Drug News
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Issue Number 201

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

European Union: Desogestrel- and Etonogestrel-containing Medicines: Risk of Meningioma and New Measures to Minimise This Risk

On 10 July 2026, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) had agreed on a direct healthcare professional communication to inform healthcare professionals about a small increased risk of meningioma associated with current, prolonged use (>1 year) of desogestrel- or etonogestrel-containing contraceptives medicines. Although the risk is increased in people using these medicines, the overall likelihood of developing meningioma remains very low and one additional meningioma is estimated to occur for every 67,300 women who use the medicines. Meningiomas are tumours of the tissue layer surrounding the brain and spinal cord. Usually they are benign (non-cancerous) and grow slowly but, depending on the size or location, they can cause serious problems.

Use of desogestrel- or etonogestrel-containing medicines is now contraindicated in women who have a meningioma or have had one in the past. Women receiving these medicines should be monitored for signs and symptoms suggestive of meningioma, including changes in vision, hearing loss or ringing in the ears, loss of smell, worsening headaches, memory loss, seizures or weakness in arms and legs.

PRAC issued these recommendations following the review of data from a large French epidemiological study. This study found a small increased risk of intracranial meningioma in women using desogestrel for one year or more, with the risk increasing with longer duration of use. In addition, the risk may be higher in women who previously used progestogens already associated with meningioma (for example cyproterone, nomegestrol, medroxyprogesterone, and chlormadinone). Previous progestogen use should therefore be considered before starting desogestrel or etonogestrel.

If a woman using desogestrel or etonogestrel is diagnosed with meningioma, use of the medicine must be discontinued.

Desogestrel and etonogestrel are progestogens used for contraception. In the European Union (EU), desogestrel-containing medicines are available as oral tablets, while etonogestrel-containing medicines are available as implants or, in combination with ethinylestradiol, as vaginal rings. The product information in the EU for these medicines will be updated to include meningioma as a side effect with a frequency "not known", together with new contraindications and warnings.

In Hong Kong, there are 4 registered pharmaceutical products containing desogestrel, and the products are over-the-counter medicines. There is 1 registered pharmaceutical product containing etonogestrel, and it is a prescription-only medicine. As of the end of July 2026, the Department of Health (DH) had received 1 case of adverse drug reaction report with regard to desogestrel-containing products, but the case was not related to meningioma, while no adverse drug reaction report with regard to etonogestrel-containing products had been received. In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 13 July 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

European Union: Litfulo (ritlecitinib): Update to Product Information to Revise Warnings in Line with Other Janus Kinase Inhibitors

On 10 July 2026, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) had agreed on a direct healthcare professional communication to inform healthcare professionals that the warnings on the potential risk of certain serious side effects with the Janus kinase (JAK) inhibitor Litfulo will be strengthened. The updated warnings are being introduced because other JAK inhibitors have an increased risk of serious side effects, including cardiovascular problems, blood clots, cancer and serious infections, and this increased risk is also considered to apply to Litfulo.

A boxed warning will be added to the Litfulo product information, stating that the medicine should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer. In addition, Litfulo should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism), other than those listed above.

Litfulo is a medicine used to treat adults and adolescents over 12 years of age with severe alopecia areata, an autoimmune disease causing hair loss of the scalp or other parts of the body. The active substance in Litfulo, ritlecitinib, works by blocking the action of certain enzymes called JAK3 and TEC kinases, which play an important role in inflammation.

The boxed warning is already included in the product information for other JAK inhibitors, which are used to treat certain chronic inflammatory disorders, including alopecia areata. For Litfulo, the PRAC reviewed available data from clinical trials, the literature and spontaneous post-marketing reports of suspected side effects. Based on this review and considering that Litfulo also works by inhibiting a JAK enzyme, the PRAC concluded that the product information and educational material for Litfulo should be amended to include the same information as for other JAK inhibitors.

