Drug News
藥 物 情 報

Issue Number 63

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in January 2015 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

The Mainland: CFDA warns against the risk of liver damage associated with benzbromarone

An announcement on the risk of liver damage associated with benzbromarone was noted from the website of the China Food and Drug Administration (CFDA) of the Mainland on 2 January 2015. Clinically, benzbromarone is mainly used for the treatment of primary and secondary hyperuricemia, gout of various causes and non-acute gouty arthritis attack. The drug is mainly used in Germany, Japan, Singapore and other Asian countries. Analysis from the National Center for Adverse Drug Reaction Monitoring database showed that liver damage is relatively prominent among the serious adverse reactions of benzbromarone. According to the domestic adverse drug reaction monitoring and the situation of foreign control measures, the CFDA carried out risk-benefit assessment of benzbromarone and found that the benefits of using benzbromarone for the treatment of gout or hyperuricemia still outweigh the risks.

The CFDA recommends that:

- Healthcare professionals should start from the low dose when using benzbromarone; regularly perform liver function tests during treatment; avoid concomitant use with other hepatotoxic drugs to reduce the incidence of serious adverse drug reactions.
- Patients during the drug treatment should pay attention to the signs and symptoms of liver damage, such as loss of appetite, nausea, vomiting, general malaise, abdominal pain, diarrhea, fever, dark urine, yellowing eye, etc. and seek medical advice for liver function test and relevant treatment if necessary.
- Pharmaceutical production enterprises should strengthen the monitoring of adverse drug reactions and the publicity of clinically safe use of the drug to ensure the product safety information can convey to the patient and the doctor in a timely manner

In Hong Kong, there are three registered pharmaceutical products containing benzbromarone. All of them are prescription only medicines. The package inserts of the products have included the related safety information on the risk of liver damage. So far, the Department of Health (DH) has not received any adverse reaction reports in relation to the drug. The DH keeps vigilant against any safety updates of the drug.

US: FDA review of possible risks of use of prescription and over-the-counter (OTC) pain medicines during pregnancy

On 9 January 2015, the US Food and Drug Administration (FDA) was aware of and understood the concerns arising from recent reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, the FDA evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. The FDA urges pregnant women to always discuss all medicines with their health care professionals before using them.

Severe and persistent pain that is not effectively treated during pregnancy can result in depression, anxiety, and high blood pressure in mother. Medicines including nonsteroidal anti-

inflammatory drugs (NSAIDs), opioids, and acetaminophen (paracetamol) can help treat severe and persistent pain. However, it is important to carefully weigh the benefits and risks of using prescription and OTC pain medicines during pregnancy.

Healthcare professionals should talk with each patient about the benefits and risks of analgesic use during pregnancy, which may differ among patients and by treatment indication. Continue to follow the existing recommendations in current drug labels regarding the use of analgesics during pregnancy.

In Hong Kong, pain medicines, including NSAIDs, opioids, and paracetamol are registered pharmaceutical products. Most of the NSAIDs and opioids are prescription only medicines. Some NSAIDs are pharmacy only medicines. Paracetamol is OTC medicine. The DH remains vigilant on safety updates of the use of pain medicines during pregnancy.

EU: PRAC considers risk of severe allergic reactions with ambroxol- and bromhexine-containing medicines to be small

On 12 January 2015, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) had completed a review of medicines containing ambroxol or bromhexine. This follows concerns over the risk of allergic reactions with these medicines, which are widely used as expectorants (to help clear mucus from the airways).

The PRAC considers that the risk of allergic reactions is small, but has recommended that the product information for these medicines should be updated with further information on severe allergic reactions, and that severe skin reactions (SCARs) should be introduced as a side effect. SCARs include conditions such as erythema multiforme and Stevens-Johnson syndrome.

The review of ambroxol and bromhexine was carried out at the request of the Belgian medicines agency (AFMPS) following reports of allergic reactions and SCARs with ambroxol. Several cases of SCARs, possibly linked to ambroxol, were also identified from the medical literature. The review also covered medicines containing bromhexine, since bromhexine is mainly converted into ambroxol in the body. In addition, there were some reports linking the use of bromhexine with allergic reactions.

