Drug News
藥 物 情 報

Issue Number 194

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in December 2025 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

Australia: GLP-1 RAs: warnings aligned over potential risk of suicidal thoughts or behaviours

On 1 December 2025, the Therapeutic Goods Administration (TGA) issued the following announcement:

Summary
Product warnings across the GLP-1 RA class of medicines have been aligned to ensure consistent information regarding the potential risk of suicidal thoughts or behaviours.

The glucagon-like-peptide-1 receptor agonist (GLP-1 RA) prescription medicines are used primarily to manage type 2 diabetes mellitus and obesity.

The updates follow investigations by Therapeutic Goods Administration (TGA) and other international regulators.

TGA sought advice from the Advisory Committee on Medicines (ACM) who found that the evidence available was not sufficient to support an association between GLP-1 RAs and suicidal or self-harming behaviours. However, the ACM noted that the Product Information (PI) and Consumer Medicines Information (CMI) documents across the class were inconsistent and should be harmonised.

The ACM stressed that updates should not imply a causal association, but reflect a class level awareness.

The GLP-1 RAs currently marketed in Australia are:
- Ozempic (semaglutide)
- Wegovy (semaglutide)
- Saxenda (liraglutide)
- Trulicity (dulaglutide)
- Mounjaro (tirzepatide)*

* Tirzepatide is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 RA.

What health professionals should do
Health professionals should monitor for the emergence or worsening of depression, suicidal thoughts or behaviours, or any unusual changes in mood or behaviour.

Consider the benefits and risks for individual patients before initiating or continuing therapy in patients with suicidal thoughts or behaviours.

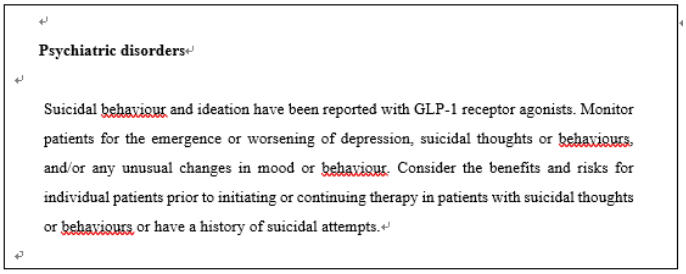
Advise patients to tell their health professional if they experience new or worsening depression, suicidal thoughts or any unusual changes in mood or behaviour.

Background
TGA conducted a comprehensive investigation following notification of a potential international signal for GLP-1 RAs and suicidal or self-injurious ideation.

As part of this investigation, independent expert advice from the ACM was sought at their June 2025 meeting.

While finding insufficient evidence for causality, the ACM noted there was a complex interplay between mental illness and chronic endocrine disorders for which GLP-1 RAs may be used for treatment, and the potential relationship between weight loss and suicidal/self-injurious ideation.

Updates to Product Information
The following wording has been added to the PIs for all GLP-1 RAs (except Saxenda as it already included suitable wording):



Psychiatric disorders

Suicidal behaviour and ideation have been reported with GLP-1 receptor agonists. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behaviours, and/or any unusual changes in mood or behaviour. Consider the benefits and risks for individual patients prior to initiating or continuing therapy in patients with suicidal thoughts or behaviours or have a history of suicidal attempts.

Adverse events reported to TGA
A search of the TGA's Database of Adverse Event Notifications (DAEN) on 23 September 2025 for the GLP-1 RA class (semaglutide, liraglutide, dulaglutide and tirzepatide) retrieved:
- 72 reports for suicidal ideation
- 6 reports for depressional suicide
- 4 reports of suicide attempt
- 2 reports of completed suicide
- 1 report of self-injurious ideation.

