Drug News
藥 物 情 報

Issue Number 200

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in June 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

Australia: Be Alert to FluMist Indicated Age Range

On 5 June 2026, the Therapeutic Goods Administration (TGA) issued the following announcement:

Summary

The TGA have identified reports of FluMist being administered in error to children under 2 years of age.

FluMist is a new influenza vaccine delivered via nasal spray and is indicated for the prevention of influenza in children and adolescents aged 24 months to less than 18 years.

Early clinical trial data indicated increased rates of hospitalisation in children aged 6–11 months and wheezing in children aged 6–23 months following vaccination.

TGA searched their Database of Adverse Event Notifications in May 2026, identified 161 adverse event reports for the trade name 'FluMist'. Most of these reports (116) involved administration errors in children under 2 years of age, including*:

- 89 'product administered to patient of inappropriate age'
- 38 'wrong product administered'
- 4 'vaccination error'
- 3 'inappropriate schedule of product information'
- 1 'product label confusion'

* More than one term can be reported per adverse event report.

None of these reports was classified as serious.

What health professionals should do

To minimise the risk of incorrect administration of FluMist, health professionals should:

- Confirm the child is 24 months or older before administering FluMist.
- Carefully review the Product Information available on the TGA website, including the indication, dose, method of administration and contraindications.

Background

FluMist is a live attenuated influenza vaccine administered as an intranasal vaccine, with one spray given into each nostril. It may be given at the same time as live or non-live vaccines and has shown similar efficacy to injectable influenza vaccines in children.

In Hong Kong, FluMist Quadrivalent Influenza Intranasal Vaccine (HK-65690) and FluMist Trivalent Influenza Intranasal Vaccine (HK-68239) are pharmaceutical products registered by AstraZeneca Hong Kong Limited. Both products are prescription-only medicine. As of the end of June 2026, the Department of Health (DH) had received 3 cases of adverse drug reaction report with regard to FluMist and these cases were not related to administration to children under 2 years of age. The current product inserts of the 2 locally registered FluMist vaccines are indicated for use in persons 2 through 49 years of age. The DH will remain vigilant on safety update of the vaccine issued by other overseas drug regulatory authorities.

The United States: FDA Approves Labeling Changes for Over-the-Counter (OTC) Weight Loss Drug Alli (orlistat) to Warn of Risk of Kidney Stones and Kidney Injury

On 10 June 2026, the United States Food and Drug Administration (FDA) issued the following announcement:

What is FDA Doing?

The FDA has approved changes to the Drugs Facts Label of the over-the-counter (OTC) weight loss drug, alli (orlistat) 60 mg capsules, to warn of risks of acute kidney injury, which is a rare side effect of the medication. The labeling now advises consumers to ask a healthcare provider before using alli if they have ever had kidney disease or kidney stones. The labeling changes also tell consumers to stop using alli and ask a doctor if they develop symptoms of kidney injury or kidney stones, such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination.

The risk of renal (kidney) injury is now described consistently across the labeling for all FDA-approved orlistat products, including those available OTC and those available in a higher strength by prescription.

What is Alli?

alli (orlistat) 60 mg capsules are approved for nonprescription use for weight loss in overweight adults 18 years and older, when used along with a reduced-calorie and low-fat diet. alli is the only FDA-approved OTC (nonprescription) weight loss aid. A higher-strength orlistat product, Xenical (orlistat) 120 mg capsules, is available by prescription. Xenical is indicated for obesity management, including weight loss and weight maintenance, when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss.

Orlistat is a lipase inhibitor that works by binding to enzymes that break down fats. As a result, people absorb less dietary fat from the digestive tract.

What Should Consumers Do?