The PRAC assessed the available data and all reports of severe allergic reactions and SCARs with ambroxol and bromhexine. The PRAC confirmed the already known risk of allergic reactions, which remains small. The Committee also identified a small risk of SCARs associated with these medicines. Based on these conclusions, the PRAC recommended adding the risk of SCARs to the product information, together with advice to discontinue treatment immediately if symptoms of SCARs occur.

The PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position.

In Hong Kong, there are 467 and 48 registered pharmaceutical products containing bromhexine and ambroxol respectively. Related news on the risk of severe hypersensitivity reactions of ambroxol injection has been released by the CFDA, and was reported in Drug News Issue No. 35. A letter to healthcare professionals to draw their attention to the matter was issued on 4 September 2012. The EMA later started a review of ambroxol and bromhexine in April 2014. So far, the DH has not received any adverse drug reaction reports in relation to the drugs. In view of the latest announcement on completion of the review by the EMA, a letter to healthcare professionals to draw their attention to the update was issued on 13 January 2015, and the matter will be discussed in the meeting of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certificate of Clinical Trial/Medicine Test) Committee (the Registration Committee) of the Pharmacy and Poisons Board. The DH remains vigilant on the safety updates of the drugs.

Canada: Domperidone Maleate is associated with Serious Abnormal Heart Rhythms and Sudden Death (Cardiac Arrest)

On 20 January 2015, the manufacturers of domperidone in collaboration with Health Canada announced important additional safety information

regarding a small increased risk of serious ventricular arrhythmias or sudden cardiac death in association with domperidone.

Domperidone is indicated in adults for the symptomatic management of upper gastrointestinal motility disorders associated with chronic and subacute gastritis and diabetic gastroparesis. Domperidone is also indicated to prevent gastrointestinal symptoms associated with the use of dopamine agonist antiparkinsonian agents.

A review of epidemiological studies and recent post -market safety data has demonstrated that domperidone exposure was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. Based on this new evidence, the labelling of domperidone is being further strengthened to better reflect and address these cardiac risks.

- Domperidone may be associated with a small increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients:

- older than 60 years of age;
- using daily doses greater than 30 mg;
- having predisposing factors for QT prolongation including concomitant use of QT -prolonging drugs or CYP 3A4 inhibitors.

- Domperidone is now contraindicated in patients:

- with prolongation of cardiac conduction intervals, particularly QT;
- with significant electrolyte disturbances;
- with cardiac disease (such as congestive heart failure);
- with moderate or severe liver impairment;
- receiving QT-prolonging drugs and potent CYP3A4 inhibitors.

- Domperidone should be used at the lowest effective dose to a maximum recommended daily dose of 30 mg and for the shortest possible duration.

Healthcare professionals should consider doing a cardiac assessment in patients at higher risk for QT interval prolongation and/or cardiac arrhythmia including an electrocardiogram (ECG) prior to initiation of domperidone and during treatment.

Patients should be advised to stop taking domperidone and seek immediate medical attention if they experience signs or symptoms of an abnormal heart rate or rhythm while taking domperidone.

In Hong Kong, there are 47 registered pharmaceutical products containing domperidone. They can be sold without prescriptions at a registered pharmacy under the supervision of pharmacist. A number of related news regarding the risk of cardiac disorder has been released by various health authorities since 2012, and was posted on the Drug News Issues No. 29, 53 and 59. Letters to inform healthcare professionals to draw their attention to the matter were issued on 8 March 2012 and 10 March 2014. So far, the DH has not received any adverse drug reaction reports on the use of domperidone.

The matter was discussed in the meeting of the Registration Committee in February 2012 and May 2014. The Committee came to the following decision:

- To update the sales pack or package insert of domperidone-containing products to include the appropriate safety information related to cardiovascular risk.
- To deregister all suppositories containing domperidone effective from 1 October 2014 as their benefits no longer outweigh the risks.
- To tighten control over the sale oral domperidone products so that they can only be sold with a prescription at pharmacies under the supervision of pharmacists.

The legislative amendments to tighten control over the sale of registered pharmaceutical products containing domperidone which is under the First Schedule and the Third Schedule of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) have been enacted with commencement date on 15 May 2015.