In Hong Kong, there are registered pharmaceutical products containing GLP-1 RAs and dual GIP/GLP1 RAs including dulaglutide (4 products), exenatide (1 product), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products) and tirzepatide (6 products). All products are prescription-only medicines. As of the end of December 2025, the Department of Health (DH) had received adverse drug reaction reports with regard to dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case), lixisenatide (1 case) and semaglutide (10 cases), but these cases were not related to suicidal thoughts or behaviours, while no adverse drug reaction report with regard to tirzepatide was received. Related news was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 165, with the latest update reported in the Drug News Issue No. 185. In light of the above TGA's announcement on the aligned class warnings for medicines containing GLP-1 RAs, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Australia: Updated contraception advice for Mounjaro (tirzepatide)

On 1 December 2025, the Australia's Therapeutic Goods Administration (TGA) announced a reminder not to use glucagon-like-peptide-1 receptor agonists (GLP-1 RAs) during pregnancy, as detailed below:

Summary
TGA's investigation into the potential for reduced effectiveness of oral contraception during initiation or dose escalations with Mounjaro (tirzepatide) has found that this association could not be ruled out.

As a precautionary measure, the Product Information (PI) and Consumer Medicines Information (CMI) for tirzepatide has been updated to include further advice for patients using oral contraceptives. Patients are advised to switch to a non-oral contraceptive or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with tirzepatide.

Tirzepatide is a dual glucose-dependent insulinotropic polypeptide (GIP)/glucagon-like-peptide-1 receptor agonist (GLP-1 RA). It is approved in the treatment of type 2 diabetes mellitus (T2DM), chronic weight management and for the treatment of obstructive sleep apnoea in adults with obesity.

It belongs to the GLP-1 RA class of prescription medicines used primarily to manage T2DM and obesity.

The GLP-1 RAs currently marketed in Australia are:
- Mounjaro (tirzepatide)
- Ozempic (semaglutide)
- Wegovy (semaglutide)
- Saxenda (liraglutide)
- Trulicity (dulaglutide)

None of these medicines are recommended for use during pregnancy.

What health professionals should do
Be alert to the PI update for tirzepatide and advise patients taking oral contraceptives to switch to a non-oral contraceptive or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation.

Advise patients that GLP-1 RAs should not be used during pregnancy and individuals of childbearing potential are advised to use effective contraception during treatment with a GLP-1 RA.

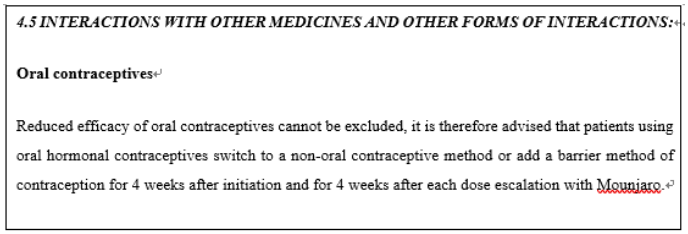
Background
In June 2025, the United Kingdom's Medicines and Healthcare products Regulatory Agency published guidance for GLP-1 medicines for weight loss and diabetes, including advice on

contraception and pregnancy.

TGA conducted an independent investigation for GLP-1 RAs and the potential for reduced effectiveness of oral contraception which resulted in the tirzepatide PI update.

TGA will continue to monitor the safety of GLP-1 RA medicines and will take appropriate regulatory action to address safety concerns when they are identified.

Updates to Product Information
The following text was added to the existing interaction for tirzepatide and oral contraceptives:



4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS:

Oral contraceptives

Reduced efficacy of oral contraceptives cannot be excluded, it is therefore advised that patients using oral hormonal contraceptives switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Mounjaro.

Adverse events reported to TGA
A search of the TGA's Database of Adverse Event Notifications (DAEN) on 9 September 2025 for 'pregnancy on oral contraceptive' retrieved 1 case report with tirzepatide and 1 case report with semaglutide.

