Drug News
藥 物 情 報

Issue No. 28 : February 2012

This is a monthly digest of local and overseas drug safety news and information released by the Drug Office of the Department of Health in the month as stated above. 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, Canada: - Clostridum Difficile-Associated Diarrhea (CDAD) can be associated with Proton Pump Inhibitors

The US Food and Drugs Administration (FDA) advised the public on 8 February 2012 that the use of proton pump inhibitors (PPIs) might be associated with an increased risk of Clostridium difficile-associated diarrhea (CDAD). The advice was given following a review of reports from the Adverse Event Reporting System, relevant medical literature and clinical studies. Although the strength of the association varied widely among various studies and there were important limitations in the studies, the weight of evidence suggestd a positive association between PPI and CDAD. The FDA was working with manufacturers to include this piece of information in the drug labels. The agency was also reviewing the risk of CDAD among patients using histamine H2 receptor blockers which were indicated for treating conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and heartburn. Patients taking PPIs were advised to seek immediate medical care if susceptible symptoms (e.g. watery stool that did not go away, abdominal pain and fever) developed. Healthcare professionals were advised to use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. They were reminded to consider the diagnosis of CDAD when PPI users developed diarrhoea that did not improve.

On 16 February 2012, Health Canada also released similar alert to advice their patients and health care professionals. The Canadian labels for PPI drugs have already provided information on the potential for an increased risk of C. difficile infection.

In Hong Kong, there are around 137 proton pump inhibitor drugs registered. The ingredients include esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole. All these products are prescription medicines except the products containing omeprazole. They are used as antacids, antireflux and antiulcerants. In view of FDA's recommendation, a letter to healthcare professionals was issued on 9 February 2012. The matter had been 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. The Registration Committee decided that the sales packs or package inserts of the products should include information that decreased gastric acidity due to any means, including PPIs, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with PPIs may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter and possibly Clostridium difficile.

WHO: Increased vigilance for certain batch of Isotab® manufactured by Efroze Chemical Industries Pvt. Ltd. in Pakistan

On 3 February 2012, World Health Organization (WHO) requested regulatory authorities to increase vigilance for batch/ lot number J093 of Isotab® (isosorbide mononitrate 20mg) manufactured by Efroze Chemical Industries Pvt. Ltd, Pakistan (Efroze), as investigation to an incident revealed that the concerned batch might be contaminated with a significant amount of pyrimethamine. The incident in Lahore of Pakistan involved 107 deaths and serious adverse reactions in more than 450. The quantity of pyrimethamine in this product was found

to be large enough to cause a substantial overdose. Samples from other batches of Isotab® were tested but did not show any contamination with pyrimethamine.

In Hong Kong, Isotab® is not a registered pharmaceutical product. However, two products namely, Zetrine Tab 10mg (HK-59993) and Emod Cap 2mg (HK-60080) are manufactured by Efroze. Zetrine is an antihistamine and Emod is an antidiarrhoeal agent. It was found that Zetrine Tab 10mg had never been imported into Hong Kong. As a precautionary measure, samples of Emod Cap 2mg were analysed by the Government Laboratory which were found to be in compliance with the specification and did not contain pyrimethamine. The Department of Health (DH) will keep vigilant against any updated safety news on this issue.

US: Lot recall of Prevnar 13 Pneumococcal 13-valent Conjugate Vaccine due to the use of expired serotype 3 conjugate material

On 10 February 2012, Pfizer Inc. conducted a recall of a lot (lot number F73652) of Prevnar 13 Pneumococcal 13-valent Conjugate Vaccine 0.5mL pre-filled syringes at the wholesale level in US. The voluntary recall was initiated because the company found that the lot concerned was formulated and filled with expired serotype 3 conjugate material.

In Hong Kong, Prevenar 13 Vaccine (HK-59600) is registered by Pfizer Corp. HK Ltd. It is a prescription medicine and is for immunisation of infant & children from age 6 weeks to 9 years against invasive disease, pneumonia & otitis media caused by *Strep pneumoniae*. According to Pfizer, the problematic batch had never been imported into Hong Kong.

