Drug News
藥 物 情 報

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

Canada: Three unauthorized health products labelled with prescription drug names seized at "Taste of Ukraine" in Burnaby, B.C.

On 2 September 2015, Health Canada was informing Canadians that three unauthorized health products from the Taste of Ukraine, 4976 Kingsway, Burnaby, B.C had been seized. The products were seized as they were labelled with prescription drug names (ampicillin, doxycycline and diclofenac). Products containing prescription drug ingredients should only be taken under the supervision of a health professional because they are used to treat specific diseases, and may cause serious side effects.

The seized products have not been approved by Health Canada. This means that they have not been assessed for their safety, effectiveness and quality. As a result, they may contain ingredients not listed on the label, other additives and/or contaminated ingredients. In addition, they may lack the active ingredients Canadians would expect them to contain to help maintain and improve their health or other ingredients that may interact with other medications and foods. For all of these reasons, they could cause serious health effects.

In Hong Kong, products containing ampicillin, doxycycline and/ or diclofenac are registered pharmaceutical products. The products need to be registered with the Pharmacy and Poisons Board before they can be sold, offered for sale, distributed or possessed for the purposes of sales, distribution or other use in Hong Kong. The Hong Kong registration number of such products is indicated on their sales pack in the form of "HK-xxxxx" ("x" denotes a number). Information related to these products can be found from the "Search Drug Database" at the Drug Offie website (http://www.drugoffice.gov.hk/eps/productSearchOneFieldAction.do).

Members of the public are strongly advised not to buy or consume any products of unknown or doubtful composition, or consume products from unknown sources including the internet. The public should consult their healthcare professionals before using any medication.

Taiwan: Announcement on updating the Chinese package insert of oral medicinal products containing Ginkgo biloba extract

The Taiwan Food and Drug Administration (FDA) was soliciting relevant information with clinical references on oral dosage form of medicinal products containing Ginkgo biloba extract for evaluation and draw the conclusion that the package insert in Chinese should be revised in the contents of (1) Contraindications; (2) The warnings and precautions; (3) The special groups; (4) Drug interactions; (5) Others. The details of the requirement are at the following website: http://www.fda.gov.tw/TC/newsContent.aspx?id=14014&chk=bc392a30-5890-4473-9272-04b0bde6963d&param=pn#.VhtbfUzyycx

In Hong Kong, there are four registered oral pharmaceutical products containing ginkgo biloba extract, ginkgo biloba or ginkgo biloba leaf. As on 8 October 2015, the Department of Health (DH) has not received any adverse drug reaction (ADR) case on the products containing the said ingredients. In view of the announcement of the Taiwan FDA, a letter to inform local healthcare professionals to draw their attention to the warning

was issued on 4 September 2015. 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.

US: FDA takes action on bulk pure powdered caffeine products - Agency continues to warn consumers about the dangers of using pure powdered caffeine

The US Food and Drug Administration (FDA) was taking action to help in preventing additional deaths from the use of pure powdered caffeine, potentially dangerous products that have already resulted in the known deaths of two teenagers.

It was noted from the website of the FDA on 7 September 2015 that the agency issued warning letters to five distributors of pure powdered caffeine because these products are dangerous and present a significant or unreasonable risk of illness or injury to consumers. The difference between a safe amount and a toxic dose of caffeine in these pure powdered products is very small. Furthermore, safe quantities of these products can be nearly impossible to measure accurately with common kitchen measuring tools. Volume measures, such as teaspoons, are not precise enough to calculate how many milligrams of caffeine are in the serving size. Pre-existing conditions can intensify the effects of caffeine and make the product more dangerous for these individuals.

Following the deaths of two young men in good health in 2014, the FDA issued Consumer Advice alerting consumers to the dangers of pure powdered caffeine. One teaspoon of pure powdered caffeine is equivalent to the amount of caffeine in about 28 cups of regular coffee. While consumers of caffeinated products such as coffee, tea, and soda may be aware of caffeine's less serious effects – such as nervousness and tremors – they may not be aware that these pure powdered caffeine products are much more potent and can cause serious health effects, including rapid or dangerously erratic heartbeat, seizures and death. Vomiting, diarrhea, stupor and disorientation are also symptoms of caffeine toxicity.