In Hong Kong, there are registered pharmaceutical products containing GLP-1 RAs and dual GIP/GLP-1 RAs including dulaglutide (4 products), exenatide (1 product), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products) and tirzepatide (6 products). All products are prescription-only medicines and should not be used during pregnancy. As of the end of December 2025, the Department of Health (DH) had received adverse drug reaction reports with regard to dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case), lixisenatide (1 case) and semaglutide (10 cases), but these cases were not related to reduced effectiveness of oral contraception, while no adverse drug reaction report with regard to tirzepatide was received. The product information of registered pharmaceutical products containing tirzepatide already included the relevant information on drug interaction that since reduced efficacy of oral contraceptives cannot be excluded, it is advised switching to a non-oral contraceptive method, or add a barrier method of contraception upon initiating tirzepatide therapy (for 4 weeks), or after each dose escalation (for 4 weeks). The DH will remain vigilant on any safety update of GLP-1 RAs issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

The United Kingdom: Mesalazine and idiopathic intracranial hypertension

On 4 December 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that idiopathic intracranial hypertension (IIH) has been very rarely reported in patients treated with mesalazine. Following a recent review, warnings for idiopathic intracranial hypertension are being added to the product information for all mesalazine products.

If idiopathic intracranial hypertension occurs in patients, discontinuation of mesalazine should be considered.

Advice for Healthcare Professionals:
- idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine
- the number of reports in the UK is very low
- patients using any form of mesalazine should be warned to look for signs and symptoms of IIH including severe or recurrent headache, visual disturbances or tinnitus
- remain vigilant of signs and symptoms of IIH in patients taking mesalazine and act promptly with a multidisciplinary approach, involving clinicians managing the patient's mesalazine as well as neurology, neurosurgery and ophthalmology teams as appropriate
- if symptoms of IIH occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately
- caution is advised when prescribing for patients who have previously diagnosed or suspected IIH

Advice for Healthcare Professionals to Provide to Patients:
- there have been very rare reports of increased pressure within your skull known as idiopathic intracranial hypertension (IIH) in some patients receiving mesalazine
- IIH is not normally life threatening; however, in rare cases can cause serious vision problems which must be monitored and treated where possible
- tell your doctor immediately if you experience progressively more severe and recurrent

headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH

Background

Mesalazine
Mesalazine is an aminosalicylate and is licensed for the treatment of inflammatory bowel disease such as ulcerative colitis and Crohn's disease.

Mesalazine is currently available in the UK in the following formulations:
- Mesalazine 1g & 2g enema
- Mesalazine 1g actuation rectal foam
- Mesalazine 500mg & 1, 2g suppositories
- Mesalazine 1, 1.5, 2, 3, 4 g granules
- Mesalazine 400, 500, 800, 1000, 1200, 1600 mg tablets

Idiopathic intracranial hypertension (IIH)
The majority of patients presenting with IIH have symptoms that include the following. It should be noted that none of these symptoms alone are unique to IIH.
- a headache that is progressively more severe and frequent; the type of headache can be highly variable
- transient visual obscurations (unilateral or bilateral darkening of the vision typically lasting seconds)
- pulsatile tinnitus
- back pain
- dizziness
- neck pain
- visual blurring
- cognitive disturbances
- radicular pain
- typically horizontal diplopia

Diagnosis may be achieved through blood pressure monitoring and ophthalmology examination. However, where diagnostic uncertainty remains, experienced clinicians should be consulted, who may consider brain imaging and/or lumbar puncture.

Following diagnosis, recommendations for the management of IIH include:
1. to address the underlying cause
2. to protect the vision
3. to minimise the headache morbidity

Mesalazine and idiopathic intracranial hypertension
A recent European review of safety data for mesalazine identified an association between mesalazine and idiopathic intracranial hypertension following very rare reports of this event. Consequently, recommendations have been made to update the product information for mesalazine products to contain warnings for idiopathic intracranial hypertension. The benefit-risk balance remains unchanged in the approved indications.

The findings of this review were considered by the UK's independent Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM) who agreed with the recommendations and advised that the MHRA inform healthcare professionals and patients of the possibility of idiopathic intracranial hypertension with mesalazine.

The number of reports of intracranial hypertension and mesalazine received in the UK and identified through the European review are very low. The MHRA had received 6 UK Yellow Card reports of increased intracranial pressure disorders associated with mesalazine. Total prescribing for mesalazine averages approximately 1.5 million items per year across all regional teams in NHS England. Additionally, the background incidence of IIH had been reported as between 1.8 and 7.8 per 100,000 population per year across Scotland, England and Wales.

