Drug News
藥 物 情 報

Issue Number 203

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in September 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 States: FDA Adds Boxed Warning to Labeling for Ferric Carboxymaltose Injection (Injectafer) to Describe Risk of Low Phosphate Levels

On 1 September 2026, the United States Food and Drug Administration (FDA) issued the following announcement:

What is FDA Doing?
FDA has approved revisions to the labeling for ferric carboxymaltose injection (currently marketed as Injectafer) that adds a boxed warning, the agency's most prominent safety warning. This boxed warning describes the risk for symptomatic hypophosphatemia (low levels of phosphate in the blood) associated with ferric carboxymaltose injection and recommends phosphate monitoring in patients at risk of hypophosphatemia and in any patient who receives a repeat course of therapy within three months of the prior course.

Clinical manifestations depend on the severity and duration of hypophosphatemia. Symptoms may include muscle weakness or pain, fatigue, tremors, confusion, seizures, and cardiac arrhythmias. Chronic severe hypophosphatemia may lead to osteomalacia (bone softening) and bone fractures.

FDA has previously approved other labeling updates for Injectafer that describe this risk. In 2019, FDA determined that ferric carboxymaltose injection can cause serious symptomatic hypophosphatemia. As a result, in February 2020, FDA approved labeling revisions that, along with other changes, added a warning about this risk. In 2023, the warning was revised to include recommendations for serum phosphate level monitoring in patients at risk for hypophosphatemia and in any patient who receives a repeat course of treatment within three months. The revised warning also included osteomalacia and fractures as potential long-term complications and added inflammatory bowel disease as a possible risk factor for hypophosphatemia. In 2025, the warning was further revised to include additional risk factors for hypophosphatemia.

In 2026, FDA conducted an assessment of hypophosphatemia in association with ferric carboxymaltose injection using multiple data sources, including the FDA Adverse Event Reporting System (FAERS) database (which has been incorporated into the FDA Adverse Event Monitoring System [AEMS] database), literature reports, and FDA's Sentinel System. FDA found that symptomatic hypophosphatemia continues to be reported with ferric carboxymaltose injection and serum phosphate testing levels are low despite labeling changes in February 2020 and May 2023.

What Is Ferric Carboxymaltose Injection (Injectafer)?
Ferric carboxymaltose injection (Injectafer) is a prescription iron replacement medicine originally approved in 2013 to treat iron deficiency anemia. Ferric carboxymaltose injection is given intravenously (through the vein). Iron deficiency anemia is a common type of anemia that can cause fatigue, weakness, shortness of breath, and other symptoms. Injectafer is approved for patients one year of age and older who cannot tolerate or do not fully respond to oral iron. It is also approved for iron deficiency in adults who have non-dialysis-dependent chronic kidney disease, and for iron deficiency in adults with heart failure and New York Heart Association class II/III to improve exercise capacity. Certain strengths of Injectafer are also approved as ferric carboxymaltose injection generic products. Generic application holders are expected to update their labeling to incorporate this change after this approval.

What Should Patients Do?
Patients should immediately report any new or worsening symptoms of low phosphate levels (e.g., muscle weakness or pain, fatigue, bone and joint pain, confusion) to their healthcare provider. Some of these symptoms may mimic those of iron deficiency anemia

What Should Healthcare Providers Do?
Healthcare providers should inform patients of the risk of hypophosphatemia with ferric carboxymaltose injection use. Healthcare providers should also:

- Check serum phosphate levels prior to a repeat course of treatment if the patient is at risk for low serum phosphate or if the patient will receive a repeat course of therapy within three months of the prior course.
- Correct pre-existing hypophosphatemia prior to administering Injectafer.
- Monitor serum phosphate levels in patients at risk for chronic low serum phosphate.
- Treat hypophosphatemia as medically indicated.
- Consider permanent discontinuation of Injectafer for severe symptomatic hypophosphatemia or persistent hypophosphatemia.

What Did FDA Find?
FDA found that symptomatic hypophosphatemia continues to be reported with ferric carboxymaltose injection, despite labeling changes in February 2020 and May 2023 adding and strengthening the warning about this risk. The FAERS case series included reports of symptomatic hypophosphatemia that occurred after both single and multiple infusions of ferric carboxymaltose injection. Consequences included hospitalization, need for phosphate replacement therapy over weeks to months, and extensive monitoring with regular follow-up medical visits.

