Drug News
藥 物 情 報

Issue Number 156

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in October 2022 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

Australia: Peripheral neuropathy with supplementary vitamin B6 (pyridoxine)

On 4 October 2022, the Therapeutic Goods Administration (TGA) announced that adverse event reports submitted to the TGA suggested there is a lack of awareness that vitamin B6, which is present in many multivitamin and mineral supplements, can cause peripheral neuropathy. In response, the TGA has strengthened labelling requirements so products containing daily doses over 10mg of vitamin B6 must carry a warning about peripheral neuropathy.

Peripheral neuropathy is a known side effect of vitamin B6 and is characterised by tingling, burning, or numbness, usually in the hands or feet. Delayed diagnosis and continued exposure can lead to progression of neuropathy. Because of this risk, medicines containing daily doses of vitamin B6 over 50mg or equivalent have been required to carry the following statement: "WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. (Contains vitamin B6)".

Vitamin B6 is commonly present in off-the-shelf products (listed medicines) such as multivitamin and mineral preparations and vitamin B complexes, often in combination with magnesium or zinc. There are currently three forms of vitamin B6 available in products: pyridoxine hydrochloride, pyridoxal 5-phosphate and pyridoxal 5-phosphate monohydrate.

Adverse event reports submitted to the TGA suggest there is a lack of awareness that vitamin B6 can cause peripheral neuropathy. This is particularly the case when symptoms have developed in patients consuming one or more products that do not carry a warning because they contain less than 50mg of vitamin B6. Up to 5 Aug 2022, the TGA had received 32 adverse event reports with sufficient information to establish a possible causal association between peripheral neuropathy and products containing vitamin B6. In many cases, people reported they were unaware they had consumed vitamin B6 as the product they were taking was a magnesium supplement. Of these 32 cases:

- 22 (69%) reported elevated vitamin B6 blood levels with peripheral neuropathy symptoms.
- 21 (66%) involved daily doses of 50mg of vitamin B6 or less.
- 9 (28%) involved multiple medicines containing vitamin B6, some of which did not have a label warning because they contained less than 50mg of vitamin B6.

The TGA is also aware of similar reports overseas, which indicate that peripheral neuropathy may occur at a daily dose of less than 50mg of vitamin B6, or in people taking more than one product containing vitamin B6.

A public consultation highlighted that there is no minimum dose, minimum duration of use, form of vitamin B6 or identified patient risk factors that are established for peripheral neuropathy. The risk appears to vary depending on individual differences in people. Some cases of peripheral neuropathy associated with vitamin B6 were also from what appears to be excessive intake, or simultaneous consumption of multiple medicines containing vitamin B6.

In response, the TGA has made the following regulatory changes:

- Products containing vitamin B6 in daily doses above 10mg now require a label warning about the risk of peripheral neuropathy.

- Products must not provide more than 100mg of vitamin B6 per day for adults (previously 200mg), with lower daily dosage limits for children depending on the age group.

In Hong Kong, there are registered pharmaceutical products containing vitamin B6 substances, including pyridoxine and pyridoxal. As of the end of October 2022, the Department of Health (DH) had received 7 cases of adverse drug reaction related to pyridoxine, but these cases were not related to peripheral neuropathy. The DH had not received any case of adverse drug reaction related to pyridoxal.

Related news was previously issued by TGA on 5 May 2020. In light of the above TGA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 5 October 2022, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Taiwan: Safety information for medicines containing Azathioprine

On 11 October 2022, the Taiwan Food and Drug Administration (TFDA) announced that the National ADR Reporting Center of Taiwan has received several reported fatal cases of serious adverse drug reactions (ADR) due to pancytopenia suspected to be associated with the use of drugs containing azathioprine.

Considering the reported ADR cases of pancytopenia suspected to be associated with the use of drugs containing azathioprine in patients with Thiopurine methyltransferase (TPMT) or Nudix hydrolase 15 (NUDT15) deficiency, and in accordance with the overall assessment results of all the relevant information, the TFDA decided to revise the package insert of azathioprine to include relevant safety information related to the following under 'Warnings and precautions for use':

- The risk of myelosuppression may be increased in patients with TPMT deficiency or mutated NUDT15 gene;
- Complete blood count (CBC) should be closely monitored in patients receiving Azathioprine.

