



# Drug

## 藥物

# News

## 情報

### Issue Number 52

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

### United States (US): Testosterone products - FDA investigating risk of cardiovascular events

It was noted from the Food and Drug Administration (FDA) of the US on 4 February 2014 that they were investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. FDA had been monitoring this risk and decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy. FDA was providing this alert while it continued to evaluate the information from these studies and other available data. FDA will communicate final conclusions and recommendations when the evaluation is complete.

Testosterone is a hormone essential to the development of male growth and masculine characteristics. Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. At this time, FDA had not concluded that FDA-approved testosterone treatment increased the risk of stroke, heart attack, or death.

Healthcare professionals should consider whether the benefits of FDA-approved testosterone treatment are likely to exceed the potential risks of treatment. The prescribing information in the drug labels of FDA-approved testosterone products should be followed.

In Hong Kong, there are six registered pharmaceutical products containing testosterone.

All of the products are prescription medicines. The Department of Health (DH) had not received any adverse event report in connection with the use of the products, and will keep vigilant on any safety updates of the drug(s) and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

### European Union (EU) / Canada: Review of emergency contraceptives started

It was noted from the European Medicines Agency (EMA) of the EU on 4 February 2014 that it had started a review of emergency contraceptives to assess whether increased bodyweight and body mass index (BMI) reduce the efficacy of these medicines in preventing an unintended pregnancy following unprotected sexual intercourse or contraceptive failure. Emergency contraceptives act by blocking and/or delaying ovulation. Available emergency contraceptive medicines in the EU contain levonorgestrel or ulipristal acetate.

EMA would evaluate the impact of new data suggesting that a high bodyweight could impair the effectiveness of emergency contraceptives. It would assess whether any changes should be made to the product information for all emergency contraceptive medicines containing levonorgestrel or ulipristal acetate. Emergency contraceptives containing levonorgestrel can be used up to 72 hours after unprotected sexual intercourse or contraceptive failure while ulipristal acetate can be used up to 120 hours.

The review of emergency contraceptives started at the request of the Swedish medicines regulatory agency. It follows a procedure finalised in November 2013 for Norlevo, an emergency

## Safety Update

contraceptive medicine containing levonorgestrel, to add the following information to the summary of product characteristics: 'In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more, and levonorgestrel was not effective in women who weighed more than 80 kg'. This information is currently not reflected in the product information for other emergency contraceptives containing levonorgestrel. For ulipristal acetate, no information regarding the woman's weight or BMI is currently included in the product information.

Similar advice was also issued by Health Canada on the same day regarding the effectiveness of levonorgestrel-containing emergency contraception that suggested these pills may be less effective in women over a certain weight. Health Canada will take appropriate action as required, such as working with the manufacturers to update drug labels and notify Canadians of new information.

In Hong Kong, there are 28 registered emergency contraceptive medicines containing levonorgestrel and one containing ulipristal. All of the products are prescription only medicines. DH had not received any adverse event report in connection with the use of the products, and will keep vigilant on any safety updates of the drug(s) and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

### **Canada: Association of lithium with hypercalcemia and hyperparathyroidism**

On 6 February 2014, Health Canada informed health professionals and patients of new safety information and treatment recommendations regarding the drug lithium and the risks of high blood calcium (hypercalcemia) sometimes associated with a hormone disorder known as hyperparathyroidism.

There is evidence that lithium affects the metabolism of calcium, which is already noted in the product labelling for lithium drugs. Lithium therapy may cause high levels of calcium in the bloodstream which may or may not be accompanied by an increased level of parathormone (also known as hyperparathyroidism). While in many cases the effects of high blood calcium and/or parathormone

are unnoticeable or mild, in severe cases they can be life threatening. Severe hypercalcemia can be a medical emergency as coma and cardiac arrest can occur.