- Consumers should read the Drugs Facts Label carefully before starting alli. It is important for consumers to read the labeling of all OTC medications because they may not have seen a healthcare provider before deciding to take the medication.
- Consumers should be aware there have been rare reports of the following side effects in people taking alli:
  - acute kidney injury (kidneys suddenly cannot filter waste products from the blood and harmful levels of waste may build up). Mild cases may be reversible, but untreated severe cases can be fatal.
  - hyperoxaluria (high urinary levels of the waste product oxalate, a compound made by the liver and ingested through the diet)
  - calcium oxalate nephrolithiasis (kidney stones that form when oxalate combines with calcium in the urinary tract)
  - oxalate nephropathy (calcium oxalate crystals form inside the kidneys and interfere with normal kidney function)
- If consumers ever had kidney disease or kidney stones, they should ask a healthcare provider before taking alli.
- If consumers experience symptoms of acute kidney injury or kidney stones, they should stop taking alli and consult a healthcare provider for further guidance. Symptoms may include:
  - back or groin pain
  - painful urination
  - blood in the urine
  - feet and leg swelling
  - less frequent urination
- If consumers experience side effects or do not respond well to alli, they should talk to a healthcare provider to consider next steps, including whether other treatment options might be right for them.

What Should Healthcare Providers Do?

Healthcare providers who counsel patients about weight loss should inform them about the rare reports of acute kidney injury, hyperoxaluria, calcium oxalate nephrolithiasis, or oxalate nephropathy associated with orlistat products. If a patient taking alli presents with signs of acute kidney injury or nephrolithiasis, providers should advise them to stop the drug and proceed with appropriate evaluation and management.

What Did FDA Find?

FDA received periodic safety reports of acute kidney injury associated with alli, which prompted a revaluation of this safety signal in the nonprescription product. Specifically, FDA searched the FDA Adverse Event Monitoring System (AEMS) and the medical literature to identify cases of acute kidney injury, oxalate nephropathy, hyperoxaluria, and/or calcium oxalate kidney stones that occurred following use of alli. Search dates were from alli's approval date on 9

February 2007 through 31 December 2023.

FDA identified 12 cases of kidney complications associated with alli use, including nine from AEMS and three from the literature. The median patient age was 61 years (range 36-76 years), and there were slightly more females (7) than males (5). Among the eight patients who reported alli use prior to kidney injury, the median exposure time was 2.5 months (range 0.7-17 months). The types of kidney complications varied among the 12 cases: eight reported acute kidney injury, two reported acute kidney injury with oxalate nephropathy, and two had hyperoxaluria with calcium oxalate kidney stones. The severity of these cases was substantial, with eight patients requiring hospitalization and five requiring dialysis. Seven patients experienced improvement in their conditions, one had not improved at the time the report was made, and four reports did not describe the outcomes. Dosing information was available for four patients, all of whom reported taking either 60 mg or 120 mg of orlistat three times daily.

Our data analysis also suggests that orlistat-associated oxalate nephropathy and kidney injury may not be dose-dependent, as the difference in dietary fat absorption inhibition between the 120 mg (Xenical) and 60 mg (alli) doses is 5%, indicating the risk exists at both prescription and nonprescription doses.

Based on these postmarketing cases demonstrating evidence of kidney injury associated with oxalate crystals in individuals using alli and biological plausibility — as well as findings that the risks may not be dose-dependent — the risk of kidney injury was added to Drug Facts Label for alli, aligning labeling for all FDA-approved orlistat products.

There are limitations to the information available to FDA. The actual number of cases involving kidney problems after alli use may be higher, as consumers and healthcare professionals do not always report side effects to FDA. Many reports were missing information, including clinical details such as kidney stone composition and past medical history. Several people had other possible reasons for their kidney diagnoses besides taking alli, including obesity, diabetes, high blood pressure, and history of kidney disease or kidney stones. These conditions could also have increased the risk of kidney problems associated with the use of alli.

In Hong Kong, there are 12 registered pharmaceutical products containing orlistat, of which 2 products containing orlistat 60mg are pharmacy-only medicines and 10 products containing orlistat 120mg are prescription-only medicines. As of the end of June 2026, the Department of Health (DH) had received 4 cases of adverse drug reaction reports with regard to orlistat, but these cases were not related to kidney stones or kidney injury.

