Drug News
藥 物 情 報

Issue Number 195

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in January 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: Improving information supplied with Gabapentinoids (Pregabalin/Gabapentin), Benzodiazepines and Z-Drugs

On 8 January 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that it has reviewed the warnings regarding addiction, dependence, withdrawal, and tolerance for gabapentin, pregabalin, benzodiazepines, and z-drugs. The findings (detailed in the Public Assessment Report) were that it was necessary to strengthen these warnings in the product information and on the packaging to better inform healthcare professionals and patients of these known risks.

Advice for Healthcare Professionals:

- gabapentinoids (pregabalin and gabapentin), benzodiazepines and z-drugs are three classes of medicines used to treat a variety of conditions such as neuropathic pain, anxiety and insomnia. Specialist use of these medications for conditions such as epilepsy, or sedation during medical procedures are not included in this review. Examples of benzodiazepines include diazepam, lorazepam, clobazam, temazepam and nitrazepam. Examples of z-drugs include zopiclone, zolpidem and eszopiclone.
- all three classes of medications are known to pose risks of addiction, dependency, withdrawal and tolerance.
- the Summary of Product Characteristics, Patient Information Leaflets and Outer Packaging of these medicines will have strengthened warnings to better communicate the risks of addiction, dependency, withdrawal and tolerance to healthcare professionals and patients. Updates are in progress and will be rolled out over the coming months
- prior to starting treatment with these medicines, a discussion should be held with patients to put in place a strategy for reducing or ending treatment. By doing this the risk of addiction, dependence, and drug withdrawal syndrome is reduced. NICE guideline, NG215, has resources that include visual summaries which are available to support these discussions. The Agency has also developed additional patient resources for benzodiazepines, gabapentinoids and z-drugs which highlight key messages concerning these risks and should be made available to patients when these medications are prescribed
- addiction and dependence are related but have distinct presentations. Healthcare professionals are reminded of the importance of using non-judgmental language when discussing these terms
- patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of symptom control as initially experienced. This could be a sign that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient
- drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to reduce symptoms of withdrawal. Tapering from a high dose may take weeks or months. Patients should be informed of this when the medication is first prescribed and should be encouraged to speak to their healthcare professional or prescriber before stopping their medicine. See NICE guideline NG 215 for identifying and managing withdrawal symptoms
- provide regular support especially to individuals at increased risk of drug

withdrawal syndrome, such as those with current or past history of substance use disorder (including alcohol misuse) or mental health disorder

Advice for Healthcare Professionals to Provide to Patients:

- as these medicines carry risks of addiction, dependence and withdrawal reactions, before starting treatment with these medicines, your healthcare professional should explain how long you might need to take them for, and how to stop safely. This helps reduce the risk of addiction, dependence, and drug withdrawal syndrome
- anyone can become physically dependent on these medicines, meaning that their body gets used to it, and this can cause them to have withdrawal symptoms if the medicine is suddenly stopped, or the dose is reduced
- drug addiction can feel like a strong desire to take the medicine, and difficulties in controlling medicine use (for example feeling like you want to take more or use the medicine when you shouldn't)
- addiction and dependence are related but they are not the same, being physically dependent on a medicine does not necessarily mean you are addicted to it
- drug tolerance can mean no longer feeling like the medicine is working well, or feeling that a higher dose is required to achieve the same symptom relief as before
- if you want to stop taking your medicine there are additional resources to help you. Never stop taking your medication without asking a healthcare professional first
- if you are taking this medicine for epilepsy, you should keep taking it for as long as your doctor says it's needed
- if you find that your treatment is not working as well, you should speak to your healthcare professional about possible alternative treatment options, and you should never take more of your medicine than you have been prescribed
- when it is time to stop your medication, your healthcare professional will tell you how to gradually reduce the amount of medicine you are taking over time (known as dose tapering). This is very important to reduce the risk of drug withdrawal syndrome. Dose tapering can sometimes take weeks or months. Mild symptoms may still occur, but you should contact your healthcare professional if the withdrawal symptoms become intolerable

Background

Review of the communication of the known risks of addiction, dependence, withdrawal and tolerance.

The MHRA undertook an assessment of awareness and understanding of information supplied with dependency-forming medicines and whether potential improvements were needed. The first two phases of the review included gabapentinoids, benzodiazepines and z-drugs. The scope of the review included review of the existing warnings in the product information and labelling of these medicines. Specific assessment of the efficacy, dose and indications of these medicines was outside of the aims of this specific review. A similar review of opioids has previously been undertaken by the Agency.

The MHRA assessed data and evidence that included UK Yellow Card data (voluntary reporting of side effects from healthcare professionals and the public), data from companies which hold the licences for these medicines (marketing authorisation holders), data from other international regulators, clinical practice research datalink data (a database of anonymised GP practice data from across the UK) and accounts of lived experience from patient charity groups and discussions with related professional stakeholders.

The MHRA presented the data and evidence to the Commission on Human Medicines (CHM) who were asked to provide independent advice and recommendations. Other independent expert groups consulted included the Pharmacovigilance Expert Advisory Group (PEAG) and the Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG) who provided their recommendations to the CHM.

Overall, it was considered that the current wording contained within the product information and labelling of gabapentinoids, benzodiazepines and z-drugs did not sufficiently communicate the extent of the known risks of addiction, dependence, withdrawal and tolerance associated with these medications. It was concluded that improved wording should be agreed which reflected current post-marketing experience of the use of these medications so that patients could be appropriately informed about the risks before starting the medication, and can be adequately supported to stop their medications appropriately.Furthermore,

CHM considered that the Agency should generate additional patient resources for benzodiazepines, gabapentinoids and z-drugs in order to highlight key messages to patients.

Additionally, further support from other healthcare stakeholders will be sought in order to influence clinical guidelines and clinical practice which extends beyond the scope of the Agency.

The information considered by the CHM and the advice issued is presented in a Public Assessment Report.