Canada: New warnings on serious risks of muscle breakdown and a neurological disorder called neuroleptic malignant

syndrome associated with Alzheimer's drug Aricept (donepezil)

On 21 January 2015, new warnings had been added to the prescribing information for the Alzheimer's drug Aricept (donepezil) advising of the risk of two rare but potentially serious conditions: muscle breakdown (rhabdomyolysis) and a neurological disorder called neuroleptic malignant syndrome (NMS). Manufacturers of generic donepezil products will also update their product information.

Donepezil is a prescription drug used to treat the symptoms of mild, moderate and severe dementia related to Alzheimer's disease. It is available under the brand names Aricept and Aricept RDT (Rapidly Disintegrating Tablet), as well as generic equivalents. Rhabdomyolysis is a rare condition involving the breakdown of muscle tissue. Rhabdomyolysis can cause serious and sometimes fatal abnormal heart rhythms, kidney damage and kidney failure, but is generally treatable if recognized promptly. NMS is a very rare life-threatening disorder characterized by a chemical imbalance that affects the nervous, muscular and cardiovascular systems. The muscular effects of NMS can sometimes lead to rhabdomyolysis.

The new warnings are the result of a Health Canada safety review that examined Canadian and international case reports and other data. Rhabdomyolysis and NMS were reported to occur independently in association with donepezil use; however rhabdomyolysis may be the result of complications of NMS. Rhabdomyolysis was most often reported to occur when donepezil therapy was started or the dose increased.

Healthcare professionals are advised on the following:

- To assess patients for risk factors for rhabdomyolysis before prescribing donepezil, such as: muscular disorders, uncontrolled hypothyroidism, liver or kidney damage, or if the patient is taking other medications known to cause rhabdomyolysis, including: statins (used to lower cholesterol), antipsychotics, and certain types of antidepressants known as SSRIs and SNRIs (selective serotonin reuptake inhibitors and serotonin norepinephrine reuptake inhibitors).
- To stop donepezil therapy if blood tests show high levels of the chemical creatine phosphokinase (CPK), and/or if NMS and/or rhabdomyolysis is diagnosed.

In Hong Kong, there are 30 registered pharmaceutical products containing donepezil, including Aricept Tab 5mg (HK-42885), Aricept Tab 10mg (HK-42889), Aricept Evess Orodispersible Tab 10mg (HK-58711) and Aricept Evess Orodispersible Tab 5mg (HK-58712). All of them are prescription only medicines. So far, the DH has not received any adverse drug reaction reports in connection with the drug. In view of the Health Canada's announcement, a letter to healthcare professionals to draw their attention to the matter, and urge them to report any adverse reactions of the drug was issued on 22 January 2015. The matter will be discussed in the meeting of the Registration Committee. The DH remains vigilant on the safety updates of the drug.

EU/UK: Suspending medicines over flawed studies conducted at GVK Biosciences

On 23 January 2015, the EMA announced that a number of medicines for which authorisation in the EU was primarily based on clinical studies conducted at GVK Biosciences in Hyderabad, India should be suspended. The recommendation is based on findings from an inspection that raised concerns about how GVK conducted studies at the Hyderabad site on behalf of marketing authorisation holders.

Upon the request of the European Commission, EMA's Committee for Medicinal Products for Human Use (CHMP) looked at over 1,000 pharmaceutical forms and strengths of medicines studied at the GVK site. For over 300 of them, sufficient supporting data from other sources were available; these will therefore remain on the market in the EU as EMA is satisfied with the available data.

For medicines that lack data from other studies, the CHMP recommended suspension unless they are of critical importance for patients because alternatives will not be able to meet patients' needs. The decision on whether a medicine is critical for patients lies with the national authorities of EU Member States depending on the situation in their country. For medicines that are considered critical,

companies are given 12 months to submit additional data. The full list of medicines for which the CHMP recommends suspension is available on the EMA website.

The inspection of GVK that led to the CHMP's recommendation was carried out by the French medicines agency (ANSM). The inspection revealed data manipulations of electrocardiograms (ECGs) during the conduct of some studies of generic medicines. The inspection cast doubt on the integrity of the way trials were performed at the site generally and on the reliability of data generated at that site.

There is no evidence of harm or lack of effectiveness with any of the medicines linked to studies conducted by GVK and patients should continue to take their medicines as prescribed.

The CHMP's recommendation will be sent to the European Commission for a legally binding decision.

