Drug News
藥 物 情 報

Issue Number 179

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in September 2024 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 United Kingdom: MHRA finds evidence does not support a link between Glucagon-Like Peptide-1 (GLP-1) receptor agonists and suicidal and self-injurious thoughts and actions

On 4 September 2024, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that following a thorough review, the MHRA has concluded that the available evidence does not establish a causal relationship between Glucagon-Like Peptide-1 (GLP-1) receptor agonists and suicidal behaviour, suicidal ideation, self-injury and depression.

In July 2023, a new potential safety risk was identified associated with the GLP-1 receptor agonists exenatide, lixisenatide, liraglutide, dulaglutide and semaglutide, and the risk of suicidal thoughts and self-harm following an initial review of post-marketing reports.

Safety reviews were carried out by the Market Authorisation Holders (MAHs) for the GLP-1 receptor agonists exenatide, lixisenatide, liraglutide, dulaglutide and semaglutide to assess the potential risk. These reviews also looked at the risk of depression. This request was made in the interest of patient safety following reports of these side effects.

The MHRA evaluation of the United Kingdom post-marketing data aligned with the conclusions of a European regulatory review which analysed the data from several sources, including post-marketing data, clinical trial data, epidemiological studies and scientific literature.

The MHRA concludes that the available data does not support a causal association between GLP-1 receptor agonists and suicide, suicidal ideation, self-injury and depression, and therefore no updates to the product information is warranted at this time.

The MHRA will continue to closely monitor the risk of severe psychiatric reactions associated with these receptor agonists and will assess new data as it becomes available.

In Hong Kong, there are registered pharmaceutical products containing exenatide (1 product), lixisenatide (2 products), liraglutide (5 products), dulaglutide (4 products), and semaglutide (11 products). All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received adverse drug reactions with regard to exenatide (2 cases), lixisenatide (1 case), liraglutide (1 case), dulaglutide (5 cases), and semaglutide (10 cases), but these cases were not related to suicidal and self-injurious thoughts and actions, or depression.

Related news were previously issued by European Medicines Agency, Health Sciences Authority and the United States Food and Drug Administration, and was reported in the Drug News since Issue No. 165, with the latest update reported in Drug News Issue No. 174. The DH will remain vigilant on safety update of the drugs issued by other overseas drug regulatory authorities.

The United Kingdom: Valproate use in men: as a precaution, men and their partners should use effective contraception

On 5 September 2024, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that a retrospective observational study has indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children. Inform male patients who may father children of this possible increased

risk and the recommendation to use effective contraception during valproate treatment and for at least 3 months after stopping valproate. No one should stop taking valproate without talking to their healthcare professional.

Information for healthcare professionals:

- Findings from a retrospective observational study, combining analyses of electronic medical records in Norway, Denmark and Sweden, indicate a possible increased risk of neurodevelopmental disorders in children born to men treated with valproate in the 3 months prior to conception, compared to those born to men treated with lamotrigine or levetiracetam.
- In the study, the cumulative risk of neurodevelopmental disorders ranged from 4.0% to 5.6% in the valproate treated group versus 2.3% to 3.2% in the composite lamotrigine/levetiracetam monotherapy treated group (pooled adjusted hazard ratio 1.50, 95% CI 1.09 to 2.07).
- This potential risk is much lower than the up to 30-40% risk of neurodevelopmental disorders in children born to mothers taking valproate during pregnancy, estimated from several studies.
- The study did not include an untreated group and background risk in this patient population is therefore unknown.
- An increased risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception is possible however the causal role of valproate is not confirmed. As such this advice is precautionary.

Advice for healthcare professionals:

- Inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate.
- As a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate.
- At the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options.
- If a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling.
- Advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate.

Changes will be made to the product information available online. The Patient Information Leaflet in the box and hard-copies of the updated safety and educational materials will be available in the coming months. The current patient card will be amended to include advice for male patients in addition to the measures relating to the Pregnancy Prevention Programme for women. The manufacturers of valproate will also send a letter to relevant healthcare professionals in October 2024.

In Hong Kong, there are 10 registered pharmaceutical products containing valproate. All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received 17 cases of adverse drug reaction with regard to valproate, but these cases were not related to neurodevelopmental disorders in children after paternal exposure to valproate. Related news was previously issued by Health Sciences Authority, MHRA and European Medicines Agency, and was reported in the Drug News since Issue No. 161, with the latest update reported in Drug News Issue No. 171. The DH issued letters to inform local healthcare professionals to draw their attention on 22 March 2023. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

European Union: EMA recommends measures to minimise the risk of meningioma with medicines containing medroxyprogesterone acetate

On 6 September 2024, the European Medicines Agency (EMA) announced that its safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), has recommended measures to minimise the risk of meningioma, a type of brain tumour, with medicines containing medroxyprogesterone acetate.