Data from the FDA's Sentinel System indicate that serum phosphate laboratory testing occurs in fewer than 20% of ferric carboxymaltose administration episodes.

Hypophosphatemia associated with ferric carboxymaltose can lead to serious outcomes including hospitalization, a need for prolonged phosphate replacement therapy, osteomalacia, and fractures. This serious adverse reaction can be prevented or reduced in severity through appropriate phosphate level monitoring and early intervention. Therefore, FDA has required a boxed warning be added to the Injectafer labeling describing the risk for symptomatic hypophosphatemia and recommending mitigation strategies. This action highlights the warning already in the Injectafer labeling.

In Hong Kong, there are 2 registered pharmaceutical products containing ferric carboxymaltose and are prescription-only medicines. As of the end of September 2026, the Department of Health (DH) had received one case of adverse drug reaction with regard to ferric carboxymaltose, but the case was not related to hypophosphatemia.

Related news was previously issued by Australia Therapeutic Goods Administration and the United Kingdom Medicines and Healthcare products Regulatory Agency, and was reported in the Drug News Issue No. 124 and 133. The DH issued letters to inform local healthcare professionals to draw their attention on 28 February 2020. In December 2020, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong discussed the matter and decided that the sales pack label and/or package insert of registered ferric carboxymaltose injection products should include safety information about the risk of hypophosphatemia and hypophosphatemic osteomalacia, and serum phosphate should be monitored in patients with existing risk factors for hypophosphataemia and those who receive multiple administrations at higher doses or long-term treatment. DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

European Union: Review Will Assess Risk of Low Blood Phosphate Levels and Related Bone Problems with Injectable Iron Medicines

On 4 September 2026, the European Medicines Agency (EMA)'s safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), announced that it has started a review of injectable iron-containing medicines following concerns about the risk of hypophosphataemia (low blood phosphate levels) and related bone problems, including osteomalacia (softening of the bones). Phosphate is important for keeping bones healthy. When phosphate levels become too low, osteomalacia can occur causing symptoms such as bone pain. In some cases, it can result in fractures.

Injectable iron-containing medicines are used to

treat iron deficiency and iron deficiency anaemia (low red blood cell levels) when iron taken by mouth does not work well enough, cannot be used, or when iron levels need to be restored quickly.

Hypophosphataemia and hypophosphataemic osteomalacia (softening of the bones caused by low blood phosphate levels) are known side effects of injectable iron medicines containing the active substance ferric carboxymaltose. Hypophosphataemia is listed as a common side effect in the product information, meaning it affects up to 1 in 10 people taking the medicine. However, the frequency of hypophosphataemic osteomalacia is unknown because the available data do not allow an estimate of how often it occurs. The product information also includes measures to reduce the risk of hypophosphataemic osteomalacia including recommendations to monitor blood phosphate levels in people receiving high doses or long-term treatment and those with known risk factors.

The review was triggered following reports that raised concerns about the effectiveness of the current measures to reduce this risk for medicines containing ferric carboxymaltose. These included serious cases of hypophosphataemia, some of which resulted in osteomalacia, including in people who had received only one or two doses of ferric carboxymaltose and who did not have recognised risk factors. Furthermore, in some cases there were delays in diagnosing hypophosphataemia. This could be because symptoms of hypophosphataemia such as tiredness, muscle pain and bone pain may overlap with those of iron deficiency. In addition, the bone problems reported in these cases, such as osteomalacia, may not always be visible on X-rays.

As similar cases have also been reported with other injectable iron-containing medicines, the scope of the review covers all of these medicines rather than only those containing ferric carboxymaltose.

Iron-containing medicines taken by mouth are not included in the review because they provide considerably lower amounts of iron over time than injectable medicines and are therefore less likely to cause hypophosphataemia. PRAC will now review the risk of hypophosphataemia and related bone disorders associated with injectable iron-containing medicines, as well as the effectiveness of existing measures to reduce these risks. The Committee will assess whether these risks affect the overall benefit-risk balance of the medicines and determine whether any changes to their marketing authorisations are needed.