In Hong Kong, Litfulo Capsules 50mg (HK-68283) is a pharmaceutical product registered by Pfizer Corporation Hong Kong Limited, and is a prescription-only medicine. As of the end of July 2026, the Department of Health (DH) had not received any cases of adverse drug reaction with regard to ritlecitinib. In light of the above EMA'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 .

The United Kingdom: Botulinum Toxin Type A Products: Updated Warnings Regarding Risk of Iatrogenic Botulism

On 15 July 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that cases of iatrogenic botulism have been reported following the therapeutic or cosmetic use of botulinum toxin containing products, where the toxin's effects extend beyond the area of treatment. Patients should seek immediate medical advice if they experience any signs and symptoms.

<u>Advice for Healthcare Professionals:</u>

- cases of iatrogenic botulism, (botulism caused by a therapeutic or cosmetic procedure) following use of botulinum toxin containing products have been rarely reported
- symptoms of iatrogenic botulism typically occur between 4 and 8 days but can take up to 4 weeks to develop following treatment with botulinum toxin
- risks of botulism may be increased in patients with underlying disorders that may predispose them, the use of high-doses of botulinum toxin, using a product off-label or administering a product into unapproved sites, or in the use of counterfeit or unauthorised products
- the product information for these products is being updated to include a warning of iatrogenic botulism
- advise new and existing patients to be aware of symptoms of botulism including, severe drooping of the upper eye lids difficulty breathing, speaking (slurred speech) and difficulty swallowing. This is a medical emergency and patients should be advised to seek immediate medical help
- if you suspect your patient may have botulism, follow the UK Health Security Agency advice on the clinical management of iatrogenic botulism
- check that the botulinum toxin product is

authorised for use and follow the product specific guidance in the product information for administration, dose and indication
- prescribers should ensure that anyone they direct to administer the product, including practitioners who may use it for cosmetic purposes, follow the directions on the prescription and that they are familiar with this Drug Safety Update and the actions to be taken

Advice for Healthcare Professionals to Provide to Patients:
- treatment with botulinum toxin has in rare cases caused botulism and other serious adverse reactions and symptoms which can occur up to 4 weeks following treatment
- if you experience any symptoms of botulism following treatment with botulinum toxin including difficulty swallowing, slurred speech and breathing difficulty, seek immediate medical attention via emergency services
- your administering practitioner (who should be appropriately trained and qualified) should verify that the product being used is licensed for use in the UK. Use of unlicensed or counterfeit products can significantly increase your risk of adverse reactions. Refer to the NHS advice for information on choosing your administering practitioner. Please refer to the MHRA website for a list of registered independent healthcare providers for England (private hospitals and clinics) Northern Ireland, Wales and Scotland

Background

Cases of iatrogenic botulism have been reported following the therapeutic or cosmetic use of botulinum toxin containing products where the toxin's effect extends beyond the area of treatment. Botulism caused by botulinum toxin is rare but can be life threatening. Symptoms can take up to four weeks to develop and may typically include difficulty breathing or shortness of breath, difficulty swallowing, talking or slurred speech and muscle weakness. In severe cases, patients may require mechanical ventilation and intensive care treatment.

Serious adverse reactions due to the distant spread of toxin have been closely monitored and have been reflected in the product information since 2007. The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for all UK-authorised botulinum toxin type A containing products will be further strengthened in the coming months to highlight the risk of iatrogenic botulism and to advise patients to seek immediate medical advice if they experience any signs or symptoms consistent with the spread of botulinum toxin effect or iatrogenic botulism.

The risk of adverse reactions from the spread of toxin or botulism may be increased in patients:
- Who have underlying conditions and comorbidities (underlying neurological disorders, or a history of dysphagia or aspiration)
- Where high doses of botulinum toxin are used
- Where a product is used outside of its licensed indications (off-label) and administered into unapproved sites
- Where a counterfeit or unauthorised botulinum toxin containing product is used

Healthcare professionals who are managing patients with suspected botulism should follow the UK Health Security Agency advice on the clinical management of iatrogenic botulism. Treatment can vary and may include the use of botulinum antitoxin to neutralise circulating toxin, supportive therapy and/or treatment of specific symptoms. Recovery will depend on the severity of symptoms.