Related news on the risk of urinary crystallization associated with the use of orlistat was previously issued by China State Food and Drug Administration (current National Medical Products Administration), and was reported in the Drug News Issue No. 31. The DH issued letters to inform local healthcare professionals to draw their attention on 8 May 2012. In December 2012, 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 products containing orlistat 120mg should include safety information about the risk of oxalate nephrolithiasis and oxalate nephropathy with renal failure. In light of the above FDA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 11 June 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

European Union: PRAC Concludes Evidence of Potential Risk of Neurodevelopmental Disorders in Children Born to Men Treated with Valproate is Inconsistent

On 12 June 2026, the European Medicines Agency (EMA) announced that its safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC) has completed its review of a safety signal for valproate and related substances, and concluded that based on the evaluation of new data, the evidence on neurodevelopmental disorders (NDDs) in children born to men treated with valproate is inconsistent and the causal role of valproate is uncertain. In light of this uncertainty, the committee recommended maintaining existing precautionary measures for male patients. These measures were put in place in 2024 to address a potential increased risk of NDDs in children born to men treated with valproate during the three months before conception.

In addition, PRAC recommended that the medicines' product information be updated to

reflect the most recent data related to NDDs.

Valproate medicines are used to treat epilepsy and bipolar disorder. In some EU Member States, they are also authorised to prevent migraine headaches. NDDs are problems with development that begin in early childhood, such as autism spectrum disorders, intellectual disability, communication disorders, attention deficit/hyperactivity disorders and movement disorders.

In January 2024, the assessment of the findings of a post authorisation safety study (PASS) which used data from multiple registry databases in Denmark, Norway and Sweden suggested an increased risk of NDDs in children born to men treated with valproate in the three months before conception compared with men treated with the epilepsy medicines lamotrigine or levetiracetam. At that time, while PRAC acknowledged that the PASS data had limitations, it concluded that NDDs are a potential risk in children born to men treated with valproate during the three months before conception, and recommended precautionary measures for men taking the medicine.

At the time, PRAC requested the marketing authorisation holders to carry out a larger study, specifically designed to address some of the limitations of the PASS study. This study is currently ongoing and is expected to conclude in 2028.

The latest safety signal was started in July 2025 after the publication of a Danish nationwide registry-based study, study which did not suggest an increased risk of NDDs in children born to men treated with valproate. In assessing this signal, PRAC reviewed all the latest evidence. While findings from one study suggested a possible link between valproate and NDDs, most studies (so-called retrospective observational studies) investigating this issue have not found an increased risk of NDDs. Differences in how these studies were designed, such as which patients were included and how patients' underlying health conditions were accounted for, may explain why findings vary.

Overall, PRAC could not conclude whether a potential risk of NDDs in children of fathers treated with valproate before conception is due to valproate or other factors, such as the fathers' underlying medical condition. The committee concluded that the available evidence is inconsistent, and a causal link with the medicine is uncertain.

In light of remaining uncertainties and pending the results of the ongoing study in 2028, PRAC agreed that the precautionary measures introduced in 2024 should remain in place. The committee also recommended updating the product information, as well as the healthcare professional guide and the guide for male patients, to ensure that healthcare professionals and patients have access to the most up-to-date information.

Further information can be found in the assessment report, which will be published in due course on the EMA website.

In Hong Kong, there are 9 registered pharmaceutical products containing valproate. All products are prescription-only medicines. As of the end of June 2026, the Department of Health (DH) had received 20 cases of adverse drug reaction with regard to valproate, of which 2 cases were reported as congenital malformations following valproate exposure in utero, and these cases were not related to neurodevelopmental disorders in children after paternal exposure to valproate. Related news was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 21, with the latest update reported in the Drug News Issue No. 189. The DH issued letters to inform local healthcare professionals to draw their attention on 4 July 2011, 7 May 2013, 13 October 2014, 12 February 2018, 13 December 2022, 22 March 2023 and 11 June 2025.

The Registration Committee of the Pharmacy and Poisons Board discussed the matter related to the risks in pregnancy associated with the use of valproate in September 2011, December 2014, December 2018, June 2019 and October 2025. Currently, the package insert or sales pack label of locally registered valproate-containing products should include safety information on an increased risk of neuro-developmental disorders (NDDs) in children born to men treated with valproate in the 3 months prior to conception, and the risk of malformations and impaired cognitive development in children exposed to valproate during pregnancy, and contraindications, e.g. in men and women of childbearing potential unless pregnancy preventive measures have been implemented, etc. The certificate holders of locally registered valproate-containing products are also required to implement risk minimisation measures, e.g. patient

information leaflet should be provided, etc. In view of the above, the DH will continue to remain vigilant on the safety update of the drug issued by EMA and other overseas drug regulatory authorities for consideration of any action deemed necessary.