Please refer to the following website in TFDA for details:
https://www.fda.gov.tw/TC/siteList.aspx?sid=1571

In Hong Kong, there are 9 registered pharmaceutical products containing Azathioprine. All products are prescription-only medicines. As of the end of October 2022, the Department of Health (DH) had received 20 cases of adverse drug reaction related to Azathioprine, of which one case was related to pancytopenia. In light of the above TFDA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 11 October 2022. The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Canada: EVUSHELD (tixagevimab and cilgavimab for injection) - Risk of prophylaxis or treatment failure due to antiviral resistance

On 26 October 2022, Health Canada announced that Evusheld (tixagevimab and cilgavimab for injection) may not be effective against certain SARS-CoV-2 Omicron subvariants when used as a prophylaxis or treatment for COVID-19.

Healthcare professionals are advised to:

- Consider local epidemiology and individual exposure to circulating SARS-CoV-2 viral variants when making decisions regarding the use of Evusheld.
- Inform patients who receive Evusheld about the potential for a lack of effectiveness against certain SARS-CoV-2 viral variants. Instruct patients to seek medical advice if signs or symptoms of COVID-19 occur, persist or worsen.
- Refer to the Evusheld Canadian Product Monograph (CPM), in conjunction with the literature and local guidelines, for information regarding specific variants and antiviral resistance.

Circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies, such as Evusheld. The CPM for Evusheld has been updated to include new information about the risk of prophylaxis or treatment failure due to antiviral resistance, including neutralization data on SARS-CoV-2 Omicron subvariants.

In Hong Kong, Evusheld Solution For Injection 150mg/1.5mL + 150mg/1.5mL (HK- 67457) is a pharmaceutical product registered by Astrazeneca Hong Kong Ltd. The product is a prescription-only medicine. As of the end of October 2022, the

Department of Health (DH) had not received any case of adverse drug reaction related to Evusheld. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 27 October 2022, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

European Union: EMA recommends measures to minimize risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders

On 28 October 2022, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) has recommended measures to minimise the risk of serious side effects associated with Janus kinase (JAK) inhibitors used to treat several chronic inflammatory disorders. These side effects include cardiovascular conditions, blood clots, cancer and serious infections.

The Committee recommended that these medicines should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer.

The Committee also recommended using JAK inhibitors with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism, VTE) other than those listed above. Further, the doses should be reduced in some patient groups who may be at risk of VTE, cancer or major cardiovascular problems.

The recommendations follow a review of available data, including the final results from a clinical trial1 of the JAK inhibitor Xeljanz (tofacitinib) and preliminary findings from an observational study involving Olumiant (baricitinib), another JAK inhibitor. During the review, the PRAC sought advice from an expert group of rheumatologists, dermatologists, gastroenterologists and patient representatives.

The review confirmed Xeljanz increases the risk of major cardiovascular problems, cancer, VTE, serious infections and death due to any cause when compared with TNF-alpha inhibitors. The PRAC has now concluded that these safety findings apply to all approved uses of JAK inhibitors in chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, ulcerative colitis, atopic dermatitis and alopecia areata).

The product information for JAK inhibitors used to treat chronic inflammatory disorders will be updated with the new recommendations and warnings. In addition, the educational material for patients and healthcare professionals will be revised accordingly. Patients who have questions about their treatment or their risk of serious side effects should contact their doctor.

The Janus kinase inhibitors subject to this review are Cibinqo (abrocitinib), Jyseleca (filgotinib), Olumiant (baricitinib), Rinvoq (upadacitinib) and Xeljanz (tofacitinib). These medicines are used to treat several chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, ulcerative colitis, atopic dermatitis and alopecia areata). The active substances in these medicines work by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the process of inflammation that occurs in these disorders. By blocking the enzymes' action, the medicines help reduce the inflammation and other symptoms of these disorders.

Some JAK inhibitors (Jakavi and Inrebic) are used to treat myeloproliferative disorders; the review did not include these medicines. The review also did not cover the use of Olumiant in the short-term treatment of COVID-19, which is under assessment by EMA.

The PRAC recommendations will now be sent to the EMA's Committee for Medicinal Products for Human Use (CHMP) which will issue a final legally binding decision applicable in all European Union Member States.