The FDA will continue to aggressively monitor the marketplace for pure powdered caffeine products and take action as appropriate. If violations exist, the FDA can pursue enforcement action, such as seizure of the product or an injunction to prevent the firm from continuing to manufacture or market the product.

In Hong Kong, there are three registered pharmaceutical products which are anhydrous caffeine used as raw materials. As on 8 October 2015, the DH has not received any ADR case on caffeine. In view of the FDA's announcement, a letter was issued to the three registered certificate holders of anhydrous caffeine to warn them of the danger of this kind of sale to consumers. The DH will remain vigilant on any safety update of anhydrous caffeine. The public should consult their healthcare professionals before using any medication.

UK: Proton pump inhibitors: very low risk of subacute cutaneous lupus erythematosus

Proton pump inhibitors (PPIs) are associated with very infrequent cases of subacute cutaneous lupus erythematosus (SCLE), a non-scarring dermatosis that can develop in sun-exposed areas.

PPIs reduce the secretion of stomach acid and are widely used medicines for management of acid-related conditions, including: reflux oesophagitis; gastric and duodenal ulcers; and Zollinger-Ellison syndrome. The following PPIs are available in the UK: esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole.

SCLE is characterised by polycyclic erythematous scaly plaques or confluent psoriasiform papulosquamous lesions, which may be accompanied by arthralgia. Skin tests (such as direct immunofluorescence) and serological tests (including presence of antibodies against Ro or Sjögren's-syndrome-related antigen A [SSA]) can be used to diagnose SCLE. Drug-induced SCLE can occur weeks, months or even years after exposure to the drug.

On 9 September 2015, considering the extensive use of PPIs, very few cases of SCLE have been reported. Nevertheless, evidence from clinical literature and from cases reported to medicines

regulators including via the Yellow Card Scheme supports a causal association between PPIs and SCLE. Product information in the UK is being updated to include this advice for healthcare professionals and patients or carers.

Healthcare professionals are reminded of the following if a patient treated with a proton pump inhibitor (PPI) develops lesions—especially in sun-exposed areas of the skin—and it is accompanied by arthralgia:

- advise them to avoid exposing the skin to sunlight,
- consider subacute cutaneous lupus erythematosus (SCLE) as a possible diagnosis,
- consider stopping use of the PPI unless it is imperative for a serious acid-related condition; a patient who develops SCLE with a particular PPI may be at risk of the same reaction with another, and
- in most cases, symptoms resolve on PPI withdrawal; topical or systemic steroids might be necessary for treatment of SCLE only if there are no signs of remission after a few weeks or months.

In Hong Kong, there are 177 registered pharmaceutical products belonging to the class of PPIs, including the ingredients containing esomeprazole, omeprazole, lansoprazole, dexlansoprazole, pantoprazole and rabeprazole. All products are prescription only medicines except omeprazole-containing products which are pharmacy only medicines. As on 8 October 2015, the DH has received one case of ADR on pantoprazole, and it is not related to SCLE. No ADR case has been received on the other PPIs. In view of the MHRA's announcement, a letter to inform local healthcare professionals to draw their attention on the warning was issued on 9 September 2015. The matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

US: Invokana and Invokamet (canagliflozin) - New information on bone fracture risk and decreased bone mineral density

The FDA has strengthened the warning for the type 2 diabetes medicine canagliflozin (Invokana, Invokamet) related to the increased risk of bone fractures, and added new information about decreased bone mineral density. On 10 September 2015, to address these safety concerns, the FDA added a new WARNING AND PRECAUTION and revised the ADVERSE REACTIONS section of the Invokana and Invokamet drug labels.

The FDA is continuing to evaluate the risk of bone fractures with other drugs in the SGLT2 inhibitor class, including dapagliflozin (Farxiga, Xigduo XR) and empaglifozin (Jardiance, Glyxambi, Synjardy), to determine if additional label changes or studies are needed.