Addiction, dependence, withdrawal and tolerance.
Product information and outer-packaging for gabapentinoids, benzodiazepines and z-drugs in the UK will have consistent warnings of the risks of addiction, dependence, withdrawal and tolerance.

For all patients, prolonged use of these medications may lead to drug addiction and dependence, but these effects can also occur with short-term use at recommended therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol use disorder) or mental health disorder (e.g., major depression). Addiction and dependence are related but have distinct presentations. Healthcare professionals are reminded of the importance of the use of non-judgmental language.

Patients should be closely monitored for signs of misuse, abuse or addiction.

Signs of addiction and misuse could include:
- Expression of craving for the medicine, even if it is causing adverse effects on overall health
- Expression of a need for more e.g. requesting early prescription refills, or reporting additional use of other equivalent medicines
- Taking medicines for reasons other than the approved indications
- Experiencing withdrawal side effects when the medicines are stopped suddenly

Note that if this medicine is being used for the treatment of epilepsy, it should be used for as long as the prescriber considers it necessary, in discussion with the patient.

Tapering Doses
Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. Prior to starting treatment with gabapentinoids, benzodiazepines or z-drugs, a discussion should be held with patients to put in place a reduction strategy for ending treatment with these medicines. There may be exceptions to this in specific clinical situations such as symptom management in end-of-life palliative care and for use in epilepsy.

The reduction schedule for a patient should be tailored to the individual and should be modified to allow intolerable withdrawal symptoms to improve before making the next reduction. If using a published withdrawal schedule, apply it flexibly to accommodate the person's preferences when appropriate, changes to their circumstances and the response to dose reductions.

If the patient is taking more than one of these medicines e.g. gabapentin and diazepam, the reduction strategy should include a discussion to determine which medicine will be tapered first.

If a patient develops intolerable withdrawal reactions, consider pausing the taper or increasing the dosage to the previous tapered dosage level.

Resources for prescribers and dispensers
The Agency has developed additional patient resources for benzodiazepines, gabapentinoids and z-drugs on the risks of addiction, dependence, withdrawal and tolerance which should be provided to patients when these medicines are prescribed. This advice for patients and their families/carers was developed following consultation with a number of stakeholder organisations, charities and the CHM/ relevant expert advisory groups. We encourage healthcare professionals to use this information alongside the statutory patient information leaflet supplied with these medicines. Prescribers are reminded to consult the Repeat Prescribing Toolkit when considering the appropriateness of providing a dependency-forming medicine on repeat prescription.

In addition, NICE have a relevant guideline, NG215, with resources that include visual summaries and patient decision aids which may aid discussions with patients concerning these risks. NHS England have also devised actions to help local healthcare systems develop plans that can support people who are taking medicines associated with dependence and withdrawal symptoms.

The Scottish Government have also published guidance on prescribing of benzodiazepines and z-drugs: Quality prescribing for Benzodiazepines and z-drugs: guide for improvement 2024 to 2027.

The All Wales Medicines Strategy Group (AWMSG) have published guidance on Appropriate Prescribing of Hypnotics and Anxiolytics across Wales and All Wales Analgesic Stewardship Guidance.

The Northern Ireland Formulary provides information for healthcare professionals on Benzodiazepine and Z drug withdrawal and Neuropathic pain. You can also find patient resources on use of Benzodiazepines and Z Drugs and Gabapentinoids in the MHRA website.

In Hong Kong, there are registered pharmaceutical products containing pregabalin (57 products), gabapentin (32 products), diazepam (25 products), lorazepam (9 products), clobazam (3 products), nitrazepam (3 products), zopiclone (27 products), and zolpidem (19 products). All these products are prescription-only medicines. There is no registered pharmaceutical product containing temazepam and eszopiclone.

As of the end of January 2026, the Department of Health (DH) had received adverse drug reaction reports with regard to pregabalin (18 cases including 5 cases reported as drug abuse or intentional overdose), gabapentin (4 cases but not related to the MHRA news), diazepam (7 cases including 3 cases reported as drug abuse or intentional overdose), lorazepam (3 cases including 2 cases reported as drug dependence or intentional overdose), clobazam (1 case but not related to the MHRA news), nitrazepam (1 case but not related to the MHRA news), zopiclone (5 cases including 4 cases reported as drug dependence or intentional overdose), and zolpidem (7 cases including 4 cases reported as drug dependence or drug abuse or intentional overdose).

The risk of addiction, dependence, withdrawal, and tolerance associated with the use of gabapentin, pregabalin, benzodiazepines, and z-drugs is documented in overseas reputable drug references such as the "Martindale: The Complete Drug Reference", "AHFS Drug Information" and "British National Formulary". As the MHRA is in progress to update the product information of the concerned drugs which will be rolled out in the coming months, DH will remain vigilant on the coming MHRA announcements and any safety update of the drugs issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

The United States: FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications

On 13 January 2026, the United States Food and Drug Administration (FDA) issued the following announcement:

What is FDA Doing?
FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications that currently include such language. The affected products are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide). This action follows a comprehensive FDA review that found no increased risk of SI/B associated with the use of GLP-1 RA medications. Saxenda, Wegovy, and Zepbound are each approved for weight reduction in persons with obesity or overweight. At the time of the original FDA approvals, the labeling for each of these products included information in the Warnings and Precautions section about the potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss.

Labeling for GLP-1 RA medications that are approved to improve glycemic (blood sugar) control or other complications in patients with type 2 diabetes mellitus does not currently include information on the risk of SI/B. Today's FDA action will ensure consistent messaging across the labeling for all FDA-approved GLP-1 RA medications.

What are GLP-1 RAs?
GLP-1 RAs are a class of medicines that mimic the effects of a natural hormone called glucagon-like peptide-1 (GLP-1) that is released by the intestine. GLP-1 helps lower blood glucose (sugar) levels after eating and acts in parts of the brain that control appetite and food intake. FDA approved the first GLP-1 RA as adjunctive therapy to improve

glycemic control in patients with type 2 diabetes mellitus in 2005. There are now several medications in this drug class on the market.