In Hong Kong, there are registered injectable iron-containing pharmaceutical products for human use including ferric carboxymaltose (2 products), iron sucrose (2 products) and iron isomaltoside 1000 (3 products). All products are prescription-only medicines. As of the end of September 2026, the Department of Health (DH) had received 10 cases of adverse drug reaction with regard to iron isomaltoside 1000 of which 1 case is related to hypophosphatemia; and 1 case of adverse drug reaction with regard to ferric carboxymaltose but the case was not related to hypophosphatemia. The DH had not received any adverse drug reaction case with regard to iron sucrose.

Related news on the risk of hypophosphatemia and hypophosphatemic osteomalacia associated with the use of ferric carboxymaltose injection was previously issued by Australia Therapeutic Goods Administration, the United Kingdom Medicines and Healthcare products Regulatory Agency and the US Food and Drug Administration, and was reported in the Drug News Issue No. 124 and 133. The DH issued letters to inform local healthcare professionals to draw their attention on 28 February 2020. In December 2020, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong discussed the matter and decided that the sales pack label and/or package insert of registered ferric carboxymaltose injection products should include safety information about the risk of hypophosphatemia and hypophosphatemic osteomalacia, and serum phosphate should be monitored in patients with existing risk factors for hypophosphataemia and those who receive multiple administrations at higher doses or long-term treatment.

As the safety review by the EMA PRAC is still ongoing, DH will remain vigilant on the conclusion of the PRAC review and safety update of the concerned drugs issued by other drug regulatory authorities for consideration of any action deemed necessary.

The United States: FDA Approves Additional Information in Labeling for Kybella (Deoxycholic Acid) Injection Warning of Adverse Reactions Associated with Unapproved Use

On 15 September 2026, the United States Food and Drug Administration (FDA) issued the following

announcement:

What is FDA Doing?
FDA has approved an additional warning in labeling for Kybella (deoxycholic acid) injection regarding adverse reactions associated with use of the drug outside of the submental fat region (fat under the chin, known as a "double chin") and recommends against this unapproved use. The agency approved this revised labeling after its review of FDA Adverse Event Reporting System (FAERS) reports (now known as the FDA Adverse Event Monitoring System) and the medical literature. In this review, FDA determined that when Kybella is administered outside the submental fat region, neuromuscular and other serious adverse events may occur.

The agency has also approved language in the Warnings and Precautions section of labeling about the serious risks of injection site nodules and masses. These newly identified risks are being added to information on other injection site reactions already described in labeling. In this same FAERS review, the agency determined that there is an association between deoxycholic acid injection and reports of injection site nodules (3 cm or smaller) or masses (larger than 3 cm), which may not resolve over time and may require medical intervention. Nodules and masses may occur when patients receive deoxycholic acid injections as indicated in the submental fat region and when patients receive injections of the drug outside the submental fat region.

What Is Kybella (Deoxycholic Acid) Injection?
Kybella (deoxycholic acid) injection was approved in 2015 for improvement in the appearance of moderate-to-severe fullness associated with submental fat in adults. Kybella is not approved for the treatment of subcutaneous fat outside the submental region and such use is not recommended. A generic deoxycholic acid injection product is also FDA-approved.

Kybella is used in an injection lipolysis (fat-dissolving) procedure, which involves breaking down fat cells in the submental area. Only healthcare providers should administer Kybella. Patients can receive up to six treatments, each at least one month apart. Each treatment consists of up to a maximum of 50 subcutaneous injections.

What Should Patients Do?
Patients should be aware of serious adverse events that have been reported when Kybella (deoxycholic acid) is injected at sites other than under the chin, including blurred or reduced vision, involuntary eye contractions, muscle and nerve damage and weakness, numbness, and difficulty walking.

Patients should also be aware that injection site nodules and masses have been reported with use of Kybella as indicated (under the chin), as have other adverse events — such as nerve injury around the lower lips, tongue and jaw; difficulty swallowing; bruising; tissue damage; vascular injury; and injection site baldness, ulceration, necrosis (tissue death), and infection — that are already included in labeling.

If patients experience adverse events from using Kybella, they should seek medical attention.

