Drug News
藥 物 情 報

Issue Number 41

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

Drug Office is delighted to announce that from April 2013 onwards, information on legal classification and sales requirements of registered drugs are available at Search Drug Database at our website. You can click into the detailed page of a registered drug, learn the legal classification of the drug and note the requirement of its sale on whether it is a prescription only medicine, a pharmacy only medicine, or an over-the-counter medicine. Please visit our website to experience the latest update.

Safety Update

UK: Detection of crystallization in Cytarabine Injection 100mg/ml (1g/10ml)

On 6 March 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) of UK announced that Hospira UK Ltd. (Hospira) had identified the potential cause for crystallisation in one batch (batch number: Z031966AA) of Cytarabine Injection 100mg/ml (1g/10ml). Hospira determined the crystals as the active ingredient cytarabine and the most probable cause of crystallization was the introduction of dry cytarabine particles, which acted as seeds for crystal formation, during the filling process. The company informed MHRA that no adverse events had been reported in connection with this crystallisation issue. Healthcare professionals were asked to visually inspect vials for particulate matter prior to use. If crystals were found, the product should not be used.

In Hong Kong, Cytarabine Inj 10% (Hospira) (HK-35149) is registered by Hospira Ltd. It is a prescription only medicine indicated for the treatment of cancer such as acute and chronic myeloid leukaemia, acute lymphoblastic leukaemia and myelodysplasias. Detection of crystallization in the product had been released by Health Canada and was reported in Drug News Issue No. 19. According to Hospira, the affected batch had been distributed to hospitals of the Hospital Authority (HA), private hospitals and veterinary clinics since December 2012. Based on the information available, a letter to healthcare professionals was issued on 7 March 2013 to advise them to visually examine the product before use; and not to use the product if crystals are found. The Department of Health (DH) had not received any adverse event report in connection with the use of the product, and any report on problematic product found in Hong Kong. DH will keep vigilant on any safety updates of the drug and actions taken by overseas regulatory authorities.

Singapore: Update on the risk management plan for strontium ranelate (Protos®) to mitigate the risks of serious skin reactions

On 7 March 2013, the Health Sciences Authority (HSA) of Singapore updated healthcare professionals on the risk management plan (RMP) for strontium ranelate (Protos®, Servier) to mitigate the higher than reported risks of serious skin reactions in the local population. The finalised RMP included: 1) a revised package insert to include information about the higher risk of serious skin reactions such as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) in the Asian population, 2) a Patient Medication Guide to alert patients to the signs and symptoms of serious skin reactions, and 3) a Patient Care Program for the collection of data on patients newly initiated on strontium ranelate.

In Hong Kong, Protos Granules for Oral Suspension 2g, (HK-53835) is registered by Servier

HK Ltd., and is a prescription only medicine indicated for the treatment of osteoporosis in postmenopausal women to reduce the risk of fracture at spine and hips. A letter to healthcare professionals was issued on 19 March 2012 to draw their attention on the above. The risks of serious skin reactions including SJS and TEN, as well as venous thromboembolic events had been released by HSA and the European Medicines Agency (EMA), and were reported in Drug News Issues No. 23, 25 and 29. 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 pack or package insert should be updated to include the appropriate safety information, such as examples given as below:

A. Contraindications:

- *"Current or previous venous thromboembolic events (VTE), including deep vein thrombosis and pulmonary embolism."*
- *"Temporary or permanent immobilisation due to e.g. post-surgical recovery or prolonged bed rest."*

B. Special warnings and precautions for use:

i. Venous thromboembolism:

- *"When treating patients over 80 years at risk of VTE, the need for continued treatment with Protos should be re-evaluated. Protos should be discontinued as soon as possible in the event of an illness or a condition leading to immobilisation and adequate preventive measures taken. Therapy should not be restarted until the initiating condition has resolved and the patient is fully mobile. When a VTE occurs, Protos should be stopped."*

ii. Skin reactions:

- *"Life-threatening cutaneous reactions (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug rash with eosinophilia and systemic symptoms (DRESS)) have been reported with the use of Protos."*
- *"Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment and usually around 3-6 weeks for DRESS."*
- *"If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) or DRESS (e.g. rash, fever, eosinophilia and systemic involvement (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease)) are present, Protos treatment should be discontinued immediately."*
- *"The best results in managing SJS, TEN or DRESS come from early diagnosis and immediate discontinuation of any suspect drug."*
- *"If the patient has developed SJS, TEN or DRESS with the use of Protos, Protos must not be re-started in this patient at any time."*

Singapore: Calcitonin – association with malignancy and new restrictions on use

It was noted from HSA website on 12 March 2013 that Novartis informed healthcare professionals regarding a recent meta-analysis from 20 randomised controlled clinical trials (of two to five years duration) showed a small but statistically significant increase (0.7% to 2.36%) in the observed incidence of malignancies with long-term calcitonin use. No pattern of specific malignancy type(s) had been observed and a causal relationship had not been established. Based on available data, HSA considered that Miacalcic® should no longer indicated for use in osteoporosis in Singapore as the benefit-risk profile of calcitonin for this indication was unfavourable in the local context. Patients being treated for osteoporosis with calcitonin should be switched to alternative treatment during the next scheduled (or routine) appointment.

In Hong Kong, four calcitonin-containing products are registered, namely Apo-Calcitonin Nasal Spray 200IU/spray (HK-58746), Miacalcic Nasal Spray 200IU (HK-43614), Miacalcic Inj 100IU/ml (HK-27880) and Miacalcic Inj 50IU/ml (HK-28413). Apo-Calcitonin is registered by Hind Wing Co. Ltd. and the rest are registered by Novartis Pharmaceuticals (HK) Ltd., and all are prescription only medicines. The nasal spray products are indicated for neurodystrophic disorders, bone pain associated with osteolysis or osteopenia and Paget's disease of bone, whereas injectable products have additional indications for hypercalcemia and as

adjuvant therapy for acute pancreatitis. All four products are no longer indicated for the treatment of osteoporosis. The approved package inserts highlight that the treatment with calcitonin should be limited to the shortest possible time using the smallest effective dose. A letter to healthcare professionals was issued on 23 July 2012, and the concern had been reported in Drug News Issue No. 33. DH had not received any adverse event report in connection with the use of calcitonin-containing medicines. The matter had been discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board in April 2013. The Registration Committee decided that the approved indications will be restricted so that Calcitonin should no longer be used for the treatment of osteoporosis and the sales pack or package insert should be updated to include the appropriate safety information, such as an example given as below:

- *"Treatment with calcitonin should be limited to the shortest possible time using the smallest effective dose."*

US: Updates on the safety review on the risk of potentially fatal heart rhythms associated with Azithromycin (Zithromax or Zmax)

As reported in Drug News Issue No. 31, the Food and Drug Administration (FDA) of the US annnouced that it would review the study about the risks of cardiovascular death in patients treated with different antibacterial drugs. On 12 March 2013, FDA had completed such review, and warned the public that azithromycin (Zithromax or Zmax) could cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. FDA advised that healthcare professionals should consider the risk of torsades de pointes and fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events. The azithromycin drug labels had been updated to strengthen the Warnings and Precautions section with information related to the risk of QT interval prolongation and torsades de pointes.

In Hong Kong, there are 62 registered pharmaceutical products containing azithromycin and are all prescription only medicines. A letter to healthcare professionals was issued on 18 May 2012. In view of FDA's recommendations, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Canada / Singapore: TYKERB® (lapatinib ditosylate)-based regimens are less effective than HERCEPTIN® (trastuzumab)-based regimens in certain settings

On 25 March 2013, GlaxoSmithKline Inc., (GSK) in consultation with Health Canada, informed healthcare professionals the important study results concerning the efficacy of TYKERB®. Recently, there had been results reported from two comparative studies of TYKERB® in combination with chemotherapy versus HERCEPTIN® (trastuzumab) in combination with chemotherapy in human epidermal receptor type 2 positive (HER2+) metastatic breast cancer patients. Based on the results of preplanned interim analyses of these two studies, GSK advised that in patients with HER2+ metastatic breast cancer who had not received prior trastuzumab, comparative data had shown that lapatinib-based regimens were less effective than trastuzumab based treatment regimens. Prescribers were reminded that TYKERB® should not be prescribed in combination with capecitabine unless patients had progressed on prior trastuzumab therapy in the metastatic setting. GSK had updated the TYKERB® Product Monograph to include a statement that lapatinib-based regimens were less effective than trastuzumab-based regimens in certain settings.