What Should Patients and Caregivers Do?
Patients and caregivers should be aware that, after a comprehensive review, FDA found no increased risk of SI/B with the use of GLP-1 RA medications. Patients should continue taking their medication as prescribed and discuss any concerns with their health care professionals.

Suicidal ideation occurs when a person is thinking, considering, or planning suicide. Suicidal behavior occurs when a person takes physical actions toward suicide, including suicide attempts or completed suicide (an act of self-harm that causes death). Tell your health care professional if you experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.

What Should Healthcare Professionals Do?
Healthcare professionals should be aware that FDA found no increased risk of SI/B with the use of GLP-1 RA medications and is requesting the removal of this Warning and Precaution from the prescribing information for the GLP-1 RA medications (Saxenda, Wegovy, and Zepbound) that include such language. Health care professionals should be prepared to discuss with patients that FDA has found no increased risk after conducting a comprehensive review of the available data. If individuals disclose that they are experiencing SI/B, refer them to mental health professionals for evaluation.

What Did FDA Find?
The labeling of GLP-1 RA medications approved for weight reduction in persons with obesity or overweight contains information in the Warnings and Precautions section regarding a potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss.

In July 2023, after receiving postmarketing reports of SI/B in patients taking GLP-1 RA medications, FDA initiated further investigation of the potential risk of SI/B for GLP-1 RA medications. FDA performed a preliminary review of clinical trial and postmarketing data, including observational studies and case reports, and publicly reported those findings in its January 2024 Drug Safety Communication.

The initial review of GLP-1 RA clinical trial data did not find an association between the use of GLP-1 RAs and the occurrence of SI/B. However, because of the small number of cases of SI/B observed in individual trials, there was considerable uncertainty in the risk estimate. To address this concern, FDA performed a comprehensive meta-analysis of clinical trials across GLP-1 RA drug development programs to improve the precision of the risk estimate. The meta-analysis assessed the risk of SI/B comparing GLP-1 RA medications to placebo. There were 91 placebo-controlled GLP-1 RA medication trials in the meta-analysis that included 107,910 patients (60,338 treated with a GLP-1 RA and 47,572 treated with placebo). The results did not show an increased risk for SI/B or for other relevant psychiatric adverse events such as anxiety, depression, irritability, or psychosis.

In addition, FDA conducted a retrospective cohort study using administrative healthcare claims data from the FDA Sentinel System to compare the risk of intentional self-harm between new users of GLP-1 RAs and sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with type 2 diabetes mellitus. The study population included 2,243,138 users (1,161,983 initiated on a GLP-1 RA and 1,081,155 initiated on a SGLT2i) from 10 data partners during the period between October 1, 2015, and September 20, 2023. After controlling for baseline confounders in the study, FDA did not find an increased risk of intentional self-harm in GLP-1 RA users compared to SGLT2i users. Similarly, FDA did not find an increased risk in the subgroup of patients with both type 2 diabetes mellitus and obesity.

FDA also reviewed published observational and pooled studies evaluating the relationship between GLP-1 RAs and SI/B, and related outcomes. Our review concluded that the totality of these studies does not support a causal relationship between the use of GLP-1 RAs and the occurrence of SI/B.

Therefore, consistent with these findings, FDA is requesting that application holders remove information regarding the risk of SI/B from the labeling of GLP-1 RA medications that currently include such language.

In Hong Kong, there are registered pharmaceutical products containing GLP-1 RAs and dual

glucose-dependent insulinotropic polypeptide (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. As of the end of January 2026, 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. 194. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Singapore: Xtandi™ (enzalutamide) interference with laboratory test CMIA leading to falsely elevated digoxin plasma levels

On 15 January 2026, the Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Astellas Pharma Singapore Pte. Ltd. to inform healthcare professionals that Xtandi™ (enzalutamide) may interfere with the chemiluminescent microparticle immunoassay (CMIA) laboratory test method. This interference can lead to falsely elevated digoxin plasma level results in patients taking enzalutamide, regardless of whether the patient is actually taking digoxin.

Healthcare professionals are advised to confirm the serum digoxin levels using another type of assay before determining the need for discontinuation or dose adjustments of digoxin in patients taking enzalutamide. Enzalutamide may also inhibit the efflux transporter P-glycoprotein (P-gp), leading to increased serum levels of digoxin, a P-gp substrate. Digoxin should therefore be used with caution when administered concomitantly with enzalutamide and may require dose adjustment to maintain optimal plasma concentrations.

In Hong Kong, there are 4 registered pharmaceutical products containing enzalutamide. They are prescription-only medicines. Enzalutamide is used in the treatment of metastatic castration-resistant prostate cancer. As of the end of January 2026, the Department of Health (DH) had received 22 cases of adverse drug reaction reports related to enzalutamide, but these cases were not related to interference with CMIA laboratory test results of digoxin. In light of the above HSA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 16 January 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Singapore: CYKLOKAPRON (Tranexamic acid) intravenous injection– Risk of serious including fatal adverse reactions due to inadvertent intrathecal administration

On 16 January 2026, the Health Science Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Pfizer Private Limited to remind healthcare professionals that tranexamic acid injection is authorised for intravenous use only. Serious, including fatal, adverse reactions have been reported following inadvertent intrathecal administration, primarily due to mix-ups with injectable local anaesthetics. Reported adverse reactions include severe back and limb pain, myoclonus, generalised seizures, cardiac arrhythmias, prolonged hospitalisation and death.

Pfizer will be updating the product information to strengthen the warnings that tranexamic acid injections should only be administered intravenously. Healthcare professionals are advised to exercise extreme caution when storing, handling and administering tranexamic acid injectables to ensure the correct route of administration.

