RACGP

Supporting smoking cessation: A guide for health professionals

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

Provisional draft for consultation

December 2023

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 and the Minister for Home Affairs Clare O'Neil 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 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 who may have never smoked but who have become dependent on nicotine. In May 2023 the Health Minister announced further regulatory reforms relating to the importation, manufacture, labelling and packaging of nicotine vaping products (NVPs) in order to improve product quality and safety, and reduce the availability and use of illegal vaping products by young people 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, including:

- Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023.
- Customs Legislation Amendment (Vaping Goods) Regulations 2023.
- Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023
- Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023
- Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023
- Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Vaping) Instrument 2023
- Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023
- Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023
- Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Devices) Instrument 2023

The RACGP has been updating its guidance on NVPs for smoking cessation and developing a new chapter to address vaping cessation. This work is challenging in several ways. First, there is little evidence on supporting vaping cessation strategies, and we rely very much on what we know works for smoking cessation. Second, legislative change is complex and some of this change needs to occur over a longer timeframe to allow industry to make the necessary changes to products available through the therapeutic access pathway. As a result, we don't currently know some of the detail that will affect prescribing pathways and product availability. With this complexity in mind, the RACGP aims to provide health professionals with information current at the time of publication about how to best support patients seeking help with nicotine addiction in an evolving regulatory environment.

We seek your input on this *provisional* consultation draft which we aim to make available for health practitioners in time for the first of the new regulatory changes from 1 January 2024. The timeframe for the implementation of the regulatory changes has resulted in very limited opportunity for stakeholder consultation but having guidance available to clinicians as soon as possible is a priority. We would be most grateful to receive any comments on this provisional guidance.

About this document

This document is a *provisional* draft guidance given that some information on the legislative reforms is currently pending. This document is in 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 for smoking cessation, information on proposed reforms to legislation relating to vaping, and further information on prescribing.

The second part is new content, which will be added to the RACGP Smoking cessation guidance as a stand-alone chapter, *Vaping Cessation*. This section currently has some unknowns due to some legislation still being finalised. This guidance will be updated further in 2024 when the legislation around prescribing pathways and indications has been finalised.

This consultation

The RACGP is seeking your input on content:

- is the information provided useful?
- what else do health practitioners need to know?
- what further clarification should be sought regarding prescribing pathways, indications for prescribing NVPs, support for youth?

We are not seeking input on formatting or structure, as this will be addressed when the chapters are incorporated into the existing smoking cessation guidelines.

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

About this section

Medicines approved by the Therapeutic Goods Administration (TGA) are listed in the Australian Register of Therapeutic Goods (ARTG). Medicines that are not in the ARTG are known as 'unapproved' or 'unregistered' medicines. At present, there is no therapeutic vape containing nicotine (Nicotine Vaping Product) listed on the ARTG.

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 NVPs for people who want to quit smoking.

For guidelines about supporting patients who want to quit vaping (whether they have used vaping as an aid to smoking cessation, or are non-smokers), 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 60 mg/mL.

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

Definitions*

Nicotine vaping products (NVP)	Products that contain nicotine (in salt or base form) in a solution designed to be inhaled using a vaping device. 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. As of 1 January 2024, the TGA will use the terminology 'therapeutic vaping substances' (whether or not containing nicotine). In this guidance, NVP refers to use as a 'therapeutic vaping substance containing nicotine'.
Vaping device	Electronic devices that are used to heat e-liquid to release an aerosol that is inhaled. They include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens. From 1 January 2024 the TGA will use the term 'therapeutic vaping devices' and introduce quality standards for these devices. Devices can be disposable or re-chargeable and also refillable. Disposable devices cannot be refilled and are non-rechargeable.[2] There are two categories of vaping devices: [2, 3, 4, 5] • Closed system: Vaping devices that come 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.

*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 (termed 'therapeutic vaping substances') but also the vaping devices that deliver the aerosol (termed 'therapeutic vaping devices').

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 glycol and glycerol, with or without flavours. Illegal vapes or imported e-liquid may not adhere to labelling requirements and could contain other ingredients which are potentially harmful to health.

Pharmacokinetics of NVPs

The pharmacokinetics of nicotine delivery, which includes rapidity of onset and peak nicotine levels, is variable and depends on the form of the nicotine, e-liquid concentration, the vaping device, and inhalation technique.

Reforms to the regulation of vaping

In response to rapidly increasing use of vaping products, 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 vaping products (i.e. nicotine vaping products and non-nicotine vaping products).

The proposed reforms are being implemented in stages. The key changes will:

- Tighten importation controls:
  - ban the importation of vapes (including devices, e-liquids and pods, whether they contain nicotine or not), except therapeutic vapes that comply with requirements of the Therapeutic Goods Act for supply in pharmacy settings by registered pharmacists or other persons authorised to supply prescription medicines under state or territory law.

- Alter Therapeutic Goods Order (TGO) limits:
  - introduce minimum quality standards for NVPs (therapeutic vapes), including restricting flavours and other ingredients
  - require all therapeutic vapes to have pharmaceutical-like packaging
  - reduce permissible nicotine concentrations and volumes.

- Implement changes to the Prescribing Pathway
  - allow all medical practitioners and nurse practitioners to write prescriptions for therapeutic vapes containing nicotine without applying for authority or approval under the Authorised Prescriber or Special Access (Category B) Schemes (SAS B)
  - closure of the personal importation pathway.

- Ban all single-use disposable vapes.

Due to the complexity of these reforms, only an indicative timeframe (Table 1) can be provided at this stage. This guide will be updated once the changes become law.