EU: Final recommendations for 14 centrally authorised medicines manufactured at Ben Venue Laboratories

Following the detection of the shortcomings in quality assurance identified at Ben Venue Laboratories as reported in Issue No. 26 of Drug News, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) released final recommendations for 12 out of 14 centrally authorised medicines manufactured at Ben Venue Laboratories (BV), Ohio, USA (Angiox, Busilvex, Vidaza, Vistide, Velcade, Ecalta diluent, Soliris, Cayston, Luminity, Mepact, Torisel and Vibativ) on 16 February 2012. For Vibativ and Luminity which were currently not marketed in the EU, CHMP had recommended suspending its marketing authorizations until a suitable manufacturing site was approved. For the remaining 10 medicines which had alternative suppliers or formulations, CHMP recommended maintaining the marketing authorisations and requested the marketing authorisation holders to remove BV as a manufacturing site. Subsequently on 16 March 2012, the review of the Caelyx and Ceplene was also released. CHMP recommended that the manufacturing processes of both medicines be transferred from BV to alternative facilities whilst maintaining the marketing authorisations as both medicines were considered to be essential for patients. CHMP also considered the fact that no concerns have been raised from the safety monitoring of these medicines.

In February 2012, there are 10 registered pharmaceutical products manufactured by BV in Hong Kong but 9 of them are no longer marketed. Only Caelyx Conc for Infusion 2mg/ml (HK-43397) is available in Hong Kong as it is an essential medicine with no alternatives. As reported in Issue No. 26 of Drug News, 2 letters were sent to healthcare professionals in 2011 and press release was issued on 23 November 2011 following the release of quality assurance problems at BV by various countries. DH will keep vigilant against any updated news.

EU: Benefit-risk balance of orlistat-containing medicines remained positive

On 16 February 2012, CHMP announced that it had completed its review on the possible risk of severe liver injuries associated with orlistat-containing medicines. The associated risk of liver-related side effects with orlistat had been under close review by CHMP since 2001. In August 2011, at the request of the European Commission, CHMP reviewed all available information including data from post-marketing surveillance and studies and made the following observations:

- There was no strong evidence that orlistat increased the risk of severe liver injury, and there was no known mechanism by which orlistat was expected to cause liver disorders.
- Given the large number of users, the number of

reported severe liver reactions in orlistat users was below the background rate expected in these people.

- The population-based studies suggested that obesity might be associated with a higher risk of liver disease.

CHMP concluded that the benefit of these medicines remained to outweigh their risks in treating obese or overweight patients with a body mass index of 28 kg/m2 or above and recommended to harmonise the product information of all orlistat-containing medicines on the possible rare liver-related side effects.

In Hong Kong, there are four registered pharmaceutical products containing the anti-obesity drug orlistat and are prescription medicines. Safety alert of the sporadic cases of liver injury among patients taking orlistat had been issued by FDA and SFDA as reported in Issue No. 8 and 17 of Drug News. In response, press release and a letter to healthcare professionals were issued on 27 May 2010. The matter had been discussed in the Registration Committee of Pharmacy and Poisons Board on 4 October 2010 and the Committee decided that the package insert of orlistat-containing products have to include the warning of severe liver injury. DH will keep vigilant against any relevant updated news.

EU: Recommendations for aliskiren-containing medicines with new contraindications and warnings

Further to the initiation of a review of aliskiren-containing medicines by different health authorities following the termination of ALTITUDE study as reported in Issue No. 26 of Drug News, EMA finalised the review on 17 February 2012. EMA concluded that aliskiren-containing medicines should be contraindicated in patients with diabetes or moderate to severe renal impairment taking angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). In addition, it also recommended including a warning that the combination of aliskiren and ACE inhibitor or ARB was not recommended in all other patients. The recommendation was based on a review of data from spontaneous reports of suspected adverse drug reactions and different studies including the ALTITUDE study. It was concluded that a risk of adverse outcomes (hypotension, sycope, stroke, hyperkalaemia and changes in renal function, including acute renal failure) in patients (especially in diabetic patients and those with renal impairment) treated with a combination of aliskiren, ACE inhibitors or ARBs could not be excluded.