The United Kingdom: ACE-inhibitors: Be Aware of the Distinction Between Bradykinin- and Histamine-Mediated Angioedema, as Treatment Strategies Differ Significantly

On 16 June 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that healthcare professionals should be aware of the potential for delayed onset of angioedema and the distinction between bradykinin- and histamine-mediated cases, as treatment strategies differ significantly and bradykinin-mediated angioedema does not respond to standard treatment.

Advice for Healthcare Professionals:

- angioedema is a known uncommon or rare side-effect of ACE inhibitor treatment. This can either be allergic (histamine-mediated) or less commonly non-allergic (bradykinin-mediated). Healthcare professionals should consider bradykinin-mediated mechanisms as a cause when standard anaphylaxis treatment is ineffective
- angioedema can occur at any time during treatment, including after weeks to years of use
- swelling of the tongue, lip, face, or larynx which may cause difficulty in breathing or swallowing may progress and can lead to airway compromise. Other symptoms can include gastrointestinal pain and cramps
- bradykinin-mediated angioedema is unlikely to respond to standard anaphylaxis treatments including adrenaline (epinephrine)
- lack of response to standard anaphylaxis treatments should prompt consideration of bradykinin-mediated angioedema, with treatment informed by clinical protocols
- if angioedema is suspected in a patient taking an ACE inhibitor, discontinue the ACE inhibitor immediately and do not restart

Advice for Healthcare Professionals to Provide to Patients:

- although uncommon or rare, angioedema (swelling of the face, lips, tongue, or throat) can occur at any time while taking an ACE inhibitor, even if you have been taking it for a long period without problems
- seek urgent medical attention if you develop swelling of the face, lips, tongue, or throat, or experience difficulty breathing or swallowing whilst taking ACE inhibitors
- do not take further doses of your ACE inhibitor if angioedema is suspected and inform a healthcare professional immediately
- inform healthcare professionals if you have ever experienced angioedema, including while taking an ACE inhibitor. Please be aware that angioedema can occur for other reasons, and a healthcare professional may still recommend an ACE inhibitor for you in these instances

Background

The product information for all ACE inhibitors is being updated to strengthen the warnings on the risk of delayed-onset angioedema, which may still occur after weeks to years of use. Healthcare professionals, particularly in emergency departments, should be aware of the potential for delayed onset of angioedema and the distinction between bradykinin- and histamine-mediated cases, as treatment strategies differ significantly and bradykinin-mediated angioedema does not respond to standard treatment.

ACE inhibitors are indicated for the treatment of hypertension, heart failure, post-myocardial infarction management, diabetic nephropathy, and cardiovascular risk reduction.

Angioedema is characterised by localised swelling of subcutaneous or submucosal tissues. Unlike histamine-mediated (allergic) angioedema, bradykinin-mediated angioedema usually occurs without urticaria and typically has a slower onset. Symptoms may involve the tongue, lips, and upper airway, and can be life-threatening.

Although uncommon or rare, ACE inhibitors are associated with both histamine-mediated and bradykinin-mediated angioedema. Certain populations, including older adults, women, people who smoke and patients of Black or African Caribbean ethnicity, may be at increased risk of angioedema.

Data review

A review of UK Yellow Card data up to and including 10 June 2026 identified that approximately one-half of angioedema cases with

reported time-to-onset occurred 30 days or more after initiation of treatment. Manufacturer data indicated that around 20–30% of reported cases occurred after at least 30 days of therapy. This pattern of delayed onset is more associated with bradykinin-mediated angioedema. Fatal cases, although rare, have involved airway compromise and have occurred after prolonged ACE inhibitor treatment.

Published literature describes bradykinin–mediated angioedema occurring weeks to many years after initiation, including cases reported after several years of continuous use. Reviews consistently highlight that bradykinin-mediated angioedema does not reliably respond to standard anaphylaxis treatment and requires prompt recognition and appropriate airway management.

Current clinical guidance used in emergency medicine recognises ACE inhibitors as a leading cause of non-allergic angioedema and advises consideration of bradykinin-mediated mechanisms when standard treatment is ineffective. The clinical guidance emphasises prompt discontinuation of the ACE inhibitor, close airway monitoring, and early specialist involvement in severe or life-threatening cases. Additional investigations, such as C4 level testing, may support identification of non-allergic causes and help guide management.