Canagliflozin is a prescription medicine in the US, and is used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin is available as a single-ingredient product under the brand name Invokana and also in combination with the diabetes medicine metformin under the brand name Invokamet. Bone mineral density relates to the strength of a person's bones.

Healthcare professionals are advised of the following:

- bone fractures have been seen in patients taking the type 2 diabetes medicine canagliflozin,
- fractures can occur as early as 12 weeks after starting canagliflozin,
- canagliflozin has also been linked to decreases in bone mineral density at the hip and lower spine,
- consider factors that contribute to fracture risk prior to initiating canagliflozin, and
- counsel patients about factors that may contribute to bone fracture risk.

In Hong Kong, there are two registered pharmaceutical products containing canagliflozin, namely Invokana Tablets 100mg (HK-63499) and Invokana Tablets 300mg (HK-63500) which are registered by Johnson & Johnson (Hong Kong) Ltd, and two registered pharmaceutical products containing dapagliflozin, namely Forxiga Tablet 5mg (HK-63301) and Forxiga Tablet 10mg (HK-63302) which are registered by Astrazeneca Hong Kong Ltd. All products are prescription only medicines. There is no registered pharmaceutical product containing empagliflozin. As on 8 October 2015, the DH has not received any ADR case on Invokana, and has received one ADR case on

Forxiga. However, it is not related to bone fracture and/ or decreased bone mineral density. In view of the US FDA's announcement on strengthened warning for canagliflozin-containing medicines, a letter to inform local healthcare professionals to draw their attention to the warning was issued on 11 September 2015. The matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Taiwan: Announcement on the result of re-evaluation on safety of medicines acting on the RAAS (renin-angiotensin-aldosterone system)

The current approved drugs on RAAS by the Taiwan FDA are including: angiotensin-converting enzyme inhibitors (ACEIs) - benazepril, captopril, cilazapril, enalapril, fosinopril, imidapril, lisinopril, perindopril, quinapril, Ramipril; angiotensin II receptor blockers (ARBs)- azilsartan, candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan; direct renin inhibitors- aliskiren.

There is evidence that the combined use of ACEIs, ARBs, or drugs containing aliskiren component will increase the risk of hypotension, hyperkalemia and renal dysfunction (including acute renal failure). To ensure patient medication safety, the Taiwan FDA was soliciting relevant information with clinical literature reports for overall assessment, and concluded that the package insert should be amended to include relevant information under the categories of: (1) Contraindications; (2) The warnings and precautions; (3) The interaction. The details of the requirement are at the following website:
http://www.fda.gov.tw/TC/newsContent.aspx?id=14037&chk=50277d2a-cb8f-4cd2-bc15-6296db3de6ea&param=pn#.Vhtg10zyycz

In Hong Kong, there are 151 registered pharmaceutical products containing ACEIs including the ingredients: benazepril, captopril, cilazapril, enalapril, imidapril, lisinopril, perindopril, ramipril, trandolapril and zofenopril; 242 registered pharmaceutical products containing ARBs including the ingredients: azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan and valsartan; and 8 registered pharmaceutical products containing aliskiren. All products are prescription only medicines. Since 2011, safety alerts regarding the combination of aliskiren with ACEIs or ARBs have been issued by various overseas drug regulatory authorities, and were reported on the Drug News Issues No. 26, 28 and 54. The DH issued letters to inform local healthcare professionals to draw their attention to the warning on 21 December 2011 and 20 February 2012. The matter was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board (the Committee) in August 2012. The Committee decided that the sales pack labels and/or package inserts of products containing aliskiren should include the appropriate safety information as reported in Drug News Issue No. 28. As on 8 October 2015, the DH has received 9 cases of ADR after taking ACEIs, including captopril, enalapril, lisinopril, perindopril and ramipril, and 1 case of ADR after taking ARBs (telmisartan). None of these cases is related to combination of aliskiren, ACEIs and/ or ARBs. In view of the announcement of the Taiwan FDA on update of package insert of ACEIs and ARBs together with update of package insert of aliskiren, the matter will be further discussed in the meeting of the Committee of the Pharmacy and Poisons Board.