In Hong Kong, there are 10 registered pharmaceutical products containing aliskiren and are prescription medicines. Aliskiren is indicated for treatment of essential hypertension. DH issued letters to inform healthcare professionals on 21 December 2011 after the notification by Novartis about the early termination of the ALTITUDE study. In view of the EMA's conclusion, another letters were sent to healthcare professionals on 20 February 2012. The matter had been discussed in the Registration Committee of the Pharmacy and Poisons Board. The Committee decided that the sales packs or package inserts of the products should include information that the combination of aliskiren with ACEIs or ARBs is contraindicated in patients with diabetes mellitus or renal impairment (GFR <60ml/min/1.73m^2). The combination of aliskiren with an ACEI or ARB is also not recommended in all other patients. In addition, aliskiren is not recommended in patients with severe renal impairment (GFR <30ml/min/1.73m^2).

EU: Benefit-risk balance of all antifibrinolytic medicines for a restricted range of indications remained positive

On 17 February 2012, EMA recommended to lift the suspension of the marketing authorisations for systemic formulations of aprotinin-containing medicines in EU. This followed a full review of the benefits and risks of all antifibrinolytic medicines which was initiated after the release of final results of the BART study. After reviewing different relevant clinical studies, scientific literature, reports of side effects and comments from the CHMP's scientific advisory group, CHMP considered that the overall data available suggested the benefits of aprotinin were greater than its risks in the restricted indication and the BART study's results were unreliable in view of the shortcomings on the study methodology. In addition, CHMP did not identify any new safety concerns for other antifibrinolytic medicines, including aminocaproic acid and tranexamic acid. However, it only recommended a restricted list of indications as there was very limited information on some of the conditions that these

medicines were used to treat. For tranexamic acid containing products, CHMP concluded that the evidence supported the use of tranexamic acid in the prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year, including haemorrhage caused by general or local fibrinolysis such as:

- menorrhagia and metrorrhagia;
- gastrointestinal bleeding;
- haemorrhagic urinary disorders further to prostate surgery or surgical procedures affecting the urinary tract;
- ear, nose and throat surgery (adenoidectomy, tonsillectomy, dental extractions);
- gynaecological surgery or disorders of obstetric origin;
- thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery;
- management of haemorrhage due to the administration of a fibrinolytic agent.

In Hong Kong, there is no systemic formulation of aprotinin-containing product registered, nor any aminocaproic acid-containing product registered. There are 26 tranexamic acid-containing pharmaceutical products registered and are prescription medicines. They are used for the management of haemorrhage and hereditary angioedema. DH will keep vigilant against any updated news from other regulatory authorities.

EU: Dose recommendations for anti-tuberculosis medicines used in children

On 17 February 2012, CHMP concluded after its review that it agreed with the WHO dosing recommendations for the following first-line anti-tuberculosis medicines in children above 3 months:

- Ethambutol: 20 (15-25) mg/kg
- Isoniazid: 10 (10-15) mg/kg
- Pyrazinamide: 35 (30-40) mg/kg
- Rifampicin: 15 (10-20) mg/kg

CHMP also acknowledged the WHO conclusion that no dosing recommendation could be made in children less than 3 months because of the lack of specific data.

The review was triggered as WHO recognised from pharmacokinetic data that prescribing these drugs in children according to weight-based dosing regimens derived from corresponding adult weight might lead to sub-optimal dose and thus recommended changes to dosing.

In Hong Kong, there are 6 ethambutol, 15 isoniazid, 7 pyrazinamide and 30 rifampicin-containing pharmaceutical products registered respectively and all are prescription medicines. The EMA/WHO dosing recommendation is in line with current drug reference. DH will keep vigilant against any updated safety news on this issue.

UK: Lot recall of Adrenaline (Epinephrine) 1:10,000 1x10ml Ampoule by Aurum Pharmaceuticals Limited

On 23 February 2012, Aurum Pharmaceuticals Ltd. conducted a recall of a lot (lot number 1255398) of Adrenaline (Epinephrine) 1:10,000 1x10ml Ampoule because there was a labelling error on the carton. The total adrenaline content of each ampoule on the carton was expressed as '100 micrograms in 10ml', whereas it should be expressed as '1mg in 10ml'. According to the company, only a very small number of units had been distributed beyond wholesaler level in UK.

In Hong Kong, Adrenaline Inj 1 in 10,000 (HK-58785) is registered by Luen Cheong Hong Ltd. It is indicated for advanced life support in critical conditions such as anaphylactic shock and acute asthma**.** According to the company, the product had never been imported nor marketed in Hong Kong.