Following the CHMP recommendation to suspend some medicines licensed in the EU that were based on clinical trials conducted at GVK Biosciences' site in Hyderabad, India, the Medicines and Healthcare Products Regulatory Agency (MHRA) had the following comments:

- This is a precautionary measure. There is no evidence to suggest that these medicines are not safe and effective and people should continue to take their medicines as prescribed.
- This recommendation will now be considered by the European Commission and it will make the final decision as to whether the suspensions should be imposed. MHRA are currently reviewing the list of medicines and will make a final decision once the European Commission has made their decision.

The DH has completed an impact assessment of the issue on local registered pharmaceutical products. It was found that there were two types of pharmaceutical products, among the product names listed by the EMA, which may be related to the products in Hong Kong, namely "Metformin" and "Amlodipine" with Actavis Group PTC ehf. and FDC Pharma as marketing authorization holders respectively. In Hong Kong, Metformin Tab 500mg (HK-35503) is registered by Actavis Hong Kong O/B Actavis Hong Kong Limited (Actavis), and is manufactured by Actavis UK Ltd. Amodep 5 Tab 5mg (HK-57510) is registered by Star Medical Supplies Ltd (Star Medical), and is manufactured by FDC Limited in India. As confirmed with Actavis and Star Medical, their respective products were not affected. The bioequivalence study of Metformin Tab 500mg was not conducted by GVK Biosciences, and the formulation of Amodep 5 Tab 5mg is different from the one registered in the UK.

UK: Risk of hypogammaglobulinaemia and bronchiectasis associated with mycophenolate mofetil (CellCept) and mycophenolic acid

An annoucement on the risk of hypogammaglobulinaemia and bronchiectasis associated with mycophenolate mofetil (brand leader: CellCept) and mycophenolic acid was noted from the website of MHRA on 29 January 2015. Mycophenolate mofetil is licensed in combination with ciclosporin and corticosteroids to prevent acute transplant rejection in patients receiving allogeneic renal, cardiac, or hepatic transplants. It is also used off-label in other specialties, such as rheumatology, gastroenterology, respiratory medicine, and dermatology. Mycophenolate mofetil is a prodrug that is completely converted to the active pharmacological form mycophenolic acid (MPA). MPA has potent cytostatic effects on both B-lymphocytes and T-lymphocytes.

A review by European regulators concluded that mycophenolate mofetil in combination with other immunosuppressants can cause hypogammaglobulinaemia in adults and children, which can be associated with recurrent infections. This conclusion was based on published reports, clinical trial data, and reports from clinical practice. Switching from mycophenolate mofetil to an alternative immunosuppressant resulted in serum immunoglobulin G (IgG) levels returning to normal in some cases.

The review also concluded that mycophenolate mofetil in combination with other immunosuppressants can cause bronchiectasis in adults and children (sometimes years after starting mycophenolate mofetil treatment). The risk of bronchiectasis may be linked to hypogammaglobulinaemia or to a direct effect of MPA on the lungs. Patients who developed

bronchiectasis usually presented with a persistent productive cough and, in some cases, recurrent upper or lower respiratory tract infections. The diagnosis was confirmed by high resolution computed tomography of the chest. In some of these cases, switching from mycophenolate mofetil to another immunosuppressant improved respiratory symptoms. Mycophenolate mofetil is also known to cause pulmonary fibrosis.

To date, the MHRA has received 13 Yellow Card reports of hypogammaglobulinaemia and 12 Yellow Card reports of bronchiectasis associated with mycophenolate use. Bronchiectasis can occur after years of mycophenolate mofetil treatment, so the link to mycophenolate mofetil may not be made.

When using mycophenolate mofetil or any other medicine containing mycophenolic acid (MPA) as its active ingredient, healthcare professionals are advised of the following:

- Measure serum immunoglobulin levels if recurrent infections develop.
- In cases of sustained, clinically relevant hypogammaglobulinaemia, consider appropriate clinical action. Take into account the potent cytostatic effects of MPA on B-lymphocytes and T-lymphocytes
- Consider bronchiectasis or pulmonary fibrosis if patients develop persistent respiratory symptoms, such as cough and dyspnoea

In Hong Kong, there are 17 registered pharmaceutical products containing mycophenolate mofetil or mycophenolic acid. All of them are prescription only medicines. So far, the DH has not received any relevant adverse reaction reports of the drug. In view of the MHRA's announcement, a letter to healthcare professionals to draw their attention to the matter and urge them to report any adverse reactions related to the drug was issued on 29 January 2015. The matter will be discussed in the meeting of the Registration Committee. The DH remains vigilant on the safety updates of the drug.

