



**Lung
Foundation
Australia**

Position Statement: Online E-cigarette dispensing in Australia

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About Lung Foundation Australia

Lung Foundation Australia is Australia's leading lung health peak body and national charity. Founded in 1990, we have become the trusted point-of-call for the one in three Australians living with a lung disease, including lung cancer.

We work to ensure lung health is a priority for all, from promoting lung health and early diagnosis, advocating for policy change, programs, and research investment, raising awareness about the symptoms and prevalence of lung disease, and championing equitable access to treatment and care. To support those living with a lung disease we deliver information and support services and facilitate access to peer support and exercise maintenance programs.

As a patient representative charity, we have partnered with patients, health professionals, researchers, medical organisations, and the Australian community to drive reform in the delivery of health services in Australia to benefit more than 7 million Australians impacted by lung disease and prevent even more Australians from developing lung disease.

Key messages

- E-cigarettes (also referred to as vapes) are known to cause multiple health harms and most contain nicotine.
- Nicotine is a highly addictive and harmful drug that is known to cause cardiovascular and respiratory problems.
- E-cigarettes should only be used as a last line smoking cessation treatment for tobacco and nicotine dependence. There are other evidence-based cessation treatments that should be considered first such as Nicotine Replacement Therapies (NRT) alongside behavioural supports under the supervision of a health practitioner.
- Pharmacists treating a customer for nicotine dependence management are required to hold a thorough consultation with the patient. This includes gathering a detailed history and conducting appropriate screening, case-finding, and risk assessments and should be held in-person.

Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024 (Cth)

- The federal *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Cth)* was introduced on July 1, 2024. The Act prohibits the importation, domestic manufacture, supply, commercial possession and advertisement of disposable single use and non-therapeutic vapes. It allowed for the sale of therapeutic vapes by a pharmacist as a Schedule 4 (S4) medicine; meaning that vapes can only be purchased with a prescription from a medical practitioner and can only be dispensed by a pharmacist.
- From 1 October 2024, therapeutic vapes with a nicotine concentration of 20mg/mL or less became available from Australian pharmacies to patients 18 years or over without a prescription where a pharmacist assesses this to be clinically appropriate subject to individual state and territory laws.
- Tasmania and Western Australia have retained therapeutic vapes as a S4 prescription only medicine. This means that in those states a health practitioner must supply a prescription for an individual to be able to buy a therapeutic vape from a pharmacy.
- No retail settings apart from pharmacies are allowed to sell vapes and accessories.

Summary

E-cigarettes (also referred to as vapes) present risks to both physical and mental health.¹⁻³ There is a lack of robust evidence for the use of e-cigarettes as a smoking cessation tool compared to existing evidence-based smoking cessation methods. The Royal Australian College of General Practitioners (RACGP) recommends behavioural support combined with first-line pharmacotherapy and follow-up. First-line pharmacotherapy options are medicines that have been demonstrated to be effective and safe such as Nicotine Replacement Therapy (NRT) including gums, patches and lozenges or medicine such as varenicline.⁴ The Therapeutic Goods Administration of Australia (TGA) has not evaluated any therapeutic vaping goods for safety, quality or effectiveness, and they are considered unapproved goods. The TGA does not recommend e-cigarettes as a first line of treatment for smoking cessation, vaping cessation or the management of nicotine dependence.⁵

The federal *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Cth) was introduced on the 1st of July 2024 with therapeutic vapes initially listed as a Schedule 4 (S4) prescription only medicine. As of 1st October 2024, therapeutic vapes became a Schedule 3 (S3) pharmacist only medicine. This means that a customer seeking a therapeutic vape can purchase it from a pharmacist without a prescription after all other smoking cessation methods have been tried unsuccessfully. It is expected that when a pharmacist dispenses a S3 therapeutic vape, the pharmacist holds a consultation with the customer to ensure that a vaping good is the most appropriate treatment option.⁶

State and Territory regulations differ between jurisdictions regarding whether a pharmacist should personally hand over the S3 product to the customer or not.

With the change of vaping to an S3 medicine, numerous pharmacies have been established to solely sell vaping products and no other pharmaceutical products. The creation of these pharmacies has been primarily online. With the expansion of this online market there are limitations on the effectiveness for customers to access accurate pharmaceutical advice. Additionally, a number of these newly established online pharmacies were previously vape shops that have now pivoted to a new business model, with many establishing a presence in QLD where there are legislative loopholes.

