



RACGP

Supporting smoking & vaping cessation: A guide for health professionals

Guidance on smoking and vaping cessation support related to changes to Australia's vaping regulation

October 2024

Australia's vaping reforms and supporting health professionals in this evolving environment

On 28 November 2023, the Minister for Health and Aged Care, Mark Butler MP announced the next steps on Australia's vaping regulation reforms. This journey of legislative change originated two years earlier, when from 1 October 2021, Australia moved into a globally unique situation of restricting consumer access to nicotine containing e-cigarettes, also referred to as nicotine vaping products (NVPs) or vapes, to therapeutic use via a prescription only model.

Since that time, further regulatory change has been called for to combat a range of challenges relating to illegal importation and supply of vaping products and the rapid rise of vaping amongst youth. In May 2023 Minister Butler announced further regulatory reforms relating to the importation, manufacture, labelling and packaging of NVPs in order to improve product quality and safety, and reduce the availability and use of illegal vaping products particularly by young people (under 18) and non-smokers.

On 15 December 2023, the Therapeutic Goods Administration (TGA) announced a suite of regulatory amendments to implement the Minister's intended reforms to change the way vapes are regulated in Australia. This included new importation requirements and increased minimum product standards for therapeutic vapes.

The reforms culminated most recently in amendments to the *Therapeutic Goods Act 1989* to specify new controls on the importation, domestic manufacture, supply commercial possession and advertisement of all vapes, irrespective of nicotine content or therapeutic claims. The [Therapeutic Goods and Other Legislation Amendment \(Vaping Reforms\) Act 2024](#) (the law) commenced in Australia on 1 July 2024. Information for stakeholders can be found on the Department of Health and Aged Care and Therapeutic Goods Administration [Vaping Hub](#).

Key changes

- Vapes can only be sold at pharmacies from 1 July 2024 – this includes all vapes including those that do not contain nicotine
- Until 30 September 2024, people need to speak with a medical or nurse practitioner to:
 - Get a prescription to buy vapes containing nicotine, and
 - Access zero-nicotine vapes
- From 1 October 2024 people 18 years or over will be able to purchase nicotine vapes with 20 mg/mL or less from a pharmacist without a prescription subject to certain conditions. However, a prescription from a medical or nurse practitioner will be required for nicotine concentrations greater than 20 mg/mL.
- From 1 October 2024 people under 18 years of age will continue to require a prescription to access vapes, where state and territory laws allow.

About this document

This document provides guidance to prescribers of NVPs under a medical framework. The guidance is comprised of two parts. The first is an update to the RACGP Smoking cessation guidance, [Electronic cigarettes and nicotine vaping products \(NVPs\) as an aid to smoking cessation](#). Changes to this section include revisions to the GRADE recommendation on e-cigarettes (NVPs) for smoking cessation, information on reforms to legislation relating to vaping, and further information on prescribing.

The second part is new content, [Vaping Cessation](#). This guidance will be updated again when further details about prescribing pathways, maximum nicotine concentrations and indications for young people are finalised (estimated late 2024 or early 2025).

Disclaimer

The information in the guidance does not necessarily represent or reflect the views of the Australian Government Department of Health and Aged Care.

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Part 1: Electronic cigarettes and nicotine vaping products (NVPs) as an aid to smoking cessation

About this section

Therapeutic goods, such as medicines and medical devices, that are approved by the Therapeutic Goods Administration (TGA) for general marketing are included in the Australian Register of Therapeutic Goods (ARTG). At present, there is no therapeutic vaping substance containing nicotine (Nicotine Vaping Product) included on the ARTG. Therapeutic goods that are not included in the ARTG are known as 'unapproved' or 'unregistered' goods.

These guidelines provide information about electronic cigarettes and NVPs, the current regulatory environment, evidence on the effectiveness of nicotine electronic cigarettes in smoking cessation, and advice about how to minimise the risks and maximise the benefits of prescribing unapproved nicotine vaping products (NVPs) for people who want to quit smoking.

For guidelines about supporting patients who want to quit vaping, see the chapter on [Vaping Cessation](#).

Introduction to vaping and e-cigarettes

Electronic cigarettes, also referred to as e-cigarettes, or vapes, are a diverse range of battery-powered devices that deliver aerosol without tobacco or smoke. The device heats an e-liquid, converting it into an aerosol for inhalation. E-cigarettes are available with and without nicotine. An e-cigarette containing nicotine is also known as a nicotine vaping product (NVP). The nicotine content of NVPs can vary from very low to over 50 mg/mL.

The use of e-cigarettes is often referred to as 'vaping' and e-cigarette users are sometimes referred to as 'vapers'.¹

Terminology for prescribers

Therapeutic vaping goods	<p>The revised Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO110), released on 15 December 2023, introduced the term 'therapeutic vaping goods'. This is because TGO110 has been expanded to not only cover the constituents of nicotine-e-liquids but also the vaping devices and vaping device accessories that deliver the aerosol when sold in the same pack.</p> <p>Separately, requirements for vaping devices and vaping device accessories are also reflected in the relevant <i>Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023</i></p>
Substances, devices, and device accessories	<p>As of 1 January 2024, the TGA has used the terminology 'therapeutic vaping substances' (whether or not containing nicotine) and 'therapeutic vaping devices'.</p> <p>The standards applying to vaping goods have since been expanded to include requirements for therapeutic vaping devices and therapeutic vaping device accessories (the part that contains the vaping substance) as well as the nicotine e-liquid (or the vaping substance)</p>
Therapeutic vaping substance	<p>A therapeutic vaping substance includes e-liquids (also known as vape liquids, and sometimes referred to colloquially as e-juice) that contain nicotine and includes the nicotine solution in nicotine e-cigarettes and pods.</p>
Vaping device	<p>Vaping device refers to the electronic device used to heat e-liquid to release an aerosol that is inhaled. Vaping devices include e-cigarettes, e- cigars, e-hookah pens, e-pens, e-pipes and vape pens.</p> <p>Devices can be disposable or re-chargeable and refillable. Disposable devices cannot be refilled and are non-rechargeable.²</p> <p>There are two categories of vaping devices: ^{2, 3, 4, 5}</p> <ul style="list-style-type: none"> • Closed system: Vaping devices that are designed for use with single-use pods or pre-filled cartridges or other disposables that are sealed and ready-filled with the e-liquid.⁵ When the pod or cartridge is empty, the user replaces it with a new one. • Open system: Vaping devices that users need to manually fill and re-fill with e-liquid.

Therapeutic vaping substance accessory	Vaping substance accessories include the cartridge, capsule, pod, vial, dropper bottle, or any other vessel that contains the vaping substance.
Nicotine vaping product (NVP)	<p>In this guidance the RACGP has continued to use the term Nicotine Vaping Product (NVP). NVP means products that contain nicotine in a solution designed to be inhaled using a vaping device.</p> <p>An NVP is made up of a nicotine containing 'therapeutic vaping substance' and a 'therapeutic vaping substance accessory. '...</p> <p>It is important to understand that both the NVP and the vaping device will need to be prescribed.</p>

Composition of NVPs

Nicotine in an e-liquid can be in free-base or salt form. In both cases, the active ingredient is nicotine.

The free-base form at concentrations >20 mg/mL causes adverse effects including throat irritation and therefore higher concentrations need to be diluted before use. The dilution process may pose an increased risk of nicotine poisoning through contact with skin. The nicotine salt is associated with less throat irritation allowing for higher concentrations of nicotine to be used.

In addition to nicotine, the e-liquid usually contains propylene, glycerol, flavourants and contaminants such as toxic metals.⁶ E-liquids may also contain preservatives, natural coolants such as menthol or synthetic coolants such as WS-3 or WS-23.7 Illegal vapes or imported e-liquid may not adhere to TGO 110 labelling requirements and could contain other ingredients which are potentially harmful to health.

Pharmacokinetics of NVPs

The pharmacokinetics of nicotine delivery, which include rapidity of onset and peak nicotine levels, are variable and depend on the form of the nicotine, e-liquid concentration, the vaping device, and inhalation technique.⁸

Reforms to the regulation of vaping

In response to rapidly increasing use of nicotine vapes, including among young people who have never smoked, in May 2023 the Federal Minister for Health and Aged Care announced proposed reforms relating to the regulation of all vapes irrespective of nicotine content or therapeutic claim (i.e. nicotine vaping products and non-nicotine vaping products).⁹

These reforms culminated in the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024, which came into effect on 1 July 2024. Information for all stakeholders can be found on the Therapeutic Goods Administration vaping hub: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>

Key changes

- Vapes can only be sold at pharmacies from 1 July 2024 – this includes all vapes including those that do not contain nicotine
- Until 30 September 2024, people need to speak with a medical or nurse practitioner to:
 - Get a prescription to buy vapes containing nicotine, and
 - Access zero-nicotine vapes
- From 1 October 2024, people 18 years or over will be able to purchase nicotine vapes with 20mg/mL or less from a pharmacist without a prescription, subject to strict conditions. However, a prescription from a medical or nurse practitioner will continue to be required for concentrations greater than 20 mg/mL.
- From 1 October 2024, people under 18 years of age will continue to require a prescription to access vapes, where state and territory laws allow.