On 6 March 2013, HSA announced that GSK notified healthcare professionals of the above findings in the clinical trials. Healthcare professionals were reminded that Tykerb® in combination with capecitabine was to be used in patients with advanced or metastatic disease with progression following prior therapy which must have included trastuzumab in the metastatic setting.

In Hong Kong, Tykerb Tab 250mg (HK-56194),

containing lapatinib, is registered by GSK Ltd. and is a prescription only medicine. One of its indication is to be used with capecitabine in patients with advanced or metastatic breast cancer whose tumours overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Regarding this issue, GSK had submitted the application to change the package insert by including the details of the clinical trials and updating the indications. In view of HSA's announcement, a letter to healthcare professionals was issued on 14 March 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.

US / EU: Incretin mimetic drugs for Type 2 Diabetes - reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas

On 14 March 2013, FDA evaluated unpublished new findings that suggested an increased risk of pancreatitis and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with incretin mimetics. These findings were based on examination of a small number of pancreatic tissue specimens taken from patients after they died from unspecified causes. FDA had asked the researchers to provide the methodology used to collect and study these specimens and to provide the tissue samples in order for FDA to further investigate potential pancreatic toxicity associated with the incretin mimetics. FDA would participate in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and National Cancer Institute's (NCI) Workshop on Pancreatitis-Diabetes-Pancreatic Cancer in June 2013 to gather and share additional information. FDA would communicate its final conclusions and recommendations when its review was completed or when FDA had additional information to report. The Warnings and Precautions section of drug labels and Patient Medication Guides for incretin mimetics had contained warnings about the risk of acute pancreatitis. FDA had not previously communicated about the potential risk of pre-cancerous findings of the pancreas with incretin mimetics, and had not concluded these drugs may cause or contribute to the development of pancreatic cancer.

On 26 March 2013, EMA also announced the above findings of an increased risk of pancreatitis and pre-cancerous cellular changes in patients with type 2 diabetes treated with incretin mimetics. The Agency's Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) were investigating the information provided by the researchers to determine the need for possible further regulatory action.

In Hong Kong, there are 15 registered products that belong to the class of incretin mimetics, which include the ingredients exenatide, liraglutide, sitagliptin, saxagliptin, linagliptin and vildagliptin. All these products are prescription only medicines indicated for diabetic mellitus. The registered package insert of the products has included safety warnings about the risk of acute pancreatitis. News regarding the risk of acute pancreatitis with Onglyza (saxagliptin) was reported in Drug News Issue No. 29, and a letter to healthcare professionals was issued on 8 March 2012. Subsequently, DH had received a local case report of suspected serious adverse drug reaction of acute pancreatitis with GalvusMet Tab 50/850mg (HK-59044) (vildagliptin/metformin) and a letter to healthcare professionals about the adverse drug reaction report was issued on 25 September 2012 to alert the professionals of the adverse event of acute pancreatitis. The association of acute pancreatitis with the use of saxagliptin had been discussed in the Registration Committee of the Pharmacy and Poisons Board in December 2012, and the Registration Committee decided that appropriate safety information should be included in the sales pack label and/or package insert of the product. In view of FDA's latest announcement, a letter to healthcare professionals was issued on 15 March 2013. Since the new information is still under evaluation, DH will keep vigilant on any safety updates of the drugs and actions taken by FDA, EMA and other overseas regulatory authorities, and will bring up to Registration Committee of the Pharmacy and Poisons Board for consideration when necessary.

