Drug News
藥 物 情 報

Issue Number 199

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in May 2026 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: Finasteride and Dutasteride – updated safety warnings for psychiatric side effects and sexual dysfunction

On 11 May 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the evidence for finasteride and dutasteride and the risk of suicidal thoughts and behaviours has been reviewed, and MHRA has recommended further measures to minimise this risk. The product information for finasteride and dutasteride containing medicines is being updated to provide more information on these side effects. The UK Finasteride patient cards, already introduced in 2024, highlighting the risks of psychiatric and sexual side effects.

Advice for Healthcare Professionals:

- finasteride is associated with depression, suicidal ideation and sexual dysfunction which may persist after treatment is stopped
- inform patients of the risks at point of prescribing and advise patients to read the Finasteride patient cards and the patient leaflet for finasteride which are both supplied in the 1 mg and 5 mg packs
- the product information for finasteride 1 mg will be updated with a warning that sexual dysfunction may contribute to mood disorders, and that sexual dysfunction has also been reported without mood alterations
- when prescribing finasteride, review their medical record, ask patients if they have a history of depression or suicidal ideation and review patients regularly for psychiatric and/or sexual side effects
- patients prescribed finasteride 1 mg should stop taking the medicine if they develop suicidal thoughts or depression and contact their healthcare professional as soon as possible
- patients prescribed finasteride 5mg or dutasteride should consult their healthcare professional as soon as possible if they develop suicidal thoughts or depression
- dutasteride works in a similar way to finasteride – therefore, as a precaution, a warning will be added to the dutasteride product information that mood alterations have been reported with the same class of medicine (finasteride)
- patients prescribed finasteride or dutasteride should contact their healthcare professional if they experience sexual dysfunction
- report suspected adverse drug reactions associated with finasteride or dutasteride using the Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- finasteride is associated with low mood, depression, suicidal thoughts and sexual dysfunction (decreased sex drive, erectile dysfunction and ejaculation disorders)
- before taking finasteride, read and keep the Finasteride patient cards and patient information leaflet within your pack and inform your doctor if you have any personal history of depression or suicidal thoughts
- if you have seriously harmed yourself or feel you are at risk of serious harm, contact emergency services on 999 immediately
- stop finasteride 1mg immediately if you develop depression or suicidal thoughts and contact your doctor as soon as possible
- if you are prescribed finasteride 5mg or dutasteride and you develop depression or suicidal thoughts, contact your doctor as soon as possible
- if prescribed finasteride or dutasteride and you experience decreased sex drive, difficulty having an erection or ejaculation problems you

should contact your doctor for medical advice

Background:
Finasteride is a 5-alpha-reductase-inhibitor. The 1mg dose is indicated in men for the treatment of male pattern hair loss (androgenetic alopecia). The 5mg dose is indicated for the treatment and control of benign prostatic hyperplasia in adults.

Dutasteride is also a 5-alpha-reductase-inhibitor. It is indicated for the treatment of benign prostatic hyperplasia (0.5 milligram daily dose) and reduction in the risk of acute urinary retention. It is available as dutasteride alone or in combination with tamsulosin.

The MHRA issued a previous Drug Safety Update in April 2024 regarding finasteride, providing a reminder of the risks of psychiatric and sexual side effects with finasteride and introducing the patient cards.

The MHRA reviewed the scientific literature included in the European referral, Yellow Card reports and the actions taken by other international regulators. Evidence was considered by the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM) and the Commission on Human Medicines (CHM). The PEAG and CHM advice included updating the product information of finasteride 1mg and retaining the UK finasteride patient cards for the 1mg and 5mg finasteride products. The data from Yellow Card reports were mainly from patients treated with 1mg finasteride for androgenetic alopecia, and the literature data showed mixed outcomes. The data for dutasteride was very limited, therefore, PEAG and CHM recommended updating the dutasteride product information as a precaution.

Product Information Update:
The SmPC and PIL for finasteride 1mg are being updated with a warning that sexual dysfunction may contribute to mood disorders, which has been reported in some patients, and sexual dysfunction has also been reported without mood alterations. For dutasteride, a warning will be added to the SmPC and PIL that depressed mood, depression or suicidal ideation has been reported in patients receiving another medicine from the same class (finasteride).

