Drug News
藥 物 情 報

Issue Number 65

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in March 2015 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

US: FDA cautions about using testosterone products for low testosterone due to aging and requires labeling change to inform of possible increased risk of heart attack and stroke

On 3 March 2015, the U.S. Food and Drug Administration (FDA) was requiring that the manufacturers of all approved prescription testosterone products changed their labeling to clarify the approved uses of these medications. FDA was also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. FDA cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone.

Based on the available evidence from studies and expert input from an FDA Advisory Committee meeting, FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use. These studies included aging men treated with testosterone. Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not.

Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests. Health care professionals should make patients aware of the possible increased cardiovascular risk when deciding whether to start or continue a patient on testosterone therapy. Patients using testosterone should seek medical attention immediately if symptoms of a heart attack or stroke are present, such as chest pain, shortness of breath or trouble breathing, weakness in one part or one side of the body, or slurred speech.

In Hong Kong, there are eight registered pharmaceutical products containing testosterone and they are prescription only medicines. The Department of Health (DH) noted that FDA and the European Medicines Agency (EMA) have started to review the risk of cardiovascular events of testosterone products, and the related news was reported in the Drug News Issues No. 52 and 60. In July 2014, Health Canada completed a safety review on the possible cardiovascular problems with testosterone products, and worked with their manufacturers to update the Canadian product labels with the safety warnings, and the news was reported in the Drug News Issue No. 57. Letters to inform local healthcare professionals on the above safety warnings and the latest EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommendations were issued on 16 July 2014 and 13 October 2014. So far, the DH has not received any adverse drug reaction reports on the drug related to cardiovascular complications. The matter was discussed by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee (the Registration Committee) of the Pharmacy and Poisons Board on 17 February 2015. The Committee noted that the DH had informed the registration certificate holders to include cardiovascular warnings on their testosterone products, and the DH is still processing their applications to update the new

warnings. The DH continues to follow up with the registration certificate holders and keeps vigilant on any further announcements on the products issued by other overseas health authorities.

US: FDA updates label for stop smoking drug Chantix (varenicline) to include potential alcohol interaction, rare risk of seizures, and studies of side effects on mood, behavior, or thinking

On 9 March 2015, FDA warned that the prescription smoking cessation medicine Chantix (varenicline) can change the way people react to alcohol. In addition, rare accounts of seizures in patients treated with Chantix have been reported. The FDA has approved changes to the Chantix label to warn about these risks. Until patients know how Chantix affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink. Patients who have a seizure while taking Chantix should stop the medicine and seek medical attention immediately.

FDA reviewed the case series submitted by Pfizer, the manufacturer of Chantix, as well as the cases in the FDA Adverse Event Reporting System (FAERS) database describing patients who drank alcohol during treatment with Chantix and experienced adverse reactions. Some patients experienced decreased tolerance to alcohol, including increased drunkenness, unusual or aggressive behavior, or they had no memory of things that happened.

FDA also reviewed FAERS and the medical literature for cases of seizures with Chantix and identified cases in which the patients who had seizures while taking Chantix either had no history of seizures or had a seizure disorder that had been well-controlled. In most of these cases, the seizures occurred within the first month of starting Chantix. Information about these risks has been added to the Warnings and Precautions section of the drug label and to the patient Medication Guide.

FDA also updated the Warnings and Precautions section of the label to include information about several studies that investigated the risk of neuropsychiatric side effects on mood, behavior, or thinking occurring with Chantix. These included observational studies, as well as analyses that Pfizer conducted of randomized controlled clinical trial data. These studies did not show an increased risk of neuropsychiatric side effects with Chantix; however, they did not examine all types of neuropsychiatric side effects, and they had limitations that prevented the FDA from drawing reliable conclusions. Pfizer is conducting a large clinical safety trial of Chantix to investigate the risk of possible neuropsychiatric side effects and results from this study are expected in late 2015. The FDA will update the public as appropriate when this new information becomes available.