US: Clozapine - FDA modifies monitoring for neutropenia; approves new shared REMS Program

On 15 September 2015, FDA was making changes to the requirements for monitoring, prescribing, dispensing, and receiving the schizophrenia medicine clozapine, to address continuing safety concerns and current knowledge about a serious blood condition called severe neutropenia. Severe neutropenia is a dangerously low number of neutrophils, white blood cells that help fight infections. Severe neutropenia can be life-threatening.

There are two parts to the changes in the requirements for treating patients with clozapine. First, FDA clarified and enhanced the prescribing information for clozapine that explains how to monitor patients for neutropenia and manage clozapine treatment. Second, FDA approved a new, shared risk evaluation and mitigation strategy (REMS) called the Clozapine REMS Program. The revised prescribing information and the Clozapine REMS Program will improve monitoring and

management of patients with severe neutropenia. The shared REMS is also expected to reduce the burden and possible confusion related to having separate registries for individual clozapine medicines. The requirements to monitor, prescribe, dispense, and receive all clozapine medicines are now incorporated into the Clozapine REMS Program.

Clozapine is an antipsychotic medicine used to treat schizophrenia in patients whose symptoms are not controlled with standard antipsychotic treatment. It is also used to treat recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder.

Patients who are currently treated with clozapine will be automatically transferred to the Clozapine REMS Program. In order to prescribe and dispense clozapine, prescribers and pharmacies will be required to be certified in the Clozapine REMS Program according to a specific transition schedule starting 12 October 2015.

In Hong Kong, there are 7 registered pharmaceutical products containing clozapine, and all of them are prescription only medicines. In January and March 2012, the DH issued letters to the registration certificate holders of the 7 products containing clozapine to remind them of the following registration requirements of their products:

1) the drug should only be supplied to psychiatrists with a prescribing guideline, a letter of undertaking to be signed by the psychiatrists declaring that he/ she is familiar with the drug, including the restricted indications and risk of agranulocytosis,
2) patient blood monitoring programme to be implemented before, during, and after the discontinuation of the drug, and
3) patient information leaflet with warnings on the risks of the drug.

As on 8 October 2015, the DH has received two cases of ADRs after the use of clozapine, and one of them was related to agranulocytosis. In view of the US FDA's announcement to enhance the prescribing information and risk management program for clozapine, the DH issued a letter to local inform local healthcare professionals about the warning on 16 September 2015. The matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

US: Tramadol - FDA evaluating risks of using in children aged 17 and younger

On 21 September 2015, FDA was investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete.

Tramadol is not FDA-approved for use in children; however, data show it is being used "off-label" in the paediatric population. Healthcare professionals should be aware of this and consider prescribing alternative FDA-approved pain medicines for children.

Parents and caregivers of children taking tramadol who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness should stop tramadol and seek medical attention immediately.

In Hong Kong, there are 43 registered pharmaceutical products containing tramadol. All are prescription only medicines. As on 8 October 2015, the DH has received 2 cases of ADRs on tramadol, and none of them was related to slowed or difficult breathing. In view of the US FDA was evaluating the available information and will draw a final conclusion and recommendations to the public when the review is complete, the DH will remain vigilant on the final conclusion made by the US FDA.

Canada: Multiple sclerosis drug Gilenya (fingolimod): Safety information on the risk of skin cancer and a rare brain infection

On 30 September 2015, Health Canada was informing Canadians that the drug label (product monograph) for the multiple sclerosis drug

Safety Update

Gilenya (fingolimod) has been updated with new safety information on the risk of skin cancer, as well as a rare brain infection known as progressive multifocal leukoencephalopathy (PML).

Gilenya is a prescription drug used in the treatment of relapsing-remitting multiple sclerosis (MS) to reduce the frequency of attacks (relapses) and delay the progression of physical disability. It is specifically used when other MS treatments have not been effective or cannot be tolerated.