Usage:
Prescribing data suggests more than 400,000 prescriptions per month are issued for finasteride 5mg and dutasteride containing medicines. As finasteride 1mg is not prescribed on the NHS and is only available by private prescription, accurate prescription numbers are not available.

Yellow Card data:
Yellow Card data since 1994 to 31 May 2025 includes 170 reports of suicidal ideation and related terms for finasteride (1mg and 5mg) and 5 reports for dutasteride 0.5mg. There were 19 fatal reports of suicide for finasteride and no fatal reports of suicide for dutasteride.

Yellow card reports have been reported to the MHRA by healthcare professionals, members of the public and pharmaceutical companies. The suspected adverse reactions that have been reported do not necessarily mean that the medicine has caused the reaction. Many factors should be considered with careful analysis to assess these data.

In Hong Kong, there are 32 and 11 registered pharmaceutical products containing finasteride and dutasteride respectively. All products are prescription-only medicines. As of the end of May 2026, the Department of Health (DH) had received 5 cases of adverse drug reaction with regard to finasteride, of which 2 cases were reported as decreased libido, erectile dysfunction and depression. With regard to dutasteride, the DH had received 4 cases of adverse drug reaction, but these cases were not related to mood changes or problems with sexual function.

Related news on the risk of mood changes and problems with sexual function associated with the use of finasteride and dutasteride was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 91, with the latest update reported in the Drug News Issue No. 187. The DH issued letters to inform local healthcare professionals to draw their attention on 25 May 2017, 20 January 2023, and 9 May 2025. In February 2015, September 2017 and April 2024, the Registration Committee of the Pharmacy and Poisons Board discussed the matter. In February 2015 and September 2017, the Committee decided that the sales pack label and/or package insert of finasteride -containing products should include safety information on mood changes (including depressed mood, depression and suicidal ideation) and problems with sexual function (including decreased

libido and erectile dysfunction). As previously reported on 9 May 2025, the matter will be further discussed by the Registration Committee of the Pharmacy and Poisons Board .

The United States: FDA Alerts Health Care Providers and Patients about Increased Risk of New Blood Cancers with Tazverik (tazemetostat) Use; Sponsor to Voluntarily Withdraw Product from Market

On 11 May 2026, the United States Food and Drug Administration (FDA) issued an announcement to alert patients and healthcare providers about the voluntary withdrawal of Tazverik (tazemetostat) tablets from the market due to an increased rate of hematologic second primary malignancies (SPMs) — the development of new blood cancers in people treated with Tazverik for a different cancer. As a result, it was determined that the risks of treatment with Tazverik outweigh its benefits.

Tazverik was approved in 2020 to treat individuals aged 16 years and older with metastatic or locally advanced epithelioid sarcoma (a rare cancer that starts as cell growth in the soft tissue) who are not eligible for complete resection. Later that year, it was approved to treat certain adults with relapsed or refractory follicular lymphoma, a slow-growing type of B-cell non-Hodgkin lymphoma. FDA approved both indications under accelerated approval. At the time of accelerated approval, SPMs were recognized as a risk with Tazverik, with an incidence rate of 1.7%. However, with the Symphony 1 trial (NCT NCT04224493), the rate was found to exceed 5% over a median treatment duration of 15.8 months (range: 6.9 to 33 months).

An increased incidence of hematologic SPMs among people taking Tazverik was observed in the study, "SYMPHONY-1: A Phase 1b/3 Double-Blind, Randomized, Active-Controlled, 3-Stage, Biomarker Adaptive Study of Tazemetostat or Placebo in Combination with Lenalidomide Plus Rituximab in Subjects with Relapsed/Refractory Follicular Lymphoma." In this study, as of March 6, 2026, 18 out of 318 (5.7%) patients treated with Tazverik developed hematologic SPMs, compared to no reported events among patients in the control arm. Most SPMs were myelodysplastic syndrome (MDS) and acute myeloid leukemia; others included B-cell acute lymphoblastic leukemia and clonal cytopenia of undetermined significance. Treatment-emergent acute leukemias and MDS are serious and life-threatening disorders that are not expected to be reversible, as evidenced by 3 deaths in the 18 patients, and 14 patients without resolution of the hematologic SPM.