These medicines are used for gynaecological (including contraception and endometriosis) and oncological indications. Meningiomas are tumours

of the tissue layer surrounding the brain and spinal cord. Usually they are benign (non-cancerous) and grow slowly but, depending on the size or location, they can cause serious problems.

The committee's recommendations followed a review of data from epidemiological studies, case studies from the medical literature and cases reported in the pharmacovigilance database of the European Union. These data show an increased risk of meningioma in people taking high doses of medroxyprogesterone acetate (injectables and ≥100 mg tablets) for several years. Although the relative risk of meningioma is significantly increased with the use of high-dose medroxyprogesterone acetate, the absolute risk is very small.

PRAC recommended that, in patients who have a meningioma or have had one in the past, medicines containing high-dose medroxyprogesterone acetate must not be used, unless medroxyprogesterone acetate is needed for the treatment of an oncological indication.

PRAC also recommended that patients taking high doses of medroxyprogesterone should be monitored for symptoms of meningioma, which can include change in vision, hearing loss or ringing in ears, loss of smell, headaches, memory loss, seizures and weakness in arms and legs. If a patient treated for a non-oncological indication is diagnosed with meningioma, treatment with high-dose medroxyprogesterone acetate must be stopped. If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with high-dose medroxyprogesterone should be carefully considered, on a case-by-case basis, taking into account individual benefits and risks.

The product information for medicines containing high-dose medroxyprogesterone acetate will be updated to include meningioma as a possible side effect of unknown frequency.

The PRAC has agreed a direct healthcare professional communication (DHPC) to inform healthcare professionals of the increased risk of developing meningioma with high doses of medroxyprogesterone acetate (all injectable and ≥100 mg oral formulations), primarily after prolonged use (several years). The DHPC will highlight that medicines containing high doses of medroxyprogesterone acetate, when used for contraception or non-oncological indications, are contraindicated in patients with meningioma or with a history of meningioma. If a meningioma is diagnosed in a patient treated with high doses medroxyprogesterone acetate, treatment must be stopped.

If a meningioma is diagnosed in an oncological patient treated with high doses medroxyprogesterone acetate, the need to continue the treatment should be carefully reconsidered, on a case-by-case basis taking into account individual benefits and risks. Patients treated with high doses medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice.

In Hong Kong, there are 10 registered pharmaceutical products containing medroxyprogesterone acetate and 6 of them contain high doses of medroxyprogesterone acetate (injectable and ≥100 mg oral formulations). All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had not received any case of adverse drug reactions related to medroxyprogesterone acetate. In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 9 September 2024, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board .

European Union: EMA recommends medicines for chemotherapy containing 5-fluorouracil: in patients with moderate or severe renal impairment, phenotyping for dihydropyrimidine dehydrogenase (DPD) deficiency by measuring blood uracil levels should be interpreted with caution

On 6 September 2024, the European Medicines Agency (EMA) announced that its safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), recommended medicines for chemotherapy containing 5-fluorouracil: in patients with moderate or severe renal impairment, phenotyping for dihydropyrimidine dehydrogenase (DPD) deficiency by measuring blood uracil levels should be interpreted with caution.

Medicines for chemotherapy containing 5-fluorouracil (5-FU) are part of the standard therapy for various cancers, including colorectal, pancreatic, gastric, breast, and head and neck

cancer.

The enzyme dihydropyrimidine dehydrogenase (DPD) is made up in the liver and helps the body break down thymine and uracil. Patients with impaired DPD enzyme function are at increased risk of severe or life-threatening toxicity when treated with 5-FU or one of its prodrugs.

To identify these patients, pre-treatment testing for DPD deficiency is recommended, despite uncertainties regarding optimal testing methodology.

Patients with complete DPD deficiency are at high risk of life-threatening or fatal toxicity and must not be treated with 5-FU or other medicines of the same class (fluoropyrimidines).

Patients with partial DPD deficiency are at increased risk of severe and potentially life--threatening toxicity. To limit the risk of severe toxicity, a reduced starting dose should be considered. Subsequent doses may be increased in the absence of serious toxicity, as the efficacy of a reduced dose has not been established.