Kybella and a generic deoxycholic acid injection product are the only drugs approved by FDA for improvement in the appearance of moderate-to-severe fullness associated with submental fat. FDA is aware of adverse events reported with the use of unapproved injection lipolysis (fat-dissolving) products and urges people not to use those products. More information is available on the FDA website.

What Should Healthcare Providers Do?
Healthcare providers should review the prescribing information prior to injecting Kybella (deoxycholic acid) injection, including that the drug is not approved for use in areas of the body other than the submental area. Healthcare providers should also be aware that FDA has identified an association between Kybella and reports of injection site reactions, including nodules and masses, which may not resolve over time and may require medical intervention.

Providers should advise patients to seek medical attention if they experience any adverse events, including signs of marginal mandibular nerve paresis (e.g., asymmetric smile, facial muscle weakness), difficulty swallowing, or serious injection site reactions.

What Did FDA Find?
FDA searched the FDA Adverse Event Monitoring System and the medical literature to identify cases of nodules and masses following deoxycholic acid injections that resolved over time or remained unresolved and required medical intervention. FDA also searched for cases describing adverse events

with deoxycholic acid injections administered in sites other than the submental fat region.

Since Kybella's approval in 2015, FDA identified 129 cases of adverse events when deoxycholic acid injection was used in areas of the body outside of the approved site (submental region). Some serious adverse events reported with use outside the submental fat region include blurred or reduced vision with periorbital use and muscle or nerve injury including facial paresis and paresthesia.

FDA also identified 117 cases of unresolved nodules (3 cm or smaller) or masses (larger than 3 cm) associated with deoxycholic acid injections. At the time of reporting, unresolved nodules or masses had been present for a mean of 143 days (approximately 5 months). These unresolved nodules or masses have occurred after either initial or subsequent deoxycholic acid injections.

In Hong Kong, there is one registered pharmaceutical product containing deoxycholic acid for injection, namely Belkyra Solution For Injection 20mg/2ml (HK-65660), and is registered by Allergan Hong Kong Limited. It is a prescription-only medicine which is indicated for use in submental fat area only. As of the end of September 2026, the Department of Health (DH) had not received any case of adverse drug reaction with regard to deoxycholic acid. In light of the above FDA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 16 September 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

Singapore: Risk of Vitamin B6 Deficiency and Associated Seizures with Carbidopa/Levodopa or Benserazide/Levodopa

On 15 September 2026, the Health Sciences Authority (HSA) announced that levodopa, a metabolic precursor to dopamine, is the cornerstone replacement therapy for Parkinson's disease, a neurodegenerative disorder characterised by the loss of dopamine-producing neurons. As levodopa is converted into dopamine via decarboxylation both centrally and peripherally, this limits the amount of levodopa available for delivery across the blood-brain barrier. To enhance its central bioavailability and reduce adverse effects, levodopa is typically co-administered with a peripheral decarboxylase inhibitor, such as carbidopa or benserazide, to prevent the peripheral conversion of levodopa to dopamine.

There are currently 14 products containing levodopa in combination with a peripheral decarboxylase inhibitor registered locally in Singapore since 1990. Post-market cases of seizures, some with fatal outcomes, have been reported overseas and in published literature in patients using combination products containing levodopa and a peripheral decarboxylase inhibitor. To date, no cases have been reported locally.

Example of a case report published in the literature
One published overseas case report described a 78-year-old male patient with a six-year history of Parkinson's disease who was taking carbidopa/levodopa and presented with new-onset myoclonus and focal to bilateral tonic-clonic seizures. His Parkinson's disease symptoms had worsened over the preceding five months despite dose escalation of carbidopa/ levodopa. Further evaluation showed an undetectable vitamin B6 level (<1 µg/dL), a critically low folate level (<2.2 ng/dL), and video electroencephalography findings consistent with moderate cerebral dysfunction and seizures with diffuse onset. Initially, the seizures did not respond to treatment with two concurrent anti-epileptic drugs (AED). They resolved only after intravenous vitamin B6 replacement together with the addition of the third AED and a five-day course of high-dose steroids. It was concluded that the patient's epileptic events were secondary to depletion of vitamin B6 due to relatively high doses of carbidopa/levodopa.