In Hong Kong, there are 3 registered pharmaceutical products containing tofacitinib, namely Xeljanz Tablets 5mg (HK-63303), Xeljanz XR Extended Release Tablets 11mg (HK-66141) and Xeljanz Tablets 10mg (HK-66833) registered by Pfizer Corporation Hong Kong Limited; 2 products containing baricitinib, namely Olumiant Tablets 2mg (HK-65663) and Olumiant Tablets 4mg (HK-65664) registered by Eli Lilly Asia, Inc.; and 2 products containing upadacitinib, namely

Rinvoq Prolonged-Release Tablets 30mg (HK-67512) and Rinvoq Prolonged-Release Tablets 15mg (HK-66872) registered by Abbvie Limited. All products are prescription-only medicines. There is no registered pharmaceutical product containing abrocitinib or filgotinib.

As of the end of October 2022, the Department of Health (DH) had received 9 cases of adverse drug reaction related to tofacitinib, of which 2 cases were related to cancer, 3 cases were related to deep vein thrombosis, one case was related to pneumonia, one case was related to herpes zoster disseminated, one case was related to cellulitis and one case was related to disseminated tuberculosis. The DH had received 3 cases of adverse drug reaction related to baricitinib, of which one case was related to deep vein thrombosis, one case was related to hypotension and one case was related to pneumocystis jirovecii pneumonia. The DH had received 6 cases of adverse drug reaction related to upadacitinib, of which one case was related to lung inflammation, 4 cases were related to herpes zoster and one case was related to cytomegalovirus colitis.

Related news on the risk of blood clots and death of tofacitinib was previously issued by various overseas drug regulatory authorities, and was reported in Drug News Issues No. 112, 115, 117, 120, 121, 125, 128, 136, 138, 143, 147, 148 and 155. The DH issued letters to inform local healthcare professionals to draw their attention on 29 July 2019 and 19 June 2020. In December 2019, the Registration Committee of the Pharmacy and Poisons Board discussed the matter, and decided that the sales pack or package insert of tofacitinib products should include safety information about increased risk of blood clots and death with higher dose (10 mg twice daily).

Related news on the risk of serious heart-related problems and cancer of tofacitinib was previously issued by various overseas drug regulatory authorities, and was reported in Drug News Issues No. 136, 137, 138, 140, 143, 144, 147, 148 and 155. The DH issued letters to inform local healthcare professionals to draw their attention on 15 June 2021. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Related news on the risk of blood clots of baricitinib was previously issued by various overseas drug regulatory authorities, and was reported in Drug News Issues No. 125, 143, 148 and 155. The current local product inserts already contain safety information on the risk of venous thromboembolism.

In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 31 October 2022, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

European Union: EMA confirms recommendation to withdraw marketing authorisations for amfepramone medicines

On 28 October 2022, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) had confirmed its recommendation to withdraw the marketing authorisations for amfepramone obesity medicines. This follows a re-examination of its previous recommendation of June 2022, which was requested by the companies that market these medicines.

The recommendation follows a review which found that measures to restrict the use of these medicines for safety reasons have not been sufficiently effective. It found that the medicines were being used for longer than the recommended maximum period of 3 months, thereby potentially increasing the risk of serious side effects such as pulmonary arterial hypertension (high blood pressure in the lungs) and dependency. The medicines were also being used in patients with a history of heart disease or psychiatric disorders, increasing their risk of heart and psychiatric problems. In addition, there was evidence of use during pregnancy, which could pose risks to the unborn baby.

The review considered all available information relating to these concerns, including data from two studies on the use of amfepramone medicines in Germany and in Denmark. In addition, the PRAC received advice from a group of experts, comprising endocrinologists, cardiologists and a patient representative.

The PRAC considered introducing further measures to minimise the risk of side effects but could not identify any that would be sufficiently effective. The PRAC therefore concluded that the benefits of amfepramone medicines do not outweigh their risks and recommended that the medicines be removed from the market in the

European Union.

The PRAC recommendation will now be sent to EMA's Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for its consideration.

Information for healthcare professionals

- EMA is recommending the withdrawal of the EU marketing authorisations for amfepramone medicines for the treatment of obesity.
- A review of available data has found that amfepramone medicines continue to be used outside the current risk minimisation measures included in the product information.
- Inappropriate use may increase the risk of serious adverse effects, including cardiovascular disease, pulmonary arterial hypertension, dependency and psychiatric disorders, as well as harmful effects if used during pregnancy.
- A review of available data also indicates that the efficacy of amfepramone in the treatment of obesity is limited.
- Healthcare professionals should advise patients about other treatment options.

The review has been carried out by the PRAC. Following a re-examination requested by the marketing authorisation holders, the PRAC subsequently confirmed its conclusions for amfepramone-containing medicines. Because these medicines are all authorised at national level, the PRAC recommendations will now be sent to the CMDh, which will adopt a position.