In Hong Kong, there are 7 registered pharmaceutical products which are tranexamic acid injectables. All products are prescription-only medicines. Tranexamic acid is used in the treatment and prophylaxis of haemorrhage associated with excessive fibrinolysis. It is also used in the prophylaxis of hereditary angioedema. As of the end of January 2026, with regard to tranexamic acid, the Department of Health (DH) had received 6 cases of adverse drug reaction, but these cases were not related to medication errors. Related news was previously issued by the US FDA and EMA, and was reported in the Drug News since Issue No. 134, with the latest update reported in the Drug News Issue No. 192. 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 of tranexamic acid injection is also documented in overseas reputable drug references such as "American Hospital Formulary Service Drug Information". The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

Singapore: Alecensa® (alectinib): Guidance for management of severe hypertriglyceridaemia

On 16 January 2026, 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 hypertriglyceridaemia, including severe and life-threatening events, has been identified as a new risk with Alecensa® (alectinib) based on cumulative data from clinical studies and postmarketing sources. Severe hypertriglyceridaemia is considered a medical emergency as it may lead to acute pancreatitis.

Healthcare professionals are advised to obtain baseline blood triglyceride measurements from patients before starting Alecensa® and periodically during treatment. Patients should be monitored for symptoms of acute pancreatitis, particularly those at increased risk. If severe or life-threatening triglyceride elevations occur, Alecensa® should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia levels. Risk factors for pancreatitis should be evaluated, and treatable factors addressed before treatment initiation. Roche will be updating the product information to include this new risk and its associated recommendations.

In Hong Kong, Alecensa Capsules 150mg (HK-64854) is an alectinib-containing pharmaceutical product registered by Roche Hong Kong Limited and is a prescription-only medicine. Alecensa is used for treatment of non-small cell lung cancer. As of the end of January 2026, the Department of Health (DH) had received 26 cases of adverse drug reaction related to alectinib but none of them are related to hypertriglyceridaemia and acute pancreatitis. In light of the above HSA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 19 January 2026, and the DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

The United Kingdom: MHRA statement on new review of paracetamol safety during pregnancy

On 17 January 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) issued the following announcement:

Following publication of a new systematic review and meta-analysis in The Lancet Obstetrics, Gynaecology, & Women's Health which found no evidence that paracetamol use during pregnancy increases the risk of autism spectrum disorder, ADHD or intellectual disability among children, the MHRA has reaffirmed that paracetamol continues to be the safest option for managing pain and fever during pregnancy.

Dr Alison Cave, Chief Safety Officer at the MHRA, said:
"Paracetamol remains safe to use during pregnancy. This large-scale analysis of the evidence found no link between taking paracetamol during pregnancy and autism, ADHD, or disability in children.
"Paracetamol has been used for many years and is the recommended first choice for treating pain or fever during pregnancy. When taken as directed, it is safe and effective.
"As with all medicines, pregnant women should speak to their doctor, pharmacist or midwife if they have any questions, and follow the guidance provided with the medicine."

Notes to Editors:
- Paracetamol is recommended as the first-choice painkiller for pregnant women, used at the lowest dose and for the shortest duration. If pain does not resolve, then patients are advised to seek advice from their healthcare professional. See NHS Guidance – Pregnancy, breastfeeding and fertility while taking paracetamol for adults
- The MHRA regularly reviews the safety of paracetamol during pregnancy to ensure that the benefits to the patient and unborn baby outweigh any risks.
- Patients should not stop taking their pain medicines as untreated pain and fever can pose risks to the unborn child.
- Members of the public and healthcare professionals are encouraged to report any suspected side effect from medicines, including paracetamol, to the MHRA's Yellow Card scheme.

- The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All work is underpinned by robust and fact-based judgements to ensure that benefits justify any risks.
- The MHRA is an executive agency of the Department of Health and Social Care.

The Department of Health ("DH") noted that the World Health Organization ("WHO") had issued a statement on 24 September 2025 indicating that there is currently insufficient scientific evidence to conclude that paracetamol (also known as acetaminophen) use during pregnancy causes autism or other neurodevelopmental disorders in children, or that there is any association between the two. Furthermore, several drug regulatory authorities, including those in the European Union, the United Kingdom, Australia, and Canada, had also made announcements and emphasised that, based on rigorous assessments of existing scientific data, paracetamol remains an important option for pregnant women to relieve pain or fever when clinically indicated and under medical advice. Some authorities specifically noted that studies suggesting a potential link between the two exhibit significant limitations and in fact failed to establish a causal relationship. Conversely, the medical community has long confirmed through more rigorous large-scale studies that there is no association between paracetamol use during pregnancy and autism or attention deficit/hyperactivity disorder (ADHD).

Based on current scientific evidence, claims that taking paracetamol during pregnancy causes autism or other neurodevelopmental disorders in children lack sufficient supporting evidence.

In this connection, the DH issued a press statement (http://www.info.gov.hk/gia/general/202509/25/P2025092501333.htm) on 25 September 2025 to emphasise that all public health policies and medical advice must be based on scientific evidence.

In Hong Kong, there are 706 registered pharmaceutical products containing paracetamol (acetaminophen). As of the end of January 2026, with regard to paracetamol, the DH had received 59 cases of adverse drug reaction, but these cases were not related to autism and ADHD in children associated with pregnancy use. Related news was previously issued by the WHO and various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 191.

As previously reported, the DH issued letters to inform local healthcare professionals to draw their attention on the above WHO announcement on 26 September 2025, and the DH will maintain vigilant oversight of the matter, and will take appropriate actions as necessary.

European Union: Use of paracetamol during pregnancy unchanged in the EU

On 20 January 2026, the European Medicines Agency (EMA) announced that recent publication confirms no increased risk of autism, ADHD or intellectual disability. A recent systematic review and meta-analysis published in The Lancet Obstetrics, Gynaecology, & Women's Health has found no evidence that using paracetamol at recommended doses during pregnancy increases the risk of autism spectrum disorder, ADHD or intellectual disability in children. This supports the existing evidence and advice that the EMA issued on the use of paracetamol during pregnancy.