Healthcare professionals are advised of the following:

- Interactions between alcohol and Chantix (varenicline) have resulted in some patients experiencing increased intoxicating effects of alcohol, sometimes associated with aggressive behavior and/or amnesia.
- Advise patients to reduce the amount of alcohol they consume while taking Chantix until they know whether the drug affects their tolerance for alcohol.
- Seizures have been reported in patients treated with Chantix.
- Weigh the potential risk of seizures against the potential benefits before prescribing Chantix in patients with a history of seizures or other factors that can lower the seizure threshold.
- Advise patients to discontinue Chantix and seek medical attention immediately if they experience a seizure while on treatment.
- Advise patients to immediately stop taking Chantix if they develop agitation, hostility, aggressive behavior, depressed mood, or changes in behavior or thinking that are not typical for them, or if they develop suicidal ideation or behavior.

In Hong Kong, there are three registered pharmaceutical products containing varenicline, namely Champix Tab 1mg (HK-55437), Champix Tab 0.5mg & 1mg (HK-55462) and Champix Tab 0.5mg (HK-55479). All of them are prescription only medicines and registered by Pfizer Corporation Hong Kong Limited. Related news on the risk of neuropsychiatric adverse events has been reported by the FDA, and was reported in the Drug News Issue No. 25. So far, the DH has not received any adverse drug reaction reports on varenicline. In view of the FDA's announcement, a letter to healthcare professionals to draw their

attention to the updates was issued on 10 March 2015, and the matter will be discussed in the meeting of the Registration Committee.

US: Treanda (bendamustine hydrochloride) Solution by Teva not compatible with closed system transfer devices, adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene

On 10 March 2015, FDA issued warning alerting health care professionals not to use Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with closed system transfer devices (CSTD), adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene (ABS). Most marketed CSTDs contain either polycarbonate or ABS and are not compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution).

N, N-dimethylacetamide (DMA), an ingredient in Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution), is incompatible with polycarbonate or ABS. Devices that contain polycarbonate or ABS dissolve when coming into contact with DMA. This can lead to device failure, possible product contamination, and potential serious adverse health consequences, including skin reactions in health care professionals preparing and administering this product and the risk of small blood vessel blockage in patients.

FDA was requiring label changes for both the solution and the powder formulations of Treanda to reflect safe preparation information. Treanda is available in two formulations, a solution, Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution); and a lyophilized powder, Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder). Closed system transfer devices are devices that are used to prepare and administer hazardous drugs for intravenous infusion, such as chemotherapy drugs.

Health care professionals should stop using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with CSTDs or vial adapters and syringes containing polycarbonate or ABS. If using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution), health care professionals should verify with the CSTD manufacturer or Teva U.S. Medical Information (1-800-896-5855) that the CSTD is compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) prior to preparing the drug. Details of the recommendation can be found in the website of the FDA.

If using Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder), healthcare professionals are advised that:

- Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder), must be reconstituted. If a CSTD or adaptor is to be used as supplemental protection during preparation, only use Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder) and not the solution formulation.
- Do not mix or combine the solution and lyophilized powder formulations of Treanda.

In Hong Kong, Treanda for Inj 100mg (HK-59067) and Treanda for Inj 25mg (HK-62300) are both in powder formulation registered by Ivax Asia Ltd. They are prescription only medicines and do not contain DMA according to the registered information. Based on the available information, the FDA's announcement regarding incompatibility of Treanda solution with certain CSTD has no impact on the products registered in Hong Kong.

EU: PRAC recommends restrictions on the use of codeine for cough and cold in children

On 13 March 2015, the EMA's PRAC had recommended restrictions on the use of codeine-containing medicines for cough and cold in children because of the risk of serious side effects with these medicines, including the risk of breathing problems.

The PRAC recommended specifically that:

- Codeine should be contraindicated in children below 12 years. This means it must not be used in this patient group.
- Use of codeine for cough and cold is not recommended in children and adolescents between 12 and 18 years who have problems with breathing.
- All liquid codeine medicines should be available in child-resistant containers to avoid accidental ingestion.

The PRAC considered that, although morphine-induced side effects may occur in patients of all ages, the way codeine is converted into morphine in children below 12 years is variable and unpredictable, making this population at special risk of such side effects. In addition, children who already have problems with their breathing may be more susceptible to respiratory problems due to codeine. The PRAC also noted that cough and cold are generally self-limiting conditions and the evidence that codeine is effective at treating cough is limited in children.

The PRAC further recommended that codeine must not be used in people of any age who are known to convert codeine into morphine at a faster rate than normal ('ultra-rapid metabolisers') nor in breastfeeding mothers, because codeine can pass to the baby through breast milk.