Biological plausibility of levodopa and peripheral decarboxylase inhibitor in causing seizures
As vitamin B6 is a cofactor required for the decarboxylation of levodopa to dopamine, the conversion process results in the depletion of vitamin B6 levels. In addition, the peripheral decarboxylase inhibitors, carbidopa and benserazide, bind irreversibly to pyridoxal 5'-phosphate (PLP), the active form of vitamin B6, further reducing the availability of functional vitamin B6. PLP is essential for the synthesis of gamma-aminobutyric acid (GABA), the primary inhibitory neurotransmitter in the central nervous system. Reduced vitamin B6 and PLP levels may therefore lead to decreased GABA concentrations and contribute to an increased risk of seizures.

International regulatory actions
In March 2026, the US Food and Drug

Administration (FDA) requested the addition of warnings on the risk of vitamin B6 deficiency and associated seizures to the prescribing information of all products containing carbidopa/levodopa. The US FDA identified 13 post-marketing cases and one case report in published literature, all with features consistent with seizures observed with vitamin B6-dependent epilepsy. These cases involved levodopa doses exceeding 1,000 mg daily, with higher doses (>1,500 mg levodopa) associated with a shorter time from treatment initiation to identification of vitamin B6 deficiency, suggesting a possible dose-related relationship. Nine patients treated with vitamin B6 supplementation had resolution of their seizures, although the majority had previously not responded to multiple AEDs. There were two fatalities, both with documented low vitamin B6 levels and poorly controlled seizures.

Local situation in Singapore
HSA has not received any local adverse event reports of vitamin B6 deficiency or associated seizures arising from the use of products containing carbidopa/levodopa or benserazide/levodopa. The package inserts of levodopa-containing products registered locally will be updated to include additional warnings on the risk of reduced vitamin B6 levels and the relevant symptoms, as well as the consequent increased risk of seizures with carbidopa/levodopa or benserazide/levodopa treatment.

HSA's advisory
Post-marketing reports indicate that seizures associated with vitamin B6 deficiency were refractory to traditional AEDs and resolved after vitamin B6 administration. Healthcare professionals may consider evaluating vitamin B6 levels in patients before initiating and periodically during treatment with carbidopa/levodopa or benserazide/levodopa, and if symptoms suggestive of vitamin B6 deficiency develop. Such symptoms include depression, confusion, cheilosis, glossitis, dermatitis, anaemia, and/or neuropathy. Higher doses of carbidopa/levodopa or benserazide/levodopa may increase the risk of vitamin B6 deficiency and vitamin B6 supplementation may be considered where clinically appropriate.

In Hong Kong, there are registered pharmaceutical products containing carbidopa/levodopa (8 products), benserazide/levodopa (3 products) and carbidopa/entacapone/levodopa (8 products). All products are prescription-only medicines. As of the end of September 2026, the Department of Health (DH) had received one case of adverse drug reaction with regard to carbidopa/levodopa and benserazide/levodopa; and one case with regard to benserazide/levodopa, but both cases were not related to vitamin B6 deficiency or associated seizures. Related news was previously issued by US FDA, and was reported in the Drug News Issue No. 197. The DH issued letters to inform local healthcare professionals to draw their attention on 23 March 2026. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

Canada: Summary Safety Review: Central Nervous System Stimulants for Attention-deficit/Hyperactivity Disorder (ADHD) - Assessing the Potential Risk of Weight Loss in Children Under 6 Years of Age

On 25 September 2026, Health Canada issued the following announcement:

Product
Central nervous system (CNS) stimulants (amphetamine-, dextroamphetamine sulfate-, lisdexamfetamine dimesylate-, mixed salts amphetamine- and methylphenidate-hydrochloride-containing products) for attention-deficit/ hyperactivity disorder (ADHD) (a common condition that includes a combination of persistent challenges, such as difficulty paying attention, hyperactivity and impulsive behavior)

Potential Safety Issue
Weight loss in children under 6 years of age

Key Messages
- Health Canada's review found a possible increased risk of weight loss with the off-label use of CNS stimulants for ADHD in children under 6 years of age, compared to older children taking the same dose.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for all CNS stimulants for ADHD to include a warning about the possible increased risk of weight loss when these medications are used off-label in children under 6 years of age.