The aim of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Cth) was to ensure that access to therapeutic vapes was only for long term smokers looking to quit, and who had tried all other smoking cessation methods available with no success. The original S4 model that was proposed was to make sure that each person was supported in their quit journey with guidance and follow up support from a health care professional to maximise quit attempts. The subsequent change to the S3 model has opened up the opportunity for vape shops to rebrand as pharmacies and continue to supply vaping products with limited oversight. A pharmacy business model that only sells vaping products does not have people's health in their best interests and undermines public health efforts.

Lung Foundation Australia makes the following recommendations:

1. **Online businesses and stores that only sell therapeutic vape products and accessories and no other pharmaceutical products should not be allowed to operate.**
2. **No therapeutic vaping products or accessories should be allowed to be sold online.**
3. **State and Territory regulations should be amended for national consistency to require a pharmacist to directly engage in-person with customers seeking a Schedule 3 (S3) therapeutic vaping good.**

Background

E-cigarettes, although marketed by tobacco and e-cigarette industry groups as a safer alternative, are products that have known and demonstrated short-term health harms and mounting evidence of long-term health harms.^{7–11}

Health impacts

E-cigarettes contain toxic chemicals that are harmful to physical health, with most containing the highly addictive drug nicotine, which is harmful to both physical and mental health.

- Known health harms include: **lung damage, mouth and airway irritation, coughing and breathlessness, nausea, headaches, dizziness, seizures, nicotine poisoning and addiction, and burns.**¹²
- Mental health harms include: **mood changes, difficulty concentrating, feeling nervous, restless, irritable and/or anxious.**¹²

There has been a large increase in the uptake of e-cigarettes by 'never-smokers', particularly in young people, which is leading to nicotine dependence. Evidence shows us that non-smokers who take up e-cigarettes are **5x more likely** to take up tobacco smoking.¹³ The dual use of e-cigarettes and tobacco can lead consumers to prolonged exposure to nicotine and all of the additional associated health risks of tobacco products.¹⁴

More research is uncovering the damage that e-cigarettes have on DNA, similar to the damage caused by tobacco smoking.^{7,8,10} The impact of tobacco on health and society more broadly has been devastating and there is a concern that the short-term and long-term health impacts of e-cigarettes may be similar. There is a risk that the widespread use of e-cigarettes creates normalisation of smoking and nicotine use, and the development or continuation of nicotine addiction.

Environmental impacts

E-cigarettes pose significant environmental health risks due to their complex composition and disposal challenges. Unlike traditional cigarettes, e-cigarettes generate plastic, chemical, and electronic waste, contributing to pollution and resource depletion.¹⁵

Plastics

Most e-cigarettes are made from non-biodegradable plastics with limited recycling options. Improper disposal leads to widespread litter and landfill accumulation, with only 13% of plastic waste being recycled.¹⁶

Chemical Waste

E-liquids are classified as hazardous waste and are harmful to humans and the environment. They contain toxic substances that can contaminate soil and water, harm aquatic ecosystems,^{17,18} and contribute to indoor air pollution.¹⁵

Electronic Waste

Lithium-ion batteries in e-cigarettes are flammable and non-recyclable. An estimated 1.8 million units are discarded weekly in Australia, often causing fires in waste facilities and posing safety risks to workers.¹⁹ These batteries also contain heavy metals and corrosive substances that threaten human and animal health.

The production of e-cigarettes contributes to air pollution, hazardous waste, resource depletion (energy, water, and finite materials for batteries), and climate change due to manufacturing and shipping emissions, creating a significant environmental burden and contributing to pollution from both production and disposal.¹⁵

E-cigarettes for smoking cessation

Tobacco and e-cigarette industries have promoted e-cigarettes as a cessation tool, yet there is limited evidence that supports e-cigarettes as an effective means of smoking cessation over other evidence-based cessation methods.^{20,21} In Australia, we promote a variety of evidence-based approved forms of smoking cessation tools and Nicotine Replacement Therapies (NRTs) that are tested for safety, quality, and efficacy. The tobacco industry uses the concept of reduced harm as a display of corporate social responsibility and to profiteer off the negative health impacts of tobacco, but in essence e-cigarettes are just another harmful product to encourage a new generation of people to become addicted to nicotine. We now know that people who use e-cigarettes are 5x more likely to go on to smoke cigarettes and that many people go on to dual use of tobacco and e-cigarettes simultaneously further increasing health harms.¹³

New research has shown that e-cigarette use does not increase smoking cessation and is actually associated with reduced tobacco abstinence.²² There are evidence-based cessation aids such as NRT and behavioural therapies and pharmacotherapies that research has shown increase peoples chance at quitting for the long term.^{23,24}

For more information on Lung Foundation Australia's position on e-cigarettes and their impact on health and the environment please refer to [Position Statement: E-cigarette use in Australia](#) and for LFA's position on cessation of smoking products refer to [Position Statement: Cessation of smoking products](#) on the LFA website.

Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Cth)

As e-cigarette use increased dramatically, particularly among young people and non-smokers, The Australian Federal government introduced a federal Bill; *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Cth)*.²⁵ The intention of the Bill was to reduce the prevalence of smoking and vaping in the community in addition to preventing the uptake of vaping among non-smokers in alignment with the National Tobacco Strategy 2023-2030.²⁶ The Bill maintained access to therapeutic vapes for the purpose of smoking cessation under the supervision of a medical practitioner as a S4 medicine. Therapeutic vapes could only be purchased from a pharmacy with a prescription from a medical practitioner.

The final iteration of the Bill was amended whereby making therapeutic vapes an S3 medicine that does not need a prescription. Some pharmacies have chosen to supply therapeutic vapes to customers while others have chosen to abstain due to concerns about the potential health harms associated with vaping.

The ability to purchase therapeutic vapes without a prescription has led to many vape retailers pivoting to become online pharmacies that only sell therapeutic vaping products. To make a purchase in this context, a typical sequence of events is that a customer registers for an account, fills out an online questionnaire, provides identification and they are then given access to vaping products to purchase which are delivered to their address anywhere in Australia.

The online pharmacy model for accessing e-cigarettes is grave cause for concern as:

- A pharmacist has little to no patient consultation or patient history oversight.
- No opportunity to discuss cessation options.
- No opportunity to discuss the appropriateness of the product for their use.

The model allows people to continue to use addictive products that are known to cause multiple health harms without encouraging them to quit smoking and vaping which should be the ultimate goal. It removes health care and patient oversight from the equation, with a focus on product sale and profit.

Expected best practice for pharmacists

Pharmacists must abide by a code of conduct, standards of practice and guidelines provided by their related professional Boards and Associations. Expectations for a pharmacist supplying an S3 medicine is that a formal consultation must be held to assess the patient's needs, to determine appropriate management options, provide education and advice and document the supply.

The Pharmaceutical Society of Australia's PSA Nicotine cessation Guidelines²⁷ call to provide in-person nicotine dependence consultations with the patient in a private consultation area/room in order to gather patient information, including screening for undiagnosed conditions if appropriate, assessing patient needs, agreeing on a management plan (including obtaining informed consent for unapproved products), discussing the agreed management plan and documenting the details of the consultation. This cannot be accomplished via an online form.

The Therapeutic Goods Administration (TGA) is responsible for classifying medicines in a scheduling system that determines where you can get your medicines from. The TGA states that for S3 medicines purchased from a pharmacy, the pharmacist must personally hand over the medicine and give the customer an opportunity to seek necessary advice on the medicine.²⁸ This stipulation negates the online sale and delivery method most of the stores solely selling vaping products have adopted.

The Pharmaceutical Society of Australia's PSA Regulation Hub contains "*State and territory regulation relevant to the supply of therapeutic vapes in addition to the Professional practice guidelines for pharmacists: nicotine dependence support.*"²⁹ Across the states and territories there are inconsistent guidelines for the supply of S3 medicines.

Tasmania and Western Australia: do not permit the supply of vapes as an S3 pharmacist only medicine. Instead, they are a S4 prescription only medicine that can only be obtained from a pharmacy with a prescription from a medical practitioner. This is due to each of these states choosing to amend their relevant tobacco legislation so that stronger measures apply to protect the health of the people in their jurisdiction.

Australian Capital Territory: the pharmacist must personally hand the medicine to a customer attending in-person.

New South Wales: the pharmacist must personally hand the medicine to the person.

Victoria: a pharmacist must personally deliver, or personally supervise the delivery of, an S3 medicine to a person.

Northern Territory and South Australia: have no specific requirements to hand over the medicine to the customer.