To note, the implementation of these regulatory changes, particularly the domestic bans on all disposable vaping products, may result in an influx of people who use NVPs seeking help from medical or nurse practitioners.

This will include people who have never smoked and who are seeking support to quit vaping. It may be reasonable, after an evidence-based discussion about alternative options and in the understanding that the longer-term aim is nicotine cessation, to prescribe patients a NVP for a specific period as they transition away from vaping.

For people 16 years and above, the Authorised Prescriber or Special Access Scheme (SAS) C pathway may be used. For people younger than 16 years, the SAS B pathway is indicated. Ethics committee approval continues to be required to become an Authorised Prescriber to supply to patients under 16 years of age. Further information on prescribing is accessible through the Therapeutic Goods Administration website: [Vaping Hub](#).

Prescribing and dispensing NVPs to people under 18 years of age

In most states and territories, it is legal to provide a prescription for NVPs to people younger than 18 years under the medical access framework, however requirements and prohibitions regarding dispensing vary across jurisdictions.

Information on your jurisdiction may be accessed through here: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers/prescribing-and-dispensing-therapeutic-vapes-patients-under-18-years>

It is important for prescribers to check this information as it is being updated frequently. Further information on prescribing and dispensing can be accessed at the Department of Health and Aged Care and Therapeutic Goods Administration [Vaping Hub](#)

If dispensing is not allowed in your jurisdiction it is recommended to not provide a prescription.

Changes to the prescribing of NVPs and minimum standards

Notified NVPs

As no NVPs are currently approved by the Therapeutic Goods Administration (TGA) in the Australian Register of Therapeutic Goods (ARTG), NVPs have not been assessed by the TGA for safety, quality and efficacy, and are therefore 'unapproved' medicines.

The TGA has published a list of [notified vapes](#)- therapeutic vaping goods that have been notified by importers or manufacturers to be indicated for the purposes of smoking cessation or the management of nicotine dependence, and compliant with the relevant product standards (as listed below). Included in this list are vaping substances, vaping accessories and vaping devices.

From July 1, 2024, only vapes included in the TGA's list of notified vapes can be prescribed and dispensed, even if a person has a prescription for a product not included in the list. The list will continue to be updated as product sponsors notify the TGA with more compliant products.

Information on notified vapes can be accessed: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/table/list-notified-vapes>

Changes to prescribing requirements

Until 1 October 2024 consumers can legally access 'unapproved' NVPs only if they have a valid prescription. After this date, people over the age of 18 may purchase vapes with a nicotine concentration up to 20 mg/mL from a pharmacist without a prescription subject to certain conditions. A pharmacist will need to be satisfied it is clinically appropriate and meet several other conditions including requesting and sighting evidence of the person's identity and age and supply no more than one month's supply at one time. People under 18 and anyone who is seeking a vape with a nicotine concentration above 20 mg/mL will still require a prescription.

For details about prescribing NVPs to be used as an aid to smoking cessation, see the section on Prescribing NVPs.

Minimum requirements for unapproved therapeutic vapes (NVPs)

The TGA's Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 (TGO 110), came into effect on 1 October 2021, and was subsequently updated on 15 December 2023. This standard sets out the minimum safety and quality requirements for NVPs supplied in Australia.

Further changes to TGO 110 are expected to occur by late 2024 or early 2025. These changes are likely to relate to the permissible nicotine concentrations in prescribed NVPs, and plain pharmaceutical packaging. Updated information will be provided on the webpage: [Vapes: information for prescribers | Therapeutic Goods Administration \(TGA\)](#)

Details of the requirements for NVPs supplied in Australia can be found in [Nicotine vaping products and vaping devices: Guidance for the Therapeutic Goods Order 2021 and related matters](#).

Current standards for NVPs

Labelling: The label must display:

- an ingredient list
- nicotine concentration (mg/mL)
- warning statements (which can be on either the actual product or on an accompanying information sheet). Currently, the warning statements do not have to include warnings about the risk of ingestion.

Packaging: The packaging must be child-resistant.

Ingredients: Ingredients must adhere to the following:

- active ingredients other than nicotine are prohibited
- maximum nicotine concentration is 100 mg/mL in free-base form or equivalent. This does not mean that products with a lower nicotine concentration are safe or appropriate (see [Dosing considerations](#))
- cannot contain any of the [Prohibited ingredients list](#) in TGO 110

Flavours:

- flavours are limited to mint, menthol, or tobacco flavours
- ingredients or components that produce a combination of flavours are not permitted

Record-keeping obligations:

- anyone who imports, exports or manufactures (for supply in Australia) must meet specified record-keeping obligations. This includes pharmacists and health practitioners who meet the criteria.

See [Information for prescribers](#) and the [TGA table](#) outlining TGO 110 requirements in [Therapeutic Goods Order 110](#) (TGO 110) and related matters.

Vaping devices

- standards for vaping devices must align with processes applied to regulation of medical devices. A [checklist for vaping devices](#) and further information is available for manufacturers of the devices.

The risks of using NVPs need to be considered in the context of the seriousness of the risks of continued smoking. When considering prescribing NVPs to your patient, you may wish to consider risks including, but not limited to, the following:

General risks associated with NVPs ^{10, 11, 12, 13}

- short term adverse effects including throat irritation, headache, cough and nausea ²
- possible adverse effects on oral health including gum disease and bone loss around teeth^{14, 15}
- unknown effects on major health conditions including asthma, bronchitis, COPD, cardiovascular diseases, venous thrombosis, reproductive health and mental health.
- unknown long-term health effects
- for pregnant users, risk of birth at small for gestational age (SGA). SGA babies are in the lower 10th percentile of weight for gestational age and are at higher risk of long-term health conditions ^{2,3, 4, 5}
- intentional and accidental poisoning particularly from e-liquids used with open system NVPs (eg. child fatalities have occurred following ingestion of liquid nicotine ³)
- interactions between nicotine and other medicines ⁶ (eg. psychiatric medications such as antipsychotics)
- burns and injuries (including lung injury) ³⁴

Risks associated with access to nicotine by NVPs

- harm to adolescent brain development due to nicotine exposure ⁷
- increased nicotine consumption, due to dual use with continued smoking ^{8, 9}
- increased duration of use leading to greater long-term exposure to nicotine compared to other smoking cessation pharmacotherapy ¹⁰
- possible diversion leading to use by non-smokers
- the potential to be a gateway to tobacco use ⁴⁵
- the potential to promote nicotine use and re-normalise smoking among those who do not smoke, especially young people ⁷

Medicolegal risks

- potential medicolegal risks for prescribers due to there being no approved NVPs. Under TGA regulations prescribing practitioners are responsible for the use of an unapproved product, including all outcomes

Potential yet unidentified risks

The RACGP Expert Advisory Group (EAG) assessed the overall magnitude of acute adverse effects in the clinical setting as small (based on the Australian National University's review of the available evidence of short- and long-term adverse effects of NVPs). However, not all risks can be determined. As more evidence emerges, the full extent of short-term and long-term risks will become clearer.

Review of the efficacy of NVPs as a smoking cessation aid

Though the evidence-base is expanding there are still only a small number of well conducted randomised controlled trials that compare the effectiveness of NVPs as a smoking cessation aid to the effectiveness of TGA-approved pharmacotherapies such as nicotine replacement therapy, varenicline and bupropion.¹¹

A review conducted in 2021 by the Australian National University (ANU) to inform the RACGP (EAG) compared nicotine e-cigarettes (nicotine concentration >0.01 mg/mL) versus nicotine replacement therapy. The review, which covered publications up until 27th April 2021, identified two randomised controlled trials that met inclusion criteria with a total of 1468 participants. Both studies used NVPs containing freebase nicotine at concentrations of less than 20mg/ml. The relative effect was 1.67 (95% CI: 1.21 to 2.28) favouring nicotine e-cigarettes over NRT.¹⁰ At the time, the RACGP EAG concluded there is a small benefit in smoking cessation in the clinical setting for NVPs compared with NRT and rated the-

certainty of the evidence as **low**. The RACGP EAG also noted that evidence from good quality randomised trials had not substantively changed since the review conducted for the RACGP by the Joanna Briggs Institute in 2019.