In patients presenting with only localised side effects where administration of botulinum antitoxin is not indicated, it may be necessary to monitor for further progression of symptoms and presentation of systemic neurological symptoms.

Botulinum toxin containing products

Botulinum toxins are prescription only medicines in the UK and should only be sold or supplied in accordance with a prescription given by an appropriate prescriber . There are a number of authorised products containing botulinum toxin which have been granted a marketing authorisation for use in the UK. Botulinum toxin products authorised for use in the UK and their respective product information (SmPC and PIL) can be found on the MHRA website.

The licensed indications for botulinum containing products vary by product and include neurologic disorders (e.g. focal spasticity, some types of spasms and chronic migraine), bladder disorders (e.g. overactive bladder), severe sweating of the axillae (hyperhidrosis) and for the temporary improvement in the appearance of facial lines

where their severity has an important psychological effect on the patient.

The product information contains the recommendations for use of each botulinum toxin containing product, including the authorised indications, administration sites and specific dosing guidance. Units of botulinum toxin are not interchangeable from one product to another.

Use of unlicensed botulinum toxin products

The MHRA are cracking down on the illegal sale and supply of unlicensed and counterfeit botulinum toxins. Buying botulinum toxins from illegal suppliers, including from within the UK or importing them from abroad, significantly increases the risk of getting a product which is either falsified or not licensed for use in the UK. This means that there are no safeguards to ensure products meet the MHRA's standards for quality and safety. Use of these products can significantly increase your risk of adverse reactions and can endanger the health of the people who take them.

The MHRA's Criminal Enforcement Unit has launched a number of investigations linked to the use of unlicensed botulinum toxin products following a spike in hospital admissions seen last year.

In Hong Kong, there are 9 registered pharmaceutical products containing botulinum toxin and are prescription-only medicines. As of the end of July 2026, the Department of Health had received 28 cases of adverse drug reaction reports with regard to botulinum toxin, of which 25 cases were reported as botulism. The systemic spread of toxin or botulism which can be life threatening is documented in overseas reputable drug references such as "Martindale: The Complete Drug Reference" and "American Hospital Formulary Service Drug Information". In light of the above MHRA's announcement on the strengthened warning in product information, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

The United Kingdom: Domperidone: New Contraindication in Patients with Phaeochromocytoma Due to the Risk of Severe Hypertension

On 21 July 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the product information has been updated for all domperidone products, to include a contraindication for patients with confirmed or suspected phaeochromocytoma (a rare tumour of the adrenal gland), due to the risk of episodes of severe hypertension.

Advice for Healthcare Professionals:

- a small number of reports have been received relating to severe episodes of hypertension in patients with phaeochromocytoma (a rare tumour of the adrenal gland) following administration of domperidone
- domperidone is now contraindicated in patients with confirmed or suspected phaeochromocytoma
- patients with confirmed or suspected phaeochromocytoma should stop taking domperidone immediately and be switched to an alternative treatment
- be aware that administration of domperidone can unmask phaeochromocytomas. If a patient taking domperidone has an episode of severe hypertension, consider further investigations for phaeochromocytoma
- domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week
- for patients receiving palliative care, an individual benefit risk decision on treatment should be made in discussion with the patient

Advice for Healthcare Professionals to Provide to Patients:

- stop taking domperidone immediately if you have been diagnosed with phaeochromocytoma (a rare tumour of the adrenal gland) by your doctor. Speak to your doctor or pharmacist about alternative treatment options
- seek medical attention immediately if you experience symptoms of severe high blood pressure. Symptoms can include, but are not limited to: persistent headache, blurred vision, shortness of breath and chest pain

Background

Domperidone is a dopamine antagonist with anti-emetic properties. It is licensed for use in adults and in children 12 years and above. Phaeochromocytomas are rare tumours of the adrenal gland and are often diagnosed through incidental imaging.