Queensland: the pharmacist must reasonably believe the patient has a therapeutic need for the medicine, however there is no specific requirement for how the medicine is to be handed over to the customer.

Many of the online pharmacies that prioritise vaping products are based in Queensland where there are no specific guidelines for handing the medicine in-person to the customer. This loophole enables the transaction to be completely online from end-to-end. The online pharmacy model removes patient safeguarding, patient assessment and product suitability.

The joint statement on professional responsibilities for prescribing and dispensing medicines³⁰ released by **Australian Health Practitioner Regulation Agency (AHPRA) and the Medical, Nursing and Midwifery and Pharmacy Boards of Australia** raises concerns regarding practitioners practising in health services providing customers with a pre-determined medicine that may be putting profit ahead of patient welfare.

The statement points out existing obligations and highlights how these responsibilities apply in the context of new models of care such as the use of telehealth. Health practitioners must ensure that their own practice meets the standard expected by their registration Board and the community, and their professional obligations in their respective codes of conduct. It is highlighted that good care includes the need for assessment of the patient in a real-time interaction to take into consideration the health history of the patient and only recommend treatments when there is an identified therapeutic need that will provide benefit for the patient.

A case study published by the Pharmacy Board of Australia details that an online pharmacy was supplying vaping products without sufficiently confirming it was therapeutically adequate.³¹ The Board pointed out that when supplying an S3 medicine a nicotine dependence support consultation should be held to establish patient needs and to work with the patient to consider all options to develop the most appropriate management plan. Management plans should be tailored to the patient and their individual needs.

Guidelines for virtual care

AHPRA and the National Boards have developed information for practitioner's who provide virtual care outlining how to comply with relevant state, territory and jurisdictional legislative requirements for prescribing medicines when prescribing within a virtual care context. Online pharmacies are exploiting the Commonwealth vaping reform laws enabling customers across borders to access vaping products without a prescription or without engaging with the customer through an in-person consultation. The guidelines highlight that best practice care involves a formal consultation with each customer and that text messages, emails or online health questionnaires do not constitute best practice.³²

Pharmacies that have set up to only sell vaping products should not be allowed to trade as a pharmacy. In most cases they were previously trading as vape shops who have pivoted and employed a pharmacist to continue selling vapes and vaping products.

Lung Foundation Australia recommendations

1. Online businesses and stores that only sell therapeutic vape products and accessories and no other pharmaceutical products should not be allowed to operate.

These online pharmacy models operate with a severe conflict of interest whereby their only interest is profiteering off a harmful product rather than helping people to quit smoking and vaping for good to protect people's health. Many, if not all of them, have transitioned from being a vape store to becoming a pharmacy only selling therapeutic vaping products. They are in essence a vape shop that has employed a pharmacist to authorise the sale of vapes. There is no place for businesses operating purely to profit off the supply of vaping products with little regard to help people to quit smoking and nicotine products for good.

2. No therapeutic vaping products or accessories should be allowed to be sold online.

Online sales of therapeutic vaping products and accessories do not allow for in-person consultations that ensure safe and appropriate access to these unapproved products. In-person consultations allow health professionals to assess suitability, provide crucial health information and advice on quitting tobacco, manage potential side effects, and determine the correct device and nicotine concentration, especially given the limited evidence of vaping effectiveness and its associated health risks.

3. State and territory regulations should be amended for national consistency to require a pharmacist to directly engage in-person with customers seeking a Schedule 3 (S3) therapeutic vaping good.

State and territory regulations should be amended for national consistency to require a pharmacist to directly engage in-person with customers seeking an S3 medication. Currently the ACT, NSW and VIC have the requirement for S3 medicines to be handed over in-person. In QLD there is no specific requirement to hand over the S3 medicine in-person, so many of the online vaping stores that have transitioned to become online vaping pharmacies are operating from QLD and selling to all states and territories in Australia. By having the need to hand over the S3 medicine in-person it removes the loophole that allows these stores to flout the rules.

Consistency across the jurisdictions limits confusion, it also defines a national and unified expectation for pharmacists when dealing with S3 medicines. A consistent approach also ensure customers are receiving the most suitable cessation treatment option for them. Any issues arising with the smoking cessation journey can be addressed thoroughly in-person between the pharmacist and the customer.

LFA recommends that the Governments of QLD, SA and NT should amend their Medicines and Poisons Act to clearly stipulate that a pharmacist must personally hand the S3 medicine to a customer attending in-person.

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