Overview
The risk of weight loss with the use of CNS stimulants for ADHD in individuals 6 years of age

and older is known and labelled in the CPM. Although CNS stimulants for ADHD are not authorized in Canada for use in children under 6 years of age, Health Canada is aware that they have been used off-label in this population. Some amphetamine-containing CNS stimulants for ADHD are authorized in other jurisdictions, such as the United States (U.S.), Australia, New Zealand and the United Kingdom, for use in children 3 years of age and older.

Following the release of a Drug Safety Communication and a label update by the U.S. Food and Drug Administration (FDA), Health Canada reviewed the potential risk of weight loss associated with the off-label use of CNS stimulants for ADHD in children under 6 years of age.

Use in Canada

- Central nervous system stimulants for ADHD are prescription drugs authorized for sale in Canada for use in individuals 6 years of age and older.
- Central nervous system stimulants have been marketed in Canada since the 1950s. Those authorized for the treatment of ADHD are currently marketed under the brand names Adderall XR, Biphentin, Concerta, Dexedrine, Dyanavel XR, Foquest, Jornay PM, Quillivant ER and Vyvanse. Generic versions are also available.
- Central nervous system stimulants for ADHD are available as immediate release tablets and extended release forms (tablets, capsules, oral suspension and powder for oral suspension).

Safety Review Findings

- Health Canada reviewed the available information provided by a foreign regulatory agency, as well as from searches of the Canada Vigilance database and the scientific literature.
- At the time of the review, Health Canada had identified 14 cases (12 Canadian and 2 international) of weight loss in children under 6 years of age taking CNS stimulants for ADHD. These cases did not meet the criteria for further assessment to determine if there was a link.
- Health Canada reviewed articles published in the scientific literature, which, overall, showed growing evidence of an association between the use of CNS stimulants for ADHD and the risk of weight loss in children under 6 years of age.
- In conducting its assessment, Health Canada considered information provided by a foreign regulatory agency. Health Canada and foreign regulatory agencies share safety information under confidentiality arrangements that restrict the disclosure of confidential information.
- In 2025, the U.S. FDA published a communication warning of an increased risk of weight loss and other adverse reactions with the off-label use of extended-release CNS stimulants for ADHD in children under 6 years of age, compared with older children taking the same medication at the same dose. Label updates in the U.S. followed for all extended-release CNS stimulants for ADHD to include a warning about this risk.
- While Canadian and international cases did not meet the criteria for further assessment to determine if there was a link, the overall evidence, including the scientific literature and information from a foreign regulatory agency, suggests that children under 6 years of age may be at greater risk of weight loss than older children taking the same dose of CNS stimulants for ADHD.

Conclusions and Actions

- Health Canada's review found a possible increased risk of weight loss with the off-label use of CNS stimulants for ADHD in children under 6 years of age, compared to older children taking the same dose.
- Health Canada will work with the manufacturers to update the CPM for all CNS stimulants for ADHD to include a warning about the possible increased risk of weight loss when these medications are used off-label in children under 6 years of age.
- Health Canada encourages consumers and healthcare professionals to report any side effects related to the use of CNS stimulants for ADHD, and other health products, to the Canada Vigilance Program.
- Health Canada will continue to monitor safety information involving CNS stimulants for ADHD, 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 registered pharmaceutical products containing methylphenidate (29 products) and lisdexamfetamine (3 products), and no registered pharmaceutical product containing

amphetamine or dextroamphetamine. All products containing methylphenidate and lisdexamfetamine are prescription-only medicines. As of the end of September 2026, the Department of Health (DH) had received 5 cases of adverse drug reaction related to methylphenidate, but these cases were not related to weight loss in children under 6 years of age; and had not received any case of adverse drug reaction related to lisdexamfetamine. Related news on the risk of weight loss in patients younger than 6 years taking extended-release stimulants for ADHD was previously issued by United States Food and Drug Administration, and was reported in the Drug News Issue No. 188. The risk of weight loss associated with CNS stimulants including methylphenidate and lisdexamfetamine in pediatric patients is documented in overseas reputable drug references such as "American Hospital Formulary Service Drug Information". The DH will remain vigilant on safety update of the drugs issued by other drug regulatory authorities.