New advice when prescribing mesalazine
Prior to prescribing, healthcare professionals should warn patients for signs and symptoms of idiopathic intracranial hypertension. Patients should be advised to tell their doctor immediately if they experience symptoms, including progressively more severe and recurrent headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH.

Additionally, caution is advised when prescribing for patients who have previously diagnosed or suspected idiopathic intracranial hypertension.

Advice in cases of idiopathic intracranial hypertension and mesalazine
If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately.
In Hong Kong, there are 23 registered

pharmaceutical products containing mesalazine. All products are prescription-only medicines. As of the end of December 2025, with regard to mesalazine, the Department of Health (DH) had received one case of adverse drug reaction report, but this case was not related to idiopathic intracranial hypertension. In light of the above MHRA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 5 December 2025, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

The United States: Update on the Safety of Andexxa: FDA Safety Communication

On 18 December 2025, the United States Food and Drug Administration (FDA) issued the following announcement:

Summary of the Issue
Since approval, the United States Food and Drug Administration (FDA) has received postmarketing safety data on thromboembolic events, including serious and fatal outcomes, in patients treated with Andexxa (coagulation factor Xa (recombinant), inactivated-zhzo). Based on available data, the serious risks including the increase in thromboembolic events are such that the FDA considers the risks of the product to outweigh its benefits. The FDA has communicated this position to AstraZeneca, and the company has submitted a request to voluntarily withdraw the Biologic License Application (BLA) for the product for commercial reasons. Additionally, the company has confirmed that it will end U.S. commercial sales by 22 December 2025. Andexxa will no longer be manufactured for or sold in the U.S. by AstraZeneca after 22 December 2025.

Continuous monitoring and assessment of the safety of all biological products, including Andexxa, is an FDA priority, and we remain committed to informing the public when we learn new information about these products.

Background:
The FDA initially granted accelerated approval (AA) of Andexxa, a recombinant modified human factor Xa (FXa) protein, in 2018, indicated for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Initial approval included a Boxed Warning for thromboembolic risks. AA was granted based on the change from baseline in anti-activated FXa (anti-FXa) activity in healthy volunteers, as a surrogate endpoint reasonably likely to predict clinical benefit.

At the time of AA of Andexxa, AstraZeneca (Applicant) was subject to a requirement to conduct a randomized controlled trial (NCT03661528) to verify the clinical benefit of Andexxa among patients with intracerebral hemorrhage following treatment with rivaroxaban or apixaban. On 31 January 2024, the Applicant submitted a supplemental Biologics Licensing Application (sBLA) for Andexxa with the results of the ANNEXA-I trial to fulfill this requirement. The FDA convened a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (AC) on 21 November 2024, to discuss the results of the ANNEXA-I trial. The major safety findings discussed at the AC meeting included a doubling of the rate of thromboses and thrombosis-related deaths at Day 30 in the Andexxa arm compared with usual care (UC):

- Increased risk of thrombosis: ANNEXA-I demonstrated an increased incidence of thrombosis (14.6% versus 6.9%) and thrombosis-related deaths at Day 30 (2.5% versus 0.9%) in the Andexxa arm compared with the UC arm, respectively.
- Of the 35 Andexxa patients who experienced a thrombotic event, 18 (53%) had their event earlier than those 1 of 16 patients (6.3%) in the usual care group.
- Death related to thrombotic events through 30 days occurred in 6 patients (2.5%) in the Andexxa arm compared with 2 patients (0.9%) in the usual care control arm. The FDA will continue working with AstraZeneca to keep providers and the public informed as AstraZeneca prepares to end sale of Andexxa.

In Hong Kong, Andexxa Powder For Solution For Infusion 200mg (HK-68130) is a pharmaceutical product registered by Astrazeneca Hong Kong Limited (Astrazeneca) and is a prescription-only medicine. As of the end of December 2025, the Department of Health (DH) had not received any adverse drug reaction report with regard to Andexxa. Arising from the FDA announcement, DH contacted Astrazeneca and the company confirmed that the product with expiry date in December 2025 has been distributed to only 2 public hospitals and 3 private hospitals since its

registration in February 2024. Besides, Astrazeneca will send notification letters to the aforesaid hospitals to advise their physicians on the safety update in the FDA announcement and to use Andexxa in line with assessed benefit–risk considerations. The DH will continue to maintain contact with the company for any updated information and remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities for consideration of any action deemed necessary and appropriate.