An updated NHMRC CEO statement on electronic cigarettes was published in June 2022⁴⁴. The statement was based on evidence reviews commissioned by the NHMRC on the topics of e-cigarette use and smoking behaviour (uptake and cessation), the effects of e-cigarette advertising, promotion and sponsorship, and e-cigarette use and health outcomes. Relevant evidence statements from the publication are:

- E-cigarettes can be harmful. All e-cigarette users are exposed to chemicals and toxins that have the potential to cause adverse health effects.
- E-cigarette-related poisonings have substantially increased over the past 5 years. E-cigarette related calls to Australian Poisons Information Centres have more than doubled between 2020 and 2021.
- There are no health benefits of using e-cigarettes if you do not currently smoke tobacco cigarettes.
- Short-term e-cigarette use may benefit smokers if they are able to quit smoking and have been previously unsuccessful with other smoking cessation aids.

In November 2022 the Cochrane Library published an update of its review on e-cigarettes for smoking cessation. The review included 78 studies of which 17 were new to the update. Forty included studies were randomised controlled trials. Six studies were relevant to the comparison of nicotine e-cigarettes versus NRT, with comparison of smoking cessation at six months or more and measures of harm at one week or longer of e-cigarette use. Five studies excluded people who were pregnant (which included 2 cartridges, 3 refillable, 1 pod) and one study was in a pregnant population. The total number of participants across the six studies was 2,378. The risk ratio was 1.63 (95% CI: 1.30 to 2.04) favouring nicotine e-cigarettes over NRT.¹² Using the GRADE (Grading of Recommendations, Assessment, Development and Evaluations)¹³ criteria, the authors rated the certainty of evidence as **high** meaning that further studies would be unlikely to change the effect estimate in a way that would alter its clinical interpretation.

A key factor in developing the rating of the strength of the evidence is the risk of bias in the included six studies. The review authors rated the risk of bias as low in five of the six studies, including the largest study (Hajek et al 2019). The Hajek (2019) study exerted the greatest influence on the risk estimate. Given the significant change in the rating of the certainty of evidence from low to high, the RACGP EAG determined further examination of the evidence was warranted in terms of its impact on clinical decision-making. To ensure no significant studies were left out of the decision-making process, an additional literature search for any publications after the Cochrane 2022 review was conducted.

E-cigarettes for smoking cessation- updated RACGP GRADE recommendation

In February 2023 the RACGP conducted a literature review using the same search strategy used by the Cochrane Collaboration, to determine if there had been any additional studies on e-cigarettes for smoking cessation published since the Cochrane 2022 update. The search included published studies from January 2022 to February 2023, with a focus on nicotine e-cigarettes versus NRT and the clinical effectiveness outcome of smoking cessation. Initially, fifteen studies were identified, however, these were either already included in the Cochrane update (Myers-Smith 2022; Morphet 2022; Hajek 2022) or did not meet inclusion criteria due to not being RCTs or having incompatible outcomes and short-term follow up.

The RACGP commissioned Health Research Consulting (HERECO) to review the certainty ratings of the GRADE evidence ratings, based on the new studies in the Cochrane 2022 review. Hereco facilitated a workshop with the RACGP EAG to discuss the evidence to decision process, and in particular, study biases that may be relevant to consider in a clinical context. Following this workshop, all EAG members cast a vote (anonymously) on the certainty of evidence rating.

The consensus was to change the certainty of the evidence of the RACGP e-cigarette GRADE evidence rating in recommendation 15 from 'low' to 'moderate'. The key reason for the difference from the Cochrane review was a different assessment of the risk of bias.

In January 2024 the Cochrane Collaboration published an updated review of e-cigarettes for smoking cessation.¹⁴ The 2024 update included a total of 10 additional studies, including unpublished data from trial protocols, data published in conference proceedings and non-trial data to address questions of efficacy and also safety and tolerability. For the question of e-cigarettes vs NRT, there was one additional study on nicotine e-cigarettes vs combination NRT.¹⁵ The total

number of people across the seven studies were 2,544. The updated risk ratio was similar to previously reported: 1.59 (95% CI:1.29 to 1.93) favouring nicotine e-cigarettes over NRT.

The RACGP GRADE recommendation-15

Recommendation 15 – For people who want to quit but have failed to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy), it may be reasonable to recommend NVPs in conjunction with behavioural support. The decision to proceed with this treatment must be part of an evidence-informed shared-decision making process, where the patient is aware of the following.

- Due to the lack of available evidence, the long-term health effects of NVPs are unknown.
- NVPs are not registered therapeutic goods in Australia and therefore their safety and quality have not been established.
- The lack of uniformity in vaping devices and NVPs (e.g. in ingredients and dosage) increases the uncertainties and risks associated with their use.
- To maximise possible benefits and minimise risk of harms, dual use (tobacco and e-cigarettes) should be avoided and the duration of NVP use should be minimised.
- The importance of the patient returning for regular review and monitoring.

Conditional recommendation for intervention, moderate certainty

The efficacy of nicotine in salt form

Nicotine salts, which have a lower pH than free base nicotine, allow high levels of nicotine to be inhaled more easily and with less throat irritation than free base. To date there have been only a small number of studies examining the efficacy of NVPs that deliver nicotine in salt form and more research is needed.¹⁶ One study (Russell 2021)¹⁷ which was included in the 2022 Cochrane review found similar quit rates between nicotine salt and free-base nicotine. This study was tobacco industry sponsored and to date has only been published as a conference abstract. Several trials are in progress but at the time of writing but are yet to be reported.

The higher concentration of nicotine in salt form NVPs has the following potential advantages and disadvantages.

Potential advantages

- The consumption of the e-liquid is reduced, which may result in reduced exposure to toxic compounds (including volatile aldehydes) as well as flavouring molecules with unknown toxicity.^{18, 19, 20}

Potential disadvantages

- The more rapid delivery and high levels of nicotine may make NVPs in salt form more addictive and harder to cease.
- A concerning level of uptake of high concentration nicotine salt products in non-smokers including young people. This has been a particular feature in countries with consumer availability such as the **United States** and **Canada**.^{21,22} Therefore, risk of diversion needs to be considered and minimised.

NVPs in combination with other pharmacotherapies

There is currently limited evidence of the efficacy of NVPs used in combination with pharmacotherapy options.

Risks of NVPs as a smoking cessation aid in particular groups

The risk of using NVPs always needs to be weighed against the risk of long-term smoking in people who have not been able to quit with first-line treatments (TGA-approved pharmacotherapies and behavioural support).

People with chronic illnesses

There is a lack of high-quality evidence relating to the use of NVPs in people with chronic illnesses.

People who are pregnant or breastfeeding

There is one study (Hajek 2022) of use of NVP in pregnancy. The study included 1,140 participants comparing refillable e-cigarettes with nicotine patches. The outcome favoured NVP with risk ratio of 1.93 (95% CI 1.14 – 3.26). No difference in birth outcomes was found between groups.²³

NVPs are not recommended as a smoking cessation aid for people who are pregnant or breastfeeding as there is currently insufficient information on their effects on foetal development and obstetric outcomes.

For further information about smoking cessation in this group, refer to [People who are pregnant or breastfeeding](#).

Adolescents

NVPs are not recommended as a smoking cessation aid for people under 18 years of age as to date there have been no studies of effectiveness and safety in this age group. For further information about smoking cessation in this group, refer to [Adolescents and other young people](#). For advice on assisting adolescents who are already vaping see the section on vaping cessation.

Aboriginal and Torres Strait Islander peoples

Currently there is no evidence relating to the effectiveness of NVPs to assist Aboriginal and Torres Strait Islander peoples to quit smoking.

For further information about smoking cessation in this population, refer to [Aboriginal and Torres Strait Islander people](#).

The use of specific culturally appropriate resources, such as the Aboriginal Quitline is recommended. Culturally appropriate resources to support smoking cessation for Aboriginal and Torres Strait Islander communities can be found at: <https://tacklingsmoking.org.au/>

[Australian Indigenous HealthInfoNet](#) maintains comprehensive information on programs, resources and publications related to Aboriginal and Torres Strait Islander health, including information on tobacco.

People with mental illness

Smoking is highly prevalent amongst people with mental illness, especially those with severe illness. If a patient with mental illness has not been able to quit with first line treatment, NVPs in combination with behavioural support may be of value, although there is no current evidence specifically relating to the use of this approach by people in this group.

People with mental illness may be at greater risk of intentional poisoning from NVPs. Therefore, avoid prescribing open systems and/or liquids with high nicotine concentration.

For further information about smoking cessation in this population, refer to [People with mental illness](#).

Prescribing Nicotine Vaping Products for Smoking Cessation

Prescription monitoring systems

NVPs are not currently included in real-time prescription monitoring systems in Australia.

Access pathways

Prescribers are under no obligation to prescribe NVPs.

Up to 1 October 2024 all people seeking NVPs will require a prescription. After this date a prescription will only be required for people under the age of 18 and for those requiring a NVP with a nicotine concentration greater than 20 mg / mL.

The following table summarises the three access pathways medical practitioners and nurse practitioners can currently use to prescribe NVPs, subject to state and territory law.