In Hong Kong, there is one registered pharmaceutical product containing amfepramone, namely Dipropion Capsules 75mg (HK-64796). The product is registered by Jean-Marie Pharmacal Co Ltd. It is a prescription-only medicine. As of the end of October 2022, the Department of Health (DH) had not received any case of adverse drug reaction related to amfepramone. Related news was previously issued by the EMA, and was reported in Drug News Issues No. 152. As previously reported, since the PRAC recommendation will be sent to the CMDh for consideration, the DH will remain vigilant on safety update of the drug issued by EMA and other overseas drug regulatory authorities for consideration of any action deemed necessary.

European Union : Comirnaty and Spikevax: heavy menstrual bleeding added as a side effect

On 28 October 2022, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that heavy menstrual bleeding should be added to the product information as a side effect of unknown frequency of the mRNA COVID-19 vaccines Comirnaty and Spikevax.

Heavy menstrual bleeding (heavy periods) may be defined as bleeding characterised by an increased volume and/or duration which interferes with the person's physical, social, emotional and material quality of life. Cases of heavy menstrual bleeding have been reported after the first, second and booster doses of Comirnaty and Spikevax.

The PRAC finalised the assessment of this safety signal after reviewing the available data, including cases reported during clinical trials, cases spontaneously reported in Eudravigilance and findings from the medical literature.

After reviewing the data, the Committee concluded that there is at least a reasonable possibility that the occurrence of heavy menstrual bleeding is causally associated with these vaccines and therefore recommended the update of the product information.

The available data reviewed involved mostly cases which appeared to be non-serious and temporary in nature.

Menstrual disorders in general are quite common and they can occur for a wide range of reasons. This includes some underlying medical conditions. Any person who experiences postmenopausal bleeding or is concerned about a change in menstruation should consult their doctor.

There is no evidence to suggest the menstrual disorders experienced by some people have any impact on reproduction and fertility. Available data provides reassurance about the use of mRNA COVID-19 vaccines before and during pregnancy. A review carried out by EMA's Emergency Task Force showed that mRNA COVID-19 vaccines do not cause pregnancy complications for expectant mothers and their babies, and they are as effective at reducing the risk of hospitalisation and deaths in pregnant people as they are in non-pregnant people.

The Committee reiterates that the totality of data available confirms that the benefits of these

vaccines greatly outweigh the risks.

Healthcare professionals and patients are encouraged to continue to report cases of heavy menstrual bleeding to their national authorities.

The PRAC will continue to monitor for cases of this condition and will communicate further if new recommendations are warranted.

In Hong Kong, the above products are not registered pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 31 October 2022. The DH will remain vigilant on any safety update of the product issued by other overseas drug regulatory authorities.

European Union : Ustekinumab (Stelara): warning on use of live vaccines in infants whose mothers received ustekinumab during pregnancy

On 28 October 2022, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) has recommended adding a warning to the product information for ustekinumab (Stelara) on the use of live vaccines in infants whose mothers received ustekinumab during their pregnancy.

Ustekinumab is authorised in the European Union (EU) to treat severe plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

The product information already advises that it is preferable to avoid use of ustekinumab during pregnancy. People of childbearing potential are advised to avoid becoming pregnant and must use adequate contraception while using Stelara and for at least 15 weeks after the last Stelara treatment.

The Committee has reviewed the available evidence regarding use of ustekinumab during pregnancy, including observational studies from the EU, United States and Canada, as well as a cumulative review requested from the marketing authorisation holder.

Ustekinumab can cross the placenta. It has been detected in the serum (the fluid component of the blood) of infants who were exposed to ustekinumab in utero (infants whose mothers were treated with the medicine during pregnancy).

Although the data on ustekinumab are limited, the risk of infection may be increased after birth in infants who were exposed to ustekinumab in utero.

Therefore, the PRAC recommended that, in infants who were exposed to ustekinumab in utero, the administration of live vaccines (vaccines made from a virus or bacterium that has been weakened) is not recommended for six months following birth or until the infant's serum levels of ustekinumab are undetectable. In case of a clear clinical benefit for the individual infant, administration of a live vaccine might be considered earlier, if the infant's serum levels of ustekinumab are undetectable.

The PRAC's recommendation will be forwarded to EMA's Committee for Medicinal Products for Human Use (CHMP) for adoption.

