Drug News
藥 物 情 報

Issue Number 39

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in January 2013 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

Singapore: Hypersensitivity and infusion reactions related to Benlysta (Belimumab)

On 9 January 2013, Health Sciences Authority (HSA) of Singapore announced that GlaxoSmithKline (GSK) informed healthcare professionals on the association of hypersensitivity and infusion reactions with Benlysta (Belimumab). It was shown that approximately 0.9% of patients in clinical trials developed hypersensitivity and serious infusion reactions including anaphylactic reaction, bradycardia, hypotension, angioedema and dyspnoea. Post-marketing reports concerning serious acute hypersensitivity reactions, some of which appear to have been delayed beyond the typical 1 to 2 hours seen in previous trials, had also been identified. Healthcare professionals were therefore advised to keep their patients under clinical supervision for a prolonged period of time (for several hours) following infusions, at least the first two infusions, and to inform patients of the potential risk, the seriousness of such reactions and the importance of seeking medical attention.

In Hong Kong, two belimumab-containing pharmaceutical products are registered, namely Benlysta Powder for Concentrate for Solution for Infusion 120 mg (HK-61384), and Benlysta Powder for Concentrate for Solution for Infusion 400 mg (HK-61385). Both are prescription medicines registered by GSK Ltd. and are indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus. Relevant safety information on hypersensitivity and infusion reactions have been included in the approved package inserts. The Department of Health (DH) will keep vigilant on any safety updates of the products and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

US: Lower recommended doses for bedtime use of zolpidem due to the next-morning impairment of certain activities

On 10 January 2013, the Food and Drug Administration (FDA) of the US notified the public of new information about zolpidem. FDA recommended that the bedtime dose be lowered because new data showed that blood levels in some patients may be high enough the next morning to impair activities that required alertness, including driving. This announcement focused on zolpidem products approved for bedtime use. Data showed that the risk for next-morning impairment was highest for patients taking the extended-release forms of these drugs (Ambien CR and generics). Women appeared to be more susceptible to this risk because they eliminated zolpidem from their bodies slower than men.

FDA therefore required the manufacturers of all zolpidem products to lower the recommended dose. FDA advised that the recommended dose of zolpidem for women should be lowered from 10mg to 5mg for immediate-release products (Ambien, Edluar, and Zolpimist) and from 12.5mg to 6.25mg for extended-release products. Whereas for men, the labelling should recommend healthcare professionals to consider prescribing the lower doses (5mg for immediate-release products and 6.25mg for extended-release products).

In Hong Kong, there are 14 registered pharmaceutical products containing zolpidem which include immediate-release 5mg or 10mg tablets and modified-release 6.25mg or 12.5mg tablets, and they are prescription medicines indicated for the treatment of insomnia. Zolpidem is also controlled as a psychotropic substance internationally including in Hong Kong. In view of

FDA's recommendations, a letter to healthcare professionals was issued on 11 January 2013. 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.

EU: Update and review on combined oral contraceptives

On 11 January 2013, European Medicines Agency (EMA) issued an update about combined contraceptives and their association with venous thromboembolism (VTE). It was well-established that combined contraceptives carried a very rare risk of blood clots, and that the risk differed between different types of combined contraceptives. These products are constantly and rigorously kept under close monitoring and there was no evidence yet to suggest any change to the known safety profile of any combined contraceptives marketed.

On 28 January 2013, EMA was asked by France to review newer generations combined oral contraceptives to determine whether there was a need to restrict the use of these medicines to women who could not take other combined oral contraceptives. France made the request amid recent initiatives to reduce the use of newer generations combined oral contraceptives by French women in favour of using second-generation oral contraceptives. There was a higher risk for newer generations contraceptives compared with older generations contraceptives. Information about the risks of VTE was included in leaflets for patients and prescribers, and had been continuously updated. EMA's Pharmacovigilance Risk Assessment Committee (PRAC) would be reviewing the newer generations combined oral contraceptives to give its opinion on whether the currently available product information provided the best information possible for patients and doctors to take appropriate healthcare decisions.