Health Canada was working with the companies to update the product labels for lithium drugs to include new warnings with respect to the risk of hypercalcemia and hyperparathyroidism, and the need to consider calcium monitoring before and during lithium therapy. Healthcare professionals are advised to consider calcium blood level before starting a patient on lithium treatment, again after six months, and on an annual basis after that, in long-term treatment. If necessary, consider measuring parathormone blood level to identify or rule out hyperparathyroidism. The benefits of this drug in the treatment of bipolar disorder, continue to outweigh the known risks of this drug.

In Hong Kong, there are eight registered pharmaceutical products containing lithium. They are prescription medicines indicated for the treatment and prophylaxis of mania and manic-depression. DH had not received any adverse event report in connection with the use of the products. In view of Health Canada's announcement, a letter to healthcare professionals was issued on 6 February 2014. DH will keep vigilant on any safety updates of the drug(s) and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

### **US: FDA to review heart failure risk of Saxagliptin (marketed as Onglyza and Kombiglyze XR):**

On 11 February 2014, FDA had requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of the type 2 diabetes drug and heart failure. FDA's request resulted from a study published in the New England Journal of Medicine (NEJM), which reported an increased rate of hospitalization for heart failure, when the heart does not pump blood well enough, with use of saxagliptin compared to an inactive treatment. The study did not find increased rates of death or other major cardiovascular risks, including heart attack or stroke, in patients who received saxagliptin. The manufacturer is expected to submit the trial data to FDA by early March 2014, after which FDA will

## Safety Update

conduct a thorough analysis and report findings publicly.

At this time, FDA considers information from the NEJM study to be preliminary. Analysis of the saxagliptin clinical trial data is part of a broader evaluation of all type 2 diabetes drug therapies and cardiovascular risk. Healthcare professionals should continue to follow the prescribing recommendations in the drug labels.

In Hong Kong, there are five registered pharmaceutical products containing saxagliptin. They are Onglyza Tab 5mg (HK-59907), 2.5mg (HK-60783), Kombiglyze XR Tab, with metformin included, 5mg/1000mg (HK-62251), 2.5mg/1000mg (HK-62252) and 5mg/500mg (HK-62253), registered by Bristol-Myers Squibb Pharma (HK) Ltd. They are prescription only medicines and indicated for diabetic mellitus. DH had not received any adverse reaction report in connection with the products. In view of FDA's announcement, a letter to healthcare professionals was issued on 12 February 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.

### **Singapore: Two post-marketing reports of Progressive Multifocal Leukoencephalopathy (PML) in patients with Systemic Lupus Erythematosus (SLE) treated with Benlysta® (belimumab)**

On 11 February 2014, GlaxoSmithKline (GSK) notified healthcare professionals of two post-marketing cases of Progressive Multifocal Leukoencephalopathy (PML) reported in patients receiving Benlysta®, mycophenolate mofetil and steroids for the treatment of Systemic Lupus Erythematosus (SLE), of which one case was fatal.

Healthcare providers are advised to consider a diagnosis of PML in any patient treated with Benlysta®, presenting with new onset or deteriorating neurological signs and symptoms. The patient should be referred to a neurologist or other appropriate specialist for evaluation and if PML is confirmed. Consideration should be given to stop immunosuppressant therapy, including

Benlysta®.

GSK is updating the labelling for Benlysta®, given the risk of PML in SLE patients and the importance of making the correct diagnosis and appropriate medical intervention quickly. The benefit-risk profile of Benlysta® remains unchanged and GSK will continue to evaluate the potential for a causal association of PML with Benlysta®.