Singapore: Risk of anaphylactic reaction and new contraindication in patients with clinically significant hypersensitivity to Prolia® (denosumab 60mg)

On 18 March 2013, HSA announced that GlaxoSmithKline (GSK) notified healthcare professionals that anaphylactic reaction was identified as an adverse drug reaction associated with Prolia®. In addition, clinically significant hypersensitivity to Prolia® was identified as a contraindication for use. In the postmarket setting, five spontaneously reported cases of anaphylactic reactions were identified and were considered causally related to Prolia®. No fatal outcomes were observed. To communicate this important information, the Prolia® package insert in Singapore had been updated with a new contraindication in patients with clinically significant hypersensitivity to denosumab (or any components of the product) and inclusion of anaphylactic reactions as an adverse drug reaction.

In Hong Kong, Prolia Solution for Injection in Pre-filled Syringe 60mg/ml (USA) (HK-60588) and 60mg/ml (The Netherlands) (HK-60589) are registered by GSK Ltd. They are prescription only medicines indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. GSK informed DH that they had issued a Dear Healthcare Professional Letter on 4 March 2013 to draw the attention from healthcare providers concerning the risk of anaphylactic reactions associated with Prolia. The approved package inserts of the products have included the warning on relevant safety information. So far, the DH had not received any related adverse drug reaction reports in connection with the drug. 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.

EU: Restricting use of cilostazol-containing medicines

On 22 March 2013, EMA's CHMP had recommended that the use of cilostazol-containing medicines in the treatment of intermittent claudication (i.e. a condition where poor blood supply to the leg muscles causes pain and affects the ability to walk) should be restricted with a range of new measures. The recommendations followed a review of evidence which indicated that the modest benefits of these medicines, i.e. their ability to increase the distance patients are able to walk, were only greater than their risks, in particular the risks of side effects affecting the heart or serious bleeding, in a limited subgroup of patients. CHMP recommended that cilostazol should only be used in patients whose symptoms had not improved despite prior lifestyle changes such as exercise, healthy diet and stopping smoking. In addition, cilostazol-containing medicines should not be used in patients who have suffered severe tachyarrhythmia, or recent unstable angina, heart attack or bypass surgery, or who took two or more antiplatelet or anticoagulant medicines such as aspirin and clopidogrel. Doctors should review their patients and assess the suitability of continuous cilostazol treatment.

In Hong Kong, three pharmaceutical products containing cilostazol are registered, namely Pletaal Tab 50mg (HK-47373), Pletaal Tab 50mg (Korea) (HK-51136) and Pletaal Orodispersible Tab 50mg (HK-61321). They are registered by Otsuka Pharmaceutical (HK) Ltd. and are prescription only medicines. The registered indications include the treatment of ischaemic symptoms in chronic arterial occlusion. In view of the EMA's recommendations, a letter to healthcare professionals was issued on 25 March 2013, and the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Singapore: Decrease in the potency of Tuberculin PPD RT 23 SSI 2TU

It was noted from HSA website on 27 March 2013 that Statens Serum Institute (SSI) informed healthcare professionals of a potential decrease in the potency of Tuberculin PPD RT 23 SSI 2TU. Several batches of Tuberculin PPD RT 23 SSI 2TU were tested and the test result for the product's potency after 18 months did not comply with its current registered specification for product potency. To avoid an out of stock situation of Tuberculin 2TU and in consideration of the absence of a diagnostic equivalent, the release of the lower potency batches of Tuberculin 2TU had been allowed by HSA on the basis of potency/ stability data provided and an evaluation of the clinical impact of the possible lower potency. Healthcare professionals were advised to interpret the test results with caution especially in high-risk

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individuals. Additional diagnostic tests in such high-risk individuals may be necessary to support the tuberculin test results.