In Hong Kong, the combined oral contraceptives are registered pharmaceutical products. The above-mentioned contraindications and precautions have been included in the package inserts of these products. DH will keep vigilant on any safety updates of the drugs and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

Canada: New labelling information for all botulinum toxin products

On 21 January 2013, Health Canada announced that in order to help prevent medication errors with the use of botulinum toxin products, all manufacturers of these products were requested to revise their product labels so as to reflect that each product had its own individual potency and as such, was not interchangeable with other botulinum products. The labelling changes were due to a risk evaluation of the active ingredients (Clostridium botulinum toxin type A and type B) within these products. Botulinum toxins were produced by different manufacturing processes, were obtained by different techniques and were derived from different Clostridium strains. As a result of these differences, these products could not be interchanged as these changes could cause unexpected side-effects.

In Hong Kong, six pharmaceutical products containing botulinum toxin are registered, namely Dysport for Inj 500 Units (HK-36983), Botox for Inj 100 Units (HK-41906), Botox for Inj 200 Units (HK-60427), Btxa for Inj 50 Units (HK-51582), Btxa for Inj 100 Units (HK-49886) and Siax Inj 100 Units (HK-56847). They are prescription medicines indicated for the treatment of blepharospasm, hemifacial spasm and strabismus. In view of Health Canada's recommendations, a letter to healthcare professionals was issued on 22 January 2013. DH will keep vigilant on any safety updates of the drugs and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

Canada: New statins labeling update on the risk of increased blood sugar levels and diabetes

On 24 January 2013, Health Canada informed Canadians of a labelling update for all cholesterol-lowering drugs ("statins") regarding the risk of increased blood sugar levels and a small increased risk of diabetes among patients already at risk for the disease. Based on the review of all available data, Health Canada concluded that the risk of

diabetes appeared to be mainly in patients with pre-existing risk factors for diabetes, such as high levels of glucose or triglycerides, obesity or high blood pressure. Health Canada continued to believe the overall cardiovascular benefits of statin drugs in reducing blood cholesterol outweigh their risks. A new warning about the increased blood sugar levels and the risk of diabetes, including information on how to identify high-risk patients, had been added to the drug labels for the statins currently marketed in Canada.

In Hong Kong, there are 239 registered pharmaceutical products which belong to the class of statins. All are prescription medicines indicated for hypercholesterolemia. The risk of increased blood sugar levels had been reported in Issues No. 28 and 37 of Drug News, whereas other safety alerts had been reported in Issues No. 20, 26 and 29 of Drug News. The matters had been discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The Committee decided that the sales pack or package insert of following pharmaceutical products should be updated to include the appropriate safety information, examples of wordings to be used are:

A. Statins-containing products:

- "It is recommended that liver function tests should be performed before the initiation of [brand name], and thereafter when clinically indicated."
- "There have been rare postmarketing reports of cognitive impairment associated with statin use. These cognitive issues have been reported for all statins. The reports are generally nonserious and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks)."
- "Increases in HbAlc and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors."

B. Atorvastatin-containing products:

- "Co-administration of strong CYP3A4 inhibitors should be avoided if possible. In cases where co-administration of these medicinal products with atorvastatin cannot be avoided, lower starting and maximum doses of atorvastatin should be considered and appropriate clinical monitoring of the patient is recommended."
- "In patients taking telaprevir, concomitant use of atorvastatin should be avoided." (Also applicable for telaprevir-containing products)
- "The dose of atorvastatin should not exceed 40mg daily when taking with boceprevir and close clinical monitoring is recommended." (Also applicable for boceprevir -containing products)

C. Simvastatin-containing products:

- "Simvastatin is contraindicated with strong CYP3A4 inhibitors, as well as gemfibrozil, ciclosporin and danazol."
- "Do not exceed 20mg simvastatin daily with amiodarone." (Also applicable for amiodarone-containing products)
- "Cases of myopathy/rhabdomyolysis have been observed for simvastatin co-administered with lipid-modifying doses (≥ 1g/day) of niacin. The dose of simvastatin should not exceed 20mg daily in patients receiving concomitant medication with niacin (nicotinic acid) ≥ 1g/ day." (Also applicable for niacin-containing products)
- "Cases of myopathy, including rhabdomyolysis, have been reported with simvastatin coadministered with colchicine. Caution should be exercised when prescribing simvastatin with colchicine." (Also applicable for colchicine-containing products)