US: Important safety label changes to cholesterol-lowering statin drugs

This is a follow-up to the news related to Zocor (simvastatin) and the risk of muscle injury as reported in Issues No. 20 and 26 of Drug News. On 28 February 2012, FDA approved the label changes for the class of cholesterol-lowering statin drugs based on its comprehensive review. The routine periodic monitoring of liver enzymes was replaced with assessment of liver enzymes before starting statin therapy and as clinically indicated thereafter. In addition, information about the potential for generally non-serious and reversible cognitive side

effects and reports of increased blood sugar and glycosylated hemoglobin (HbA1c) levels were added. Healthcare professionals were advised to stop statin therapy when serious liver injury with clinical symptoms developed during treatment and not to restart the therapy if an alternate etiology could not be found.

Following the label revisions for simvastatin-containing medicines in June 2011, a literature review of drug-drug interactions with lovastatin was conducted because of its comparable physicochemical and pharmacokinetic properties with simvastatin. The lovastatin label was subsequently updated with new contraindications and dose limitations when it was taken with certain medicines that could increase the risk for muscle injury. Healthcare professionals were advised to follow the recommendations in the lovastatin label when giving prescriptions. Public were reminded to seek advice from their healthcare professional for any questions or concerns about statins.

In Hong Kong, there are around 241 registered pharmaceutical products which belong to the class of statins and 11 of them contain lovastatin. All are prescription medicines and they are indicated for hypercholesterolemia. In view of FDA's recommendation, a letter was sent to healthcare professionals on 29 February 2012. The matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Safety information update on ondansetron about the risk of abnormal heart rhythms

Background:

Ondansetron is a 5-HT3-receptor antagonist and there are a total of 24 ondansetron-containing products registered in Hong Kong. They are all prescription medicines and are indicated for nausea and vomiting associated with cancer chemotherapy and/or radiotherapy; prevent delayed emesis following chemotherapy; and prophylaxis and/or postoperative nausea and vomiting.

Major concerns:

In September 2011, FDA notified healthcare professionals of an ongoing safety review for the anti-nausea drug Zofran (ondansetron and ondansetron hydrochloride). Ondansetron might increase the risk of developing prolongation of the QT interval of the electrocardiogram, which could lead to an abnormal and potentially fatal heart rhythm, including Torsade de Pointes. Patients at particular risk for developing Torsade de Pointes included those with underlying heart conditions, such as congenital long QT syndrome, those who were predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that led to QT prolongation.

In Hong Kong, Department of Health had reported the risk of abnormal heart rhythms associated with the use of Zofran (ondansetron) in the website of Drug Office on 16 September 2011 and issued a letter to healthcare professionals on the same day. The safety news was also reported in Issue No. 24 of Drug News.

Actions of overseas drug regulatory authorities:

US FDA required the manufacturer of Zofran (GlaxoSmithKline) to conduct a thorough QT study to assess the potential for the drug to prolong the QT interval, and the results were expected to be available in the summer of 2012. Although the US approved Zofran labels already contained information about the potential for QT prolongation, the labels were being revised to include a warning to avoid its use in patients with congenital long QT syndrome because these patients were at particular risk for Torsade de Pointes. Recommendations for ECG monitoring in patients with electrolyte abnormalities (e.g. hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmias, or those taking other medications that could lead to QT prolongation, were also being included in the labels under “Electrocardiographic Changes” of “Warnings and Precautions” section.

It is noted that information regarding the ECG changes associated with the use of ondansetron was already available in the latest Summary of Product Characteristics of Zofran in UK.

Local regulatory actions:

The safety concerns and the relevant control on ondasetron of various regulatory authorities was discussed in the meeting of the Registration Committee. To ensure the safe use of registered pharmaceutical products containing ondansetron, the sales pack label and/or package insert of the products should include safety information on risk of QT prolongation and Torsade de Pointes such as:

"Rarely, transient ECG changes including QT interval prolongation have been reported in patients receiving ondansetron. In addition, postmarketing cases of Torsade de Pointes have been reported in patients using ondansetron. Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc. These conditions include patients with electrolyte abnormalities, with congenital long QT syndrome, or patients taking other medicinal products that lead to QT prolongation."