In Hong Kong, Tuberculin PPD RT 23 SSI Injection 2TU/0.1ml (HK-44951), containing tuberculin, is registered by Mekim Ltd. (Mekim) and manufactured in Denmark. It is indicated for skin testing for diagnostic use in patients infected with tuberculous mycobacteria. The approved shelf life of the product is 36 months. The World Health Organization informed DH about the news announced by Danish Health and Medicines Authority on 27 November 2012, and DH issued a letter to healthcare professionals on the same day. Regarding this issue, Mekim had submitted the application to change the specification for shelf-life potency. 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

Batch recall of Honey Child Cough Syrup (HK-58852)

On 1 March 2013, DH instructed a licensed drug manufacturer, Meyer Pharmaceuticals Ltd. (Meyer), to recall from shelves one batch (batch number: 021203) of Honey Child Cough Syrup because the label was printed with wrong expiry date. Honey Child Cough Syrup is an over-the-counter medicine containing chlorpheniramine, noscapine and ammonium chloride, and is indicated for the relief of cough.

During DH's routine inspection of Meyer, it was found that the label of one batch of Honey Child Cough Syrup manufactured by Meyer was wrongly printed with expiry date as February 2015. The correct expiry date of the product should be February 2014. As a result, this batch of the product indicated a three-year shelf life while the registered shelf life of the product was actually two years. According to the Pharmacy and Poisons Regulations (Cap 138A), such an error rendered the product an unregistered pharmaceutical product.

About 300 bottles of the affected batch of Honey Child Cough Syrup had been supplied to local pharmacies and medicine stores since August 2012. DH had alerted the concerned parties about the matter and closely monitored the recall. So far, DH had not received any adverse drug reaction reports in connection with the product. A press statement was released on the same day to alert the public of the recall.

Pharmacies and medicine stores must stop supplying the said product to clients. Members of the public who are in doubt or feeling unwell after using the product should consult healthcare professionals for advice.

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

Total recall of Pharmaniaga Clarithromycin Tablet 250mg (HK-52623)

On 27 March 2013, DH instructed a licensed drug wholesaler, Healthcare Pharmascience Ltd. (HPL), to recall from shelves all batches of a pharmaceutical product, namely Pharmaniaga Clarithromycin Tablet 250mg, because an unapproved package insert was used in the product package. Pharmaniaga Clarithromycin Tablet 250mg is an antibiotic indicated for the treatment of infections.

Under the surveillance system of DH, it was found that the above product was using an unapproved package insert, which rendered the product an unregistered pharmaceutical product under the Pharmacy and Poisons Regulations (Cap 138A). The unapproved package insert had included, in addition to Pharmaniaga Clarithromycin Tablet 250mg, information of another dosage form of the product.

According to HPL, the product was supplied to private doctors and local pharmacies as well as exported to Macau. DH had alerted the concerned parties about the matter and closely monitored the recall. So far, DH had not received any adverse drug reaction reports in connection with the product. A press statement was released on the same day to alert the public of the recall.

Drug Incident

Public urged not to buy or consume unregistered pharmaceutical products

On 13 March 2013, DH appealed to members of the public not to buy or consume unregistered pharmaceutical products, including 10 slimming products, namely, "Leisure 18 Slimming Coffee" (瘦身咖啡), "7 Days Slimming Coffee" (七天享瘦), "Brazilian 7 Days Slimming Coffee" (巴西減肥咖啡), "Beauty Secret Slimming Coffee", "Body Beauty 5 Days Slimming Coffee" (美体咖啡), "Leisure 18 Slimming Mango Juice", "Leisure 18 Slimming Orange Juice", "Authentic Leisure 18 Slimming Orange Juice", "Super Slim Orange Juice" and "Coffee Fashion Slimming" (咖啡瘦身).

During DH's surveillance programme, samples of the above slimming products were obtained from various retail shops for analysis and were found to contain undeclared and banned drug ingredients that may be dangerous to health. Laboratory test on the product samples revealed that all of them contain either one or both of the banned drug ingredients (i.e., sibutramine and phenolphthalein).

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.

In response to the laboratory findings, four retail shops, three in Central and one in Wan Chai, were raided on the same day in a joint operation by DH and the Police. During the operation, apart from the slimming products mentioned above, other unregistered pharmaceutical products, including controlled medicines (containing Part I poisons and antibiotics), were found in three of the shops resulting in the arrests of three men and one woman aged between 40 and 46.

