Drug News
藥 物 情 報

Issue Number 113

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in March 2019 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

Canada: Opsumit (macitentan) - Assessing the potential risk of liver injury

On 1 March 2019, Health Canada announced that it reviewed the potential risk of liver injury with Opsumit (macitentan) use following reports of liver injury internationally that led to an update to the United States (US) product safety information for this drug.

At the time of the review, the Canadian product safety information for Opsumit included a warning about potential effects on the liver that had been observed with the group of drugs to which Opsumit belongs. The Canadian product safety information also included requirements for blood tests to monitor liver function.

Health Canada looked at 15 Canadian reports of liver injury with Opsumit from the Canada Vigilance database. Of these reports, 14 were not found to be relevant to this review (e.g., reports that were duplicates, that did not meet the definition of liver injury, or reports where the patient had a history of liver disease). In the 1 remaining case, it was determined that the liver injury was unlikely to be linked to the use of Opsumit. Health Canada also assessed 16 international reports (1 published) that were found to be relevant to the review. There was a link between the risk of liver injury and the use of Opsumit in 1 report. The link was found to be possible in 13 reports and unlikely in 1 report. In the remaining 1 report, the link could not be assessed due to the nature of the information provided. Death was reported in 1 of the 13 cases where the risk of liver injury was found to have a possible link with the use of Opsumit. However, the death was not linked to Opsumit, but was the result of disease progression. In the majority of the reports assessed, other factors may have also caused the liver injury, such as: heart failure that results from pulmonary arterial hypertension (PAH), other conditions linked with PAH, or the use of other medications for PAH. No published studies assessing the risk of liver injury with the use of Opsumit were identified in the literature.

Health Canada's review found that there may be a link between Opsumit and liver injury. Health Canada will notify the manufacturer to update the product safety information for Opsumit in Canada in order to inform healthcare professionals and patients about the potential for liver injury.

In Hong Kong, Opsumit Tablets 10mg (HK-64419) is a registered pharmaceutical product containing macitentan. The product is registered by DKSH Hong Kong Limited, and is a prescription-only medicine. As of 8 April 2019, the Department of Health (DH) has received 8 cases of adverse drug reaction (ADR) related to macitentan, but these cases are not related to liver injury. In light of the above Health Canada's announcement, the DH issued a letter to inform local healthcare professionals to draw their attention on 4 March 2019 and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board (Registration Committee).

Singapore: Update on the recent study findings on the risk of non-melanoma skin cancer with prolonged use of hydrochlorothiazide

On 8 March 2019, the Health Sciences Authority

(HSA) of Singapore announced an update to healthcare professionals on two recent pharmacoepidemiological studies using data from Danish registries which suggested a cumulative dose-dependent association between the prolonged use of hydrochlorothiazide-containing medicines and non-melanoma skin cancer.

Hydrochlorothiazide is a diuretic that is commonly used alone or in combination with other antihypertensives for the treatment of hypertension. High cumulative usage of hydrochlorothiazide (i.e. ≥50,000mg, corresponding to 12.5mg daily for 11 years) was found to be associated with an increased risk of basal cell carcinoma (adjusted odds ratio [OR]=1.29; 95% CI=1.23-1.35) and squamous cell carcinoma (OR=3.98; 95% CI=3.68-4.31). The HSA is currently assessing the available data on this potential risk, including the two studies, and will provide an update on their regulatory recommendations upon the completion of their review.

In Hong Kong, there are 102 registered pharmaceutical products containing hydrochlorothiazide, and all products are prescription-only medicines. As of 8 April 2019, the DH has received 3 cases of ADR related to hydrochlorothiazide, but these cases are not related to skin cancer. Related news was previously issued by the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA), the HSA and Health Canada, and was reported in the Drug News Issue No. 109 and 111. The DH issued a letter to inform local healthcare professionals to draw their attention on 15 November 2018. The matter has been discussed by the Registration Committee on 16 April 2019 and decided that the DH should keep vigilant on any update from other health authorities on this issue.