A recent European review of safety data for

domperidone identified an association between domperidone and episodes of severe hypertension in patients with phaeochromocytoma following a small number of reports of this event. As a result, recommendations have been made to update the product information to include a contraindication for use of domperidone in patients with phaeochromocytoma due to the risk of severe hypertension.

Domperidone and introduction of contraindication for use in phaeochromocytoma

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

The MHRA has not received any UK Yellow Card reports of domperidone and severe hypertension in patients with phaeochromocytoma. Four reports were considered in the European review. Phaeochromocytomas themselves are rare with a global prevalence of 19.8 per 1,000,000 people. Total prescribing of domperidone averages 222,000 items per year across NHS England. There are existing restrictions on domperidone prescribing, see further detail below.

New advice when prescribing domperidone

Do not prescribe domperidone to patients with confirmed or suspected phaeochromocytoma as domperidone is now contraindicated in this patient population. If patients with confirmed or suspected phaeochromocytoma are taking domperidone, treatment should be discontinued immediately and the patient switched to an alternative treatment. Patients should be advised to seek medical attention immediately if they experience symptoms of severe high blood pressure. Symptoms can include, but are not limited to: persistent headache, blurred vision, shortness of breath and chest pain.

For patients receiving palliative care, an individual benefit risk decision on treatment should be made in discussion with the patient.

Reminder of existing domperidone advice

Healthcare professionals are reminded of the existing recommendations and restrictions on domperidone prescribing:

- domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week
- for adults and adolescents 12 years of age or older and weighing 35 kg or more, the recommended maximum dose in 24 hours is 30 mg (dose interval: 10 mg up to 3 times a day)
- domperidone is authorised for the relief of symptoms of nausea and vomiting only in adults and adolescents 12 years of age or older or weigh 35kg or more
- consider alternative treatments to domperidone in children younger than 12 years of age who need relief of symptoms of nausea and vomiting
- domperidone is contraindicated in people receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors

In Hong Kong, there are 41 registered pharmaceutical products containing domperidone and are prescription-only medicines. As of the end of July 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. 146. The DH issued letters to inform local healthcare professionals to draw their attention on 8 March 2012, 10 March 2014, 19 April 2016 and 17 December 2019, 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. In light of the above MHRA's announcement on the new contraindication for domperidone use in patients with phaeochromocytoma, the DH issued letters to inform local healthcare professionals to draw their attention on 22 July 2026, and the matter will be discussed by the Registration Committee .

Australia: GLP-1 RAs and Rare Vision Disorder

On 23 July 2026, the Therapeutic Goods Administration (TGA) announced that safety information was updated across the glucagon-like-peptide-1 receptor agonist (GLP-1 RA) class of medicines.

Summary
Product warnings across the glucagon-like-peptide-1 receptor agonist (GLP-1 RA) class of medicines have been updated due to the potential for these products to cause a rare, but severe, form of eye disorder.

The GLP-1 RA class of prescription medicines are used primarily to manage type 2 diabetes mellitus and obesity.

The eye disorder, non-arteritic anterior ischaemic optic neuropathy (NAION), is a rare but serious condition that may result in permanent visual impairment, including blindness, and no treatment has been shown to improve visual acuity outcomes.

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

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

What healthcare professionals should do
Be alert to the new class-wide warnings in the Product Information (PI) documents for GLP-1 RAs (see 'Updates to the Product Information' below).

Advise patients to seek urgent medical attention if they experience sudden vision loss, including partial loss of vision.

The Consumer Medicine Information (CMI) leaflets for each product will be aligned with the updated PI documents and these should be provided to patients, if deemed clinically appropriate, as part of the counselling process.