Most participants who developed the new blood cancers were receiving Tazverik for 1-3 years. The SPMs started as early as 7.5 months after beginning treatment and occurred in some patients after stopping treatment. Based on these findings, an independent data monitoring committee recommended that enrollment on the SYMPHONY-1 trial should be stopped and that all patients receiving Tazverik should discontinue treatment immediately. Shortly thereafter, the sponsor, Ipsen, notified FDA of their plans to discontinue Tazverik treatment for patients in the clinical study and withdraw Tazverik from the U.S. market. The study will remain open for long-term safety follow-up of participants. All expanded access programs for Tazverik will be discontinued as well.

In Hong Kong, Tazverik Tablets 200mg (HK-68216) was a pharmaceutical product registered by Hutchmed (Hong Kong) Limited O/B Hutchmed (Hong Kong) Limited (Hutchmed). The product was a prescription-only medicine. As of the end of May 2026, the Department of Health (DH) had received one adverse reaction report associated with the product, but the case was not related to secondary haematologic malignancies.

On 9 March 2026, the DH endorsed a licensed drug wholesaler, namely Healthcare Division O/B DCH Auriga (Hong Kong) Limited (DCH Auriga), distributor appointed by Hutchmed, to voluntarily recall the above product from the market due to the above potential safety risks related to secondary haematologic malignancies. A recall statement was issued by the DH, and was reported in the Drug News Issue No. 197. Related news was previously issued by Macao Pharmaceutical Administration Bureau, and was posted on the Drug Office website on 10 March 2026. On 14 April 2026, the registration of the above product was voluntarily cancelled by Hutchmed.

Australia: Tranexamic acid: risk of serious adverse events after inadvertent spinal administration

On 18 May 2026, the Therapeutic Goods Administration (TGA) issued the following announcement:

Summary
Cases of medication errors have been identified internationally where tranexamic acid injection was inadvertently administered to the spinal cord (intrathecally or epidurally), resulting in severe pain, seizures, cardiac arrhythmias and deaths.

Injectable tranexamic acid should only be administered intravenously and must not be given intrathecally or epidurally.

Tranexamic acid is a clotting medicine that helps to control bleeding. Intravenous tranexamic acid is used during or after surgical procedures.

Most of the administration errors involved mix-ups of vials or ampoules resulting in administration of tranexamic acid instead of the intended injectable local anaesthetic (e.g., bupivacaine, levobupivacaine, prilocaine). At particular risk are procedures that may include intravenous injection of tranexamic acid along with intrathecally administered injectable products.

What Healthcare Professionals Should Do
To minimise the risk, health professionals should consider taking preventative measures with both storage and administration of tranexamic acid.

It is highly recommended that syringes containing tranexamic acid be clearly labelled for intravenous use only. This will help to prevent any mix-ups during administration.

Additionally, it is advised that tranexamic acid injectables be stored separately from injectable local anaesthetics. This segregation will further reduce the risk of incorrect administration and enhance patient safety.

Background
The US Food and Drug Administration (FDA) published an alert in October last year after strengthening warnings to the Prescribing Information (PI) over this issue.

The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee reviewed cases in which tranexamic acid was given intrathecally or epidurally that resulted in severe pain, seizures, cardiac arrhythmias and deaths. Following this review, they issued a Dear Healthcare Professional letter to remind providers that tranexamic acid must not be administered intrathecally, epidurally, by intraventricular injection or by intracerebral application.

TGA reviewed the Australian PIs and found the wording was adequate and did not require updating, with the PIs stating that tranexamic acid is contraindicated for intrathecal or epidural use.