Canada: Summary Safety Review: Domperidone - Assessing the Potential Risk of Episodes of Severe Hypertension in Patients with Pheochromocytoma

On 25 September 2026, Health Canada issued the following announcement:

Product
Domperidone-containing products

Potential Safety Issue
Episodes of severe hypertension (high blood pressure) in patients with pheochromocytoma (a rare tumour of the adrenal gland)

Key Messages
- Health Canada's review did not find sufficient evidence to establish a definite link between the use of domperidone and the risk of episodes of severe hypertension in patients with pheochromocytoma.
- Health Canada will continue to monitor the safety of domperidone.

Overview
Health Canada reviewed the potential risk of episodes of severe hypertension in patients with pheochromocytoma who are using domperidone. The safety review was triggered by a labelling update for all domperidone-containing products by the European Medicines Agency.

Use in Canada
- Domperidone is a prescription drug authorized for sale in Canada to treat symptoms of slowed stomach emptying seen with certain gastrointestinal conditions, and to prevent symptoms, such as nausea and vomiting, caused by some drugs used to treat Parkinson's disease.
- Domperidone has been marketed in Canada since 1985. It is currently available in 10 mg tablets. Various generic domperidone products are available in Canada.
- Since 2020, the number of prescriptions for domperidone dispensed by Canadian retail pharmacies appears to be decreasing.

Safety Review Findings
- Health Canada reviewed the available information from foreign regulatory agencies, as well as from searches of the Canada Vigilance database and the scientific literature.
- At the time of the review, Health Canada had not received any Canadian reports of episodes of severe hypertension in patients with pheochromocytoma using domperidone.
- In conducting its assessment, Health Canada considered information provided by foreign regulatory agencies. Health Canada and foreign regulatory agencies share safety information under confidentiality arrangements that restrict the disclosure of confidential information.
- Health Canada also reviewed 6 articles published in the scientific literature, which included 3 international cases of episodes of severe hypertension in patients with pheochromocytoma who were using domperidone. Due to the presence of confounders (other factors that may have contributed to the occurrence of episodes of severe hypertension), such as the use of other prescription drugs known to cause this adverse event, a definitive conclusion on this potential risk could not be reached. The articles highlighted the need for further investigations.

Conclusions and Actions
- Health Canada's review did not find sufficient evidence to establish a definite link between the use of domperidone and the risk of episodes of severe hypertension in patients with pheochromocytoma.
- Health Canada encourages consumers and healthcare professionals to report any side effects related to the use of domperidone, and

Safety Update

other health products, to the Canada Vigilance Program.
- Health Canada will continue to monitor safety information involving domperidone, 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 41 registered pharmaceutical products containing domperidone and are prescription-only medicines. As of the end of September 2026, the Department of Health (DH) had received one case of adverse drug reaction with regard to domperidone, but the case was not related to severe hypertension in phaeochromocytoma. Related news on the risk and restrictions of domperidone use was previously issued by various drug regulatory authorities, and was reported in the Drug News since Issue No. 29, with the latest update reported in the Drug News Issue No. 201. The DH issued letters to inform local healthcare professionals to draw their attention on 8 March 2012, 10 March 2014, 19 April 2016, 17 December 2019 and 22 July 2026, and the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) had discussed the risk and restrictions of domperidone use in February 2012, May 2014 and June 2020. As previously reported on 22 July 2026, the matter will be discussed by the Registration Committee .

Drug Incident

Two Persons Arrested on Suspicion of Illegally Supplying Unregistered Pharmaceutical Products

Concerning certain premises offering customers a vaccine called "Wilms' tumour 1" (WT1) and alleging that it could prevent multiple types of cancer, the Department of Health (DH) conducted another series of raids with the Police at multiple premises across Hong Kong on 2 September 2026. Over 50 vials of unregistered injectable pharmaceutical products were seized at two of those premises so far. During the operation, two individuals were arrested so far on suspicion of illegally possessing unregistered pharmaceutical products and Part 1 poisons. The DH will continue to crack down rigorously on the illegal sale or possession of unregistered pharmaceutical products to safeguard public health.

WT1 vaccine is not a registered pharmaceutical product in Hong Kong, and no person shall illegally sell or possess unregistered pharmaceutical products. Any advertisement claiming to provide this vaccine for cancer prevention is misleading and constitutes suspected fraud.