Canada: TECENTRIQ (atezolizumab) - Risk of Immune-related myositis

On 13 March 2019, Health Canada announced that cases of immune-related myositis, some with a fatal outcome, have been reported in patients receiving TECENTRIQ (atezolizumab).

Myositis or inflammatory myopathies are a group of disorders sharing the common feature of inflammatory muscle injury. Dermatomyositis and polymyositis are among the most common disorders. Diagnosis is based on clinical (muscle weakness, muscle pain, skin rash in dermatomyositis), biochemical (serum creatine-kinase increase), and imaging (electromyography/ Magnetic Resonance Imaging [MRI]) features, and is confirmed with a muscle biopsy.

As of 4 February 2019, a comprehensive analysis was performed across the TECENTRIQ program and identified 51 serious and 14 non-serious cases of immune-related myositis. Of the identified serious and non-serious cases, 53 were from clinical trials and 12 from post-marketing. Of the 53 clinical trial cases, 5 were identified as category A confirmed with a muscle biopsy. There were no Canadian cases reported. Approximately 19,323 clinical trial patients and 28,975 post-marketing patients have been exposed to TECENTRIQ as of 17 November 2018. The incidence of myositis (including related terms of dermatomyositis, polymyositis, rhabdomyolysis) observed across the atezolizumab monotherapy clinical program was <0.1%. Based on the assessment of all available data, immune-related myositis is considered an important identified risk for TECENTRIQ.

Healthcare professionals are advised to:

- Hold TECENTRIQ treatment in patients with moderate or severe (Grade 2 or 3) immune-related myositis until symptoms resolve.
- Permanently discontinue TECENTRIQ treatment in patients with recurrent, severe, or life-threatening myositis (recurrent Grade 3 and Grade 4).
- Administer corticosteroids (1-2 mg/kg intravenous methylprednisolone or equivalent per day) to patients who develop severe signs of myositis, such as weakness limiting mobility, respiratory function, or dysphagia.
- For patients with severe or life-threatening myositis (Grade 3 and Grade 4) who do not improve following corticosteroid therapy, consider administration of other immunosuppressive agents as described in the American Society of Clinical Oncology Clinical Practice Guideline.

Health Canada is working with the manufacturer to

include the risk of immune-related myositis in the Canadian Product Monograph for TECENTRIQ.

In Hong Kong, Tecentriq Concentrate for Solution for Infusion 1200mg/20ml (HK-65567) is a registered pharmaceutical product containing atezolizumab. The product is registered by Roche Hong Kong Limited, and is a prescription-only medicine. As of 8 April 2019, the DH has received 25 cases of ADR related to atezolizumab, but these cases are not related to myositis. Related news was previously issued by the HSA, and was reported in the Drug News Issue No. 112. The DH issued a letter to inform local healthcare professionals to draw their attention on 26 February 2019. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee.

Canada: Pro Doc Limitée voluntarily recalls two lots of irbesartan drugs because of nitrosamine impurity

On 14 March 2019, Health Canada announced that Pro Doc Limitée was voluntarily recalling two lots of irbesartan tablets because of a nitrosamine impurity, *N*-nitrosodiethylamine (NDEA). The lots were distributed in Quebec only. The affected products were:

- IRBESARTAN (PRO DOC LIMITEE) 150 mg (lot: 604292; expiry: 10/2019)
- IRBESARTAN (PRO DOC LIMITEE) 300 mg (lot: 601795; expiry: 08/2019)

NDEA is classified as a probable human carcinogen, which means that long-term exposure could increase the potential risk of cancer. Pro Doc Limitée was conducting the recall after testing identified levels of NDEA above what is considered reasonably safe if the drug were taken over a lifetime.

The irbesartan active pharmaceutical ingredient (API) in the recalled lots was manufactured by Teva API India Ltd. An API is the active ingredient in a drug that produces an effect on the body. APIs are used in the manufacturing of finished dosage form drugs (such as pills, capsules or tablets).

In Hong Kong, the above products of IRBESARTAN (PRO DOC LIMITEE) 150 mg and IRBESARTAN (PRO DOC LIMITEE) 300 mg are not registered pharmaceutical products.