In Hong Kong, there are two registered pharmaceutical products containing belimumab, namely Benlysta Powder for concentrate for solution for infusion 120 mg (HK-61384) and 400 mg (HK-61385). They are prescription only medicines and are registered by GSK Ltd. DH had not received any adverse reaction report in connection with the products. In view of announcement made by Health Sciences Authority (HSA) of Singapore, a letter to healthcare professionals was issued on 13 February 2014, and the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

### **Singapore: New data suggest that individuals who were previously vaccinated with Mencevax ACWY but remain at high risk of exposure to serogroups A, W-135 and Y should be considered for earlier revaccination**

It was noted from the HSA website on 17 February 2014 that GSK informed healthcare professionals of the new antibody persistence data for Mencevax ACWY. The immunity to serogroups W-135 and Y in individuals 11-55 years of age who were vaccinated two years earlier with Mencevax ACWY is 24.0% and 44.0%, respectively. Limited data showed a waning of serum bactericidal antibody titres against serogroup A one year post-vaccination when using human complement in the assay (hSBA). Individuals remaining at high risk of exposure to serogroups A, W-135 and Y should be considered for earlier revaccination according to local recommendations. It is to be noted that revaccination with group C polysaccharide-containing vaccines may induce lower antibody responses to meningococcal group C polysaccharide compared to primary vaccination. The product information for Mencevax ACWY will be updated to include these new antibody persistence data.

## Safety Update

In Hong Kong, Mencevax ACWY Vaccine (HK-48475) is registered by GSK and is a prescription only medicine. As informed by GSK, a Dear Healthcare Professional Communication had been issued by GSK on 11 November 2013 about the new antibody persistence data of the product. GSK had submitted application to change the package insert of the product to include the relevant safety information and the application was under evaluation and process. DH will keep vigilant on any safety updates of the drug.

### **Australia: Medicines with soft gel capsules marketed for children**

On 19 February 2014, the Therapeutic Goods Administration (TGA) advised consumers and health professionals that medicines that come in the form of soft gel capsules may pose a choking risk for children, especially those aged under five years.

Soft gel capsules are typically a gelatine-based shell, containing a liquid. They can be used as a dosage form for a variety of medicines, including complementary medicines, such as vitamins. In some cases, these medicines may have directions for use saying that they can or should be chewed. Even when chewed, soft gel capsules may pose a choking risk for children.

The TGA's advisory is precautionary. Medicines that come in the form of soft gel capsules are not necessarily unsafe products and the choking risk posed by these capsules is similar to that for many food items. Moreover as the age of the child being given the medicine increases, the risk of choking reduces. Parents and caregivers are advised to be mindful of the risk of choking when medicines in the form of soft gel capsules are given to children, especially those aged under five years.

The TGA reiterates the importance of the following:

- all medicines be kept out of reach of children,
- children be supervised when taking any medicine, with extra care taken when using medicines that come in the form of soft gel capsules,
- parents and caregivers follow the instructions for use for all medicines given to children.

Soft gel capsules may be used as a dosage form for a variety of medicines. DH will keep vigilance on any safety updates of the issue and actions taken by other overseas regulatory authorities for consideration of any action deemed necessary.

## Drug Recall

### **Batch recall of Gomec 20mg Capsules (HK-49774)**

On 10 February 2014, DH instructed a licensed drug wholesaler, Trenton-Boma Co. Ltd. (Trenton-Boma), to recall one batch of Gomec 20mg Capsules (Gomec 20mg) (batch number: 10230) from shelves. The recall was due to some samples of the above batch drawn from the market by DH were found to have failed the dissolution test. Gomec 20mg, containing omeprazole, is a Part I poison used for the treatment of peptic ulcer and gastric hyperactivity. It can only be supplied by pharmacies under the supervision of a registered pharmacist.

DH had closely monitored the recall. As on 10 February 2014, DH had not received any adverse drug reaction reports in connection with the product. A notice was released on the Drug

Office's website on the same day to alert the public of the recall.

Members of the public who are using the affected batch of the product should consult their healthcare professionals if in doubt.

### **Batch Recall of Cosopt Preservative Free Eye Drops**

On 13 February 2014, DH endorsed two licensed drug wholesalers, namely PWP International (HK) Ltd (PWP) and Vantone Medical Supplies Co Ltd (Vantone), to voluntary recall 4 batches of Cosopt Preservative Free Eye Drops because of a problematic container design. The batches under recall were MK13D001, MK13C004 and MK13C002 (3 batches imported by PWP) and 2086590 (imported by Vantone).