The DH will continue to work closely with relevant departments to monitor the situation, gather intelligence, conduct in-depth investigations, and crack down on illegal activities involving the sale or possession of unregistered pharmaceutical products. The DH will take decisive enforcement action against such violations and will not tolerate lawbreakers abusing their professional authority or committing fraud under the pretext of cancer prevention or treatment, thereby endangering public health.

Furthermore, the DH has sent a letter to all doctors and private healthcare facilities in Hong Kong, reminding them that they must comply with the law in Hong Kong. In response to allegations that a registered doctor and nurse provided the WT1 vaccine to clients, the DH has referred the cases to the Medical Council of Hong Kong and the Nursing Council of Hong Kong for follow-up.

A press release was posted in the Drug Office website on 2 September 2026 to alert the public of the drug incident.

One Person Arrested for Suspected Illegal Sale and Possession of Product with Undeclared Controlled Drug Ingredient

Following an earlier investigation that revealed the suspected illegal sale of a product containing undeclared controlled medicine, the Department of Health (DH) carried out an enforcement operation with the Police on 10 September 2026. During the operation, a 70-year-old man was arrested on suspicion of the illegal sale and possession of Part 1 poison and an unregistered pharmaceutical product.

Following up on a report received earlier, the DH purchased a product named "Natural Herbs Coffee Kopi Panggung AL-Ambiak" from a premises in Sham Shui Po. Test results from the Government Laboratory revealed that the sample contained sildenafil, which is a Part 1 poison regulated under

the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance). The product is also suspected to be an unregistered pharmaceutical product.

Sildenafil is a prescription drug used for the treatment of erectile dysfunction and should only be used under a doctor's professional 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 blood pressure to decrease to dangerous levels. Improper use of sildenafil may pose such serious health risks, especially for patients with heart problems.

The DH will continue to investigate the incident and take appropriate follow-up actions. A press release was posted in the Drug Office website on 10 September 2026 to alert the public of the drug incident.

The Department of Health and Police Raid Premises Suspected of Illegally Supplying and/or Possessing Unregistered Pharmaceutical Products for Injection Treatments

In view of the fact that certain premises were suspected to provide injectable treatments involving unregistered pharmaceutical products to the public, the Department of Health (DH), in collaboration with the Police, conducted a raid in Tsim Sha Tsui on 30 September 2026. More than 5,900 vials/ampoules of suspected unregistered pharmaceutical products and/or Part 1 poisons have been seized so far. The case remains under investigation and further arrests cannot be ruled out.

During the operation, the DH and the Police seized more than 5,900 vials/ampoules of suspected unregistered pharmaceutical products and/or Part 1 poisons from two premises in Tsim Sha Tsui, including a company claiming to provide medical health management services.

Where the DH suspects that a person has illegally supplied and/or possessed unregistered pharmaceutical products, it will conduct an investigation and take enforcement action. Where healthcare professionals are involved, the case will be referred to the relevant professional regulatory body for follow-up.

The DH has been taking stringent enforcement action against the illegal supply and/or possession of unregistered pharmaceutical products to safeguard public safety. From 2021 to June 2026, the DH's Drug Office handled 138 cases resulting in convictions for the sale and/or possession of unregistered pharmaceutical products. The maximum penalty was 10 months' imprisonment (total for all counts of offences) or a fine of up to $242,000 (the total fine for all counts of offences).

The DH will continue to closely monitor pharmaceutical products on the market, whether via online or offline channels, in accordance with established mechanisms. The DH will also take appropriate follow-up action upon receiving intelligence or complaints. When necessary, the DH will conduct joint operations with other law enforcement departments, or refer the cases to the relevant department for follow-up.

Furthermore, the DH has sent a letter to all doctors and private healthcare facilities in Hong Kong, reminding them that they must comply with the law in Hong Kong, as the illegal sale or possession of unregistered pharmaceutical products is a criminal offence in Hong Kong.

The DH also reminded members of the public that injection procedures are medical procedures which should only be performed by locally registered medical practitioners or registered dentists.

A press release was posted in the Drug Office website on 30 September 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/

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,
100 How Ming Street,
Kwun Tong, Kowloon

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.