In Hong Kong, there are 6 registered pharmaceutical products containing ustekinumab, namely Stelara solution for injection in pre-filled syringe 90mg/1ml (HK-60837), Stelara solution for injection in pre-filled syringe 45mg/0.5ml (HK-60838), Stelara solution for injection in pre-filled syringe 45mg/0.5ml (Switzerland) (HK-62386), Stelara solution for injection in pre-filled syringe 90mg/1ml (Switzerland) (HK-62387), Stelara concentrate for solution for injection 130mg/26ml (HK-65510) and Stelara solution for injection 45mg/0.5ml (HK-67380) registered by Johnson & Johnson (Hong Kong) Ltd. All products are prescription-only medicines. As of the end of October 2022, the Department of Health (DH) had received 4 cases of adverse drug reaction related to ustekinumab, of which one case was related to mycobacterial infection, one case was related to cardiac arrest, one case was related to severe urticaria and one case was related to Crohn's disease. In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 31 October 2022, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Drug Recall

Batch Recall of Poliformin Tab 500mg

On 6 October 2022, the Department of Health (DH) endorsed a licensed drug wholesaler, Natural Health Resources Company Limited (Natural Health), to recall one batch (batch number: 90558) of Poliformin Tab 500mg (HK-50589) from the market as a precautionary measure due to the presence of an impurity in the product.

The DH received notification from Natural Health on 6 October 2022 that the overseas manufacturer of the product is initiating a voluntary recall of the above batch due to the presence of a higher than accepted level of an impurity, N-nitrosodimethylamine (NDMA) in the affected batch. NDMA is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Natural Health is voluntarily recalling the affected product from the market.

The above product, containing metformin, is a prescription medicine used for the treatment of diabetes mellitus. According to Natural Health, the product has been imported into Hong Kong and supplied to local doctors.

As of the end of October 2022, the DH had not received any adverse drug reaction report related to the affected batch of product. A notice was posted on the Drug Office website on 6 October 2022 to alert the public of the product recall. The DH noted that the recall was completed.

Batch recall of Port Delivery System with Ranibizumab

On 17 October 2022, the Department of Health (DH) endorsed a licensed wholesaler, Roche Hong Kong Limited (Roche), to recall two batches (batch number 1171684S04 and 1171684S07) of investigational medicinal product "Port Delivery System with Ranibizumab" due to a potential quality defect of the product.

The DH received notification from Roche that its headquarter in Switzerland initiated recall of the product due to the Port Delivery System not meeting the specifications of intended use. Septum dislodgement was noted in the Port Delivery System which was considered as a defect of the product. As a precautionary measure, Roche voluntarily recall the affected batches. DH's investigation is continuing.

The above product, containing Ranibizumab, is a prescription medicine under clinical trial for the treatment of macular degeneration. According to Roche, the affected batches have been supplied to two HA hospitals for clinical trial purpose.

As of the end of October 2022, the DH had not received any adverse drug reaction report related to the affected product. A notice was posted on the Drug Office website on 17 October 2022 to alert the public of the product recall. The DH noted that the recall was completed.

Drug Incident

Public urged not to buy or use topical product containing undeclared controlled ingredient

On 14 October 2022, the Department of Health (DH) appealed to the public not to buy or use a topical product named "LAB LUMINUS ANTI-SENSITIVE SERUM" as it was found to contain an undeclared controlled drug ingredient.

Acting upon a public complaint, a sample of the above product was collected by the DH from a shop in Central for analysis. The test result from the Government Laboratory revealed that the product sample contained betamethasone valerate, a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138). The product is also suspected to be an unregistered pharmaceutical product.

The DH conducted an operation against the shop on 14 October 2022, and seized a quantity of suspected Part 1 poisons and unregistered pharmaceutical products. The DH's investigation is continuing.

Betamethasone valerate is a steroid substance for treating inflammation. Its side effects include moon face, high blood pressure, high blood sugar, skin atrophy, adrenal insufficiency and osteoporosis. Products containing betamethasone valerate are prescription medicines that should be used under a doctor's directions and supplied in a pharmacy under the supervision of a registered pharmacist upon a doctor's prescription.

Drug Incident

A press release was posted on the Drug Office website on 14 October 2022 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 $50,000 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 accordance 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

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2319 6319

E-mail: adr@dh.gov.hk

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

Post: Adverse Drug Reaction and Adverse Event Following Immunization Unit,
Drug Office, Department of Health,
Room 1856, 18/F, Wu Chung House,
213 Queen's Road East,
Wanchai, Hong Kong

The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.