In Hong Kong, there are 7 registered pharmaceutical products which are tranexamic acid injectables. All products are prescription-only medicines. As of the end of May 2026, with regard to tranexamic acid, the Department of Health (DH) had received 6 cases of adverse drug reaction reports, but these cases were not related to medication errors. Related news was previously issued by FDA, EMA and Singapore Health Sciences Authority, and was reported in the Drug News since Issue No. 134, with the latest update reported in the Drug News Issue No. 195. The current product inserts of the locally registered tranexamic acid injectables have listed that the route of administration is for intravenous or intramuscular only. The precautions on the risk of inadvertent neuraxial administration (i.e. intrathecal, epidural) of tranexamic acid injection is also documented in overseas reputable drug references such as “American Hospital Formulary Service Drug Information”. DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

Canada: Summary Safety Review: Diosmin and Hesperidin: Assessing the potential increased risk of bleeding

On 28 May 2026, Health Canada issued the following announcement:

Product
- Diosmin-containing natural health products (NHPs)
- Diosmin- and hesperidin-containing NHPs

Potential Safety Issue
Increased risk of bleeding

Key Messages
- Health Canada’s review of the available information found a possible link between the use of either diosmin or diosmin in combination with hesperidin, and the increased risk of bleeding.
- Although there is a possible increased risk of bleeding with the use of either diosmin or diosmin in combination with hesperidin across

the general population, evidence suggests that the severity of bleeding may be greater in individuals who are taking medications that affect blood clotting, such as anticoagulants (also known as blood thinners).
- Health Canada will update the related monographs to include a recommendation for consumers to consult a healthcare professional prior to taking the product if they are taking medications, including anticoagulants.
- Health Canada expects licence holders to update the risk information on product labels for all licensed diosmin-containing NHPs, as well as diosmin- and hesperidin-containing NHPs, to include a recommendation for consumers to consult a healthcare professional prior to taking the product if they are taking medications, including anticoagulants.
- Health Canada will also inform healthcare professionals about these updates through a Health Product InfoWatch communication.

Overview

Health Canada reviewed the potential increased risk of bleeding with the use of either diosmin or diosmin in combination with hesperidin. This safety review was triggered by a Canadian case of severe rectal bleeding in a patient who had been taking Hemovel, a diosmin-containing NHP, in combination with other medications (including an anticoagulant), for 2 days.

Bioflavonoids are a diverse group of phytochemicals (compounds produced by plants to provide colour, flavour and protection against pests or disease). Diosmin and hesperidin are bioflavonoids present in a number of plants, including citrus fruits (also known as citrus bioflavonoids). As medicinal ingredients, diosmin and hesperidin may be present in a variety of NHPs, including those for the relief of symptoms of hemorrhoids, varicose veins and chronic veinous insufficiency. In addition to diosmin and hesperidin, there are many compounds that are classified as citrus bioflavonoids. However, this safety review only focused on diosmin and hesperidin as Health Canada had not received reports of bleeding events concerning other citrus bioflavonoids.

Use in Canada

- Diosmin and hesperidin are authorized in Canada for use in NHPs for their antioxidant effects (helps protect cells from harmful free radicals, which have been linked to certain health conditions), and for the relief of symptoms of venous insufficiency (failure of veins to adequately circulate blood), varicose veins (swollen veins that bulge under the surface of the skin) and hemorrhoids (swollen veins in the anus and lower rectum).
- Health Canada has authorized diosmin- and/or hesperidin-containing NHPs (either as a single ingredient product or in combination with other ingredients) for oral use under the Natural Health Products Regulations.
- In Canada, diosmin-containing NHPs, with or without hesperidin, are the primary available treatments to help strengthen vein walls and improve circulation in people with chronic venous insufficiency.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance database, the World Health Organization's (WHO) adverse drug reaction database and the scientific literature.
- Health Canada reviewed 19 cases (4 Canadian and 15 international) of bleeding events in patients taking either diosmin or diosmin in combination with hesperidin, including 1 case from the published literature. Of the 19 cases, 4 international cases were found to be possibly linked to the use of either diosmin or diosmin in combination with hesperidin, and the remaining 15 (4 Canadian and 11 international) were unassessable due to limited clinical information and the presence of confounders (other factors that may have contributed to the occurrence of bleeding), such as underlying medical conditions, and the use of prescription drugs and other NHPs. Two deaths (1 Canadian and 1 international) were reported among the unassessable cases.
- Health Canada also reviewed the scientific literature and real-world evidence, which suggested the presence of multiple factors that could increase the risk of bleeding when using either diosmin or diosmin in combination with hesperidin.
    - The scientific literature provided evidence that diosmin may interfere with how certain medications, including anticoagulants, function in the body, such as how they are cleared and/or eliminated from the body. This could result in increased levels of anticoagulants in the blood, increasing their blood thinning effects and the

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risk of bleeding. Some manufacturers of diosmin-containing health products and diosmin- and hesperidin-containing health products marketed in other countries, such as the United States and Australia, have voluntarily updated the risk information on the product labels for these products to include warnings about their use with anticoagulants or during medical procedures.