During its review, the PRAC consulted EMA's Paediatric Committee as well as healthcare professionals' organisations. The review was triggered by a previous review of codeine for pain relief in children, which resulted in several restrictions being introduced in order to ensure that only children for whom the benefits are greater than the risks are given the medicine for pain relief. As the reasons for these restrictions could also apply to the use of codeine for cough and cold in children, an EU-wide review of such use was initiated. The restrictions the PRAC has now recommended for codeine for cough and cold are largely in line with the previous recommendations for codeine when used for pain relief.

A previous review was carried out in 2012-2013 by the PRAC, to evaluate the risk of toxicity with codeine-containing medicines when used for pain relief in children. This led to warnings and contraindications being included in the prescribing information for these medicines.

It was noted from the website of the EMA on 25 April 2015 that the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) had agreed the PRAC measures (except for the measure related to the child-resistant containers) by consensus, and the measures will be directly implemented by the Member States where the medicines are authorised, according to an agreed timetable.

In Hong Kong, there are 338 registered pharmaceutical products containing codeine, which is an ingredient used to relieve pain and cough. Related news regarding the use of codeine has also been released by the US FDA, EMA, MHRA, Health Canada and HSA and was reported in the Drug News Issues No. 12, 34, 40, 44 and 54. Letters to inform healthcare professionals on the issue were issued on 16 August 2012 and 7 June 2013. On 5 July 2013, the Registration Committee decided that codeine is not recommended for use in children less than 12 years of age and the sales pack and/or package insert of pharmaceutical products containing codeine should be updated to include the appropriate safety information. The DH keeps vigilant on the safety updates of the drug.

US: Hepatitis C treatments containing sofosbuvir in combination with another direct acting antiviral drug associated with serious slowing of heart rate when used with antiarrhythmic drug amiodarone

On 24 March 2015, the FDA announced warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. The FDA is adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. FDA is recommending that health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct acting antiviral, such as the investigational drug daclatasvir or Olysio (simeprevir), with amiodarone.

FDA review of submitted postmarketing adverse event reports found that patients can develop a serious and life-threatening symptomatic bradycardia when either Harvoni or Sovaldi combined with another direct-acting antiviral is taken together with amiodarone. The reports included the death of one patient due to cardiac arrest and three patients requiring placement of a pacemaker to regulate their heart rhythms. The other patients recovered after discontinuing either the hepatitis C drugs or amiodarone, or both. The cause of these events could not be determined.

FDA will continue to monitor Harvoni and Sovaldi for risks of serious symptomatic bradycardia and further investigate the reason why the use of amiodarone with these hepatitis C drugs led to the heart-related events.

Health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone. However, in cases where alternative treatment options are unavailable, FDA recommends heart monitoring in an inpatient hospital setting for the first 48 hours. Subsequently, monitoring in a doctor's office or self-monitoring of the heart rate should be done every day through at least the first 2 weeks of treatment.

Due to the long half-life of amiodarone, patients discontinuing amiodarone just prior to starting Harvoni, or Sovaldi in combination with another direct-acting antiviral, should also undergo similar cardiac monitoring as outlined above.

Patients taking either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone should seek medical attention right away if they experience signs or symptoms of symptomatic bradycardia

In Hong Kong, Harvoni is not a registered pharmaceutical product. Meanwhile, there is one registered pharmaceutical product containing sofosbuvir, namely Sovaldi Tablets 400mg (HK-63501). It is a prescription only medicine registered by Gilead Sciences Hong Kong Limited. The company has informed the DH that they have issued letters to inform local healthcare professionals on the new warnings, and will apply to include the new warnings in the local product information. So far, the DH has received two adverse drug reaction reports on Sovaldi Tablets, and none of them was associated with symptomatic bradycardia adverse events. In view of the FDA's announcement, a letter to healthcare professionals was issued on 25 March 2015 to draw their attention to the issue, and the matter will be discussed in the meeting of the Registration Committee.

EU: Further measures to minimise risk of osteonecrosis of the jaw with bisphosphonate medicine

On 27 March 2015, the EMA had completed a periodic review of Aclasta (zoledronic acid), one of the bisphosphonate medicines with a known risk of osteonecrosis of the jaw. The Agency concluded that the risk of osteonecrosis (or death of bone tissue) in the jaw remains very low, but has recommended a number of measures to minimize the risk, including an update to the product information and the introduction of a patient reminder card.