In Hong Kong, as of 8 April 2019, there are 248 registered pharmaceutical products containing valsartan (83 products), candesartan (19 products), irbesartan (62 products), losartan (67 products) and olmesartan (17 products). All products are prescription-only medicines.

Regarding impurities in sartan-containing products, a public announcement was first issued on 6 July 2018, and the DH issued letters to inform local healthcare professionals on 6 July 2018, 9 July 2018, 25 July 2018 and 3 August 2018. Related news was also previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 105, 106, 107, 108, 109, 110, 111 and 112.

Regarding the announcements issued by various overseas drug regulatory authorities on the detection of *N*-nitrosodimethylamine (NDMA) and NDEA in sartan-containing products, the following 5 valsartan products and 1 irbesartan product were affected and recalled from the Hong Kong market on 6 July 2018 and 20 December 2018 respectively: HK-61786, HK-61787, HK-61784, HK-61785, HK-60794 and HK-63378. The recalls were reported in the Drug News Issue No. 105 and 110. The DH noted that these recalls were completed.

The DH had collected samples of sartan-containing products in the local market for analysis. No NDMA and NDEA were detected.

Regarding the announcements issued by various overseas drug regulatory authorities on the detection of *N*-nitroso-*N*-methyl-4-aminobutyric acid (NMBA) in losartan, the DH endorsed the recall of 4 losartan products (HK-61932, HK-61933, HK-62634 and HK-62635) from the local market as a precautionary measure due to the potential for NMBA in the products on 11 March 2019. The DH noted that the recall was completed.

As of 8 April 2019, the DH has received 17 cases of ADR related to valsartan, candesartan, irbesartan, losartan and olmesartan. None of them is concluded to be related to the presence of

impurities such as NDMA, NDEA and/or NMBA. The DH has provided update information at Drug Office's website (www.drugoffice.gov.hk) and will keep vigilant on any safety updates on detection of impurities in sartan-containing products issued by overseas regulatory authorities.

Patients who are taking sartan-containing products should not stop taking the medicines, but should seek advice from their healthcare professionals as soon as possible for proper arrangement.

EU: EMA starts review on screening patients before treatment with fluorouracil, capecitabine, tegafur and flucytosine

On 15 March 2019, the European Medicines Agency (EMA) of the European Union (EU) announced that it has started a review of medicines containing fluorouracil (also known as 5-fluorouracil or 5-FU) and the related medicines capecitabine, tegafur and flucytosine, which are converted to fluorouracil in the body. The review will examine existing screening methods and their value in identifying patients at increased risk of severe side effects.

Fluorouracil (given by injection), capecitabine and tegafur are cancer medicines, whereas topical (applied to the skin) fluorouracil is used for various skin conditions and flucytosine is a medicine used in severe fungal infections.

It is known that some patients lack a working enzyme called dihydropyrimidine dehydrogenase (DPD) which is needed to break down fluorouracil. Prescribers may be unaware that their patients lack working DPD, and if these patients are given fluorouracil or related substances, their bodies cannot break fluorouracil down, resulting in its build-up in the blood. Build-up of high levels of fluorouracil seen with some of these medicines can lead to severe and life-threatening side effects such as neutropenia (low levels of neutrophils, a type of white blood cells needed to fight infection), neurotoxicity (damage to the body's nervous system), severe diarrhoea and stomatitis (inflammation of the lining of the mouth). Patients with a complete deficiency of DPD should therefore not be given fluorouracil, or medicines that can form it in the body.

The product information for most of these medicines states that they should not be used in patients with complete DPD deficiency. Genetic testing for DPD deficiency is recommended for most medicines used in the treatment of cancer, but systematic screening for DPD deficiency before starting treatment is not mandatory. In addition, new data on genetic testing and other DPD screening methods were recently published which may impact current recommendations.

The EMA will now assess the available data in relation to existing screening methods to detect DPD deficiency and recommend whether any changes are needed to the way these medicines are used in order to ensure their safe use. Patients who have concerns about their medicines should consult their doctor and should not stop taking their medicines without seeking medical advice.