Regulatory action

The MHRA is implementing updates to the Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) in a phased approach. The SmPC and PIL for ACE inhibitors will be updated to strengthen warnings and improve communication on the risk of delayed-onset angioedema and the potential for standard anaphylaxis treatments to be ineffective. These updates are currently in progress and will be implemented over the coming months.

In Hong Kong, there are registered pharmaceutical products containing ACE inhibitors and are prescription-only medicines. As of the end of June 2026, the Department of Health (DH) had received 14 cases of adverse drug reaction reports with regard to ACE inhibitors, of which one case was reported as angioedema. The onset of ACE inhibitor-induced angioedema from within hours of starting treatment to weeks, months or even years into treatment; the risk of non-allergic angioedema (bradykinin-mediated) associated with ACE inhibitors; and the management of non-allergic angioedema are documented in overseas reputable drug references such as “Martindale: The Complete Drug Reference”. In light of the above MHRA’s announcement on regulatory action to update product information, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Canada: Summary Safety Review - Finasteride and Dutasteride - Assessing the Potential Risk of Sexual Dysfunction

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

Product

Finasteride-containing products and dutasteride-containing products

Potential Safety Issue

Sexual dysfunction

Key Messages

- The risk of sexual dysfunction with the use of finasteride and dutasteride is known. Health Canada reviewed this risk to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate.
- Health Canada’s review, which builds on the evidence that existed at the time of market authorization for finasteride and dutasteride, provides a larger body of evidence on the link between the use of these products and the risk of sexual dysfunction.
- Health Canada will work with the manufacturers to enhance the existing product safety information in the Canadian product monograph (CPM) for all finasteride-containing products and dutasteride-containing products to also include a warning about the risk of sexual dysfunction. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview

The risk of sexual dysfunction with the use of finasteride and dutasteride is known and labelled in the CPM for all finasteride-containing products and dutasteride-containing products. However, following media attention, Health Canada reviewed this risk to identify and assess newly emerging safety information, and to determine whether

current risk minimization measures remain appropriate.

Use in Canada

- Finasteride is a prescription drug authorized for sale in Canada for the treatment and control of prostate gland enlargement (benign prostatic hyperplasia), and for the treatment of male pattern hair loss (androgenic alopecia).
- Finasteride has been marketed in Canada since 1992 under the brand name Proscar (5 mg tablets), and since 1998 under the brand name Propecia (1 mg tablets). Generic versions are also available.
- Dutasteride is a prescription drug authorized for sale in Canada for the treatment of benign prostatic hyperplasia.
- Dutasteride has been marketed in Canada since 2003 under the brand name Avodart (0.5 mg oral capsules) and since 2011 under the brand name Jalyn (0.5 mg dutasteride/0.4 mg tamsulosin oral capsules). Generic versions are also available.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance Database and the scientific literature.
- Health Canada reviewed 18 Canadian cases of sexual dysfunction in patients taking finasteride (17 cases) or dutasteride (1 case). Of the 18 cases, 17 (16 finasteride and 1 dutasteride) were found to be possibly linked to their use, while the remaining case, which was in a patient taking finasteride, was unassessable due to limited clinical information.
- Health Canada also reviewed articles published in the scientific literature, which, overall, provided a growing body of evidence supporting the link between the use of finasteride and dutasteride, and the risk of sexual dysfunction.

Conclusions and Actions

- Health Canada's review, which builds on the evidence that existed at the time of market authorization for finasteride and dutasteride, provides a larger body of evidence on the link between the use of these products and the risk of sexual dysfunction.
- Health Canada will work with the manufacturers to enhance the existing product safety information in the CPM for all finasteride-containing products and dutasteride-containing products to also include a warning about the risk of sexual dysfunction.
- 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 finasteride and dutasteride, 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 32 and 11 registered pharmaceutical products containing finasteride and dutasteride respectively. All products are prescription-only medicines. As of the end of June 2026, the Department of Health (DH) had received 5 cases of adverse drug reaction with regard to finasteride, of which 2 cases were reported as decreased libido and erectile dysfunction. With regard to dutasteride, the DH had received 4 cases of adverse drug reaction, but these cases were not related to problems with sexual function.