D. Lovastatin-containing products:

- "Lovastatin is contraindicated with strong CYP3A4 inhibitors."
- "The combined use of lovastatin with gemfibrozil or ciclosporin should be avoided."
- "The dose of lovastatin should not exceed 20mg daily in patients receiving concomitant medication with danazol, diltiazem, verapamil or dronedarone."
- "The dose of lovastatin should not exceed 40mg daily in patients receiving concomitant medication with amiodarone."

"Grapefruit juice should be avoided in patients taking lovastatin."

E. Rosuvastatin-containing products:

- "The concomitant use with protease inhibitors is not recommended."
- "In JUPITER study, there was a significantly higher frequency of diabetes mellitus reported in patients taking rosuvastatin (2.8%) versus patients taking placebo (2.3%). Mean HbAlc was significantly increased by 0.1% in rosuvastatin-treated patients compared to placebo-treated patients. The number of patients with a HbAlc > 6.5% at the end of the trial was significantly higher in rosuvastatin-treated versus placebo-treated patients."

F. Products containing HIV protease inhibitors:

- "Co-administration of atorvastatin should be avoided. In cases where co-administration of atorvastatin cannot be avoided, lower starting and maximum doses of atorvastatin should be considered and appropriate clinical monitoring of the patient is recommended."
- "Concomitant use of lovastatin or simvastatin is contraindicated. Rosuvastatin is not recommended to be used with protease inhibitors." (Also applicable for boceprevir-containing and telaprevir-containing products)

US: Potential risk of liver injury with Samsca (tolvaptan)

Following the previous announcement by the Medicines and Healthcare Products Regulatory Agency of UK on the risk of rapid increases in serum sodium as reported in Issue No. 29 of Drug News, Otsuka and FDA notified healthcare professionals of cases of significant liver injury associated with the use of Samsca on 25 January 2013. In a double-blind, 3-year, placebo-controlled trial in about 1,400 patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) and its open-label extension trial, 3 patients treated with the drug developed significant increases in serum alanine aminotransferase with concomitant, clinically significant increases in serum total bilirubin. In the trials the maximum daily dose of Samsca administered (90mg in the morning and 30mg in the afternoon) was higher than the maximum 60mg daily dose approved for the treatment of hyponatremia. An external panel of liver experts assessed these 3 cases as being either probably or highly likely to be caused by tolvaptan. These findings indicated that Samsca had the potential to cause irreversible and potentially fatal liver injury. Samsca was not approved for the treatment of ADPKD. Healthcare providers should perform liver tests promptly in patients who reported symptoms that may indicate liver injury. If hepatic injury was suspected, Samsca should be promptly discontinued, appropriate treatment should be instituted, and investigations should be performed to determine probable cause.

In Hong Kong, Samsca Tablet 15mg (HK-59910) and 30mg (HK-59911) are registered by Otsuka Pharmaceutical (HK) Ltd. and are prescription medicines. They are indicated for the treatment of euvolaemic and hypervolaemic hyponatraemia including in heart failure, syndrome of inappropriate antidiuretic hormone secretion, and cirrhosis. Letters to healthcare professionals were issued on 2 April 2012 and 28 January 2013 respectively. The matters had been discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The Committee decided that the sales pack or package insert should be updated to include the appropriate safety information, examples of wordings to be used are:

- "increases in serum sodium which are too rapid can be harmful and cause osmotic demyelination, resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma, or death;"
- "close monitoring of serum sodium during tolvaptan treatment is recommended, especially in patients with very low serum sodium (< 120 mmol/L) at baseline or in those at high risk of demyelination syndromes - for example, those with hypoxia, alcoholism, or malnutrition;"
- "sodium correction that exceeds 6 mmol/L during the first 6 hours of administration or 8 mmol/L during the first 6 – 12 hours may be too rapid; in such patients close monitoring of serum sodium and administration of hypotonic fluid is recommended;"