Background
TGA first identified the potential association of GLP-1 RAs and NAION in July 2024 following a study published in JAMA Ophthalmology. Since then, the association has been closely monitored including through analysis of Australian cases reported to us, and investigations and regulatory actions by overseas regulators.

TGA conducted an independent assessment of the potential association between GLP-1 RAs and NAION. As the available evidence was conflicting, we sought expert advice from the Advisory Committee on Medicines (ACM) on whether the evidence supported additional risk mitigation measures.

Following discussion at its October 2025 meeting, the ACM concluded that the current evidence may support the signal for semaglutide, but not dulaglutide or tirzepatide and recommended a range of risk mitigation strategies, including:
- updates to the PI and CMI documents
- communication to relevant health professionals, including general practitioners, optometrists and ophthalmologists.

After considering all available evidence, including the ACM advice, TGA made a final decision on regulatory actions including PI and CMI document updates, and publication of safety communications.

Adverse events reported to TGA
A search of TGA's Database of Adverse Event Notifications (DAEN) found 36 cases of optic ischaemic neuropathy with GLP-1 RAs, 23 for semaglutide and 3 for liraglutide, 10 for tirzepatide. No cases were found for dulaglutide, though one semaglutide case had a history of prior dulaglutide use.

Updates to Product Information
Australian PI documents have been updated with the following wordings:

Semaglutide

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Non-arteritic anterior ischaemic optic neuropathy (NAION)

It is known that individuals with an anatomical predisposition ('disc at risk'), whether or not they are taking a GLP-1 agonist, are at highest risk of developing non-arteritic anterior ischaemic optic neuropathy (NAION). This pre-existing risk can be assessed by an optometrist or ophthalmologist. Some epidemiological studies indicate an increased risk of NAION during treatment with semaglutide. There is no identified time interval for when NAION may develop following treatment start. Patients reporting a sudden loss of vision (including partial loss) should be urgently referred for ophthalmological examination and treatment with semaglutide should be discontinued if NAION is confirmed (see section 4.8 ADVERSE EFFECTS).

4.8 ADVERSE EFFECTS

Post-Market Adverse Effects

- Eye disorders: Non-arteritic anterior ischaemic optic neuropathy (NAION)

Cases of NAION have been reported with GLP-1 RAs, including semaglutide. A sudden loss of vision should lead to ophthalmological examination.

Dulaglutide and Tirzepatide

4.8 ADVERSE EFFECTS

Postmarketing data

Eye disorders - Events of non-arteritic anterior ischaemic optic neuropathy (NAION), a rare condition associated with the potential for decreased vision including permanent loss of vision, have been reported in patients treated with products with GLP-1 receptor agonist activity. A sudden loss of vision should lead to ophthalmological examination.

Liraglutide

4.8 ADVERSE EFFECTS

Post-marketing adverse effects:

Non-arteritic anterior ischaemic optic neuropathy (NAION): Cases of NAION have been reported with GLP-1 RAs, including liraglutide. A sudden loss of vision should lead to ophthalmological examination.

In Hong Kong, there are registered pharmaceutical products containing GLP-1 receptor agonists including dulaglutide (4 products), semaglutide (11 products), liraglutide (5 products), lixisenatide (2 products), exenatide (1 product), and tirzepatide (6 products). All products are prescription-only medicines. As of the end of July 2026, the Department of Health (DH) had received 2 cases of adverse drug reaction with regard to tirzepatide, of which one case was reported as blurred vision. DH had also received adverse drug reaction cases with regard to dulaglutide (5 cases), semaglutide (11 cases), liraglutide (1 case), lixisenatide (1 case) and exenatide (2 cases), but these cases were not related to NAION or eye disorder. Related news on the risk of NAION associated with semaglutide was previously issued by the European Medicines Agency and the United Kingdom Medicines and Healthcare products Regulatory Agency, and was reported in the Drug News Issue No. 183, 188 and 196. The DH issued letters to inform local healthcare professionals to draw their attention on 9 June 2025. In light of the above TGA's announcement on the update of product information across the GLP-1 RA drug class, the DH issued letters to inform local healthcare professionals to draw their attention on 23 July 2026, and 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: Finasteride and Dutasteride: Assessing the potential risk of suicidal ideation