More detailed information on prescribing schemes can be found: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers>

Table 1 Access pathways for NVPs

Scheme (click on the scheme for further information)	To use this scheme:
Authorised Prescriber Scheme (medical practitioners only)	<ol style="list-style-type: none"> 1. Apply online to the TGA for authority to prescribe NVPs for patients under your immediate care (without needing separate approval for each patient). 2. Every six months, you must report to the TGA the number of patients for whom you have prescribed NVPs. (See the TGA infographic on becoming an Authorised Prescriber for NVPs.)
Special Access Scheme B (medical or nurse practitioners)	<ol style="list-style-type: none"> 1. Apply online to the TGA for approval to prescribe an NVP for a single patient. 2. Approval required for each patient.
Special Access Scheme C (medical or nurse practitioners)	<ol style="list-style-type: none"> 1. A medical practitioner or nurse practitioner can use the online notification system to access the unapproved products, immediately. 2. You must submit a form for each individual patient to notify the TGA within 28 days of use of the unapproved product. <ol style="list-style-type: none"> a. Note: it is best to submit the notification at the time of prescribing to allow for efficient dispensing by the pharmacist 3. A copy of the online submission receipt must be kept with the patient's medical record. No approval letter is required. 4. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber, if agreed.

Note that the Personal Importation Scheme which allowed patients with a prescription to import NVPs for personal use ceased to operate on 1 March 2024.

After 1 October 2024 NVPs will become Schedule 3 medicines and available from behind the counter in pharmacies subject to certain conditions. Certain groups will still require a prescription:

- People requiring a nicotine concentration greater than 20 mg/mL
- Young people under the age of 18

Initial prescription

When you prescribe an NVP under the Authorised Prescriber or SAS B the pharmacist will need to check that the submission number is valid before dispensing. Therefore, the submission number or a copy of the TGA AP prescriber approval letter need to be provided to the pharmacist.

The TGA has set up an online SAS and AP submission validation to assist pharmacists with validation:
<https://compliance.health.gov.au/sas/>

Under a SAS C pathway available since 1 January 2024, medical practitioners and nurse practitioners are able to prescribe therapeutic vaping goods for patients aged 16 years and over without pre-authority or approval from the TGA subject to state and territory laws. A notification to the TGA needs to be made within 28 days of issuing the prescription. It is best practice to submit the notification at the time of prescribing to allow the pharmacist to check the SAS C online system and immediately dispense the medication.

Information is available on the TGA website: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>

Clinical notes

You should document:

- a brief clinical justification for prescribing NVPs
- that you have explained the benefits and risks and obtained informed consent. The TGA vaping hub stated this needs to be in writing for the AP scheme. It is good practice to obtain written, signed informed consent for all unapproved medicines.
- any adverse reactions to the NVP the patient reports during follow-up consultations so that you can report them to [the TGA - Adverse event reporting pathway](#).

Contents of each prescription

Each prescription should include:

- the brand and product of both the NVP and vaping device (not essential but good practice in the current context)
- nicotine concentration in mg/mL
- recommended daily dose
- the initial quantity and number of repeats as applicable. The RACGP EAG recommends limiting the prescription to a maximum of 3 months' supply and arranging a follow-up appointment that coincides with the expiry of the prescribed amount. This could also be earlier if required, eg a younger patient.
- If using AP pathway, the Authorised Prescriber number that appears on your TGA letter or your online application number.
- If using the SAS pathway, the approval or notification number.

You can also specify a flavouring, eg tobacco, mint or menthol.

Specifying the device

Premixed 'closed' systems are preferred to open or tank devices that use liquid nicotine because:

- as diluting liquid nicotine is not a straightforward process, consumers might dilute incorrectly, resulting in an incorrect dose and/or concentration
- the patient or others could intentionally or accidentally ingest the liquid nicotine, or experience exposure through their skin or eyes
- closed systems reduce the risk of poisoning (including of children), the likelihood of contamination, and the likelihood of potentially toxic or illegal substances being present in the liquid.

From 1 October 2024 pharmacists may only lawfully supply a vaping substance in final dosage form. Pharmacists will not be able to dispense component ingredient for consumers to use to mix their own substances.

If you are prescribing for a new user of NVPs, we recommend you prescribe devices with closed systems in order to reduce the risks described above. Most available closed systems deliver nicotine salt.

If you are prescribing for an experienced user, you may consider any preferences they have for a vaping device and/or liquid however pharmacists will only be able to dispense a vaping substance in final dosage.

Pharmacists will only be able to dispense vaping products included in the TGA's list of notified vapes.

More information can be accessed on the TGA vaping hub: <https://www.tga.gov.au/resources/resource/guidance/vapes-information-prescribers>

Specifying the brand and products

- Because different NVP brands have different nicotine concentrations and are designed to work with that manufacturer's vaping device, specifying the brand and product can reduce confusion or uncertainty during dispensing. Vapes that are in the TGA list of notified vapes are now included in the drug database of most general practice software programs. Discuss availability of products with your local pharmacist.
- Prescribers may wish to avoid vaping products manufactured by the tobacco industry or companies with links to the tobacco industry. For example, Vive™ is manufactured by a tobacco company.
- A list of TGA notified vapes can be accessed: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/table/list-notified-vapes>

Determining the initiation dose

The dose of nicotine a person receives from an NVP can vary depending on the vaping device, the electrical power of the device, the concentration of nicotine, the type of nicotine (nicotine salts or free-base nicotine) and the length and intensity of the person's inhalation.

For example:

- the amount of nicotine inhaled from 15 puffs of an NVP can vary from 0.025 to 3.1 mg, whereas the amount of nicotine per combustible cigarette varies from 1.54 to 2.6 mg.^{24, 25} (This comparison is based on the assumption that 15 puffs of an NVP is the equivalent of smoking one cigarette)
- liquid nicotine concentrations of ≤ 20 mg/mL can result in blood concentrations similar to or greater than those from combustible cigarettes.^{24, 26}

Currently, there is no clear evidence about the effect of different doses, and available literature provides only limited guidance about doses of free-base nicotine. It is also important to note that people who use nicotine will self-titrate to achieve their desired nicotine level whether this is from smoking, or vaping.^{27, 28, 29}

Starting doses

While acknowledging the lack of evidence about dosages, the RACGP EAG provided the following suggestions relating to NVP prescriptions:

- **When prescribing for new users of NVPs**, choose a starting dose based on the patient's level of nicotine dependence.

Type of product	Reasonable starting strength	
	Less dependent smokers	More dependent smokers
Nicotine salt pods	18–30 mg/mL	>30 mg/mL
Nicotine free-base liquid	6–12 mg/mL	18–20 mg/mL

- **When prescribing for current users of NVPs**, consider any preferences they have for concentration, device, and daily use, however supply can only be those on the [TGA list of notified vapes](#) . It will be important to speak to the pharmacist to determine availability of supplies.
- If the patient is currently using an open system device and moderate to high nicotine concentration, reduce the risk of poisoning by recommending they change to nicotine free-base with a concentration of ≤ 20 mg/mL and/or a closed system device in order to avoid the risks involved in dilution of nicotine liquid.

Nicotine toxicity

Therapeutic guidelines on nicotine toxicity state that the potentially lethal dose via oral exposure is 5 mg/kg.³⁰ Therefore, about 4 mL of a 100 mg/mL NVP is potentially fatal for an adult and <1 mL is potentially fatal for the average 2-year-old.

Specifying flavourings

There is limited evidence about the long-term safety of inhaled flavourings, as, while some flavouring chemicals may be safe to consume as food or medication, they may not be safe to inhale.^{31, 32, 33}

In addition to safety concerns of inhaled flavouring chemicals, the TGO 110 restricts the range of flavours to reduce the appeal to children and young people. Under the December 2023 amendment to TGO110 only mint, menthol flavours or tobacco flavour are permitted. Given this restriction, the choice of these three flavours can be left to the patient's discretion.

To reduce the risks of inhaling flavourings or additives that may not be safe, prescribe devices with closed systems so that users cannot purchase and add their own flavours or other additives that may pose dangers such as lung injury (see below).