Gilenya works by modifying the body's immune system and reducing the access of certain immune cells (white blood cells known as lymphocytes) to the brain and spinal cord, which may reduce the damage that happens in these areas in MS and the frequency of MS relapses. A Health Canada safety review found that Gilenya, like other drugs that suppress the immune system, may increase the risk of lymphomas (lymphocyte cancer) and other cancers, particularly of the skin.

Medicines that suppress the immune system are also known to reduce the body's ability to fight infections. Cases of PML, a rare infection caused by the John Cunningham (JC) virus, have been reported with Gilenya use - including in patients who were not currently taking and had not previously taken other medications that suppress or change the immune system. The JC virus is a common virus that is harmless in most people but can cause PML in some patients who have weakened immune systems. In severe cases, it can lead to disability or death.

Gilenya labelling in Canada already contained information on the possible risk of lymphoma, and warnings about how this drug reduces the body's ability to fight infection. It has been updated to include the risk of skin cancer and PML specifically, and to advise that patients and health professionals be vigilant for symptoms.

Additional information for healthcare professionals:

- Physicians should be vigilant for skin cancer.
- Physicians should be vigilant for clinical symptoms or MRI findings that may be suggestive of PML. MRI signs of PML may be apparent before clinical symptoms develop.
- If PML is suspected, suspend Gilenya treatment until PML has been ruled out.

In Hong Kong, Gilenya Hard Capsules 0.5mg (HK-61192) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Ltd (Novartis), and is a prescription only medicine. Related news on risk of PML has been released by the FDA, and was reported on the Drug News Issue No. 46. The DH issued a letter to local inform local healthcare professionals about the warning on 5 August 2015. As on 8 October 2015, the DH has not received any ADR case on fingolimod. Novartis has applied to the DH to update the package insert of the product to include the relevant warning of PML and basal cell carcinoma (a kind of skin cancer), and the application is under evaluation. As previously reported, the matter concerning PML will be discussed by the Registration Committee of the Pharmacy and Poisons Board (the Committee).

In view of the Health Canada's announcement on the risk of lymphomas (lymphocyte cancer) and other cancers, particularly of the skin, in addition to PML mentioned by the US FDA, the DH issued a letter to inform local healthcare professionals of the warning on 2 October 2015. The information will also be forwarded to the Committee for consideration.

Batch recall of Panadol Caplets 500mg (HK-53362)

On 2 September 2015, the DH endorsed a licensed drug wholesaler, GlaxoSmithKline Consumer Healthcare (Hong Kong) Ltd (GSK), to recall two batches (batch number: XCB041 and XCC003) of Panadol Caplets 500mg from the market due to a quality issue.

The DH was notified by GSK that a complaint was received by GSK involving a small fragment of plastic found in a tablet of the product. Investigation by the manufacturer in Ireland found that the plastic fragment might have been introduced into the product during the manufacturing process. As a precautionary measure, GSK voluntarily recalls the above affected batches from the market.

The above pharmaceutical product (containing paracetamol) is an over-the-counter medicine indicated for headache and fever.

According to GSK, about 21,000 boxes (each box containing 150 tablets) from the two affected batches have been supplied to the Hospital Authority. As on 8 October 2015, the DH has not received any adverse reaction reports related to the affected batches of this pharmaceutical product. The DH closely monitored the recall. A notice was released on the website of the Drug Office on the same day to alert the public of the recall.

DH endorses batch recall of Korus-Atenolol 50mg tablets (HK-61254)

On 25 September 2015, the DH endorsed a licensed drug wholesaler, LSB (HK) Ltd, to recall one batch (batch number: 424801) of Korus-Atenolol 50mg tablets from the market due to a quality issue.

Upon notification from the drug regulatory authority of Macau that the above batch manufactured in Korea has failed the dissolution test, the DH commenced investigations immediately and obtained a sample from LSB for analysis. The Government Laboratory confirmed that the sample failed the dissolution test.