In Hong Kong, there are 4 registered pharmaceutical products containing fluorouracil, 20 products containing capecitabine and 4 products containing tegafur. All products are prescription-only medicines. There is no registered pharmaceutical product containing flucytosine. As of 8 April 2019, the DH has received 86 cases of ADR related to fluorouracil, 37 cases related to capecitabine (of which one case is related to dihydropyrimidine dehydrogenase deficiency) and 1 case related to tegafur. The DH has not received any case of ADR related to flucytosine. In light of the above EMA's announcement, the DH issued a letter to inform local healthcare professionals to draw their attention on 18 March 2019, and the DH will remain vigilant on the conclusion of the review and any safety updates issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Singapore: Benlysta (belimumab) and risk of serious depression and/or suicidal ideation or behaviour or self-injury

On 18 March 2019, the HSA announced that GlaxoSmithKline would like to inform healthcare professionals about the risk of serious depression and/or suicidal ideation or behaviour or self-injury

associated with Benlysta (belimumab).

An imbalance in selected serious psychiatric events was reported in a recent one-year, randomised, double-blind, placebo-controlled post-marketing study of 4,003 subjects with systemic lupus erythematosus. The Benlysta package insert will be updated to include safety information on this risk in Singapore. Healthcare professionals are advised to consider if patients are at risk before treatment with Benlysta, and to continue monitoring of their patients during treatment.

In Hong Kong, Benlysta Powder for Concentrate for Solution for Infusion 120mg (HK-61384) and Benlysta Powder for Concentrate for Solution for Infusion 400mg (HK-61385) are registered pharmaceutical products containing belimumab. These products are registered by GlaxoSmithKline Limited (GlaxoSmithKline), and are prescription-only medicines. As of 8 April 2019, the DH has received 2 cases of ADR related to belimumab, but these cases are not related to depression, suicidal ideation or behaviour or self-injury.

In March 2019, GlaxoSmithKline submitted application for change of product insert for the above products to include warnings on depression and suicidality. The DH is working with the company to update the safety information of the products. Adverse effects and precautions of depression and suicide are also documented in overseas reputable drug references such as the "Martindale: The Complete Drug Reference". The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

US: FDA warns about the risks associated with the investigational use of Venclexta in multiple myeloma

On 21 March 2019, the US Food and Drug Administration (FDA) alerted healthcare professionals, oncology clinical investigators and patients about the risks associated with the investigational use of Venclexta (venetoclax) for the treatment of patients with multiple myeloma based on data from a clinical trial. Venclexta is not approved for the treatment of multiple myeloma.

The FDA reviewed data from the BELLINI clinical trial (NCT02755597, Study M14-031) evaluating the use of Venclexta combined with bortezomib, a proteasome inhibitor, and dexamethasone in patients with multiple myeloma. The interim trial results demonstrated an increased risk of death for patients receiving Venclexta as compared to the control group. On 6 March 2019, the FDA required no new patients be enrolled on the BELLINI trial. Patients who are receiving clinical benefit can continue treatment in the trial after they reconsent. More information about the BELLINI clinical trial findings can be found in the FDA website.

This statement does not apply to patients taking Venclexta for an approved indication. Patients taking Venclexta for an approved indication should continue to take their medication as directed by their healthcare professional. Venclexta is safe and effective for its approved uses.

The FDA suspended enrollment in other ongoing multiple myeloma clinical trials of Venclexta. Patients who are receiving clinical benefit can continue treatment in these trials after they reconsent. The FDA will be working directly with sponsors of Venclexta, as well as other investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The FDA will communicate any new information as appropriate.

In Hong Kong, Venclexta Tablets 10mg (HK-65284), Venclexta Tablets 50mg (HK-65283) and Venclexta Tablets 100mg (HK-65285) are registered pharmaceutical products containing venetoclax. All products are registered by Abbvie Limited, and are prescription-only medicines. As of 8 April 2019, the DH has not received any case of ADR related to venetoclax. As the review of the trial data is ongoing, the DH will remain vigilant on the results of the trial and safety update of the drug issued by the FDA and other overseas drug regulatory authorities for consideration of any action deemed necessary.