The EMA is planning similar measures for other intravenous bisphosphonates and denosumab, used for osteoporosis or for preventing bone complications of cancers, as these are also associated with a risk of osteonecrosis of the jaw. Measures for these medicines will be considered during their upcoming and on-going periodic reviews, which are planned to take place over the course of 2015/2016.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has now adopted the recommendations for Aclasta, following a review by the PRAC. The CHMP opinion will be sent to the European Commission for a legally binding decision valid throughout the EU.

Healthcare professionals should follow the following recommendations for Aclasta:

- Delay the start of treatment or a new course of treatment in patients with unhealed open soft tissue lesions in the mouth that may require dental or oral procedures.
- Ensure patients have a dental examination and an individual benefit-risk assessment before starting treatment in patients with concomitant risk factors.
- Consider the following when evaluating a patient's risk of developing osteonecrosis of the jaw:

  - Potency of the medicinal product that inhibits bone resorption (higher risk for highly potent compounds), route of administration (higher risk for parenteral administration) and cumulative dose of bone

resorption therapy.

- Cancer, co-morbid conditions (e.g. anaemia, coagulopathies, infection) and smoking.

- Concomitant therapies: corticosteroids, chemotherapy, angiogenesis inhibitors and radiotherapy to head and neck.

- Poor oral hygiene, periodontal disease, poorly fitting dentures and a history of dental disease, invasive dental procedures, e.g. tooth extractions.

- Encourage patients to maintain good oral hygiene, undergo routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain or swelling, non -healing of sores or discharge during treatment with zoledronic acid. While patients are on treatment, invasive dental procedures should be performed with caution and these procedures should be avoided close to their treatment.

- Managing patients who develop osteonecrosis of the jaw should involve close collaboration between the treating physician and a dentist or oral surgeon with expertise in osteonecrosis of the jaw. Consider interrupting treatment temporarily until the condition resolves and the contributing risk factors are mitigated, where possible.

In Hong Kong, there is one registered pharmaceutical product for Aclasta Solution for Infusion 5mg/100ml (HK-54084) which is a prescription only medicine. The product information has already included warnings on osteonecrosis of the jaw. Related news on further measures to minimize risk of osteonecrosis of the jaw with bisphosphonate medicine recommended by PRAC was posted on the website of the Drug Office on 14 March 2015. So far, the DH has not received any adverse drug reaction reports in relation to the drug. In view of the latest announcement of further measures to minimise the risk of osteonecrosis of the jaw recommended by PRAC are adopted by CHMP, letters to local healthcare professionals were issued on 30 March 2015 to draw their attention to the safety updates, and the matter will be discussed in the meeting of the Registration Committee.

Canada: ADHD drugs may increase risk of suicidal thoughts and behaviours in some people; benefits still outweigh risks

On 30 March 2015, Health Canada announced that stronger, clearer warnings on the risk of suicidal thoughts and behaviours are being incorporated into the prescribing information for drugs used in the management of Attention Deficit Hyperactivity Disorder (ADHD).

The new warnings advise that there have been reports of suicide-related events in patients treated with ADHD drugs. The reports involved thoughts of suicide, suicide attempts, and in a very small number of cases, completed suicide. These events have been reported at various times during treatment, particularly at the start or during dose changes, and also after stopping the drug treatment.

There are different types of ADHD drugs and the evidence varies with respect to the risk of suicidal thoughts and behaviours. This risk is already known for one ADHD drug, Strattera (atomoxetine), and was incorporated into its prescribing information and communicated in 2005.

New information has emerged since to suggest that the risk of suicidal thoughts and behaviours may apply to all other ADHD drugs. There is little evidence to establish that these drugs cause suicidal thoughts and behaviours, but it is possible that they may contribute to the risk. It is important to note that people with ADHD may already have a slightly increased risk of suicidal thoughts and behaviours. ADHD may also affect people who have other mental health conditions that are associated with an increased risk of suicide, such as depression or bipolar disorder.

The prescribing information for all ADHD drugs is being revised to include standardized warnings that better reflect the available evidence on the risk of suicidal thoughts and behaviours, except the monograph for Strattera which already includes detailed safety information on this risk. ADHD drugs are available by prescription only and are authorized for use in adults and children over the age of six years. There are several brand name and

generic drugs available in Canada: ADDERALL XR (mixed salts amphetamine extended-release), BIPHENTIN (methylphenidate controlled release), CONCERTA (methylphenidate extended release), DEXEDRINE (dextroamphetamine sulfate), INTUNIV XR (guanfacine extended release), RITALIN (methylphenidate), RITALIN SR (methylphenidate extended release), STRATTERA (atomoxetine) and VYVANSE (lisdexamfetamine dimesylate).