On 30 July 2026, Health Canada issued the following announcement:

Product

Finasteride-containing products and dutasteride-containing products

Potential Safety Issue

Suicidal ideation (thoughts of suicide)

Key Messages

- Health Canada completed a review of the known risk of suicidal ideation with the use of finasteride to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate. Health Canada also reviewed the potential risk of suicidal ideation with the use of dutasteride, and evaluated a possible relationship between sexual dysfunction and suicidal ideation in patients using finasteride or dutasteride.
- Based on the review, Health Canada continues to find a link between the use of finasteride and the risk of suicidal ideation. It was determined that the existing product information in the Canadian product monographs (CPMs) for all finasteride-containing products is appropriate, and no updates are needed at this time.
- Health Canada's review found limited evidence describing a possible link between the use of dutasteride and the risk of suicidal ideation. However, given that dutasteride works in the same way as finasteride, a precautionary approach is warranted. Therefore, Health Canada is working with the manufacturers to update the CPM for all dutasteride-containing products to include a warning on the risk of suicidal ideation. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Despite reports of patients experiencing both sexual dysfunction and suicidal ideation while using finasteride or dutasteride, a conclusion on the relationship between these two adverse events could not be confirmed due to the complexity of the evidence and the presence of confounders (other factors that may have contributed to the occurrence of suicidal ideation).

Overview

Health Canada has been monitoring the risk of suicidal ideation with the use of finasteride since 2012. The information generated as part of Health Canada's 2012 and 2015 reviews was considered

too limited to determine whether there was a link between the use of finasteride and suicidal thoughts and behaviours (suicidality).

In 2019, following reports of Canadian and international cases of suicide, suicidal ideation and self-injury with the use of finasteride, Health Canada completed a third review that found a possible link between finasteride and the risk of suicidal ideation. The CPMs for all finasteride-containing products were updated to include the risk of suicidal ideation.

In 2022, following the publication of a media article that discussed the potential risk of suicide in patients using finasteride, Health Canada completed a fourth review on the risk of suicidal ideation and the potential risks of suicide and self-injury with the use of finasteride. The review found a possible link between the use of finasteride and the risks of suicidal ideation and self-injury. However, at the time, there was not enough information to establish a link for the risk of suicide.

In 2026, following the European Medicines Agency's (EMA) assessment of the benefit-risk balance for finasteride and dutasteride, Health Canada completed a review of the known risk of suicidal ideation with the use of finasteride to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate. Health Canada also reviewed the potential risk of suicidal ideation with the use of dutasteride, and evaluated a possible relationship between sexual dysfunction and suicidal ideation in patients using finasteride or dutasteride.

Use in Canada

- Finasteride and dutasteride are prescription drugs belonging to a class of drugs called 5-alpha reductase inhibitors, which are authorized for sale in Canada for:
  - the treatment and control of prostate gland enlargement (benign prostatic hyperplasia) (finasteride and dutasteride), and
  - the treatment of male pattern hair loss (androgenic alopecia) (finasteride).
- 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 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 collected as part of its 2022 safety review on finasteride and from the EMA's 2025 assessment, as well as from searches of the Canada Vigilance database and the scientific literature.
- Health Canada did not identify any new significant information in the EMA's assessment on the risk of suicidal ideation with the use of finasteride.
- Health Canada reviewed 1 Canadian case of self-injury in a patient using dutasteride. The case was found to be possibly linked to the use of dutasteride.
- Health Canada also considered the 13 international cases of suicidal ideation with the use of dutasteride and the scientific literature identified as part of the EMA's assessment. Though the EMA concluded neither source of information provided sufficient evidence linking a risk of suicidal ideation with the use of dutasteride, they recommended a labelling update for all dutasteride-containing products given the common mechanism of action of drugs within the 5-alpha reductase inhibitors class, of which dutasteride is part.
- At the time of the review, Health Canada had received 18 Canadian reports of suicidal ideation in patients taking finasteride or dutasteride who also reported sexual dysfunction. However, a conclusion on the relationship between these two adverse events could not be confirmed due to the complexity of the evidence and the presence of confounders.
- Health Canada also reviewed 17 articles published in the scientific literature that discussed a possible relationship between sexual dysfunction and suicidal ideation in patients using finasteride or dutasteride. However, due to the complexity of the evidence and the presence of confounders, the role of sexual dysfunction as a risk factor for suicidal ideation could not be confidently concluded.