Safety information update on fluoxetine and paroxetine about the risk of congenital heart defects in an unborn child

Background:

Fluoxetine and paroxetine are selective serotonin reuptake inhibitors (SSRIs) and there are 28 fluoxetine and 13 paroxetine-containing pharmaceutical products registered in Hong Kong. They are all prescription medicines indicated for depression; obsessive compulsive disorder; panic disorder with or without agoraphobia; social anxiety disorder / anxiety; post-traumatic stress disorder; premenstrual dysphoric disorder; and bulimia nervosa.

Major concerns:

The MHRA and the Pharmacovigilance Working Party of EMA conducted a meta-analysis on seven published clinical studies to assess the risk of congenital cardiac defects with fluoxetine use during the first trimester (three months) of pregnancy. Cardiac defects were reported in five of these seven studies and the meta-analysis of these five studies suggested a small increased risk of cardiac congenital defects (odds ratio =1.43; 95% confidence interval= 0.83 - 2.47). Furthermore, while the risk of congenital cardiac defects is approximately 1 per 100 pregnancies, the meta-analysis results of 5 studies suggested the risk of congenital cardiac defects with maternal fluoxetine use was in the region of 2 per 100 pregnancies, which was similar to that for paroxetine. MHRA had also reviewed data for paroxetine and the results suggested that there was an increased risk of all malformations, particularly cardiovascular, in infants exposed to paroxetine during the first trimester of pregnancy.

In Hong Kong, Department of Health had reported the risk of congenital heart defects associated with the use of fluoxetine in the website of Drug Office on 14 September 2011 and issued a letter to healthcare professionals on the same day. The safety news had also been reported in Issue No. 23 of Drug News.

Actions of overseas drug regulatory authorities:

In the UK, the Summary of Product Characteristics for all fluoxetine-containing products were updated with the appropriate warning about the increased risk of cardiovascular defects associated with the use of fluoxetine during the first trimester of pregnancy and the Summary of Product Characteristics for all paroxetine-containing products were updated with the appropriate warning about the increased risk of congenital malformations, particularly cardiovascular (e.g., ventricular and atrial septum defects), associated with the use of paroxetine during the first trimester.

It is noted that information regarding the risk of cardiac congenital defects associated with the use of fluoxetine and paroxetine in the first trimester was already mentioned in the Pregnancy section of the FDA approved Product Information of Prozac (fluoxetine) and Paxil (paroxetine) in the US.

Local regulatory actions:

The safety concerns and the relevant control on fluoxetine and paroxetine in the UK and the US were discussed in the meeting of the Registration Committee. To ensure the safe use of registered pharmaceutical products containing fluoxetine and paroxetine, the sales pack label and/or package insert of the products should be updated to include the appropriate safety information based on the epidemiological studies, examples of wordings to be used are:

"Some epidemiological studies suggest an increased risk of cardiovascular defects associated with the use of fluoxetine during the first trimester of pregnancy.", and "Some epidemiological studies suggest an increased risk of congenital malformations, particularly cardiovascular (e.g., ventricular and atrial septum defects), associated with the use of paroxetine during the first trimester."

Drug Recall

Recall of Centiplex-B Tab (HK-58444) and Abacod Cod Liver Oil Cap (HK-59342)

On 1 February 2012, DH instructed a licensed drug wholesaler, Allways (Germany) Medicine Ltd. (Allways), to recall from consumers two unregistered pharmaceutical products namely Centiplex-B Tab and Abacod Cod Liver Oil Cap (100's and 300's) as the products bore unapproved labels and rendered them unregistered. Both products are over-the-counter medicines as dietary supplements.

The matter came to light upon the DH's investigation into a public enquiry about the products. Investigation revealed that Allways was the product registration certificate holder of the two products. Allways had not authorized any person to import and sell Centiplex B-Tab and Abacod Cod Liver Oil Cap 300's. Allways imported unlabelled cod liver oil cap 100's and transferred them to W&S International Medicine Ltd (W&S), an unlicensed pharmaceutical product trader. Subsequently, the unregistered products were packed with unapproved labels and sold to local pharmacies by W&S.

DH closely monitored the recall and had not received any adverse event report in connection with the products. Press statement was issued on the same day.

Recall of Uni-Betasone 0.1% Cream (HK-58723)

On 7 February 2012, DH instructed a licensed drug manufacturer, Universal Pharmaceutical Laboratories Ltd. (Universal), to recall from shelf all batches of Uni-Betasone 0.1% Cream because of suspected quality defect. Uni-Betasone contains betamethasone which is used for the treatment of inflammatory skin disorders. It is a prescription medicine which can only be sold under the supervision of a pharmacist.