Cosopt Preservative Free Eye Drops contains



## Drug Recall

timolol and dorzolamide and is indicated for treatment of glaucoma. According to the manufacturer, Merck Sharp & Dohme, in the UK, there was an increase number of product complaints, e.g. difficult in administration, dosing problems and eye injuries, after the introduction of a new design of the tip of the container since July 2013. Merck Sharp & Dohme has re-designed the container to address the problem.

Further to the recall issued earlier on, on 18 February 2014, the Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK has announced that the manufacturer of the product Merck Sharp and Dohme was recalling two more batches of the above product with batch number MK 13D002 and MK 13D004 in the UK.

In Hong Kong, Cosopt Preservative Free Eye Drops is not a registered pharmaceutical product. However, PWP and Vantone, have respectively imported 180 boxes and 12 boxes, including the affected batch MK13D002, for the treatment of particular patients. DH endorsed PWP and Vantone to extend the recall further to cover the affected batch and will closely monitor the recall. As on 18 February 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 Drug Office's website on the same day to alert the public of the recall.

### **Batch recall of Korus-Omeprazole 20mg Capsules (HK-60896)**

On 18 February 2014, DH instructed a licensed drug wholesaler, LSB (HK) Ltd. (LSB), to recall one batch (batch number: 217602) of Korus-Omeprazole 20mg Capsules from shelves. The recall was due to some samples of the above batch drawn from the market by DH were found to have failed the dissolution test. Korus-Omeprazole 20mg Capsules, containing omeprazole, is a Part I poison used for the treatment of peptic ulcer and gastric hyperactivity. It can only be supplied by pharmacies under the supervision of a registered pharmacist.

About 2000 boxes of the affected batch were imported into HK and they were supplied to private doctors and local pharmacies. DH had closely monitored the recall. As on 18 February 2014, DH had not received any adverse drug reaction reports in connection with the product. A notice was

released on Drug Office's website on the same day to alert the public of the recall.

Members of the public who are using the affected batch of the product should consult their healthcare professionals if in doubt.

### **Batch recall of Apo-Naproxen Tablet 250mg (HK-34921)**

On 19 February 2014, DH endorsed a licensed drug wholesaler, Hind Wing Co. Ltd, to conduct a voluntary recall of one batch (batch number: KJ3194) of Apo-Naproxen Tablet 250mg from the market due to a potential quality issue. Apo-Naproxen Tablet 250mg, containing naproxen, is a prescription medicine used for relief of inflammation and pain. It can only be supplied by pharmacies under the supervision of a registered pharmacist upon doctors' prescription.

DH today received notification from Hind Wing that the product's manufacturer in Canada, Apotex Inc., had found some batches of the product may contain foreign material embedded in tablets and the foreign material originated from silicon tubing in contact with the tablets during the manufacturing process. Inadvertent ingestion of small particles of silicon is not expected to cause serious systemic effects. However, there is a potential risk of mechanical irritation or trauma to the upper gastrointestinal tract. Apotex Inc. initiated this voluntary recall in co-ordination with Health Canada.

According to Hind Wing, only one of the affected batches (batch number: KJ3194), with 198 bottles (1,000 tablets each) in total, had ever been imported to Hong Kong since March 2013. Among the imported stock, 188 bottles were supplied to DH clinics, a private hospital, local private doctors and pharmacies while the rest were exported to Macau. DH had already informed the relevant authority of Macau on details of the recall. DH had closely monitored the recall. As on 19 February 2014, DH had not received any adverse drug reaction reports in connection with the product. A notice was released on Drug Office's website on the same day to alert the public of the recall.

Healthcare providers should stop supplying the affected product to their clients. Members of the public who are consuming the product should consult their healthcare professionals if in doubt.