Safety Update

Conclusions and Actions

- Based on the review, Health Canada continues to find a link between the use of finasteride and the risk of suicidal ideation. It was determined that the existing CPMs for all finasteride-containing products are appropriately labelled for this risk and no updates are needed at this time.
- Health Canada's review also found limited evidence describing a possible link between the use of dutasteride and the risk of suicidal ideation. However, given that dutasteride works in the same way as finasteride, a precautionary approach is warranted. Therefore, Health Canada is working with the manufacturers to update the CPMs for all dutasteride-containing products to include a warning about the risk of suicidal ideation. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Despite reports of patients experiencing both sexual dysfunction and suicidal ideation while using finasteride or dutasteride, a conclusion on the relationship between these two adverse events could not be confirmed due to the complexity of the evidence and the presence of confounders.
- 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 July 2026, the Department of Health (DH) had received 5 cases of adverse drug reaction with regard to finasteride, of which 2 cases were related to sexual dysfunction and none was reported as suicidal ideation. With regard to dutasteride, DH had received 4 cases of adverse drug reaction, but these cases were not related to suicidal ideation or sexual dysfunction.

Related news on the risk of suicidal ideation and sexual dysfunction 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. 200. The DH issued letters to inform local healthcare professionals to draw their attention on 25 May 2017, 20 January 2023 and 9 May 2025. In February 2015, September 2017 and April 2024, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) discussed the matter, and decided in the meetings in February 2015 and September 2017 that the sales pack label and/or package insert of finasteride-containing products should include safety information on suicidal ideation and sexual dysfunction. As previously reported, the matter will be further discussed by the Registration Committee .

Drug Incident

Woman Arrested on Suspicion of Illegal Sale and Possession of Topical Product with Undeclared Controlled Drug Ingredients

On 31 July 2026, the Department of Health (DH) carried out an enforcement operation with the Police against the suspected illegal sale of a topical product containing undeclared controlled medicines at a beauty parlour in Causeway Bay. During the operation, a 40-year-old woman was arrested on suspicion of the illegal sale and possession of Part 1 poisons and an unregistered pharmaceutical product.

Acting on a complaint, the DH earlier purchased a sample of the product labelled "Dermasa" from a beauty parlour on Hysan Avenue in Causeway Bay for analysis. Test results from the Government Laboratory revealed that the product sample contained prilocaine, as well as lignocaine and tetracaine, which are Part 1 poisons 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 using it immediately, and reminded the public not to buy or use products of doubtful composition or from unknown sources. The DH would continue to investigate the incident and take appropriate follow-up actions.

Lignocaine, tetracaine and prilocaine are local

anaesthetics which are used topically to relieve pain. Common side effects are hypersensitivity reactions.

Topical products containing the combination of lignocaine, tetracaine and prilocaine are prescription medicines and should be used under a doctor's directions and be supplied on the premises of an Authorized Seller of Poisons (i.e. a pharmacy) under the supervision of a registered pharmacist upon a doctor's prescription.

A press release was posted in the Drug Office website on 31 July 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,
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.