It is Health Canada's view that the benefits of these drugs in the effective management of ADHD continue to outweigh their risks. The possible occurrence of psychiatric side effects with ADHD drugs is included in the prescribing information (product monographs) in a warning section that emphasizes the importance of monitoring moods, behaviours, thoughts and feelings in adults and children taking these medications, and the importance of taking psychiatric disorders into account when prescribing these drugs.

In Hong Kong, among the ingredients listed by Health Canada, there are 19 and 11 registered pharmaceutical products containing atomoxetine and methylphenidate respectively, and they are prescription only medicines. There are no registered pharmaceutical products containing mixed salts amphetamine, dextroamphetamine sulfate, guanfacine and lisdexamfetamine dimesylate. So far, the DH has not received any adverse drug reaction reports on the drugs. In view of the Health Canada's announcement, a letter to healthcare professionals was issued on 31 March 2015 on the new warning, and the matter will be discussed in the meeting of the Registration Committee.

Drug Recall

A batch recall of Rosuvastatin Actavis 5mg Tablets (HK-62375)

On 4 March 2015, the DH endorsed a licensed drug wholesaler, Actavis Hong Kong Ltd. (Actavis), to voluntary recall one batch of Rosuvastatin Actavis 5mg Tablets (registration number: HK-62375) from the market due to potential quality issue. The affected batch was F50270.

The DH received notification from Actavis that the manufacturer of the product in Malta found that the impurity content of certain batches of the product has been elevated during the stability study. Although the levels of the impurity were still within specifications, the manufacturer decided to recall the affected batches as a precautionary measure. According to Actavis, only one of these affected batches has been imported into Hong Kong. Since the affected batches did not fail the tests, risk posed by the issue is negligible.

Rosuvastatin Actavis 5mg Tablets, containing rosuvastatin, is a prescription medicine used for the treatment of hyperlipidaemia. According to Actavis, about 1,244 boxes of 28 tablets of the affected batch had been supplied to a private hospital, private doctors and pharmacies. The DH closely monitored the recall. As on 4 March 2015, the DH had not received any adverse reports in connection with the product. A notice was released on the website of the Drug Office on the same day to alert the public of the recall.

Recall one batch of Dextrose Injection 5% USP (Baxter) 1000ml (HK-41323)

On 12 March 2015, the DH endorsed a licensed drug wholesaler, Baxter Healthcare Limited (Baxter), to conduct a voluntary recall of one batch (batch number: C926899) of Dextrose Injection 5% USP (Baxter) 1000ml (HK-41323) from the market due to potential quality issue.

The DH received notification from Baxter that the US manufacturer of the product has received complaints for missing closure and/or leaks in some packs of the affected batch of the product. Since missing closure and/or leaks in the product may place patients at an increased risk of infection, the US manufacturer decided to recall the affected batch as a precautionary measure. The DH has requested Baxter to provide a detailed investigation report as soon as possible.

Dextrose Injection 5% USP (Baxter) containing dextrose is a solution for fluid replenishment and caloric supply for intravenous administration. According to Baxter, 476 packs of the affected batch have been supplied to private and HA hospitals. The DH closely monitored the recall. As on 12 March 2015, the DH had not received any adverse reports in connection with the product. A notice was released on the website of the Drug Office on the same day to alert the public of the recall.

Drug Recall

DH instructed batch recall of Betasalic Ointment (HK-49244)

On 16 March 2015, the DH instructed a licensed pharmaceutical manufacturer, Europharm Laboratoires Co Ltd (Europharm), to recall one batch (batch number: 408179) of Betasalic Ointment (registration number: HK-49244) from the market due to a quality issue.

Under the DH's market surveillance, samples of Betasalic Ointment were taken for analysis. Upon the Government Laboratory's testing, the content of one of the active ingredients, betamethasone, was found to be lower than the labelled claim in samples of the above batch. The root causes of the issue were under investigation. Since the quality defect may affect the efficacy of the pharmaceutical product, Europharm was ordered to recall the affected batch from the market.