Canada: Summary Safety Review: Brukinsa (zanubrutinib), Calquence (acalabrutinib) and Imbruvica (ibrutinib) - Bruton's Tyrosine Kinase (BTK) Inhibitors: Assessing the potential risk of serious hepatotoxicity

On 18 December 2025, Health Canada issued the following announcement:

Product
Brukinsa (zanubrutinib), Calquence (acalabrutinib) and Imbruvica (ibrutinib) - Bruton's tyrosine kinase (BTK) inhibitors

Potential Safety Issue
Serious hepatotoxicity (liver injury), including drug-induced liver injury (DILI; a rare, but potentially life-threatening, drug reaction with elevated liver enzymes that may lead to liver failure or a need for liver transplant)

Key Messages
- Health Canada's review found a possible link between the use of BTK inhibitors and the risk of serious hepatotoxicity.
- Health Canada is working with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for all BTK inhibitors to include the risk of serious hepatotoxicity. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview
Health Canada reviewed the potential risk of serious hepatotoxicity with the use of BTK inhibitors. This safety review was triggered by notifications of foreign action received from manufacturers.

Prior to Health Canada beginning its review, the manufacturer of Imbruvica initiated a labelling update to include the risk of serious hepatotoxicity in the CPM. Health Canada's safety review, therefore, aimed to determine whether this risk is associated with all other BTK inhibitors (a class effect) and whether a labelling update is warranted across the drug class.

Use in Canada
- Bruton's tyrosine kinase inhibitors are a class of prescription drugs authorized for sale in Canada for the treatment of various blood cancers. In addition, Imbruvica specifically can be used for the treatment of chronic graft-versus-host-disease (a complication of bone marrow transplantation), when other treatments did not work and additional therapy is needed.
- Bruton's tyrosine kinase inhibitors have been marketed in Canada since 2014. All BTK inhibitors are available as oral formulations.
- Approximately 65,000 prescriptions for BTK inhibitors were dispensed by Canadian retail pharmacies in 2024.

Safety Review Findings
- Health Canada reviewed the available information provided by manufacturers and a foreign regulatory agency, as well as from searches of the Canada Vigilance database and the scientific literature.
- Health Canada reviewed 11 cases (1 Canadian and 10 international) of serious hepatotoxicity in patients using Brukinsa or Calquence, including 2 from the published literature. All 11 cases were found to be possibly linked to the use of BTK inhibitors.
- Health Canada also reviewed 20 articles published in the scientific literature. Despite limitations, including the presence of confounders (other factors that may have contributed to the occurrence of hepatotoxicity) and insufficient clinical information, the evidence reviewed supported a possible link between all BTK inhibitors and the risk of serious hepatotoxicity.

Conclusions and Actions
- Health Canada's review of the available information found a possible link between the use of BTK inhibitors and the risk of serious hepatotoxicity.
- Health Canada is working with the manufacturers of BTK inhibitors to update the CPM to include the risk of serious hepatotoxicity. The CPM for Jaypirca

(pirtobrutinib), a BTK inhibitor that was authorized for sale in Canada after the completion of this review, will also include this risk.
- Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Health Canada will continue to monitor safety information involving BTK inhibitors, 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 if and when any new health risks are identified.

In Hong Kong, there are registered pharmaceutical products containing zanubrutinib (1 product), acalabrutinib (2 products), ibrutinib (3 products) and pirtobrutinib (2 products). All products are prescription-only medicines. As of the end of December 2025, the Department of Health (DH) had received adverse drug reaction reports with regard to acalabrutinib (1 case) and ibrutinib (37 cases), but all these cases were not related to hepatotoxicity, while no adverse drug reaction report with regard to zanubrutinib and pirtobrutinib had been received. Related news on the risk of hepatotoxicity associated with Imbruvica (ibrutinib) was previously issued by Singapore Health Sciences Authority and was reported in Drug News Issue No. 179. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 19 December 2025, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Drug Recall

Batch Recall of Erythromycin Ophthalmic Ointment USP

On 5 December 2025, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Trackcircle.com Limited (Trackcircle), to recall one batch (batch number: 2024K02) of Erythromycin Ophthalmic Ointment USP, from the market due to potential quality issue.