The PRAC has agreed a direct healthcare professional communication (DHPC) to inform healthcare professionals about the fact that if blood uracil levels are used to determine the DPD phenotype, the phenotype result must be interpreted with caution in patients with moderate or severe renal impairment, as renal impairment can lead to increased blood uracil levels. This could result in an incorrect diagnosis of DPD deficiency and consequently underdosing of 5-FU or other fluoropyrimidines in these patients.

In Hong Kong, there are 2 registered pharmaceutical products which are fluorouracil injectable products. All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received 110 cases of adverse drug reaction related to fluorouracil, but these cases were not related to DPD deficiency.

Related news was previously issued by European Medicines Agency, the United Kingdom Medicines and Healthcare products Regulatory Agency and Australia Therapeutic Goods Administration, and was reported in the Drug News since Issue No. 113, with the latest update reported in Drug News Issue No. 173. The DH issued letters to inform local healthcare professionals to draw their attention on 18 March 2019.

In June 2021, the Registration Committee of the Pharmacy and Poisons Board discussed the matter, and decided that the labelling of fluorouracil injectable products should include safety information regarding the increased risk of toxicity in patients with DPD deficiency. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

Singapore: Lunsumio (mosunetuzumab): New important identified risk of Hemophagocytic Lymphohistiocytosis

On 13 September 2024, the Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to inform healthcare professionals that Hemophagocytic Lymphohistiocytosis (HLH) is a new important identified risk for LUNSUMIO.

HLH is a life-threatening syndrome, and early detection and management is essential. HLH, including immune effector cell-associated HLH-like syndrome (IEC-HS), may resemble severe cytokine release syndrome (CRS), but with clinical differences from CRS including a delayed onset, rapid increases in serum ferritin, and differences in cytokine profile.

For any case of suspected HLH, LUNSUMIO should be interrupted and treatment should be considered per current practice guidelines or ASTCT expert consensus guidelines. Consensus guidelines recommend frontline treatment with anakinra (an interleukin1 receptor antagonist), with or without corticosteroids. Expert consultation is recommended if HLH is suspected. The prescribing information of LUNSUMIO will be updated accordingly.

In Hong Kong, there are 2 registered pharmaceutical products containing mosunetuzumab. All products are prescription-only medicines. As of the end of September 2024, the Department of Health had not received any case of adverse drug reaction with regard to mosunetuzumab. In light of the above HSA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 13 September 2024, and the matter will be discussed by the Registration Committee of

the Pharmacy and Poisons Board .

Singapore: Plaquenil® (Hydroxychloroquine sulfate): Risk of major congenital malformations and new risks of phospholipidosis and aggravation of myasthenia gravis symptoms

On 19 September 2024, the Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Sanofi-Aventis Pte Ltd to inform healthcare professionals that the Huybrechts study published in 2021 suggested a small increase in the relative risk of major congenital malformations associated with the use of hydroxychloroquine in the first trimester of pregnancy, especially when used at a high daily dosage (≥ 400mg daily).

Healthcare professionals are advised to avoid prescribing daily doses of ≥ 400mg in the first trimester of pregnancy except when, in the judgement of the healthcare professional, the individual's benefits outweigh the risks. It is also advisable to closely monitor the pregnancy, especially during the first trimester, for early detection of major congenital malformations. If there is no alternative treatment to hydroxychloroquine, the lowest effective dose should be used.

In addition, new risks of phospholipidosis and aggravation of myasthenia gravis symptoms have been reported with the use of hydroxychloroquine. Healthcare professionals are advised to discontinue hydroxychloroquine in patients if cardiac, renal, muscular or nerve toxicity is suspected or if aggravation of myasthenia gravis symptoms is suspected. The local package insert of Plaquenil® is being updated to include these information.

In Hong Kong, there are 5 registered pharmaceutical products containing hydroxychloroquine. All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received 9 cases of adverse drug reaction with regard to hydroxychloroquine, but these cases were not related to congenital malformations, phospholipidosis and aggravation of myasthenia gravis symptoms. Avoidance in pregnancy has already been included in the package insert of Hong Kong registered hydroxychloroquine products. Risk of aggravation of myasthenia gravis symptoms is documented in overseas reputable drug references such as the "Martindale: The Complete Drug Reference". In light of the above HSA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 20 September 2024. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

Canada: Summary Safety Review: Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors (canagliflozin, dapagliflozin, empagliflozin) - Assessing the potential risks of prolonged or incident diabetic ketoacidosis despite stopping treatment in adult patients with type 2 diabetes

On 26 September 2024, Health Canada announced that diabetic ketoacidosis (DKA) is a serious and potentially life-threatening complication of diabetes that develops when the body breaks down fat for energy, which causes a buildup of ketones in the blood. Increased blood levels of ketones can lead to symptoms such as difficulties in breathing, stomach pain, nausea and vomiting, confusion, tiredness, loss of appetite, and excessive thirst. Severe cases of DKA can lead to coma. DKA can happen to anyone with diabetes but it is not common in people with type 2 diabetes.