In the EU, paracetamol (also known as acetaminophen) can be used for reducing pain or fever during pregnancy if clinically needed. There is currently no new evidence that would require changes to the current EU recommendations for use.

"Paracetamol remains an important option to treat pain or fever in pregnant women. Our advice is based on a rigorous assessment of the available scientific data and we have found no evidence that taking paracetamol during pregnancy causes autism in children."- EMA's Chief Medical Officer, Steffen Thirstrup.

As included in the product information for paracetamol in the EU, a large amount of data from pregnant women who used paracetamol during pregnancy indicates no risk of malformations in the developing foetus or in newborns.

In 2019, EMA reviewed available studies that investigated the neurodevelopment of children exposed to paracetamol in utero and found that the results were inconclusive and that no link with neurodevelopmental disorders could be established.

When needed, paracetamol can be used during pregnancy. As with any medicine for acute treatment, it should be used at the lowest effective dose, for the shortest possible time and as infrequently as possible.

Pregnant women should speak to their healthcare professional if they have questions about any medication during pregnancy.

As for all medicines, EMA and the national competent authorities in the EU will continue to monitor the safety of medicines containing paracetamol and promptly evaluate any new data as they emerge. Regulatory actions will be taken as necessary to protect public health.

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The United Kingdom: Isotretinoin – changes to prescribing guidance and additional risk minimisation measures

On 22 January 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the Commission on Human Medicines (CHM) has endorsed changes to the risk minimisation measures for isotretinoin, following a review of the impact of the measures implemented in 2023. The MHRA ask healthcare professionals to review these new measures and supporting materials and integrate them into their clinical practice.

Second prescriber no longer required plus updated risk minimisation measures

Following the review of the impact of the 2023 risk minimisation measures for isotretinoin and the October 2025 survey of dermatology services, the CHM has recommended an updated approach to the prescribing requirements for isotretinoin. From today, healthcare professionals can prescribe isotretinoin to those under 18-years old without seeking the agreement of a second prescriber.

However alternative risk minimisation measures have been introduced to ensure isotretinoin continues to be prescribed and dispensed safely and all other existing risk minimisation measures continue to remain in place. The updated approach is designed to strengthen the MHRA ability to monitor safe prescribing while supporting patient access to treatment. The associated Public Assessment Report contains further details of the data considered and advice given by CHM.

Advice for healthcare professionals:
Healthcare professionals are asked to review these new measures and supporting materials and integrate them into their clinical practice

Second prescriber requirement for under 18 years of age no longer required

- The second prescriber regulatory requirement for patients under 18 years of age has been replaced by alternative risk minimisation measures. The product information for isotretinoin will be updated over the coming months to reflect this change. Services can implement this change immediately, although we acknowledge that some transition time may be required.

New Risk Minimisation Measures

- the Acknowledgement of Risk Form for all patients has been updated. The digital version is now available online and should be used in clinical practice as soon as is feasible. Hardcopies will be available in the coming months (see section below for further information). The revised Acknowledgement of Risk Form:
  a) asks the patient to confirm that they understand the therapeutic indication of isotretinoin. The prescriber is also asked to confirm that isotretinoin is clinically indicated for the patient and that there is no other appropriate effective treatment. This provides additional safeguards on appropriate prescribing for all patients
  b) asks the patient to confirm that they understand they can seek a second opinion about their treatment
  c) has been streamlined to fit two pages
- a clinical audit of risk minimisation measures is to be developed and implemented by the British Association of Dermatologists (BAD). Healthcare professionals are expected to fully engage in the clinical audit which will be initiated in 2026 (see section below for further information)
- a patient information video has been produced by the BAD with oversight from the MHRA and CHM, to explain the risks associated with isotretinoin treatment in an accessible format. Healthcare professionals should advise patients to watch the video prior to starting treatment (see section below for further information). Patients will need to confirm they are aware of the video on the Acknowledgement of Risk Form

Existing Measures

- healthcare professionals should continue to follow the other existing measures including:
  - patients should continue to be counselled about the potential mental health and sexual side effects of isotretinoin, and monitoring of these side effects should continue to take place throughout treatment
  - patients of child-bearing potential should continue to be entered into the Pregnancy Prevention Programme (this also applies to other oral retinoid medications)
  - healthcare professionals should continue to use the patient reminder card and pharmacist checklist
  - prescribers should assess a patients' mental health before prescribing isotretinoin including the use of patient-reported outcome measures and ask patients about any sexual function concerns before prescribing isotretinoin
  - prescribers should monitor patients for side effects including mental health and sexual function side effects at each follow up appointment including objective mental health patient reported outcome measures
  - the Lead Prescriber, who initiates isotretinoin treatment, must have expertise in the use of systemic retinoids for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements

Reminder of October 2025 changes to isotretinoin guidance

- healthcare professionals are also reminded about the updates and clarifications to the isotretinoin prescribing advice announced in October 2025:
  - follow-up consultations do not necessarily need to be in person (face to face) and could be remote if appropriate, however the first appointment should be in person
  - medically supervised pregnancy testing may be performed remotely with appropriate oversight to ensure tests are performed correctly and safely
  - patients should be asked about sexual

function at follow up appointments, although by the third appointment, this may be brief

- healthcare professionals should continue to report any suspected adverse drug reactions associated with isotretinoin on a Yellow Card

Advice for healthcare professionals to provide to patients:

- isotretinoin is an effective treatment for acne. It should be used for acne that is severe or at risk of causing permanent scarring when other appropriate treatments have not been effective
- all medicines have side effects. Not every patient experiences side effects. Side effects of isotretinoin include possible mental health and sexual function side effects
- following a review of the impact of the current safety measures, a new monitoring approach has been put into place to ensure that isotretinoin continues to be given to patients safely and that patients are fully informed of the risk of side effects
- patients under 18 will no longer require the agreement of two independent healthcare professionals before they can begin treatment, however services who prescribe isotretinoin will take part in regular audits to ensure safe prescribing practices
- as with any medical treatment, all patients have the option to continue to seek a second opinion from another healthcare professional if they are unsure about starting treatment, your doctor will offer this to you during your first consultation
- a patient information video has been developed which explains when isotretinoin treatment should or should not be used for a patient, and potential side effects of isotretinoin. All patients are advised to watch this video before starting treatment
- although some measures related to isotretinoin are changing, the majority are remaining in place:
    - patients must continue to sign an Acknowledgement of Risk form to confirm that they understand the risk of side effects - your doctor will check that you understand the information in the form - make sure to keep your copy of the completed form safe. This form has been updated to confirm that the patient understands that isotretinoin is indicated for use with severe acne after other treatment options have failed
    - patients receiving isotretinoin treatment will continue to receive a Patient Reminder Card with important safety information – make sure you read the card and keep it safe
    - patients who are taking isotretinoin who may be able to get pregnant will continue to be entered into a Pregnancy Prevention Programme by their doctor, because isotretinoin can seriously harm an unborn baby if taken during pregnancy. Your doctor will explain what this involves
    - mental health will continue to be assessed before prescribing isotretinoin and patients will be asked about any sexual function concerns before prescribing isotretinoin
    - patients will continue to be monitored for side effects including mental health and sexual function side effects at each follow up appointment
- patients already being treated with isotretinoin should continue to follow their agreed treatment plan from their prescriber, but seek advice from their healthcare professional if they have any side effects or concerns
- report side effects associated with isotretinoin directly to the MHRA via the Yellow Card scheme

Background

Following the implementation of the recommendations of the Commission on Human Medicines (CHM) Isotretinoin Expert Working Group (IEWG) and Isotretinoin Implementation Advisory Expert Working Group (IIAEWG) in 2023, the MHRA has conducted a review of the impact of these measures and has sought advice from the CHM. To support the CHM in their decision making, in October 2025, the MHRA asked all dermatology services who prescribe isotretinoin to complete a survey regarding their service. The MHRA review and survey data was presented to the CHM to inform their recommendations on the regulatory requirements of isotretinoin.

The CHM reviewed and considered the effectiveness of the implementation of the new regulatory requirements for isotretinoin after considering all the available data.

The associated Public Assessment Report contains

further details of the data considered and advice given by CHM.

Second Prescriber

The CHM conducted a review concerning the regulatory requirement for two independent prescribers when initiating isotretinoin therapy in patients under 18. The intention behind this requirement was to ensure that two clinicians agreed there were no alternative effective treatments before starting isotretinoin, thus providing greater oversight for young patients.

The CHM considered the risks of maintaining the requirement for two prescribers (specifically in relation to delays to treatment and reduced access) against the benefits gained from a second prescriber, in the light of new data from BAD and clinical practice. The CHM considered that there had been positive structural changes made to clinical pathways, to improve patient counselling and monitoring. The CHM also noted the limited treatment options for severe acne, which meant that there was little disagreement between prescribers regarding isotretinoin treatment.

Concerns were also noted about private practice adherence to regulations and limitations in available data from this sector. The October 2025 survey was conducted to improve the oversight of prescribing practices including in the private sector.

On the basis of the findings and results of the October 2025 survey, the CHM recommended replacing the two-prescriber requirement with other risk minimisation measures. These include an enhanced Acknowledgment of Risk Form, new clinical audit processes, and accessible patient information resources developed by the BAD.

These new measures will provide patients with the same level of information, continued monitoring and the option of a second opinion, whilst enabling the MHRA to strengthen monitoring of adherence to the risk minimisation measures.

The associated Public Assessment Report contains further details of the data considered and advice given by CHM.

Guidance on New Risk Minimisation Measures

New Acknowledgement of Risk Form for Patients

The Acknowledgement of Risk Form for all patients has been updated. The digital version is now available online and should be used in clinical practice as soon as is feasible. Hardcopies will be available to order in the coming months from the Marketing Authorisation Holders.

New Clinical Audit

A regular clinical audit of risk minimisation measures is to be developed and implemented by the BAD. Healthcare professionals are expected to fully engage in the clinical audit which will be initiated in 2026. Relevant dermatology services were asked if they would commit to taking part in future clinical audits as part of our survey released in October 2025 and the vast majority (97%) of services who responded agreed to this. Based on this information, the CHM were able to advise removal of the two-prescriber requirement. The BAD will be in contact later in 2026 to explain what the audit will involve and what data will be required from services as part of the audit. Audits will continue on a regular basis in the future.

With each audit, the information will be gathered by the BAD and then submitted to the CHM for review. If there is evidence that services are not following the risk minimisation measures in place for isotretinoin, further regulatory measures will need to be considered.

Patient Information Video

A patient information video has been produced by the BAD, with oversight from the MHRA and CHM, to explain the risks associated with isotretinoin treatment in an accessible format. Healthcare professionals should advised patients to watch the video prior to starting treatment. For example, they may wish to send a link to the video to patients before their initial appointment takes place. Patients will need to confirm they are aware of the video on the Acknowledgement of Risk Form.

In Hong Kong, there are 13 registered pharmaceutical products containing isotretinoin. All products are prescription-only medicines and are required to have risk minimisation measures in place including a bilingual patient information leaflet in each sales pack, highlighting the teratogenic effect of the product. As of the end of January 2026, the Department of Health (DH) had received 2 cases of adverse drug reactions related to isotretinoin.

Related news was previously issued by various drug regulatory authorities, and was reported in the

Drug News since Issue No. 96, with the latest update reported in the Drug News Issue No. 186. The DH issued letters to inform local healthcare professionals to draw their attention on 27 October 2017 and 27 April 2023. In October 2024, the Registration Committee of the Pharmacy and Poisons Board had discussed the safety of isotretinoin and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing isotretinoin should contain the strengthened safety information about the risks of psychiatric and sexual disorders. The DH will continue to remain vigilant on safety update of the drug issued by other drug regulatory authorities.

