablet 180mg (100's) (HK-54364), Frelet- 75 Tablet 75mg (30's) (HK-54952) and Melocam Tablet 7.5mg (1000's) (HK-56016)

On 24 November 2016, DH endorsed a licensed drug wholesaler, Leon Medical Supplies Limited (Leon), to recall all batches of Alfex-180 Tablet 180mg with pack size 100 tablets , Frelet -75 Tablet 75mg with pack size 30 tablets and Melocam tablet 7.5mg with pack size 1,000 tablets from shelves due to the above mentioned pack sizes are unregistered.

During DH's market surveillance, samples of the above pharmaceutical products were collected for analysis and examination. It was found that the collected samples were not registered. The above three products are registered in Hong Kong but only the above pack sizes are unregistered. Since the supply of unregistered pharmaceutical product contravenes the Pharmacy and Poisons Regulations (Cap. 138A), Leon recalls the unregistered products from the market.

Frelet -75 Tablet 75mg containing clopidogrel and Melocam tablet 7.5mg containing meloxicam are both prescription only medicines for the treatment of heart disease and pain respectively while Alfex-180 Tablet 180mg containing fexofenadine is a Part 1 poison for the treatment of allergy. According to Leon, the products have been supplied to private doctors and local pharmacies.

As on 13 February 2017, DH has not received any ADR report in connection with the affected products. A notice was posted on the Drug Office website on 24 November 2016 to alert the public of the product recall.

Drug Incident

Public urged not to buy or consume slimming product with undeclared banned ingredient sibutramine

On 7 November 2016, DH appealed to the public not to buy or consume a slimming product as it was found to contain an undeclared and banned drug ingredient that might be dangerous to health. The product is called "Slim fast" with two different types of packaging (please refer to the photo in the Drug Office website).

Acting upon intelligence, samples of the product were purchased from an Internet seller for analysis. Test results from the Government Laboratory revealed that the samples contain sibutramine.

Sibutramine is a Part 1 poison and was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned in Hong Kong because of increased cardiovascular risk.

Weight control should be achieved through a balanced diet and appropriate exercise. The public should consult healthcare professionals before using any medication for weight control.

A notice was posted on the Drug Office website on 7 November 2016 to alert the public of the drug incident.

DH urges public not to buy or use two facial masks with controlled substance fluocinolone

On 23 November 2016, DH appealed to the public not to buy or use two facial masks, namely Great Beauties Activated Peptide Recovery Anti-Ageing Face Mask and Great Beauties Advanced Activated Peptide Anti-Ageing Sculpting Face Mask, as they were found to contain an undeclared and controlled substance.

During DH's market surveillance, samples of the above products were collected from the market for analysis. Test results from the Government Laboratory revealed that both samples contained a Part 1 poison, fluocinolone.

Fluocinolone is a steroid substance and products containing fluocinolone should only be sold at pharmacies under the supervision of registered pharmacists upon a doctor's prescription. Inappropriate or excessive application of steroids could cause skin problems and body-wide side effects like moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and even osteoporosis.

A notice was posted on the Drug Office website on 23 November 2016 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 $30,000 fine and one year's 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.

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/pharmaceutical_trade?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

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2319 6319

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.