In 2016, Health Canada reviewed the potential risk of DKA in patients using SGLT2 inhibitors and concluded that this class of drugs may increase the risk of DKA. At that time, the Canadian product monograph (CPM) for all products in the drug class were updated to include this risk, as well as the symptoms associated with DKA and recommendations on what to do if patients experienced these symptoms. DKA generally resolves within 48 hours with standard management, including discontinuing the medication.

In 2023, following a manufacturer requested labelling update for canagliflozin-containing products [Invokana (canagliflozin) and Invokamet (canagliflozin / metformin)] to include the risk of prolonged DKA despite stopping treatment as part of standard DKA management, Health Canada reviewed this potential risk to determine the need for labelling changes across the SGLT2 inhibitor drug class. Health Canada also reviewed the potential risk of incident DKA after temporary treatment cessation prior to surgical procedures for SGLT2 inhibitors to determine the optimal time to stop these medications before scheduled surgery.

In this review, DKA was considered prolonged if it started during treatment with SGLT2 inhibitors and lasted 3 or more days after treatment was stopped as part of standard management. Incident DKA occurred after treatment with SGLT2 inhibitors was stopped before a planned surgery, and while the patient was recovering from the surgery. Patients often need to fast before surgery or other invasive procedures, which may also increase the risk of DKA in patients with type 2 diabetes.

Health Canada reviewed information from searches of the Canada Vigilance database and the scientific literature.

Prolonged DKA after stopping SGLT2 inhibitor treatment as part of standard DKA management:

- Health Canada reviewed 167 cases (144 Canadian and 23 international) of DKA in adult patients with type 2 diabetes taking SGLT2 inhibitors where treatment was stopped when DKA was suspected or confirmed (67 in patients taking empagliflozin, 31 in patients taking dapagliflozin and 69 in patients taking canagliflozin). Twenty-six of the 167 cases (3 Canadian) were from the published literature.
- DKA was prolonged in over half of the Canadian cases despite stopping SGLT2 inhibitor treatment.
- DKA lasted 18 days in 1 Canadian patient taking dapagliflozin. There were 6 Canadian cases of DKA lasting longer than 10 days in patients taking canagliflozin, which included 1 case where DKA lasted 21 days. There were no cases of DKA lasting longer than 10 days in patients taking empagliflozin.
- Health Canada's review could not confirm a definitive link between the use of SGLT2 inhibitors and prolonged DKA despite stopping treatment because other factors, such as pre-existing liver or kidney disease, restricted food intake, stress of surgery, dehydration and other medications, may have been involved in the prolongation of DKA. However, a possible link could not be ruled out.

Incident DKA after stopping treatment before scheduled surgery:

- Health Canada reviewed 44 cases (10 Canadian and 34 international) from the published literature of DKA following surgery in adult patients with type 2 diabetes taking SGLT2 inhibitors where treatment was temporarily stopped before surgery (22 in patients taking empagliflozin, 7 in patients taking dapagliflozin, and 15 in patients taking canagliflozin). Forty-one of the 44 cases reviewed were in patients who stopped treatment with SGLT2 inhibitors 2 days or less before surgery (20 of the 22 patients taking empagliflozin, 6 of the 7 patients taking dapagliflozin, and all patients taking canagliflozin).
- No relationship was found between the number of days before surgery the treatment with SGLT2 inhibitor was stopped and the onset of DKA.
- Health Canada also reviewed 5 epidemiologic studies, which indicated that temporarily stopping treatment with SGLT2 inhibitors for a longer period of time before surgery may lower the risk of incident DKA after surgery by 30-50%. However, none of these studies investigated the optimal time for temporary treatment cessation of SGLT2 inhibitors before surgery and there were study limitations.
- Based on the pharmacology of SGLT2 inhibitors, stopping treatment at least 3 days before surgery or other invasive procedure requiring prolonged fasting is reasonable to ensure that the drug has enough time to be eliminated from the body.