Canada: Summary Safety Review: Dimethyl Fumarate: Assessing the potential risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction

On 29 January 2026, Health Canada issued the following announcement:

Product
Dimethyl fumarate-containing products

Potential Safety Issue
Gastrointestinal events of perforation (hole in the wall of the gastrointestinal tract), ulceration (open sore on the lining of the gastrointestinal tract), hemorrhage (bleeding in the gastrointestinal tract) and obstruction (blockage of the gastrointestinal tract)

Key Messages
- Health Canada's review found a possible link between the use of dimethyl fumarate and the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for all dimethyl fumarate-containing products to include the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview
Health Canada reviewed the potential risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction with the use of dimethyl fumarate. The safety review was triggered by a labelling update in the United States for all dimethyl fumarate-containing products.

Use in Canada
- Dimethyl fumarate is a prescription drug authorized for sale in Canada for the treatment of adult patients with relapsing remitting multiple sclerosis. Dimethyl fumarate helps to reduce the number of relapses (flare-ups) and delay physical problems due to multiple sclerosis.
- Dimethyl fumarate has been marketed in Canada since 2013. It is currently available as 120 mg and 240 mg delayed-release capsules, under the brand name Tecfidera, and as generics.
- There were 279,470 prescriptions for dimethyl fumarate dispensed by Canadian retail pharmacies between 2019 and January 2025.

Safety Review Findings
- Health Canada reviewed the available information provided by the manufacturer of Tecfidera, as well as from searches of the Canada Vigilance database, international databases and the scientific literature.
- At the time of the review, Health Canada had received 51 Canadian reports of gastrointestinal events of perforation, ulceration, hemorrhage or obstruction, in patients taking dimethyl fumarate. However, these cases did not meet the criteria for further assessment to determine if there was a link. This was due to incomplete information, the reported events not meeting the definition of perforation, ulceration, hemorrhage or obstruction, or the presence of confounders (other factors that may have contributed to the occurrence of gastrointestinal events), such as underlying medical conditions that are known to affect the gastrointestinal tract.
- Health Canada reviewed 22 international cases of gastrointestinal events of perforation, ulceration, hemorrhage or obstruction, in patients taking dimethyl fumarate, including 2 cases from the published literature. Of the 22 cases, 18 cases (11 of hemorrhage unrelated to an ulcer, 4 of hemorrhage and ulcer, 2 of ulceration and 1 of ulcer perforation) were found to be possibly linked, 1 case of obstruction was unlikely to be linked, and 3 cases (2 of hemorrhage and 1 of ulcer perforation) were unassessable due to limited or conflicting clinical information. No deaths were reported.

- Health Canada also reviewed 3 articles published in the scientific literature, which included the 2 cases from the published literature mentioned above. They supported a link between the use of dimethyl fumarate and the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.

Conclusions and Actions
- Health Canada's review found a possible link between the use of dimethyl fumarate and the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.
- Health Canada will work with the manufacturers to update the CPM for all dimethyl fumarate-containing products to include the risk of gastrointestinal events of perforation, ulceration, hemorrhage and obstruction.
- 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 dimethyl fumarate, 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 3 registered pharmaceutical products containing dimethyl fumarate. All products are prescription-only medicines. As of the end of January 2026, the Department of Health had not received any case of adverse drug reaction report with regard to dimethyl fumarate. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 30 January 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

The United Kingdom: GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists: strengthened warnings on acute pancreatitis, including necrotising and fatal cases

On 29 January 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the product information for all Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists has been further updated to highlight the potential risk of severe acute pancreatitis with these products, including rare reports of necrotising and fatal pancreatitis.

Summary
The product information for all Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists (dulaglutide, exenatide, liraglutide, semaglutide and tirzepatide) has been further updated to highlight the potential risk of severe acute pancreatitis with these products, including rare reports of necrotising and fatal pancreatitis. Healthcare professionals should remain vigilant for signs and symptoms of acute pancreatitis in patients treated with GLP-1 and GLP-1/GIP receptor agonists.

Advice for Healthcare Professionals:
- be alert to the risk of acute pancreatitis in patients receiving Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists. There have been rare reports of necrotising and fatal pancreatitis associated with GLP-1 and GLP-1/GIP receptor agonists
- advise patients to seek urgent medical attention if they develop severe and persistent abdominal pain that may radiate to the back and may be accompanied by nausea and vomiting
- privately prescribed GLP-1s and GLP-1/GIPs may not appear on the patient's medical history so if a patient presents with these symptoms, enquire about GLP-1 or GLP-1/GIP use
- if pancreatitis is suspected, discontinue treatment with the GLP-1 or GLP-1/GIP receptor agonist immediately;
- do not restart therapy if the diagnosis of pancreatitis is confirmed
- GLP-1 and GLP-1/GIP receptor agonists should be used with caution in patients with a history of pancreatitis

Advice for Healthcare Professionals to Provide to Patients:
- pancreatitis (inflammation of the pancreas) is a possible side effect with GLP-1 receptor agonists and dual GLP-1/ GIP receptor agonists. In rare reports this can have serious or fatal outcomes
- seek urgent medical attention if you

experience severe, persistent abdominal pain, that may radiate to your back and may be accompanied by nausea and vomiting, as this may be a sign of pancreatitis
- do not restart GLP-1 receptor agonist or GLP-1/GIP receptor agonist treatment if pancreatitis is confirmed

Background

Glucagon-like peptide-1 (GLP-1) receptor agonists and dual GLP-1/ glucose-dependent insulinotropic polypeptide (GIP) receptor agonists are used for the treatment of type 2 diabetes mellitus and, for some products, for weight management and cardiovascular risk reduction. The GLP-1 and GLP-1/GIP receptor agonists authorised in the UK include dulaglutide, exenatide, liraglutide, semaglutide and tirzepatide. Exenatide is no longer marketed in the UK and lixisenatide is no longer authorised.