Canada: DARZALEX (daratumumab) and Hepatitis B Virus Reactivation

On 25 March 2019, Health Canada announced that

cases of hepatitis B virus (HBV) reactivation, some with a fatal outcome, have been reported in patients treated with DARZALEX.

A recent cumulative review of clinical trial and post-marketing data identified 15 cases of HBV reactivation in patients treated with DARZALEX. Ten of the 15 cases were reported as serious. Of the 10 serious cases, 2 cases had a fatal outcome. No Canadian cases of HBV reactivation related to DARZALEX treatment have been reported at the time of the cumulative analysis. As of 15 November 2018, DARZALEX has been received by approximately 4,407 patients in clinical trial settings, and an estimated world-wide post-marketing exposure of 34,316 person-years. The estimated patient exposure in Canada is 390 person-years. The overall frequency of HBV reactivation in DARZALEX clinical trials, including serious and non-serious reports, is uncommon (0.2%). The majority of clinical trial cases were considered non-serious, although fatal HBV reactivation cases have been reported in clinical trials and in the post-market setting.

DARZALEX could cause the HBV to become active again (HBV reactivation) in patients with previously stable or undetectable levels. Patients should tell their doctor if they have ever had or might now have a hepatitis B infection. Patients should contact their healthcare professional for more details on this new safety information. Patients should immediately tell their healthcare professional if they get worsening tiredness or yellowing of the skin or white part of the eyes, as these may be symptoms of HBV reactivation. Patients receiving DARZALEX should also inform their healthcare professional if they experience any other side effects.

Healthcare professionals are advised:

- HBV screening should be performed in all patients before starting treatment with DARZALEX.
- For patients with evidence of positive HBV serology, the clinical and laboratory signs of HBV reactivation should be monitored during, and for at least six months following the end of, DARZALEX treatment. Patients should be managed according to clinical guidelines.
- In patients who develop reactivation of HBV, treatment with DARZALEX, any concomitant steroids and chemotherapy should be suspended, and appropriate treatment should be instituted.
- Resumption of DARZALEX treatment in patients whose HBV reactivation is adequately controlled should be discussed with physicians with expertise in managing HBV.

Health Canada, in collaboration with Janssen Inc., will update the DARZALEX Product Monograph to include information related to the risk of HBV reactivation.

In Hong Kong, Darzalex Concentrate for Solution for Infusion 100mg/5ml (Germany) (HK-65066), Darzalex Concentrate for Solution for Infusion 400mg/20ml (HK-65067) and Darzalex Concentrate for Solution for Infusion 100mg/5ml (Switzerland) (HK-65068) are registered pharmaceutical products containing daratumumab. All products are registered by Johnson & Johnson (Hong Kong) Ltd., and are prescription-only medicines. As of 8 April 2019, the DH has received 7 cases of ADR related to daratumumab, but these cases are not related to HBV reactivation. In light of the above Health Canada's announcement, the DH issued a letter to inform local healthcare professionals to draw their attention on 26 March 2019, and the matter will be discussed by the Registration Committee.

EU: EMA confirms omega-3 fatty acid medicines are not effective in preventing further heart problems after a heart attack

On 29 March 2019, the EMA announced its confirmation that omega-3 fatty acid medicines containing a combination of an ethyl ester of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) at a dose of 1 g per day are not effective in preventing further problems with the heart and blood vessels in patients who have had a heart attack. This is the outcome of a re-examination requested by some of the companies that market the medicines concerned, following the EMA's original recommendation in December 2018.

This means that these medicines should no longer be used in this way. However, they can still be used

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to reduce levels of certain types of blood fat called triglycerides.

The review concerned omega-3 fatty acid medicines containing a combination of an ethyl ester of EPA and DHA. EPA and DHA are commonly found in fish oils.

Omega-3 fatty acid medicines have been authorised for use after a heart attack, in combination with other medicines, in several EU countries since 2000, at a dose of 1 g per day. At the time of their authorisation, available data showed some benefits in reducing serious problems with the heart and blood vessels.