While a definitive link could not be confirmed, Health Canada's review of the available information could not rule out a possible drug class effect for the risk of prolonged DKA despite stopping SGLT2 inhibitor treatment as part of standard management in adult patients with type 2 diabetes. Health Canada's review of the available information also identified a number of cases of incident DKA following surgery in adult patients with type 2 diabetes taking SGLT2 inhibitors where treatment was temporarily stopped 2 days or less before surgery.

To reduce the potential risk of incident DKA, Health Canada recommends stopping treatment with SGLT2 inhibitors at least 3 days before surgery or other invasive procedures requiring prolonged fasting, which is consistent with recommendations from Canadian and international diabetes associations and the U.S. Food and Drug Administration. Health Canada also recommends monitoring for DKA following the surgery or procedure, with the decision to reinitiate treatment

with SGLT2 inhibitors to be made by the healthcare professional.

Health Canada is working with the manufacturers to update and align the CPM for SGLT2 inhibitors to include a warning about the risk of prolonged DKA despite stopping treatment as part of standard DKA management in adult patients with type 2 diabetes, and a recommendation for temporary treatment cessation before a surgical procedure. Health Canada will also inform healthcare professionals about these updates through a Health Product InfoWatch communication.

In Hong Kong, there are 20 registered pharmaceutical products containing SGLT2 inhibitors, including canagliflozin (4 products), dapagliflozin (5 products), empagliflozin (10 products) and ertugliflozin (1 product). All products are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received 4 cases of adverse drug reaction of diabetic ketoacidosis related to SGLT2 inhibitors: canagliflozin (1 case), dapagliflozin (1 case) and empagliflozin (2 case).

Related news on the risk of diabetic ketoacidosis of SGLT2 inhibitors was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 67, with the latest update reported in Drug News Issue No. 148. In February 2017, the Registration Committee of the Pharmacy and Poisons Board discussed the matter, and decided that the package insert of products containing SGLT2 inhibitors should include safety information on the risk of diabetic ketoacidosis.

In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 27 September 2024, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Singapore: New identified risk of hepatotoxicity (including hepatic failure) in patients treated with Imbruvica®

On 26 September 2024, the Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Johnson & Johnson International (Singapore) Pte Ltd to inform healthcare professionals about a new identified risk of hepatotoxicity, including hepatic failure, which has been reported in patients treated with Imbruvica® (ibrutinib).

This causal association is based on a recent cumulative review of data from clinical trials, post-marketing cases and literature by Johnson & Johnson and the Imbruvica® package insert will be updated accordingly. Healthcare professionals are advised to discuss with patients the risks associated with the use of Imbruvica®, including hepatoxicity and hepatic failure. It is recommended to assess liver function before initiating treatment with Imbruvica® and monitor patients periodically for changes in liver function parameters during treatment.

In Hong Kong, there are 3 registered pharmaceutical products containing ibrutinib, namely Imbruvica Capsules 140mg (HK-65397), Imbruvica Tablets 140mg (HK-67062) and Imbruvica Tablets 280mg (HK-67063). All products are registered by Johnson & Johnson (Hong Kong) Ltd. They are prescription-only medicines. As of the end of September 2024, the Department of Health (DH) had received 36 cases of adverse drug reaction with regard to ibrutinib, but these cases were not related to hepatotoxicity, including hepatic failure.

Safety information on the risk of hepatotoxicity and hepatic failure has already been included in the package insert of Hong Kong registered Imbruvica products. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

Drug Incident

Woman arrested for suspected illegal sale of topical whitening product with undeclared drug ingredient

On 3 September 2024, the Department of Health (DH) conducted an operation against the sale of a topical whitening cream, namely 88 Total White Underarm Cream, which was found to contain an undeclared controlled ingredient. During the operation, a 37-year-old woman was arrested by the Police for suspected illegal sale of unregistered pharmaceutical product and Part 1 poison.

During the DH's market surveillance, a sample of the above product was purchased via an online platform for analysis. Test results from the Government Laboratory revealed that the sample contained betamethasone valerate, which is 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's investigation is ongoing.

Betamethasone valerate is a steroid substance for treating inflammation. Inappropriate application of steroids could cause skin problems and systemic side effects such as 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.

A press release was posted in the Drug Office website on 3 September 2024 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

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Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920
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Link: http://www.drugoffice.gov.hk/adr.html
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The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.