Acute pancreatitis is a recognised side effect with GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists. Although the overall frequency remains uncommon, post-marketing experience has shown that some rare reports of acute pancreatitis have been particularly severe, including necrotising and fatal pancreatitis.

In the UK between 2007 and October 2025, the MHRA has received 1,296 Yellow Card reports of pancreatitis (including acute, autoimmune, chronic, haemorrhagic, necrotising, subacute and obstructive forms of pancreatitis) associated with GLP-1 receptor agonists or dual GLP-1/GIP receptor agonists. Of these, 19 reports were fatal and 24 were reported as necrotising pancreatitis. For context, in the past 5 years, it is estimated that roughly 25.4 million packs of the GLP-1 receptor agonists have been dispensed.

The Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM), has advised that the product information for all GLP-1 and dual GLP-1/GIP receptor agonists receptor agonists should be strengthened to highlight the potential severity of acute pancreatitis and to ensure consistency across the class of medicines.

Pancreatitis may be challenging to recognise in its early stages, as initial symptoms such as abdominal pain, nausea or vomiting may be attributed to other causes such as common gastrointestinal side effects of GLP-1 and GLP-1/GIP treatment or infection. Clinicians should remain vigilant for the possibility of pancreatitis in patients treated with GLP-1 or GLP-1/GIP receptor agonists and investigate in line with local clinical practice. Advise patients to seek urgent medical attention if they develop severe, persistent abdominal pain that may radiate to the back and may be accompanied by nausea and vomiting.

Product Information Update

The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for all UK-authorised GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists have been updated to highlight reports of necrotising pancreatitis and reports with a fatal outcome and to advise that patients seek immediate medical attention if symptoms of acute pancreatitis occur.

In Hong Kong, there are registered pharmaceutical products containing GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists 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 January 2026, the Department of Health had received adverse drug reaction reports with regard to exenatide (2 cases including 1 case related to pancreatitis) and lixisenatide (1 case and is related to pancreatitis); and for dulaglutide (5 cases), liraglutide (1 case), semaglutide (10 cases) with all cases not related to pancreatitis, while no adverse drug reaction report with regard to tirzepatide was received.

Related news on the risk of acute pancreatitis associated with GLP-1 receptor agonists was previously issued by the US Food and Drug Administration and European Medicines Agency, and was reported in the Drug News since Issue No. 41, with the latest update reported in the Drug News Issue No. 45. In light of the above MHRA's announcement on highlighting the risk of severe acute pancreatitis including rare reports of necrotising and fatal pancreatitis, the DH issued letters to inform local healthcare professionals to draw their attention on 30 January 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Two persons arrested for suspected illegal Internet sale of product with undeclared controlled drug ingredient

On 14 January 2026, the Department of Health (DH)'s investigation revealed the suspected illegal sale of a product containing undeclared controlled medicines via an instant messaging application and carried out an enforcement operation with the Police. During the operation, a 27-year-old woman and a 46-year-old man were arrested on suspicion of illegal sale of Part 1 poisons and unregistered pharmaceutical products.

Following up on a public complaint, the DH purchased samples of a product named "The Goat Sublingual Strip" via an instant messaging application for analysis. The label of the oral pills indicated it was a natural virility product. Test results from the Government Laboratory revealed that the samples contained sildenafil, which is a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance). The product is also suspected to be an unregistered pharmaceutical product.

The DH urged members of the public who have purchased the product concerned to stop consuming it immediately and reminded the public not to buy or consume products of doubtful composition or from unknown sources.

The DH reminded the public that selling medicines controlled under the Ordinance illegally, regardless of the sales channel (including instant messaging apps or social media), carries criminal liability. Do not risk breaking the law.

The DH will continue to investigate the incident and take appropriate follow-up actions.

Sildenafil is a prescription drug used for the treatment of erectile dysfunction and should only be used under a doctor's advice and supplied in a pharmacy under the supervision of a registered pharmacist upon a doctor's prescription. Side effects of sildenafil include low blood pressure, headaches, vomiting, dizziness and transient vision disturbances. It may interact with some drugs (such as nitroglycerin for the treatment of angina) and cause a decrease in blood pressure to dangerous levels. Improper use of sildenafil may pose serious health risks, especially for patients with heart problems.

A press release was posted in the Drug Office website on 14 January 2026 to alert the public of the drug incident.

DH investigates illegal online sale of slimming product containing controlled drug ingredients

On 29 January 2026, the Department of Health (DH) investigated a case of illegal sale of a slimming product containing undeclared controlled drug ingredients on the Internet. Members of the public are urged not to buy or consume the product concerned (please refer to the photo in the press release) to avoid health risks.

Acting upon intelligence, the DH purchased a slimming product for analysis via an instant messaging application. The product's paperboard packaging bore the English labels "KRN+PM" and "KOREAN PREMIUM". Inside were 30 sealed packaging bags, each containing seven pills and capsules. There was Korean wording displayed on the product's packaging that the product may have originated in Korea.

Laboratory test results revealed that a sample of the orange, round tablet debossed with "Y|H" contained hydrochlorothiazide; and a sample of the green/yellow capsule with "TG" and "FLM" printing contained fluoxetine. Both substances are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO).

The product is suspected to be an unregistered pharmaceutical product. The DH will continue to investigate the incident and take appropriate follow-up actions.

Hydrochlorothiazide is used for the treatment of hypertension and its side effects include low blood pressure and electrolytes imbalance. Fluoxetine is used for treatment of depression and may cause hallucinations and insomnia. Medicines containing hydrochlorothiazide and fluoxetine should be used under a doctor's direction and 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 who have purchased the product concerned to stop consuming it immediately and reminded the public not to buy 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.

The DH also reminded the public that selling medicines controlled under the PPO illegally, regardless of the sales channel (including instant messaging apps or social media), carries criminal liability. Do not risk breaking the law.

A press release was posted in the Drug Office website on 29 January 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:

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,
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
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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.