The EMA's committee for human medicines, the Committee for Medicinal Products for Human Use, has re-assessed the evidence accumulated over the years on these medicines for this specific use and consulted additional experts in the field. It concluded that, although there are no new safety concerns, the effectiveness of these medicines in preventing recurrence of problems with the heart and blood vessels has not been confirmed.

The EMA concluded that the marketing authorisations of these medicines should be updated to remove this use.

Information for healthcare professionals

- Omega-3 fatty acid medicines containing a combination of an ethyl ester of EPA and DHA will no longer be authorised for secondary prevention after myocardial infarction.
- This is based on a review of all the available data on the efficacy of omega-3 fatty acid medicines in this indication.
- The review looked at results of the open-label 'GISSI Prevenzione' study performed in 1999 which supported the initial authorisation of these medicines, as well as more recent randomised controlled clinical trials, retrospective cohort studies and meta-analyses.
- The review concluded that, while a small relative risk reduction was seen in the original open label GISSI Prevenzione study, the beneficial effects were not confirmed in more recent randomised controlled trials.
- This review does not affect the authorisation of omega-3 fatty acid medicines for the treatment of hypertriglyceridaemia.

In Hong Kong, there are 3 registered pharmaceutical products in oral dosage form containing omega-3 fatty acids, namely Seven Seas Jointcare Extra Pro Capsules (HK-63558), Seven Seas JointCare Extra New Capsules (HK-63563) and Nature's Way Women's All-In-One Plus Fish Oil Cap (HK-59992). They are all classified as Not a Poison. They are not indicated for use in cardiovascular diseases.

Drug Recall

DH endorsed batch recall of four losartan-containing pharmaceutical products

On 11 March 2019, the DH endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall four products, involving seven batches, containing losartan from the market as a precautionary measure due to the potential for an impurity in the products.

The affected products were:

Product	Hong Kong Registration Number	Batch Number
Apo-Losartan Tablets 50mg	HK-61932	NK 1253
Apo-Losartan Tablets 100mg	HK-61933	NG 2092, NH 5932, NL 1460
Apo-Losartan/HCTZ Tablets 50mg/12.5mg	HK-62635	NZ 8848, NL 1441
Apo-Losartan/HCTZ Tablets 100mg/25mg	HK-62634	NZ 8845

Drug Recall

Through its surveillance system, the DH noted that Health Canada was advising that multiple lots of losartan-containing products were being voluntarily recalled because of the potential for an impurity, NMBA. NMBA is a potential human carcinogen.

Losartan-containing products are prescription medicines used to treat hypertension. According to Hind Wing, the affected batches of the above products have been supplied to private doctors and pharmacies. The DH noted that the recall was completed.

As of 8 April 2019, the DH has not received any adverse reactions related to the above affected products.

Patients who are taking the above products are advised that they should not stop taking the medicines, but should seek advice from their healthcare professionals for appropriate arrangement. Press release was posted on the Drug Office website on 11 March 2019 to alert the public of the products recall.

Drug Incident

Public urged not to buy or consume health product with doubtful composition

On 21 March 2019, the DH urged the public not to buy or consume a health product named BIONERGY as it was found to contain an undeclared controlled substance.

Acting upon intelligence, the DH collected samples of the above product for analysis. Test results from the Government Laboratory confirmed that the samples contain nortadalafil, a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138).

Nortadalafil is an analogue of tadalafil, a prescription drug ingredient used for the treatment of erectile dysfunction. Side effects of tadalafil include low blood pressure, headache, vomiting, dizziness and transient vision disturbances. It may interact with some drugs (such as nitroglycerin for the treatment of angina) and cause decrease in blood pressure to dangerous levels. Nortadalafil, being chemically similar to tadalafil, is expected to pose similar health risks.

Press release was posted on the Drug Office website on 21 March 2019 to alert the public of the drug incident.

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 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $30,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordnance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

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.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.
Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/reListRPP_index.html.

Useful Contact

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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.