E-cigarette or Vaping use-associated Lung Injury (EVALI)

The severe respiratory illness known as E-cigarette or Vaping-Associated Lung Injury (EVALI) was first identified in the United States in early 2019. Investigations by the US Centers for Disease Control found that:

- in the majority of EVALI cases, the e-liquids that patients had used contained tetrahydrocannabinol (THC)
- the additive vitamin E acetate was strongly linked to the EVALI outbreak and was far more common in e-liquids that contained THC. However, the CDC could not rule out the contribution of other chemicals of concern including chemicals in either THC or non-THC products in some of the reported EVALI cases.³⁴

The following sample prescriptions may be used as a guide when prescribing NVPs:

Sample prescription for nicotine vaping pod and device

<p>Dr Peter Pain 123 Disney Street Neverland 4000 Ph: 0712345678</p>	<p>Dr Peter Pain 123 Disney Street Neverland 4000 Ph: 0712345678</p>
 BPS06943007631846	
<p>Patient's Medicare no. 999999999-1</p> <p>Pharmaceutical benefits entitlement no. </p> <p><input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder</p> <p>Patient's name Mickey Mouse Address 123 Fake Street Elanora 4221</p> <p>Date 07/08/2024 Script ID: 999999 XXXXXXXXXX <input checked="" type="checkbox"/> Brand substitution not permitted Non PBS </p>	<p>Patient's Medicare no. 999999999-1</p> <p>Pharmaceutical benefits entitlement no. </p> <p><input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder</p> <p>Patient's name Mickey Mouse Address 123 Fake Street Elanora 4221</p> <p>Date 07/08/2024 Script ID: 999999 XXXXXXXXXX <input checked="" type="checkbox"/> Brand substitution not permitted Non PBS </p>
<div style="border: 1px solid black; padding: 5px;"> <p>[Brand] Nicotine Vaping Pod Nicotine 35mg/ml 1 puff PRN. Up to one pod daily Approved AP/SAS# MAP21-99999 Quantity 28 Repeat 2</p> <p>Brand Nicotine vaporiser device Quantity 1</p> <p>Dr Peter Pain MBBS</p> <p><small>If not a Medical Practitioner, tick your prescriber type:</small></p> <p>Dentist <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Midwife <input type="checkbox"/> Optometrist <input type="checkbox"/></p> </div>	<div style="border: 1px solid black; padding: 5px;"> <p>[Brand] Nicotine Vaping Pod Nicotine 35mg/ml 1 puff PRN. Up to one pod daily Approved AP/SAS# MAP21-99999 Quantity 28 Repeat 2</p> <p>Brand Nicotine vaporiser device Quantity 1</p> <p>Dr Peter Pain MBBS</p> <p><small>If not a Medical Practitioner, tick your prescriber type:</small></p> <p>Dentist <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Midwife <input type="checkbox"/> Optometrist <input type="checkbox"/></p> </div>
<p style="background-color: #e0f0ff; padding: 2px; text-align: center;">Prescriber to sign original and duplicate</p>	<p style="text-align: center;">Turn over for privacy notice</p> <p style="font-size: small;">I declare that I have received this/these medicine(s) and the information relating to any entitlement to a pharmaceutical benefit is correct.</p> <p>Patient's or agent's signature _____ Date of supply ____/____/____</p> <p>Agent's address _____</p> <p style="font-size: x-small;">P6023.2008</p>

Sample prescription for liquid NVP and device

Dr Peter Pain 123 Disney Street Neverland 4000 Ph: 07123456		Dr Peter Pain 123 Disney Street Neverland 4000 Ph: 07123456	
123456		123456	
Patient's Medicare no. 99999 <input checked="" type="checkbox"/> 1		Patient's Medicare no. 99999 <input checked="" type="checkbox"/> 1	
Pharmaceutical benefits entitlement no. <input type="text"/>		Pharmaceutical benefits entitlement no. <input type="text"/>	
<input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box)		<input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box)	
<input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder		<input type="checkbox"/> Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder	
Patient's name Mickey Mouse Address 123 Fake Street Elanora 4221		Patient's name Mickey Mouse Address 123 Fake Street Elanora 4221	
Date 07/08/2024 PBS <input checked="" type="checkbox"/> Non PBS		Date 07/08/2024 PBS <input checked="" type="checkbox"/> Non PBS	
Script ID: 999999		Script ID: 999999	
<input checked="" type="checkbox"/> Brand substitution not permitted		<input checked="" type="checkbox"/> Brand substitution not permitted	
<div style="border: 1px solid black; padding: 5px;"> [Brand] Nicotine Vaping Liquid Nicotine 12mg/ml. Up to 5mls daily Approved AP/SAS# MAP21-99999 Quantity 120 ml Repeat 2 </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Brand Nicotine vaporiser device Quantity 1 </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Dr Peter Pain MBBS </div>		<div style="border: 1px solid black; padding: 5px;"> [Brand] Nicotine Vaping Liquid Nicotine 12mg/ml. Up to 5mls daily Approved AP/SAS# MAP21-99999 Quantity 120 ml Repeat 2 </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Brand Nicotine vaporiser device Quantity 1 </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Dr Peter Pain MBBS </div>	
<input type="checkbox"/> Optometrist		<input type="checkbox"/> Optometrist	
Turn over for privacy notice		Turn over for privacy notice	
Prescriber to sign original and duplicate		I declare that I have received this/these medicine(s) and the information relating to any entitlement to a pharmaceutical benefit is correct.	
Patient's or agent's signature		Date of supply	
Agent's address		/ /	
PB023.2008			

Behavioural supports and counselling

In addition to prescribing a NVP, encourage the use of behavioural supports and plan follow-up. Consider suggesting Quitline, which is demonstrated to increase smoking cessation through multi-session behavioural counselling.³⁵

Patients can be referred to their local Quitline via a form available at <https://www.quitcentre.org.au/>

Costs of NVPs

When prescribing a NVP, the prescriber should consider the costs of the therapy for the patient. NVPs are not subsidised on the PBS and therefore patients will pay the full cost of the treatment. Affordability for the patient should be a consideration in therapy selection in consultation with the patient.

Monitoring NVP use and follow-up

As with any intervention you suggest for smoking cessation, arrange follow-up visits to discuss progress and provide support. If the patient has had previous failed attempts to quit, they may need more intensive and personalised support. Arrange the first follow-up appointment within a week of the quit day (refer to [Chapter 1 Arrange follow-up](#)). After this, it is reasonable to review at least every 3 months, which coincides with prescribing PBS-subsidised NRT.

At follow up appointments

- Ask the patient about their consumption of the prescribed NVPs and any non-prescribed vaping products.
- Based on their response, provide appropriate advice and suggestions, discuss dose titration, and maintain or adjust the dosage in the next prescription (see [Titration of NVPs](#))
- Ask the patient if they have had any adverse effects associated with NVP use and manage appropriately.
- Encourage the patient to completely transition to NVPs and cease their use of combustible tobacco.

Reporting adverse reactions

- Report any adverse reactions to the TGA (see <https://www.tga.gov.au/safety/reporting-problems>).

Titration of NVPs

There is currently a lack of evidence about the optimal length of NVP use, or how to titrate NVPs down in order to achieve nicotine cessation. It is good practice to discuss this strategy of titrating down nicotine dose with the patient prior to prescribing a NVP.

Suggested approaches include:

- attempting a weaning or cessation of NVPs after 12 weeks of use
- transitioning from NVPs to NRT—a form of nicotine less associated with long-term use
- consideration of other approved oral smoking cessation pharmacotherapies; however, further research is needed before these can be recommended.

In the absence of evidence on how long to continue treatment, a maximum duration of 12 months' use of NVPs is a reasonable consideration.

Practice points

NVPs are unapproved goods (or unregistered products) and it is valid and reasonable for medical and nurse practitioners to choose not to prescribe them.

To minimise risk of harms, the RACGP EAG recommends the following measures for prescribers:

1. **Recommend closed systems and avoid open systems** in order to minimise the risk of poisoning and the exposure of toxic or illegal substances and contamination. The risks of poisoning through skin contact and accidental ingestion are far greater when patients choose to dilute their own liquids (ie when they use open systems)
2. **Avoid prescribing free-base liquid nicotine at concentrations over 20 mg/mL.** Concentrations above this level require dilution which is associated with risks of poisoning.
3. **Limit the quantity of nicotine vaping products per prescription to a maximum of 3 months' supply.** Consider aligning the duration of supply with the timing of follow-up.
4. **Where possible, avoid flavour. Available options are limited to unflavoured, mint, menthol or tobacco**
5. **Provide follow-up and behavioural support:**
 - The role of the GP and / or nurse practitioner is important in providing follow-up and ongoing support to assist with successful cessation.
 - Consider also referring patients to Quitline. Quitline counsellors will contact your patient to offer free multi-session behavioural counselling. Quitline counsellors are behaviour change experts experienced in counselling people who are using nicotine vaping products to quit smoking and in supporting people trying to cease vaping: www.quitcentre.org.au/referral-form

Preventing tobacco relapse

Although cessation of both tobacco smoking and use of other forms of nicotine including NVPs is always the goal, there may be instances where you and the patient agree that longer use of NVPs will help prevent relapse to tobacco use.

If you and the patient are considering longer-term use of NVPs inform the patient of the risks and benefits of NVPs compared to other smoking cessation pharmacotherapies, and explain that:

- the long-term safety of NVPs is unknown
- dual use of tobacco and NVPs must be avoided
- people who use NVPs have approximately twice the risk of relapsing to combustible tobacco smoking compared to non-NVP users³⁶
- suggest they re-try other approved smoking cessation pharmacotherapies
- consider obtaining written consent from the patient, acknowledging that the risks of longer-term NVP use have been discussed

Regular follow-up, monitoring and consideration of re-trialling other first-line interventions over time is recommended.