The controlled medicines found included creams that either contained tretinoin or clobetasol (steroid) with ketoconazole (antifungal) for skin disorders, non-steroidal anti-inflammatory drugs (naproxen, mefenamic acid) for the relief of pain, and amoxycillin (antibiotic) for the treatment of infections. These are prescription only medicines that should only be used under the advice of medical practitioners.

Public urged not to buy or use slimming products with banned drug ingredients

In March 2013, DH appealed to members of the public not to buy or consume two slimming products called "Li Da Dai Dai Hua Jiao Nang" (麗達代代花膠囊) and "Conting Qianweisu Slimming Herbs Capsule" (康婷纖維素) as they were found to contain undeclared and banned drug ingredients that are dangerous to health.

DH was notified by the HA about two patients feeling unwell after consumption of the products. Investigation showed that both products were purchased from the Internet website. The details of these two cases were summarized as follows:

Patients	Products consumed	Symptoms developed	Drug ingredients detected in laboratory test
23-year-old female	"Li Da Dai Dai Hua Jiao Nang" (麗達代代花膠囊)	psychiatric symptoms of auditory hallucination and delusion	sibutramine and phenolphthalein
23-year-old female	"Conting Qianweisu Slimming Herbs Capsule" (康婷纖維素)	confusion and psychiatric symptoms including auditory and visual hallucination	sibutramine and phenolphthalein

This was the second incidence of "Conting Qianweisu Slimming Herbs Capsule" and the previous news was reported in Drug News Issue No. 33.

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

Press statements related to the cases were issued on 13 March and 26 March 2013 respectively.

Retail shops raided for selling unregistered pharmaceutical products

In March 2013, three joint operations were conducted by DH and the Police against three retail shops, which were 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 were summarized as follows:

Case No.	Products concerned	Drug ingredients	Indications / Side effects	Locations
1.	Various unregistered pharmaceutical products, e.g., Kirkman Vitamin C capsules 250mg and Vitamin E capsules 100IU	Vitamins	* Vitamin supplementation for people who are at risk of deficiency. * Side effects include headache, dizziness, insomnia, gastrointestinal (GI) reactions (such as nausea, stomach pain, vomiting and diarrhoea) and hypersensitivity reactions (such as rash, pruritus).	Causeway Bay
2.	a. Counterpain Cool Analgesic Gel b. Counterpain Analgesic Balm	a. Menthol b. Menthol, methyl salicylate and eugenol	* Menthol, methyl salicylate and eugenol are commonly used for the relief of muscle pain. * One of their common side effects is skin irritation.	Mongkok
3.	Various unregistered pharmaceutical products, e.g., Primaforce Yohimbine HCl capsules and Joint Tech capsules	Yohimbine (a Part I poison), glucosamine or vitamins	* Yohimbine was sometimes used in the treatment of orthostatic hypotension. Side effects include anxiety, manic reactions and increased heart rate. * Glucosamine is indicated for joint pain. Side effects are GI disturbances, headache, leg pain and oedema.	Sham Shui Po

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.

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.

Drug Incident

Pharmacy raided for suspected illegal sale of antibiotic

On 13 March 2013, a joint operation was conducted by DH and the Police against a registered pharmacy resulting in the arrest of a 40-year-old salesman for suspected illegal sale of antibiotic.

Through the DH's surveillance programme, the pharmacy was found to be selling a bottle of topical antibiotic solution without a doctor's prescription. The antibiotic concerned contains clindamycin, which is used for the treatment of acne. Side effects include skin irritation such as swelling, itching, and peeling.

Members of the public should only use antibiotics prescribed by a doctor and follow health professionals' instructions. Inappropriate and irrational use of antibiotics provides favourable conditions for resistant microorganisms to emerge and spread.

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 is an offence under the Antibiotics Ordinance (Cap 137) and the maximum penalty is a $30,000 fine and one year's imprisonment for each offence.

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: 2186 9845
E-mail: adr@dh.gov.hk
Link: http://www.drugoffice.gov.hk/adr.html
Post: ***Pharmacovigilance Unit,***
Drug Office, Department of Health,
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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.