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- "if the increase in serum sodium exceeds 12 mmol/L in 24 hours, or 18 mmol/L in 48 hours tolvaptan treatment should be interrupted or discontinued and followed by administration of hypotonic fluid;"
- "co-administration of tolvaptan with medicines with a high sodium content or with other treatments for hyponatraemia (for example normal or hypertonic saline) is not recommended;" and
- "the effect of vasopressin analogues such as desmopressin may be attenuated in patients using them to prevent or control bleeding when given with tolvaptan."

EU / Canada / Australia: Safety review of Diane 35 and its generics

On 31 January 2013, EMA announced that the French medicines agency (ANSM) planned to suspend the marketing authorisation for Diane 35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms) and its generics for acne treatment in France within 3 months. In France, these medicines were only authorised for the treatment of acne. However, they were also authorised for the treatment of acne in women who wished to receive oral contraception, as well as for the treatment of other skin conditions, in a number of other Member States in the European Union (EU). The announcement in France came after a review by ANSM that Diane 35 and its generics carried a risk of thromboembolism which had been well known for many years, and while their effectiveness in treating acne was only moderate and with alternatives available.

Although Member States could take unilateral action to suspend the marketing authorisation of a medicine, European legislation required that there was a coordinated European approach in these instances. France had already indicated that it would ask EMA to carry out a European-wide review of Diane 35 and its generics. EMA's PRAC would evaluate all evidence on the benefits and risks of these medicines and give a recommendation on whether their marketing authorisations should be varied, suspended or revoked, in the interest of all patients in the EU. After the meeting in February 2013, EMA stated it was expected that PRAC would adopt a recommendation at its May 2013 meeting.

Both Health Canada and the Therapeutic Goods Administration of Australia announced on 31 January and 5 February 2013 respectively that they were reviewing the safety information on Diane-35, and would advice and take appropriate action as necessary.

In Hong Kong, Diane-35 Tab (HK-43330) is registered by Bayer Healthcare Ltd. and there are nine registered generics. All are prescription medicines indicated for the treatment of acne; other registered indications include androgenetic alopecia, mild forms of hirsutism and contraception. The package inserts have included the precaution of blood clot. Letter to healthcare professionals was issued on 31 January 2013. DH will keep vigilant on any safety updates of the drug and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

Drug Recall

Total recall of Tredaptive (Extended Release Niacin/Laropiprant) 1g/20mg Tablet (HK-57317)

On 21 January 2013, DH endorsed a licensed drug wholesaler, Merck Sharp & Dohme (Asia) Ltd. (MSD), to conduct a total recall of Tredaptive (ER Niacin/Laropiprant) 1g/20mg Tablet (Tredaptive) from the market because new data showed that the benefits of the product no longer outweigh its risks. It is a prescription medicine which can only be sold with doctor's prescription and under the supervision of pharmacists at registered pharmacies. It is indicated for the treatment of dyslipidemia.

The recall was initiated because on 11 January 2013, EMA's PRAC considered the risks of the identical medicines Tredaptive, Pelzont and Trevaclyn were greater than their benefits and recommended the suspension of their marketing authorisations. The recommendation of PRAC was based on the results from a large, long-term study

Drug Recall

called HPS2-THRIVE, which concluded that treatment with Tredaptive together with statin therapy failed to show significant benefit on the reduction of major vascular events compared with statin therapy alone.

In Hong Kong, only Tredaptive is registered. MSD announced a global suspension of the availability of Tredaptive on 11 January 2013.

According to MSD, about 22,300 packs (size 28's) of Tredaptive were imported into Hong Kong in 2012. About 13,300 packs were supplied to pharmacies, doctors and hospitals. DH had alerted the relevant parties about the matter and closely monitored the recall. So far, DH had not received any adverse drug reaction reports related in connection with the product. A press statement was released on the same day to alert the public of the recall.