UK: Risk of chemical burns in premature infants associated with chlorhexidine solutions

An announcement on the risk of chemical burns in premature infants associated with chlorhexidine solutions was noted from the website of MHRA on 29 January 2015. The risk of severe chemical injuries associated with the use of both alcohol-based and water-based chlorhexidine solutions for skin disinfection in premature infants was communicated to healthcare professional in June 2014. This was based on Yellow Card reports and reports identified in the literature. A European review has since considered the MHRA evidence together with additional information from spontaneous reporting and published literature. The risk appears to be higher in infants born before 32 weeks of gestation than in full term infants and in the first 2 weeks of life than in later life. Healthcare professionals are advised of the following:

- When using alcohol-based or water-based chlorhexidine solutions on premature infants, bear in mind the risk of severe chemical injuries.
- Use the minimum amount of chlorhexidine solution required and do not allow the solution to pool. Remove any excess solution and any soaked materials, drapes, or gowns from the skin.
- Monitor patients frequently to detect and manage cutaneous side effects at an early stage

In Hong Kong, there are 86 registered pharmaceutical products containing chlorhexidine. So far, the DH has not received any adverse reaction reports of the drug. The DH remains vigilant on the safety updates of the drug.

UK: Basiliximab is indicated for renal transplantation only and its efficacy and safety is not shown in heart transplantation

An announcement on the use of basiliximab in heart transplantation was noted from the website of MHRA on 29 January 2015. European regulatory review investigated the safety and efficacy of basiliximab for off-label use in heart transplantation. This review was triggered by three unexplained deaths in Sweden in patients who received basiliximab for heart transplantation. All three patients had signs and symptoms of thromboembolic events and potential cardiac disorders. The review found no adequately powered randomised studies of basiliximab in heart transplantation. The clinical trials that have been

done in heart transplantation did not prove basiliximab to be effective. Furthermore, serious cardiac side effects such as cardiac arrest, atrial flutter, and palpitations were observed more frequently with basiliximab than with other induction agents. Therefore a new warning has been included in the basiliximab product information regarding the lack of proven safety and efficacy in heart transplantation.

In Hong Kong, there are two registered pharmaceutical products containing basiliximab, namely Simulect Powder for Inj 10mg (HK-52661) and 20mg (HK-44725). Both of them are registered by Novartis Pharmaceuticals (HK) Ltd, and are prescription only medicines. According to the package insert of the products, the products are only indicated for renal transplantation. A letter to healthcare professionals to draw their attention to the matter and urge them to report any adverse reactions related to the drug was issued on 29 January 2015. So far, the DH has not received any adverse reaction reports of the drug. The DH remains vigilant on the safety updates of the drug.

UK: St John's wort interacts with hormonal contraceptives, including implants

An announcement on the interaction of St John's wort (Hypericum perforatum L.) with hormonal contraceptives was noted from the website of MHRA on 29 January 2015. St John's wort is a herbal medicine traditionally used to relieve slightly low mood and mild anxiety. The MHRA has received two Yellow Card reports in the last quarter of 2013 of suspected interactions in women with implanted contraceptives containing etonogestrel (Nexplanon and Implanon). These women started taking St John's wort and then had unplanned pregnancies. A total of 19 reports of suspected interactions between St John's wort and hormonal contraceptives have been received through the Yellow Card scheme since 2000 (four for contraceptive implants and 15 for contraceptive pills). Of these suspected interactions, 15 cases resulted in unplanned pregnancies and the remaining four cases in association with contraceptive pills resulted in breakthrough bleeding without pregnancies. Healthcare professionals are advised to advise women taking hormonal contraceptives for pregnancy prevention not to take herbal products containing St John's wort.

In Hong Kong, hormonal contraceptives (excluding implants) are registered pharmaceutical products. So far, the DH has not received any adverse reaction reports associated with the use of St John's wort. The DH remains vigilant on the safety updates of the drug.