Related news on problems with sexual function associated with the use of finasteride and dutasteride was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 91, with the latest updated reported in the Drug News Issue No. 199. The DH issued letters to inform local healthcare professionals to draw their attention on 25 May 2017 and 9 May 2025. In February 2015, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the sales pack label and/or package insert of finasteride-containing products should include safety information on problems with sexual function (including decreased libido and erectile dysfunction). As previously reported on 9 May 2025 and 12 May 2026, the matter will be further discussed by the Registration Committee of the Pharmacy and Poisons Board.

Canada: Summary Safety Review - Tramadol - Assessing the Potential Risk of Prolonged, Persistent or Recurrent Hiccups

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

Safety Update

Product
Tramadol-containing products

Potential Safety Issue
Prolonged (lasting under 48 hours), persistent (lasting longer than 48 hours but less than 1 month), or recurrent (occurring often or repeatedly) hiccups

Key Messages
- Health Canada's review found a possible link between the use of tramadol and the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) of all tramadol-containing products to include the risk of prolonged, persistent or recurrent hiccups.

Overview
Health Canada reviewed the potential risk of prolonged, persistent or recurrent hiccups with the use of tramadol. The safety review was triggered by Health Canada's identification of published case reports both in Canada and internationally.
Generally, hiccups are not harmful. However, prolonged, persistent or recurrent hiccups can significantly impact an individual's quality of life. Hiccups lasting for hours, days or months can affect an individual's ability to eat, sleep and communicate.

Use in Canada
- Tramadol is a prescription opioid drug authorized for sale in Canada to manage pain in adults.
- Tramadol has been marketed in Canada since 2005. It is currently available in capsule or tablet form under different brand names and generic versions. It is available as a single ingredient product or in combination with acetaminophen.
- Tramadol is a widely used opioid medication among Canadians for acute or chronic pain.

Safety Review Findings
- Health Canada reviewed the available information from searches of the Canada Vigilance database and the scientific literature.
- Health Canada reviewed 8 cases (2 Canadian and 6 international) of prolonged, persistent or recurrent hiccups in patients taking tramadol, including 2 unique cases from the published literature. Despite the presence of confounders (other factors that may have contributed to the occurrence of prolonged, persistent or recurrent hiccups), such as underlying medical conditions and the use of other prescription drugs, all 8 cases were found to be possibly linked to the use of tramadol.
- Health Canada also reviewed articles published in the scientific literature, which identified a potential biological mechanism that may explain how the use of tramadol could lead to hiccups.

Conclusions and Actions
- Health Canada's review found a possible link between tramadol and the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will work with the manufacturers to update the Canadian product monograph of all tramadol-containing products to include the risk of prolonged, persistent or recurrent hiccups.
- Health Canada will continue to monitor safety information involving tramadol, 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 44 registered pharmaceutical products containing tramadol. All products are prescription-only medicines. As of the end of June 2026, the Department of Health (DH) had received 9 cases of adverse drug reaction related to tramadol, but these cases are not related to prolonged, persistent or recurrent hiccups. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 26 June 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Drug Recall

Batch Recall of Co-Codamol Tab

On 30 June 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely KLN Pharma (Hong Kong) Limited O/B KLN Pharma (Hong Kong) Limited, the distributor appointed by Teva Pharmaceutical Hong Kong O/B Teva Pharmaceutical Hong Kong Limited (Teva), to voluntarily recall one batch (batch number: CH2734) of the pharmaceutical product, namely Co-Codamol Tab (Hong Kong registration number: HK-33414) from the market as a precautionary measure due to potential quality issues.

The DH received notification from Teva that the overseas manufacturer of the concerned product is recalling the above batch of Co-Codamol Tab because the impurities levels are out of specification in the affected batch. As a precautionary measure, Teva voluntarily recalled the above batch from the market.

The above product, containing paracetamol and codeine, is a prescription medicine indicated for relieving pain and fever. According to Teva, the affect batch was imported into Hong Kong and supplied to private doctors, private hospitals and pharmacies.

As of the end of June 2026, the DH had not received any adverse reaction reports in connection with the above product. A notice was posted in the Drug Office website on 30 June 2026 to alert the public of the product recall. The DH continues to monitor the recall.

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.

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.