# Drug Incident

## **Retail shops raided for suspected illegal sale of unregistered pharmaceutical product**

On 6 February 2014, a joint operation was conducted by the DH and the Police against two retail shops in Causeway Bay and Kwun Tong respectively resulting in the arrest of a 22-year-old woman for suspected illegal sale of an unregistered pharmaceutical product.

Acting on a public complaint, DH found that the above two shops, which mainly sold cosmetic products, were offering for sale an eye drops product, namely Latisse, labelled as containing a Part I poison, bimatoprost. No Hong Kong pharmaceutical product registration number was found on the label. Preliminary investigation has so far revealed that the product was sourced outside Hong Kong.

Bimatoprost is a prescription only medicine used for the treatment of glaucoma or conditions with an inadequate amount of eyelashes. Side-effects include ocular pruritus (eye itching), conjunctival hyperaemia and headache. It should only be used under doctors' advice.

## **Medicine Company raided for suspected illegal sale of unregistered pharmaceutical product with controlled drug ingredients**

On 10 February 2014, a joint operation was conducted by DH and the Police against a medicine company in Tsing Yi resulting in the arrests of two men both are 50-year-old for the suspected illegal sale of "Gefitinat 250mg tablets", an unregistered pharmaceutical product containing a Part I poison. Gefitinib tablet is a prescription drug used for the treatment of lung cancer and its side effects include gastrointestinal disorders, anorexia and haemorrhage. It should only be used under the direction and supervision of medical doctor. It can only be sold in pharmacies under the supervision of registered pharmacist upon doctor's prescription.

Based on the market surveillance system of DH, the medicine company was found to have offered for sale an anti-cancer drug "Gefitinat 250mg tablets". The product, labelled as containing gefitinib (a Part I poison), is a pharmaceutical product not registered with the Pharmacy and Poisons Board of Hong Kong. During the operation, a number of other controlled medicines, including Part I poisons (some of which are prescription only medicines) and antibiotics were also found upon search of the

premises.

## **Public urged not to buy or use product labelled Betalin Cream**

On 13 February 2014, DH urged the public not to buy or use a product called "Betalin Cream" as it was found to contain undeclared and controlled ingredients.

Acting on a public complaint, a pharmacy located in North Point was found to be offering the product for sale. A sample of Betalin Cream was purchased for analysis and the Government Laboratory's results showed that the sample contains tolinaftate (an antifungal drug) and a Part I poison betamethasone (a steroid), which is a prescription drug. The product is not a registered pharmaceutical product in Hong Kong. A joint operation was conducted by the DH and the Police on the same day against the pharmacy resulting in the arrest of a 38-year-old man for suspected illegal sale of an unregistered pharmaceutical product and selling a prescription drug without prescription.

Topical betamethasone is used for the treatment of inflammatory skin disorders and should only be used under the advice of a doctor. The product can only be sold at pharmacies under the supervision of a registered pharmacist upon a doctor's prescription. Inappropriate use of steroids may cause serious side effects such as Cushing's Syndrome, with symptoms including moon face and muscle atrophy. Tolinaftate is commonly used for fungal infection of the skin. It can cause side effects such as irritation and allergic reaction.

## **Public urged not to buy or use product with undeclared and controlled substance**

On 13 February 2014, DH urged the public not to buy or use a product (without English name) as it was found to contain an undeclared and controlled substance.

Acting on intelligence, DH commenced investigation which found that the product was offered for sale on the Internet. A sample of the product was purchased for analysis by the Government Laboratory. Results showed that the sample contains a Part I poison sildenafil. The product's label did not bear a product name but a leaflet showing the name was provided with the product.

# Drug Incident

On the same day, a joint operation was conducted by DH and the Police against the product supplier, a company located in Mong Kok, resulting in the arrests of two men aged 24 and 54 for suspected illegal sale and possession of Part I poison and unregistered pharmaceutical product.