- Studies have also shown that diosmin and hesperidin can themselves have blood-thinning effects.

Conclusions and Actions

- Health Canada's review found a possible link between the use of either diosmin or diosmin in combination with hesperidin and the increased risk of bleeding.
- Although there is a possible increased risk of bleeding with the use of either diosmin or diosmin in combination with hesperidin across the general population, evidence suggests that the severity of bleeding may be greater in individuals who are taking medications that affect blood clotting, such as anticoagulants. Health Canada will update the related monographs to include a recommendation for consumers to consult a healthcare professional prior to taking the product if they are taking medications, including anticoagulants.
- Health Canada expects licence holders to update the risk information on product labels for all licensed diosmin-containing NHPs, as well as diosmin- and hesperidin-containing NHPs to include a recommendation for consumers to consult a healthcare professional prior to taking the product if they are taking medications, including anticoagulants.
- Health Canada will also inform healthcare professionals about these updates through a Health Product InfoWatch communication.
- Health Canada will continue to monitor safety information involving diosmin and hesperidin, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

In Hong Kong, there are 18 registered pharmaceutical products containing diosmin, of which 17 are combination products with hesperidin. All products are over-the-counter medicines. As of the end of May 2026, the Department of Health had not received any case of adverse drug reaction report with regard to diosmin or hesperidin. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 29 May 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

Drug Recall

Batch Recall of Primidone Tablets USP 250mg

On 11 May 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Trackcircle.com Limited (Trackcircle), to recall one batch (batch 25284105A) of Primidone Tablets USP 250mg, from the market due to a potential quality issue.

The DH received notification from Trackcircle that the overseas manufacturer of the product is recalling the above batch of Primidone Tablets USP 250mg due to a potential for cross-contamination with acemetacin active pharmaceutical ingredient. Acemetacin is a non-steroidal anti-inflammatory drug used for relieving pain and inflammation. As a precautionary measure, Trackcircle voluntarily recalls the above affected batch from the market.

The above product, containing primidone, is a prescription-only medicine used for the treatment of epilepsy. The product is not registered in Hong Kong but was imported for the treatment of particular patients by the Hospital Authority (HA). According to Trackcircle, the affect batch was imported into Hong Kong and supplied solely to the HA.

As of the end of May 2026, the DH had not received any adverse reaction reports in connection with the above product. A notice was posted in the Drug Office website on 11 May 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Recall of eight batches of two products of Apo-Hydroxyzine Capsules

On 13 May 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, Hind Wing

Drug Recall

Company Limited (Hind Wing), to recall one batch (batch number: AW6448A) of the product, namely Apo-Hydroxyzine Cap 10mg (Hong Kong Registration number: HK-39891) and seven batches (batch numbers: AW5758A, AW6084A, AW7380A, AW7456A, AW7457A, AW8516A and AW8647A) of product, namely Apo-Hydroxyzine Cap 25mg (Hong Kong Registration number: HK-43483) from the market because the products were supplied with incorrect shelf-life.

The DH received notification from Hind Wing that the overseas manufacturer of the products is recalling the above batches of Apo-Hydroxyzine Capsules from the market because the products were labelled with a shelf-life longer than the approved shelf-life. Hind Wing therefore is voluntarily recalling the affected batches from the market.

The above two products both contain hydroxyzine in different strengths which are prescription-only medicines used for the management of anxiety, allergic itch, premedication before surgical procedures, and control of nausea and vomiting. According to Hind Wing, the affected batches had been imported into Hong Kong and supplied to private doctors, private hospitals and pharmacies, and exported to Macao.