The DH received notification from Trackcircle that the overseas manufacturer of the product is recalling the above batch because the sterility of the product might be compromised. As a precautionary measure, Trackcircle voluntarily recalls the above affected batch from the market.

The above product containing antibiotic Erythromycin, is a prescription-only medicine used for the treatment of eye infections. The product is not registered in Hong Kong but was imported for the treatment of particular patients by registered medical practitioners. According to Trackcircle, the affect batch was imported into Hong Kong and supplied solely to the Hospital Authority.

As of the end of December 2025, the DH had not received any adverse reaction reports in connection with the above batch of product. A notice was posted in the Drug Office website on 5 December 2025 to alert the public of the product recall. The DH continues to monitor the recall.

Batch Recall of Maxilin Powder for Solution for Infusion 500mg

On 10 December 2025, the Department of Health (DH) endorsed a licensed drug wholesaler, Hong Kong Medical Supplies Ltd. (HKMS), to recall one batch (batch number: 24F040) of the product, namely Maxilin Powder for Solution for Infusion 500mg (Hong Kong Registration number: HK-65860) from the market as a precautionary measure due to potential quality issue.

The DH received notification from HKMS that the overseas manufacturer of the concerned product is recalling the above batch of Maxilin Powder for Solution for Infusion 500mg from the market because of misrepresentation of its active pharmaceutical ingredient (API) manufacturing site which is breaking the traceability of the supply chain of the API source. HKMS therefore is voluntarily recalling the affected batch from the market.

The above product contains clarithromycin which is a prescription medicine used for the treatment of bacterial infections. According to HKMS, the affected batch had been imported into Hong Kong and supplied to Hospital Authority and private hospitals.

As of the end of December 2025, the DH had not received any adverse reaction report in connection with the product. A notice was posted in the Drug

Drug Recall

Office website on 10 December 2025 to alert the public of the product recall. The DH noted that the recall was completed.

Drug Incident

Woman arrested on suspicion of illegally possessing and selling slimming products containing banned and controlled drug ingredients

On 11 December 2025, the Department of Health (DH) carried out enforcement operations in Tseung Kwan O and Tai Po with the Police in response to suspected illegal sales of slimming products containing banned and undeclared controlled drug ingredients on social media platforms. During the operations, a 27-year-old woman was arrested.

Acting upon intelligence, the DH had earlier purchased samples of two slimming products via an instant messaging application and sent them to the Government Laboratory for analysis. The test results revealed that one capsule sample, packaged in a black plastic container labelled "HELLO GIRL time to show your figure", contained sibutramine and frusemide. The other capsule sample, packaged in an unlabelled blue plastic container, contained sibutramine, N-desmethylsibutramine and frusemide. All three ingredients are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The two products concerned are also suspected to be unregistered pharmaceutical products.

The DH urged members of the public who have purchased the products concerned to stop consuming them immediately, and reminded the public not to buy or consume products of doubtful composition or from unknown sources. The DH will continue to investigate the incident and take appropriate follow-up actions.

Sibutramine was once used as an appetite suppressant. Since November 2010, pharmaceutical products containing sibutramine have been banned for use and sale in Hong Kong due to an increased cardiovascular risk. N-desmethylsibutramine is a substance structurally similar to sibutramine. Frusemide is used for the treatment of heart diseases, and its side effects include low blood pressure and electrolyte imbalance. Medicines containing frusemide should be used under a doctor's direction and be supplied on the premises of an Authorized Seller of Poisons (i.e. pharmacy) under the supervision of a registered pharmacist upon a doctor's prescription.

A press release was posted in the Drug Office website on 11 December 2025 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/

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: Clinical Trials and Pharmacovigilance Unit,
Drug Office, Department of Health,
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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.