Weaning former smokers from vaping

See Part 2: Vaping Cessation

Part 2: Vaping Cessation

About this section

This section provides information to help you support patients who want to cease vaping.

For general information about e-cigarettes and nicotine vaping products (NVPs) and for guidance on using NVPs as an aid to smoking cessation, see [Electronic cigarettes and nicotine vaping products as a smoking cessation aid](#).

Reforms to the regulation of vaping

As described in **Part 1: Electronic cigarettes and nicotine vaping products (NVPs) as an aid to smoking cessation**, the Therapeutic Goods and Other legislation Amendment (Vaping Reforms) Act 2024 commenced on 1 July 2024. Detailed information about these changes for all stakeholders can be found on the Department of Health and Aged Care and Therapeutic Goods Administration vaping hub: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>

Key changes

- Vapes can only be sold at pharmacies from 1 July 2024 – this includes all vapes regardless of whether they contain nicotine or not
- Flavours in vapes are restricted to mint, menthol and tobacco
- The requirement for a prescription for all vapes will continue until 30 September 2024
- From 1 October 2024 people 18 years or over will be able to purchase nicotine vapes with 20mg/mL or less from pharmacies without a prescription subject to conditions
- From 1 October 2024 people under 18 years of age will require a prescription to access vapes, where state and territory laws allow and where they are able to be supplied
- People requiring a vape with more than 20 mg/mL will still need to obtain a prescription.

To note, the implementation of these regulatory changes, particularly the domestic bans on all disposable vaping products, may result in an influx of people who use NVPs seeking help from medical or nurse practitioners.

This will include people who have never smoked before and who are seeking support to quit vaping. It may be reasonable, after an evidence-based discussion about alternative options and in the understanding that the longer-term aim is nicotine cessation, to prescribe patients a NVP for a specific period as they transition away from vaping.

For people age 16 years and above, the authorised prescriber or SAS C pathway may be used. For people younger than 16 years, the SAS B pathway is indicated. More detailed information on the prescribing pathways can be accessed: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers>

It is legal to provide a prescription for NVPs to people younger than 18 years of age under the medical access scheme however, the law around dispensing varies across jurisdictions. Information on your jurisdiction may be accessed here: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers/prescribing-and-dispensing-therapeutic-vapes-patients-under-18-years>

If dispensing is not allowed in your jurisdiction it is recommended to not provide a prescription.

Further information for prescribers can be found at: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>

Unregulated Vaping: the scope of the problem

Ease of access and availability of vaping products containing nicotine prior to changes in 2024

Despite legislation in 2021 making the sale and supply of NVPs legal only via prescription, they have continued to be widely available in Australia. A Victorian study found that fewer than 9% of people who had vaped in the past year had a prescription for nicotine from their doctor.³⁷

Until 2024, in most Australian states and territories retail outlets such as convenience stores and tobacconists could legally sell vaping products that do not contain nicotine. However despite product labelling to the contrary, testing has shown that many of these products do contain nicotine which may be at a concentration as high as 60 mg/mL.^{38, 39} Consequently, people may have been unknowingly exposing themselves to nicotine and becoming nicotine dependent.

The increasing prevalence of vaping

Since the introduction of NVPs in Australia in the early 2000s, the number of people who vape has steadily increased, particularly among youth and alarmingly, those who have never previously smoked.⁴⁰

The Australian National Drug Strategy Household Survey 2019 found life-time e-cigarette use by non-smokers aged 18 to 24 increased from 4.9% in 2013 to 19.6% in 2019.⁴ More recent data has shown prevalence of current vaping in people aged 14 and over increased markedly from 2.0% (data from last six months of 2020) to 8.9% (data from first three months of 2023). In the 2023 data the highest prevalence of current vaping was in the 18-24 age group (19.8%) followed by 25-34 (17.4%) and 14-17 (14.5%).⁴¹

Current vaping among older Australians is also increasing. A review of prevalence data conducted by the Cancer Council Victoria showed vaping by Australians aged 35-49 increased from 1.4% in 2018 to 6.6% in 2023.⁴¹

The profile of people who vape includes:

- ex-smokers who have switched to using e-cigarettes
- dual users of combustible cigarettes and e-cigarettes, and
- those who have never previously smoked.

The increase in exclusive vaping and dual use of tobacco and e-cigarettes was most notable among people aged under 35 years.⁴¹ Use by people who have never smoked is most common in children and adolescents.⁴¹ This may begin as occasional use but can rapidly escalate as the young person becomes dependent on nicotine.

This steadily increasing use of e-cigarettes in Australia is consistent with vaping trends in other countries.⁴²

Health risks of vaping

There may be less motivation to quit vaping due to a perception that vaping is “safer” than smoking due to no combustion occurring in the product and fewer chemicals being present.⁴³ Vaping may pose fewer health risks than smoking, however it is not risk-free and the nature and extent of longer-term health risks are yet to be determined and may take decades to emerge.⁴⁴

As well as risks of poisoning through nicotine liquid coming into contact with skin or ingestion, there is risk of injury such as burns due to the e-cigarette or vaping device catching fire or exploding.⁴⁴

There are numerous shorter-term potential adverse health effects of vaping, including: acute lung injury; mouth and airway irritation; cough; nausea; dizziness and headache⁴⁴ as well as unknown effects on chronic health conditions and unknown long-term health effects. Some of these have been listed previously in Part 1: [Risks of NVPs](#).

Vaping as a gateway to smoking

The increase in vaping among youth is particularly alarming because there is strong evidence that vaping is associated with progression to smoking by approximately three-fold.⁴⁵ The extent of progression varies by context and may be less likely where access to tobacco is tightly regulated and tobacco products are expensive.

The progression from vaping to smoking among young never-smokers may be due to increased curiosity. A survey of young never-smokers who vape found an increased curiosity and willingness to try smoking combustible cigarettes, with a significantly higher intention to smoke within the next six months compared to those who have never vaped.^{46, 47}

Identifying vaping behaviours and supporting cessation

How vaping behaviours differ to smoking behaviours

There are some notable differences between vaping and tobacco smoking behaviours. Unlike combustible cigarettes, e-cigarettes do not have a distinct “end-point”: vaping is not punctuated by finishing and stubbing out a cigarette.

Vapes are easy to conceal and people can vape in a wider range of settings without detection. Finding a suitable location to “light up” is not a limiting factor. Therefore, frequent and sustained vaping can occur, with the user being less aware of how much or how often they vape.⁴⁸

In the context of frequent and sustained vaping, e-cigarettes can deliver as high or higher nicotine concentrations than combustible cigarettes.⁴⁹

Behaviours that trigger vaping are not necessarily the same as for smoking. It will be important to understand the triggers for vaping which may differ for individual patients, and also in the context of supporting dual users to quit.⁵⁰

Supporting vaping cessation

Currently there is limited research on interventions specifically targeting vaping cessation.^{51 52 53} In the absence of evidence specific to vaping, strategies shown to be effective for smoking cessation – behavioural support and pharmacotherapy - may be considered to support vaping cessation.^{52 54 56 55}

There are specific challenges to treating vaping addiction in youth, particularly for those who are quite young (as young as 12 years),^{52 54} and dual users for which there is even less evidence currently available.⁵²

A scoping review of cessation interventions for e-cigarettes identified recommendations for behavioural support interventions based on the 5As approach, motivational interviewing, individual or group counselling, cognitive behavioural therapy and mindfulness as most recommended.^{52 56} Quitline counselling incorporates many of these strategies and is available Australia-wide.

Novel interventions targeting youth included the “SmokeSCREEN” video game,^{57 58} smart phone apps and the “This is Quitting” text messaging program. These have demonstrated positive early results in reducing vaping among youth.⁵⁹ The national cessation platform quit.org.au can direct patients to digital tools available in Australia, such as the My QuitBuddy app.

Young people wishing to quit either vaping or dual use, reported value in having assistance to increase their readiness and motivation to quit through finding behavioural substitutions to vaping, increasing barriers to obtaining e-cigarettes and having in place peer support.⁶⁰

Many people quit vaping without assistance or going ‘cold turkey’.⁶¹ If a patient wishes to stop immediately, they may find distraction techniques useful when wanting to vape. It may take several attempts to achieve success, as is the case with quitting smoking.⁷⁰

Impact of regulatory changes on vaping behaviours and seeking assistance

As outlined previously, a domestic ban on single-use disposable vaping products took effect on 1 January 2024. This regulatory change is very likely to result in an influx of people who use NVPs seeking advice from a GP on how best to manage their nicotine addiction.

Young people who vape – including those under 18 years of age - who may have never previously smoked are likely to seek advice on how to manage their vaping behaviour.