UK: Orlistat theoretically interacts with antiretroviral HIV medicines

An announcement on the theoretical interaction of orlistat with antiretroviral HIV medicines was noted from the website of MHRA on 29 January 2015. Orlistat is indicated for weight loss in combination with a low-calorie, low-fat diet. It is available as 120 mg capsules under the brand name Xenical and as 60 mg capsules under the brand name alli. Xenical is only available with a prescription, whereas alli is available without a prescription under the supervision of a pharmacist. Orlistat is a potent, specific, and long-acting inhibitor of gastrointestinal lipases which decreases the amount of fat absorbed from the diet.

On the basis of reports from literature and data obtained after licensing, orlistat may theoretically reduce the absorption of antiretroviral HIV medicines. This may be due to retention of lipophilic medicines in the gastrointestinal tract or reduced gastrointestinal tract transit time. This interaction could negatively affect the efficacy of antiretroviral HIV medications. Reports have been received of suspected interactions between orlistat and efavirenz, and between orlistat and lopinavir. However, the theoretical interaction mechanism described above could also apply to other antiretroviral medicines.

Healthcare professionals are advised to initiate orlistat treatment only after careful consideration of the possible impact on efficacy of antiretroviral HIV medicines. Pharmacists should advise people who take antiretroviral HIV medicines to consult their doctor before taking alli in light of the possible interaction.

In Hong Kong, there are nine registered pharmaceutical products containing orlistat. Two products contain orlistat 60mg and seven products contain orlistat 120mg, and are pharmacy only medicines and prescription only medicines respectively. So far, the DH has not received any adverse reaction reports of the drug. The DH remains vigilant on the safety updates of the drug.

Drug Recall

Recall one batch of pms-Rosuvastatin Tablets 40mg (HK-61934)

On 6 January 2015, the DH endorsed a licensed drug wholesaler, Trenton-Boma Limited (T-Boma), to voluntary recall one batch (batch number 481460) of pms-Rosuvastatin Tablets 40mg from the market due to potential quality issue.

T-Boma notified DH that the product's manufacturer in Canada found, during the stability study, that the samples of the affected batch contained a degradated compound exceeding the specification limit. As such, the manufacturer decided to recall the affected batch. The manufacturer is still conducting investigation on the root cause of the issue. So far, there is no indication that other batches available in Hong Kong are affected.

pms-Rosuvastatin tablets 40mg, containing rosuvastatin, is a prescription medicine used for the treatment of hypercholesterolaemia. According to T -Boma, 46 boxes of the affected batch had been supplied to private doctors and pharmacies since Sep 2014. A notice was released on the website of Drug Office on 6 January 2015 to alert the public of the recall. As on 9 January 2015, the DH had not received any adverse drug reaction reports in relation to the product and had been notified by T-Boma that the recall of the product had been completed.

Drug Incident

Retail shop raided for suspected illegal sale of unregistered pharmaceutical products

On 28 January 2015, a retail shop in Causeway Bay was raided in a joint operation by the DH and the Police for suspected illegal sale and possession of unregistered pharmaceutical products that were labelled to contain Part I poison and antibiotic.

Acting upon a public complaint, it was found that the retail shop was offering for sale of a cream product which was labelled to contain fluocinonide and two cream products which were labelled to contain erythromycin. Fluocinonide is a part I poison whereas erythromycin is an antibiotic. Products containing fluocinonide or erythromycin are prescription medicines which should only be used under the advice of a medical doctor and could only be supplied at pharmacies under the supervision of a registered pharmacist upon doctor's prescription.

During the operation, a man aged 83 and a woman aged 61 were arrested by the Police for suspected illegal sale and possession of Part I poisons, unregistered pharmaceutical products and antibiotics.

Fluocinonide is a kind of steroid. Prolonged usage or application on large skin area could induce body-wide side effects like moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and even osteoporosis. Erythromycin is used topically for treatment of microbial infection of skin, side effects include pruritus and skin rash.

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. 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.

Drug Incident

All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". The products mentioned in the above incidents were not registered pharmaceutical products under the Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. Members of the public were exhorted not to use products of unknown or doubtful composition. They should stop using the aforementioned products immediately if they had them in their possession and to consult healthcare professionals if they felt unwell after taking the products. The products should be destroyed or disposed properly, or submitted to the Department's Drug Office during office hours.

Useful Contact

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,
Rm 1856, 18/F, Wu Chung House,
213 Queen's Road East,
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