Korus-Atenolol 50mg tablets contain atenolol and are prescription medicine used for the treatment of hypertension.

According to LSB, about 1,558 boxes of 100 tablets of the affected batch have been supplied to private doctors and pharmacies since April 2014. Currently, no other batches of the pharmaceutical product are available in Hong Kong. As on 8 October 2015, the DH has not received any adverse reports in connection with the concerned pharmaceutical product. The DH closely monitored the recall. A notice was released on the website of the Drug Office on the same day to alert the public of the recall.

Members of the public who are in doubt after taking the pharmaceutical product should consult their healthcare professionals for advice.

Woman arrested for suspected illegal sale of slimming product with undeclared banned drug ingredients

On 4 September 2015, a 24-year-old woman was arrested in a joint operation by the DH and the Police for suspected illegal sale of a slimming product (no English name) which is suspected to contain undeclared banned drug ingredients.

Upon the investigation of a public complaint, it was found that a local Internet seller has been offering for sale the above slimming product. A sample of the product was purchased for analysis and test results of the Government Laboratory showed that the product contained the banned drug ingredients sibutramine and phenolphthalein. During the operation of that day, the Police arrested the seller for suspected illegal sale of an unregistered pharmaceutical product and a Part I poison.

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

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

Retail shops raided for suspected illegal sale and possession of unregistered pharmaceutical products

On 11 September 2015, two retail shops in Mongkok area have been raided in a joint operation between the DH and the Police for suspected illegal sale and possession of unregistered pharmaceutical products.

Following a public complaint, it was found that the above shops have been offering for sale suspected unregistered pharmaceutical products. During the operation various products, including an oral gel and two ointments, were seized. Preliminary investigation indicated that the oral gel contains benzocaine while one of the ointments contains hydrocortisone and cinchocaine and the other ointment contains neomycin, polymyxin B and bacitracin. Hong Kong pharmaceutical product registration numbers were not found on any of the products' label.

Benzocaine, cinchocaine and hydrocortisone are Part I poisons. Benzocaine and cinchocaine are local anaesthetics for the relief of pain and itching. Common side effects include hypersensitive reactions. Hydrocortisone is a corticosteroid. Inappropriate or excessive application of it could cause skin problems. Neomycin, polymyxin B and bacitracin are antibiotics and inappropriate use of antibiotics may lead to antibiotic resistance.

Use of unregistered pharmaceutical products may pose health threats to people as their safety, efficacy and quality are not guaranteed. Members of the public should not self-medicate without advice from healthcare professionals.

Public urged not to buy or consume slimming product with undeclared banned ingredient

On 15 September 2015, the DH appealed to members of the public not to buy or consume a slimming product labelled as "USA purchasing" as it was found to contain an undeclared and banned drug ingredient that might be dangerous to health.

During the DH's market surveillance, a sample of the above slimming product was purchased through the Internet for analysis. Test results from the Government Laboratory revealed that the product contains sibutramine.

Sibutramine is a Part I poison and was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned in Hong Kong because of increased cardiovascular risk.

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

Drug Incident

Woman arrested for suspected illegal sale of unregistered pharmaceutical product

On 17 September 2015, a woman aged 29 was arrested in a joint operation by the DH and the Police for suspected illegal sale of an unregistered pharmaceutical product.

Acting upon a public complaint, it was found that an oral product labelled in Japanese as containing tranexamic acid was being offered for sale via the Internet. No Hong Kong pharmaceutical registration number was found on the product label.

Products containing tranexamic acid are prescription drugs which should only be used under the direction of a medical practitioner and can only be sold at a pharmacy by a registered pharmacist or under his supervision upon a doctor's prescription. Tranexamic acid is used in the treatment and prophylaxis of haemorrhage and can cause gastrointestinal disturbances. Inappropriate use may cause cerebral thrombosis.

People who have purchased the above product should stop using it and consult healthcare professionals if they are in doubt or feeling unwell after use.

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.

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: 2319 6319

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,
Wan Chai, 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.