As of the end of May 2026, the DH had not received any adverse reaction reports in connection with the above products. A notice was posted in the Drug Office website on 13 May 2026 to alert the public of the product recall. The DH noted that the recall was completed.

Drug Incident

Department of Health clamps down on illegal online sale of unregistered anti-obesity medicine

The Department of Health (DH) has long strived to combat the illegal online sale of unregistered medicine and has continuously monitored the sale of controlled anti-obesity medicine in the market. On 6 May 2026, the Department of Health (DH) announced that the DH carried out an enforcement operation with the Police in Tin Shui Wai district, and arrested a 43-year-old woman suspected of illegally selling Part 1 poisons and unregistered pharmaceutical products on the Internet.

Following up on a complaint, the DH purchased, via an instant messaging application, controlled medicines which included a box of anti-obesity injections labelled as containing tirzepatide, and 10 tablets labelled as containing frusemide, used for the treatment of heart disease. Tirzepatide and frusemide are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The products are suspected to be unregistered pharmaceutical products in Hong Kong. The DH will continue to investigate the incident.

Tirzepatide is used for the treatment of obesity, and its side effects include hair loss, nausea and diarrhoea. Frusemide is used for the treatment of heart diseases, and its side effects include low blood pressure and electrolyte imbalance. Medicines containing tirzepatide and frusemide should be used under a doctor's direction and must be supplied on the premises of an Authorized Seller of Poisons (commonly known as a pharmacy) under the supervision of a registered pharmacist upon a doctor's prescription.

The DH strongly urges members of the public not to self-purchase or consume products of doubtful composition or from unknown sources. Purchasing controlled medicines (including slimming drugs) online poses health risks. Besides the lack of a doctor's assessment of an individual's health condition, it is difficult to ascertain the legitimate source of the drugs. It is also impossible to know whether the drugs were properly stored during transportation (especially for drugs requiring cold-chain storage). This leaves their safety, quality and efficacy unguaranteed.

A press release was posted in the Drug Office website on 6 May 2026 to alert the public of the drug incident.

Department of Health and Hong Kong Customs carry out joint operation to crack down on illegal online sale and illegal import of controlled anti-obesity injection

On 12 May 2026, the Department of Health (DH) and Hong Kong Customs carried out a joint enforcement operation in Tin Shui Wai to combat the illegal online sale and illegal import of controlled anti-obesity injections. A 31-year-old woman was arrested on suspicion of illegally selling Part 1 poison and unregistered pharmaceutical product, and of importing a

pharmaceutical product not under and in accordance with a licence.

Following up on a complaint, the DH and Hong Kong Customs purchased two boxes of an anti-obesity injection (please refer to the photos in the press release) from the woman in question via an online social media platform. The product packaging indicated in Japanese that it contains tirzepatide, a substance classified as Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The product is suspected to be an unregistered pharmaceutical product in Hong Kong.

The DH and Hong Kong Customs will continue to investigate the case, and the arrested person has been released on bail pending further investigation.

Tirzepatide is used for the treatment of obesity, and its side effects include hair loss, nausea and diarrhoea. Medicines containing tirzepatide should be used under a doctor's direction and must be supplied on the premises of an Authorized Seller of Poisons (commonly known as a pharmacy) under the supervision of a registered pharmacist upon a doctor's prescription.

The DH strongly urged members of the public not to self-purchase or consume products of doubtful composition or from unknown sources. Purchasing controlled medicines (including anti-obesity injections) online poses health risks. Besides the lack of a doctor's assessment of an individual's health condition, it is difficult to ascertain the legitimate source of the drugs. It is also impossible to know whether the drugs were properly stored during transportation (especially for drugs requiring cold-chain storage). This leaves their safety, quality and efficacy unguaranteed.

A press release was posted in the Drug Office website on 13 May 2026 to alert the public of the drug incident.

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $50,000 fine and one year's imprisonment for each offence.

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

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

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.

Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/reListRPP_index.html.

Useful Contact

Drug Complaint:

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Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920
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Link: http://www.drugoffice.gov.hk/adr.html
Post: Clinical Trials and Pharmacovigilance Unit,
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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.