Some people may wish to quit vaping ‘cold turkey’ as their vaping products become unavailable. However, from 1 October 2024 vapes up to 20 mg/mL will be accessible without a prescription from pharmacies. It is unclear to what degree these will meet the needs of people with a higher nicotine dependence.

There may be a proportion of people who will need a higher concentration vape and will seek assistance from a GP or nurse practitioner to obtain a NVP by prescription either with the intention to continue vaping or with the intention to quit vaping.

Ideally, the aim is to assist people to stop vaping using first-line approaches such as behavioural support (e.g. a referral to Quitline for behavioural counselling and/or information on digital tools may assist), distraction techniques, and when necessary, a registered pharmacotherapy licenced for smoking cessation.

Supporting young people to cease vaping

There may be a sub-group of young people, including some aged < 18 years, who are highly dependent on nicotine, for whom first-line strategies may be less effective. It will be important to weigh up the risk of a person in this category returning to smoking or initiating smoking, and to discuss this risk with the patient. In some instances, it may be reasonable to consider a short-term prescription of NVPs on the understanding that the aim is for the patient to transition off these and become nicotine free.

Whilst it is legal in most states and territories to provide a prescription for NVPs to people younger than 18 years under the medical access scheme, the law around dispensing varies across jurisdictions. In some jurisdictions it is illegal to supply a NVP to a person aged under 18 years.

Information on your jurisdiction may be accessed through the relevant contact in your state or territory:

<https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers/prescribing-and-dispensing-therapeutic-vapes-patients-under-18-years>

Important information for prescribers is being updated frequently and can be accessed at the Department of Health and Aged Care and Therapeutic Goods Administration [Vaping Hub](#)

Note: for patients under 16 years of age, SAS B must be used or AP with ethics approval.

It is also important to note that research on this approach is still evolving and as for prescribing NVPs for smoking cessation, an evidence-informed shared-decision making process and evidence-based discussion is needed (see Recommendation 15).

Brief interventions: 3 step and 5As approaches to vaping cessation

Advice from health professionals to quit vaping should be encouraged. A brief intervention based on the Ask, Advise, Help (AAH) structure can be delivered in a short time.

A more comprehensive approach to supporting vaping cessation, modelled on the 5As structure used for smoking cessation is a reasonable approach to guide vaping cessation, including among youth.⁵⁵ This approach involves:

- Asking about vaping and smoking and document in patient records
- Assessing nicotine dependence and barriers to quitting
- Advising them about vaping cessation (and smoking cessation if relevant)
- Assisting them to quit vaping
- Arranging follow-up

Ask all patients about vaping status

Health professionals should ask patients whether they vape or use e-cigarettes, the frequency of use and products used, and whether they vape and / or smoke combustible cigarettes (dual use). As with smoking it is reasonable to start asking about vaping from > 10 years of age but the context of asking is important.⁶² It is vital to ensure confidentiality for young people, so they feel safe to disclose the behaviour to a health professional.⁶² Their vaping status should be recorded. It is known that implementing recording systems that document tobacco use almost doubles the rate at which clinicians intervene with patients who smoke, resulting in higher rates of cessation.

Assess nicotine dependence, barriers to quitting and psychosocial context

The level of nicotine dependence impacts cessation success.⁶³

As with assessing tobacco dependence, a useful and quick approach to assess dependency is to ask:

- “How long after waking do you vape?”

The Time To First Vape (TTFV) within 5 minutes of waking suggests very high level of dependence and within 30 minutes of waking, a high level of dependence.⁶⁴

In addition to TTFV, the Modified Hooked On Nicotine Checklist (M-HONC) (Table 2) can be used to assess nicotine dependence. Both TTFV and the HONC have been well studied and shown to be clinically effective in assessing nicotine dependence.⁶⁴

The M-HONC is scored by adding the number of yes responses. A score above zero indicates a level of nicotine dependence and that an individual is not in full control of their vaping.

Table 2 The modified Hooked on Nicotine Checklist (M-HONC)

Questions	Yes	No
1. Have you ever tried to stop vaping, but couldn't?		
2. Do you vape <u>now</u> because it is really hard to quit?		
3. Have you ever felt like you were addicted to vaping?		
4. Do you ever have strong cravings to vape?		
5. Have you ever felt like you really needed a vape?		
6. Is it hard to keep from vaping in places where you're not supposed to, like school?		
7. When you tried to stop vaping... (or, when you haven't vaped for a while...)		
a. did you find it hard to concentrate because you couldn't vape?		
b. did you feel more irritable because you couldn't vape?		
c. did you feel a strong need or urge to vape?		
d. did you feel nervous, restless or anxious because you couldn't vape?		

Nicotine withdrawal symptoms

Nicotine withdrawal symptoms include cravings for nicotine and onset of other symptoms. Briefly, nicotine withdrawal symptoms include:

- Changes in mood – irritability, frustration, anger, depressed mood
- Cravings
- Anxiety
- Difficulty in concentrating
- Increased appetite
- Insomnia

Barriers to quitting vaping

There are many potential barriers patients face when attempting to quit nicotine. Identifying beliefs and attitudes about quitting at the time of the quit attempt is important because these may otherwise serve to derail quit attempts.

Among young people, peer and social pressure are cited as typical barriers to quitting vaping,⁶⁵ as are factors related to convenience of use, the discreetness of e-cigarettes and the enjoyment of different flavours.⁶⁶

Those who have previously quit smoking and continue to vape may fear returning to smoking combustible cigarettes.

Other barriers may include:

- dependency on nicotine
- lack of confidence to attempt ceasing
- use of e-cigarettes to reduce stress
- the belief that vaping is not harmful
- enjoyment of the feeling and flavour
- low cost compared to smoking
- the acceptability of vaping in a wider range of places compared with smoking.

Biopsychosocial context

It is also important to consider the broader context in which the vaping behaviour is occurring including the family and social environment, mental health, and other drug use. All these may need to be considered as part of the support offered.

Advise all patients who vape that the aim is to become nicotine free

In discussing vaping cessation, it is important to establish and understand the patient's history of both vaping and smoking. Ensure that your patient understands that using NVPs is safer than smoking, so that the patient is able to consider the relative risks of the two behaviours.

In a way that is clear but non-confrontational, encourage patients who vape to quit.

'The best thing you can do for your health is not to smoke'

'It is also important to not vape'

The experience from smoking cessation is that brief, repeated, positive reminders to quit by a range of health professionals can increase success rates.⁶⁷ It is not known if this applies to vaping cessation.

Discussing information about the potential health risks of vaping may assist with motivating patients to consider quitting. In particular, the hazards of undisclosed ingredients that may be in illegally purchased vaping liquids. Illegal vaping products are not labelled accurately and often contain undisclosed nicotine and other hazardous compounds.^{39 44 68} The damaging environmental impact of disposable vaping products may also motivate patients to quit.

Nicotine use is known to affect the rapidly developing adolescent brain, risking changing brain structure and function which may affect cognition and mental health.⁶⁹

Offer brief cessation advice in routine consultations and appointments, whenever possible.

Assist those who vape to quit

It is reasonable to manage nicotine addiction from vaping similarly to that from smoking⁷⁰ which includes behavioural support (eg. a referral to Quitline for behavioural counselling and/or information on digital tools such as the My QuitBuddy app) and consideration of smoking cessation pharmacotherapy.

How to offer assistance to patients who wish to quit vaping and/or dual use will depend on a number of factors, including the age of the patient, their vaping and smoking history, and the biopsychosocial context:

- Whether the patient exclusively vapes, with no prior experience of smoking combustible tobacco
- Continued vaping subsequent to quitting smoking combustible cigarettes
- Dual use of vaping and smoking combustible cigarettes

- The age of the patient i.e. younger than 18 years of age
- The biopsychosocial context including mental health and other drug use

Other motivational factors include:

- willingness to quit
- individual patient needs
- preference
- suitability of available support
- capacity of the health professional and their service.

Adults who vape

For adults who vape, approved nicotine replacement therapy (NRT) with behavioural support (eg. referral to Quitline for behavioural counselling and/or information on digital tools) is a reasonable pathway.⁷⁰ It is important to note that medicines approved for smoking cessation may not be approved for a PBS rebate for vaping cessation and that prescribing for vaping cessation is off label.

Further information on eligibility for nicotine replacement therapies is available:

<https://www.health.gov.au/sites/default/files/2023-12/eligibility-for-nicotine-replacement-therapies-advice-for-health-professionals.pdf>

Youth and adolescents

How best to support young people to stop vaping is uncertain given the lack of evidence.⁶³

The Sydney Children's Hospital Network guidance to vaping and e-cigarette use provides advice to support young people in quitting e-cigarettes, which is based on the 5 As Brief Intervention Framework.⁶⁴

<https://www.health.nsw.gov.au/tobacco/Publications/e-cigarette-young-people-guide.pdf>

KidsQuit is a free interactive resource also based on the 5As framework. It provides strategies for advising adolescents, parents and carers on smoking and vaping cessation.