According to Europharm, the affected batch was manufactured in August 2014 and 6,379 tubes have been supplied to public hospitals under the Hospital Authority, pharmacies and private doctors in Hong Kong. The DH closely monitored the recall. As on 16 March 2015, the DH had not received any adverse reports in connection with the above pharmaceutical product. A notice was released on the website of the Drug Office on the same day to alert the public of the recall.

Betasalic Ointment, containing betamethasone and salicylic acid, is a prescription medicine indicated for the relief of inflammation of the skin. Side-effects include ulceration of the skin, moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency or even osteoporosis. Using ointment with content lower than its labelled claim may lead to delayed treatment due to insufficient efficacy. Members of the public using the above pharmaceutical product should consult their healthcare providers if in doubt or when symptoms persist.

Drug Incident

Retail shops raided for suspected illegal sale of unregistered pharmaceutical product

On 20 March 2015, two retail shops in Mong Kok were raided in a joint operation by the DH and the Police for suspected illegal sale and possession of an unregistered pharmaceutical product labelled to contain Part I poison.

Acting upon a public compliant, it was found that retail shops were offering for sale a slimming product which was labelled as containing orlistat. Orlistat is a Part I poison and a prescription medicine (except when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day) which should only be used under the advice of a medical doctor and can only be supplied by pharmacies under the supervision of a registered pharmacist upon doctor's prescription.

During the operation, a woman aged 33 was arrested by the Police for suspected illegal sale and possession of Part I poisons and unregistered pharmaceutical products.

Orlistat is used for the treatment of obesity. Its side effects include faecal urgency, fatty stool, increased frequency of defaecation, faecal incontinence, headache and abdominal pain. Severe liver injuries may also be induced.

People who have purchased the above product should stop using it and consult healthcare professionals if they are in doubt or feeling unwell after use. 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. They should not use controlled medicines on their own without advice from a doctor.

Man arrested for suspected illegal sale of unregistered pharmaceutical products with controlled drug substance

On 30 March 2015, a 38-year-old man was arrested in a joint operation by the DH and the Police for illegal sale of unregistered pharmaceutical products labelled to contain a Part I poison, oxandrolone.

During the DH's surveillance, it was found that injectable and oral drugs labelled as containing oxandrolone were being offered for sale to bodybuilders through the Internet. Products containing oxandrolone are prescription medicines which should only be used under the advice of a medical doctor or supplied by pharmacies under the

supervision of a registered pharmacist upon a doctor's prescription.

Oxandrolone is a steroid with androgenic activity. Its side effects include oedema, hypercalcaemia, headache, depression, irritability and gastrointestinal bleeding. It may also cause acute liver failure.

Members of the public who have purchased the above products should stop using them immediately. They should consult healthcare professionals for advice if feeling unwell or in doubt after use. They should not to use controlled medicines on their own without advice from a medical doctor.

Retail shop raided for suspected illegal sale of unregistered pharmaceutical products with undeclared drug ingredients

On 31 March 2015, a retail shop in Tsim Sha Tsui was raided in a joint operation by the DH and the Police for suspected illegal sale and possession of unregistered pharmaceutical products that contain undeclared Part I poisons.

During the DH's surveillance, samples of two products, namely SLYN Both Plus and SLYN Both, were previously purchased from the retail shop for analysis. Analytical results from the Government Laboratory revealed that both products contained orlistat and fluoxetine. In addition, SLYN Both also contained sibutramine.

Orlistat, fluoxetine and sibutramine are all Part I poisons. 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. Orlistat is used for the treatment of obesity. Its side effects include faecal urgency, fatty stool, increased frequency of defecation, faecal incontinence, headache and abdominal pain. Severe liver injuries may also be induced. Fluoxetine is used for depression and may cause hallucination and insomnia.

Products containing orlistat and fluoxetine are prescription medicines which must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold legally in the market. Prescription medicines should only be used under the advice of a medical doctor or supplied at pharmacies under the supervision of a registered pharmacist upon doctor's prescription.

During the operation, a woman aged 53 was arrested by the Police for suspected illegal sale and possession of Part I poisons and unregistered pharmaceutical products.

People who have purchased the above products should stop using them and consult healthcare professionals if they are in doubt or feeling unwell after use. 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. They should not use controlled medicines on their own without advice from a doctor.

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. 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.

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.