During DH's routine inspection of Universal, a sample of the above was drawn for end product analysis. Subsequently, the Government Laboratory found the product contained 1.2mg/g betamethasone instead of just 1mg/g betamethasone, meaning that the steroid content had actually fallen outside the registered specifications of the drug.

According to Universal's trade record, 537 bottles of Uni-Betasone 0.1% Cream had been supplied to local pharmacies and private doctors. DH closely monitored the recall and had not received any adverse event report in connection with the product. Press statement was issued on the same day. The certificate holder applied to cancel its registration and so the product was no longer registered since 11 April 2012.

Selling unregistered pharmaceutical products is an offence under the Pharmacy and Poisons Ordinance (Cap 138). The maximum penalty is a fine of $100,000 and two years' imprisonment.

Selling any drug not of the nature, substance or quality demanded by the purchaser is an offence under Section 52(1) of the Public Health and Municipal Services Ordinance (Cap 132). The maximum penalty involved is $10,000 and three months' imprisonment.

Drug Incident

Warning on slimming products found with undeclared and banned drug ingredients

In February 2012, DH appealed to the public not to buy or consume three slimming products called Xiu Zhi Su L-Carnitine Slimming Capsule (秀の素左旋肉碱溶脂减肥膠囊), Sheng Yuan Fang (生源坊) and Lexscl Fat Rapid Loss Capsule as they were found to contain undeclared and banned drug ingredients that may cause serious side effects.

For the first two cases, DH received notifications from the HA about two women feeling unwell after consumption of slimming products. While one patient obtained her product from the Internet, the source of product from another patient could not be verified. The details of these two cases are listed as follows.

Drug Incident

Patient	Slimming products consumed	Symptoms developed	Drug ingredients detected in laboratory test
21-year old woman	Xiu Zhi Su L-Carnitine Slimming Capsule (秀の素左旋肉碱溶脂减肥膠囊)	shortness of breath and palpitation	Sibutramine and phenolphthalein
53-year old woman	Sheng Yuan Fang (生源坊)	insomnia and psychiatric symptoms including suicidal ideation and auditory hallucination	Sibutramine, phenolphthalein and sildenafil

For the third case, it was discovered through DH's surveillance programme that the slimming product Lexscl Fat Rapid Loss Capsules was sold on the Internet. On 17 February 2012, a joint operation was conducted by DH and the Police resulting in the arrest of a 30-year-old woman for illegal sale of this product. Laboratory test findings revealed that the product contains sibutramine and phenolphthalein.

Sibutramine is a Part I poison and was once a western medicine used as appetite suppressant. Since November 2010, products containing sibutramine had been banned because of the increased cardiovascular risk. Phenolphthalein was another banned drug. It was once used for treating constipation but has been banned for its possible cancer-causing effect. Products containing sibutramine or phenolphthalein are banned and are not accepted for registration as pharmaceutical products in Hong Kong.

Sildenafil is also a Part I poison used for treating male sexual dysfunction. Its side effects include low blood pressure, headaches, vomiting, dizziness, and transient vision disturbances. It may interact with some drugs (such as nitroglycerin for treatment of angina) and cause decrease in blood pressure to dangerous levels. Improper use of sildenafil may pose serious health risks, especially for patients with heart problems.

Press statements related to the three cases were issued.

Weight control should only be achieved through a good diet and appropriate exercise. People ought to consult healthcare providers for professional advice if they have questions and definitely before using any medication for weight control.

The products mentioned in the above incidents were not registered pharmaceutical products under the Pharmacy and Poisons Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. A product containing any western drug ingredient must be registered under the Ordinance before it can be sold in Hong Kong. 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 product should be destroyed, disposed or submitted to the Department's Drug Office during office hours.

Useful Contact

Drug Complaint:

Tel: 2572 2068
Fax: 2147 0457 & 2123 1996
E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920
Fax: 2147 0457
E-mail: adr@dh.gov.hk
Link: http://www.drugoffice.gov.hk/adr.html
Post: ***Pharmacovigilance Unit,***
Drug Office, Department of Health,
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon

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.