<https://kidshealth.schn.health.nsw.gov.au/kidsquit-brief-interventions-smoking-cessation-e-learning>

Also based on the 5As framework, the Queensland centre for alcohol and other drugs training and workforce development (Insight) have developed Vape Check. This tool is designed to help youth and health workers conduct a one-on-one single session brief intervention with young people who regularly use nicotine vaping products.

<https://insight.qld.edu.au/shop/vape-check>.

Pharmacotherapy is covered in the next section. The use of pharmacotherapy (excluding varenicline) in young people may be considered from age 12 years.^{64, 71}

Quitline services are building capacity to counsel young people who vape (and/or smoke). Many psychosocial and developmental factors as well as situational factors (e.g. whether a parent or teacher is also present) can impact on a young person's understanding of, and ability to engage with Quitline counselling.

Quitline counsellors can offer individual counselling to help young people make sense of their vaping, decide what they want to do about it, and work collaboratively with them to develop a realistic plan that is relevant to their developmental stage and life circumstances.

A [referral](#) to Quitline so they can contact your patient to discuss digital tools and offer behavioural counselling increases uptake. Quitline services have also increased access options in some jurisdictions e.g. webchat, social media messaging to encourage contact from younger people.

Dual users of both cigarettes and vapes

Advise people who use both cigarettes and vapes to switch completely from smoking to vaping only, and then implement intervention strategies to cease nicotine use. This should be done in conjunction with appropriate discussions about the benefits of quitting vaping and the possible side-effects (eg nicotine withdrawal, the possible relapsing to using tobacco). If a patient is a dual user and wants to quit both then this should be discussed and encouraged.

Arrange follow-up

Follow-up appointments, at a similar schedule to support for smoking cessation, are important to maintain a therapeutic relationship, to manage pharmacotherapy, manage relapse and maintain support.

Social support is important and for young people this includes from parents, peers and, if applicable, in the school environment.

Pharmacotherapy for vaping cessation

Evidence-based treatments for smoking cessation among adults include pharmacotherapies such as NRT, varenicline, bupropion and cytidine in combination with behavioural support. **However, the evidence for their use in vaping cessation is limited, especially in young people.** If patients are aged 18 years and over pharmacotherapy options for which there is some evidence for use in vaping cessation are NRT and varenicline. Patients should be informed that this approach and these medication options are largely based on evidence from tobacco cessation treatment.

At present, medicines approved for smoking cessation are not approved for vaping cessation, and so prescribing for vaping cessation is off label and on a private prescription. Further information on eligibility for nicotine replacement therapies is available: <https://www.health.gov.au/sites/default/files/2023-12/eligibility-for-nicotine-replacement-therapies-advice-for-health-professionals.pdf>

The use of pharmacotherapies, including among younger people, is increasingly being used as part of the treatment for nicotine use disorder,⁷² which may include vaping cessation. In 2020 the US Preventative Services Task Force reviewed its 2013 recommendation on the treatment of tobacco use in children and adolescents and included e-cigarettes in their evidence review. They found insufficient evidence, due to a lack of adequately powered studies, to determine the benefits or harms of primary care interventions including medications, for school-aged children who smoke.⁷³

The use of pharmacotherapy may be considered from age 12 if there are no contraindications,⁷⁴ however this is based on evidence from studies for smoking cessation. In patients aged 12-17 years NRT is the preferred pharmacotherapy option for vaping cessation given the greater evidence of safety, in conjunction with behavioural support and counselling.⁷⁵

NRT

NRT medicines can be useful for those who want to quit vaping immediately, and for those who want to wean themselves from vaping.

Combination NRT (eg patch plus faster-acting product) can be useful for patients with higher levels of nicotine dependence and/or in their early stages of quitting, while a single NRT product (eg gum, lozenge, mouth spray or patch) may assist those with lower levels of nicotine dependency.

A small (30 subjects) randomised trial of combination NRT for vaping cessation found that in participants who completed the end of treatment (28 days) survey 6/18 (33.3 %; 6 mono and 0 dual users) in the intervention group reported abstinence from vaping, compared to 0 in the control group (Fisher = 5.00, p = .057).⁷⁶

All forms of NRT are also available over the counter in pharmacies and supermarkets in Australia.

The PBS does not currently subsidise NRT for the purpose of vaping cessation and NRT is currently not TGA approved for vaping cessation in Australia.

Varenicline

Varenicline is a nicotinic receptor partial agonist drug developed specifically for smoking cessation that relieves symptoms of craving and withdrawal.

There is currently very limited direct evidence on the use of varenicline to support vaping cessation. A randomised controlled trial (N=140) found that a cessation program that combined varenicline with counselling for people who vape and intend to quit may improve abstinence. The trial consisted of a 12-week treatment phase followed by a 12-week follow-up non-treatment phase. Vaping quit rates for varenicline plus counselling were double that of counselling alone (34% vs 17% OR = 2.52, 95% CI = [1.14–5.58], P = 0.0224).⁷⁷ A small randomised trial of 8 weeks of therapy also found a benefit but was not statistically significant.⁷⁸

Varenicline is not recommended for pregnant and breastfeeding women, or for adolescents.

Cytisine

Cytisine (or cytisinicline) is a plant-based alkaloid which reduces nicotine dependence and has been shown to assist adults to stop smoking. A randomised controlled trial involving 160 adults in the US compared behavioural support plus cytisine to behavioural support plus placebo. Biochemically validated abstinence in weeks 9-12 of treatment were higher for cytisine (OR 2.64, 95% CI 1.06 to 7.10 p = 0.04). More studies with longer term follow-up are needed.⁷⁹

Cytisine is not approved in Australia, however it is under review for scheduling by the [Therapeutic Goods Administration](#).

Bupropion

Bupropion is a non-nicotine oral therapy, originally developed and approved for use as an antidepressant. It reduces symptoms of nicotine withdrawal and reduces the urge to smoke, therefore may reduce the urge to vape. Given its potential for drug interactions and the lack of published evidence on use to support vaping cessation **it is not currently recommended as an option.**

Short-term use of NVPs

Preferences of e-cigarette users who wish to quit vaping include tailored approaches consisting of behavioural support from health professionals and from peers, to gradually taper down the nicotine concentration or cutting back first and then quitting.^{52 80} Where necessary, a registered pharmacotherapy licenced for smoking cessation may be used and this may be sufficient to assist with managing cravings.

However, in some patients dependent on nicotine, it may be reasonable to prescribe them a NVP for a limited time, with the aim of helping them to become nicotine free. In considering this option the person's vaping and smoking history is relevant. While the objective is to reduce patients' dependence on nicotine in any format, a key consideration is to minimise the chance of the patient relapsing to, or initiating, cigarette smoking.

As previously indicated it may be illegal in some jurisdictions to supply a person under 18 years of age with a NVP even with a prescription. Check with your state or territory first before providing a prescription. For patients under 16 years of age, SAS B or AP with ethics approval must be used.

Information on your jurisdiction may be accessed through the relevant contact in your state or territory:

<https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers/prescribing-and-dispensing-therapeutic-vapes-patients-under-18-years>

Further information for prescribers can be found at: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub>

Tapering the nicotine dose

Although there is currently little evidence about whether tapering is effective and the optimal method to achieve this, a reasonable approach is to reduce the nicotine level every two to four weeks as well as the number of daily vape sessions in conjunction with behavioural support.^{81 82}

Before attempting to taper a patient's nicotine dose, it is important to discuss with them that relapse, or initiation of smoking needs to be avoided and that they should cease the weaning strategy and return for further advice if this occurs, or the patient fears it may occur.

Zero nicotine vaping products

As patients taper down the nicotine concentration, some may prefer to use nicotine-free vaping products for a short time by prescription as a final step toward quitting nicotine and then stopping vaping.

There is, however, no evidence to suggest the use of zero nicotine vaping products prevents relapse to smoking.

Other nicotine weaning strategies

Other weaning strategies include: ⁷³

- limiting vaping to particular places /situations /times and gradually reducing those places/situation/times (eg only vape outside, don't vape with friends)
- extending the time between vapes (eg 15 minutes to 30 minutes to 45 minutes)
- avoiding flavours, or moving to a flavour the user finds less attractive

Harm-reduction strategies

If people are not yet willing to quit, provide users with strategies to reduce the risks of vaping.

To encourage patients to adopt harm-reduction strategies, advise them to:

- not add other drugs such as cannabinoids to their vaping liquid
- not share vaping products with friends
- restrict flavours as these can contain toxic substances feared to be linked to gum disease and poor oral health⁸³
- avoid “dry vaping” that is when the device is running out of e-liquid and products of combustion will be inhaled
- keep all vaping products and paraphernalia well out of the reach of children.

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