Members of the public currently receiving Tredaptive should consult healthcare professionals to review their treatment plans.

Drug Incident

Warning on oral products with undeclared drug ingredients

In January 2013, DH appealed to members of the public not to buy or consume two orally consumed products called "Chashoot"「喘舒妥納」 and "Te Xiao Feng Shi Wang"「特效風濕王」 as they were found to contain undeclared drug ingredients that are dangerous to health.

DH was notified by the Hospital Authority (HA) about the patients feeling unwell after consumption of the products. Investigation showed that both products were obtained from friends who purchased them from the Mainland. The details of these two cases are listed as follows.

Patients	Products consumed	Symptoms developed	Drug ingredients detected in laboratory test
75-year-old man	Chashoot「喘舒妥納」	high blood potassium level	prednisone, ibuprofen, piroxicam, theophylline, diazepam, trimethoprim, sulphamethoxazole and chlorpheniramine
61-year-old man	Te Xiao Feng Shi Wang「特效風濕王」	coughing, haemoptysis and shortness of breath	prednisone and non-steroidal anti-inflammatory drugs (NSAIDs): indomethacin, diclofenac, piroxicam, naproxen and ibuprofen

Prednisone is a steroid and a prescription medicine. Taking prednisone for a long time, especially in substantial dosage, can cause side-effects such as moon face, high blood pressure, high blood sugar, muscle atrophy, peptic ulcer, adrenal insufficiency and even osteoporosis.

Indomethacin, diclofenac, piroxicam, naproxen and ibuprofen are NSAIDs used to relieve pain and inflammation. Their known side-effects include gastrointestinal discomfort, nausea, peptic ulcers and renal impairment. It is well-known that users will have increased risks of developing complications like gastrointestinal ulcers, some of which may be undetected until more serious complications like gastrointestinal bleeding set in.

Theophylline is used to treat asthma. It can cause an irregular heart rate, gastrointestinal discomfort and nausea.

Diazepam is a tranquiliser. It is a prescription medicine and can cause drowsiness and dizziness.

Trimethoprim and sulphamethoxazole are antibiotics and should only be sold on a doctor's prescription and dispensed under the supervision of a pharmacist.

Chlorpheniramine is an anti-histamine commonly used for relieving allergic symptoms. The most well-known side-effect is drowsiness and, therefore, precautions should be taken while taking this medicine.

Press statements related to the cases were issued on 16 January and 18 January 2013 respectively.

Drug Incident

Public urged not to buy or consume slimming product of unknown composition and person subsequently arrested upon investigation

On 17 January 2013, DH appealed to members of the public not to buy or consume a slimming product called "Leisure 18 Slimming Coffee" 「Leisure 18 瘦身咖啡」 as it was found to contain undeclared and banned drug ingredients that are dangerous to health.

DH was notified by HA that a 24-year-old woman was hospitalized because of unstable emotions, with psychiatric symptoms of delusion and auditory hallucination, after consumption of the above slimming product. The laboratory test on the product sample revealed that it was found to contain two undeclared and banned drug ingredients, namely sibutramine and phenolphthalein.

Investigations revealed that the above product was purchased from a grocery shop located on the 1/F of Liksang Plaza, Tsuen Wan. Apart from the adulterated slimming product, a quantity of suspected Part I poisons (external creams) and unregistered pharmaceutical products (mainly vitamins) were also found at the same shop. The investigation revealed that the products were sourced from places outside Hong Kong. During the operation, a 39-year-old man was arrested for illegal possession of Part I poisons and unregistered pharmaceutical products.

Sibutramine is a Part I poison and was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned because of an increased cardiovascular risk. Phenolphthalein was once used for treating constipation but has been banned for its possible cancer-causing effect.

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.

Persons arrested for illegal sale of unregistered pharmaceutical products and Part I poisons on the Internet

In January 2013, four joint operations were conducted by DH and the Police resulting in the arrests of various persons. Press statements related to the cases were issued on the days of the operations. The details of these cases are summarized as follows.