Products containing sildenafil are prescription drugs for the treatment of erectile dysfunction and should only be supplied at pharmacies under the supervision of a registered pharmacist and upon the production of a doctor's prescription. The side effects of sildenafil include low blood pressure, headache, vomiting, dizziness and transient vision disturbances. It may interact with some drugs (such as nitroglycerin for treatment of angina) and cause a decrease in blood pressure to dangerous levels. Improper use of sildenafil may pose serious health risks, especially for patients with heart problems.

## **Public urged not to buy or consume slimming product with undeclared and banned Western drug ingredients**

On 14 February 2014, DH appealed to members of the public not to buy or consume a slimming

product called SULAMI capsule as it is suspected to contain undeclared and banned drug ingredients that might be dangerous to health.

DH was notified by Hospital Authority (HA) about a 50-year-old female patient who was hospitalized for having the psychotic symptoms including unstable mood, abnormal behaviour and auditory hallucination. It was found that she had a history of consuming the above slimming product which she had bought locally. An analytical report from the Government Laboratory on the samples of the product showed that they contained the Part I poisons sibutramine and spironolactone.

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

Spironolactone is a prescription drug used in the management of heart failure and should only be used under supervision of a doctor. Side effects include headache, gastrointestinal disturbances, mental confusion, hyponatraemia and hyperkalaemia.

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.

### **De-registration of oral pharmaceutical products containing Ketoconazole**

On 27 February 2014, DH issued a press statement to announce the decision made by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee of the Pharmacy and Poisons Board to deregister pharmaceutical products containing Ketoconazole with effect from 1 July 2014, because the benefits of the products no longer outweigh their risks.

The Committee's decision was made at its meeting on 26 February 2014, after taking into consideration the findings from the review conducted by the EMA's Committee on Medicinal Products for Human Use, decisions by overseas drug regulatory agencies, and the use of the products in Hong Kong.

Ketoconazole is an anti-fungal agent used orally or topically. It is given orally in chronic mucocutaneous or vaginal candidiasis, fungal infections of the gastrointestinal tract, dermatophyte infections of the skin and fingernails not responding to topical treatment, and systemic fungal infections.

The EMA concluded that the incidence and seriousness of liver injury with oral ketoconazole were higher than with other antifungals. In light of the increased rate of liver injury and the availability of alternative anti-fungal treatments, the EMA concluded that the benefits did not outweigh the risks and recommended suspending oral ketoconazole throughout the European Union. Topical formulations of ketoconazole (such as creams, gels, shampoos and topical solutions) could

continue to be used as the amount absorbed throughout the body surface is very low with these formulations,

Currently, there are 21 registered oral pharmaceutical products containing ketoconazole, marketed by 17 manufacturers and wholesalers. They are all prescription-only medicines which can only be sold by pharmacies under the supervision of registered pharmacists upon doctors' prescription.

According to local clinical experts in infectious diseases, dermatology and oncology, the use of oral ketoconazole in clinical practice has almost been completely replaced by alternative anti-fungal agents. DH had issued letters to healthcare professionals to inform them of the Registration Committee's decision to deregister oral pharmaceutical products containing ketoconazole, and to advise them to arrange suitable alternative treatments for their patients.

When the Registration Committee's decision takes effect on 1 July, 2014, all drug manufacturers, wholesalers, retailers and healthcare professionals must stop selling or supplying oral pharmaceutical products containing ketoconazole. Drug manufacturers and wholesalers are also required to recall all products concerned from the market by 30 June, 2014. DH will take enforcement action against any illegal possession or sale of such products afterwards.

Doctors and pharmacies should stop prescribing or dispensing oral ketoconazole products. Patients taking oral ketoconazole products are advised to consult their healthcare professionals to review their treatment plans as soon as possible.



## *Useful Contact*

### Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: [pharmgeneral@dh.gov.hk](mailto:pharmgeneral@dh.gov.hk)

### Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2186 9845

E-mail: [adr@dh.gov.hk](mailto: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.***