Case No.	Products concerned	Drug ingredients	Indications / Side effects	Arrested persons
1.	Diane 35 「達英」	Cyproterone, ethinylestradiol (both Part I poisons)	* For the treatment of severe acne caused by excessive androgen in women. * Headaches, gastric upsets, nausea, a feeling of tension in the breasts, intermenstrual bleedings, changes in body weight and libido, depressive moods and chloasma.	26-year-old woman
2.	NOW Glucosamine & Chondroitin with MSM	Glucosamine	* Indicated for joint pain. * Gastrointestinal (GI) disturbances, headache, leg pain and oedema.	23-year-old man
3.	Lidiprine Cream 「利遞皮乳膏」	Lidocaine (a Part I poison)	* Commonly used as a local anaesthetic to relieve pain or desensitise skin before minor operations. * Hypersensitivity reactions.	65-year-old woman
4.	SM Capsules 「SM 瘦妹」	Sibutramine, phenolphthalein (both undeclared and banned drug substances; sibutramine is a Part I poison)	* Sibutramine was once used as an appetite suppressant, but has been banned because of its increased cardiovascular risk. * Phenolphthalein was used previously to treat constipation, but has been banned for its cancer-causing effect.	27-year-old woman

Drug Incident

Retail shops raided for selling unregistered pharmaceutical products with controlled drug ingredients

In January 2013, six joint operations were conducted by DH and the Police resulting in the shops raided for selling unregistered pharmaceutical products. Press statements related to the cases were issued on the days of the operations. The details of these cases are summarized as follows.

Case No.	Products concerned	Drug ingredients	Indications / Side effects	Locations
1.	Nurofen For Children, Nurofen for Children Singles, Nurofen Gel and Calprofen and vitamin products	Ibuprofen (a Part I poison) and Vitamins	* Ibuprofen is indicated for the relief of minor ailments such as colic, cough and colds. * GI disturbances and bleeding, peptic ulceration, rash, exacerbation of asthma, headache, dizziness and hearing disturbances are the common side effects of Ibuprofen.	Aberdeen, Central
2.	Centrum, Citracal, Caltrate, Kyolic, Tripleflex etc	Vitamins, Glucosamine	* Indicated for joint pain. * GI disturbances, headache, leg pain and oedema.	Yuen Long, Cheung Sha Wan
3.	Performa condom 「持久裝安全套」, Prolonger Desensitizing Spray	Benzocaine (a Part II poison for the first product, and a Part I poison for the second product)	* Commonly used as a local anaesthetic to relieve pain or to desensitize skin before minor operations. * Hypersensitive reaction.	Sham Shui Po
4.	Calcium & Vitamin D 「寶骨鈣」	Vitamin D	* Vitamin D is a dietary supplement. * Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia.	Jordan, Kwai Chung
5.	Trankal Capsules 「强骨力」	Dexamethasone and indomethacin (both Part I poisons)	* Dexamethasone is a steroid. Taking dexamethasone for a long time, especially in substantial dosage, can cause side-effects such as moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and even osteoporosis. * Indomethacin is used to relieve pain and inflammation. Its known side-effects include gastrointestinal discomfort, nausea, peptic ulcers and renal impairment.	Aberdeen
6.	Country Life Maxi-Hair, Now Turmeric & Bromelain, and Primaforce Yohimbine HCl	Vitamins, digestive enzymes and yohimbine (a Part I poison) respectively	* Vitamins and digestive enzymes are dietary supplements. * Yohimbine is sometimes used in the treatment of orthostatic hypotension. Side effects include anxiety, manic reactions and increased heart rate.	Fo Tan

Possession or sale of unregistered pharmaceutical products and possession or sale of Part I poisons 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. Traders trading in substances, such as Poisons or pharmaceutical products, regulated under Cap 138, should obtain the appropriate licence before trading in the substances concerned to prevent contravention of the Law.

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. 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

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Fax: 3904 1224

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Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

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Link: http://www.drugoffice.gov.hk/adr.html

Post: ***Pharmacovigilance Unit,***
Drug Office, Department of Health,
Rm 1856, 18/F, Wu Chung House,
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The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.