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

Table 1 Vaping regulatory reforms: indicative timeframe for date of effect

Regulatory Reform	Dec 2023	Jan 2024	Feb 2024	Mar 2024	Jun 2024	Dec 2024
Tighter importation controls (disposable vapes)		✓				
Tighter importation controls (all other vapes)				✓		
Implementation of SAS C prescribing pathway – new option by which medical and nurse practitioners can prescribe therapeutic NVPs		✓				
Closure of the personal importation pathway (disposable vapes)		✓				
Closure of the personal importation pathway (all other vapes)				✓		
Importation and manufacture of non-therapeutic vapes banned (all vapes imported or manufactured in Australia irrespective of nicotine content must comply with the Therapeutic Goods Act)				✓		
Therapeutic Goods Order (TGO) limits to ingredients introduced:				✓		
• Any formulation changes eg. restrictions to flavours, nicotine dose etc to take effect in late 2024						✓

Note: The implementation of these regulatory changes, particularly the domestic bans on certain types of vaping products, is likely to result in an influx of people who use NVPs seeking help from their doctor or another health professional.

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.

In most jurisdictions across Australia the dispensing of NVPs to people younger than 18 years is permitted under the medical access scheme, except for Tasmania where NVPs are classified as smoking products and may not be supplied to persons aged under 18 years. In Victoria, the Tobacco Act prohibits the sale of NVPs, however the Drugs Act, which regulates the prescribing and dispensing of Schedule 4 poisons does not contain any restrictions relating to the prescribing and dispensing to minors. Guidance by the Victorian Department of Health confirms that the Drugs Act prevails: https://www.health.vic.gov.au/sites/default/files/2022-11/the-retail-sale-of-e-cigarettes-guidance-for-e-cigarette-vape-retailers.pdf. In the Northern Territory the vaping device is considered a tobacco product and may only be sold when included on a prescription.

For people 16 years and above, the SAS C pathway may be used. For people younger than 16 years, the SAS B pathway is available.

Current legislation and standards relating to vaping

In Australia, NVPs are regulated under various regulatory frameworks that may apply to tobacco products, poisons, medicines and consumer products.[5] It is illegal everywhere in Australia to sell any e-cigarette containing nicotine, any nicotine liquid for vaping, or any other nicotine vaping product, to a person who does not have a prescription for it.

From 1 October 2021, changes in scheduling and regulation came into effect that added the requirement of a valid Australian medical prescription to legally import NVPs.

Australia is currently the only country to have NVPs available only on prescription, and the regulatory arrangements for NVPs within and across other countries vary considerably. In some countries there is total prohibition while others such as the UK, US and New Zealand have a consumer access model with varying degrees of regulation.

NVPs and the Therapeutic Goods Administration (TGA)

No NVP is TGA-approved

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.

Legally, consumers can access 'unapproved' NVPs only if they have a valid prescription. For details about prescribing NVPs to be used as an aid to smoking cessation, see the section on Prescribing NVPs.

The TGA's Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 (TGO 110), which came into effect on 1 October 2021, sets out the minimum safety and quality requirements for NVPs supplied in Australia. They include:

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. 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 listed in TGO 110

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 TGA table "TGO 110 Requirement".

An amendment to TGO110 was published by the TGA on 15th December 2023. Key aspects of the amended order are:

- flavours are limited to mint, menthol flavour or tobacco flavour.
- ingredients or components that produce a combination of flavours are not permitted
- standards for therapeutic vaping devices which align with processes applied to regulation of medical devices

Though not available at the time of writing, the TGA will publish a list of 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.

Risks of NVPs

The risks associated with NVP use need to be considered in the context of the seriousness of the risks of continued smoking. When carrying out a risk-benefit analysis before prescribing NVPs to your patient, you may wish to consider risks including, but not limited to, the following:

General risks associated with NVPs [6, 7, 8]

- unknown long-term health effects
- intentional and accidental poisoning particularly from e-liquids used with open system NVPs (eg. child fatalities have occurred following ingestion of liquid nicotine [3])
- short term adverse effects including throat irritation, headache, cough and nausea [2]
- interactions between nicotine and other medicines (eg. psychiatric medications such as antipsychotics)
- burns and injuries (including lung injury)
- harm to adolescent brain development due to nicotine exposure [9]

Risks associated with access to nicotine by NVPs

- increased nicotine consumption, due to dual use with continued smoking[10]
- increased duration of use leading to greater long-term exposure to nicotine compared to other smoking cessation pharmacotherapy [8]
- possible diversion leading to use by non-smokers
- the potential to be a gateway to tobacco use [40]
- the potential to promote nicotine use and re-normalise smoking among those who do not smoke, especially young people [9]

Medicolegal risks

- potential medicolegal risks for prescribers.

Other 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), but as more experience and evidence emerges, the 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 27 April 2021, identified two randomised controlled trials that met inclusion criteria with a total of 1468 participants. Both studies used NVPs containing freebase nicotine. The relative effect

was 1.67 (95% CI: 1.21 to 2.28) favouring nicotine e-cigarettes over NRT.[8] 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**. At that time, the 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 National Health and Medical Research Council (NHMRC) CEO statement on electronic cigarettes was published in June 2022 [39]. 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. The comparison of nicotine e-cigarettes versus NRT was of studies comparing smoking cessation at six months or more and measures of harm at one week or longer of e-cigarette use. There were five studies that excluded people who were pregnant (which included 2 cartridges, 3 refillable, 1 pod) and one study in a pregnant population. The total number of participants 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 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 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) which 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 EAG determined that 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 Library, 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; Morphett 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.

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. One study (Russell 2021)[13] which was included in the 2022 Cochrane review found similar quit rates between nicotine salt and free-base nicotine. The higher concentration of nicotine in salt form NVPs has the following potential advantages and disadvantages.

Potential advantages

- The pharmacokinetics of nicotine salts more closely replicate nicotine delivery from smoking, which may help people transition away from combustible tobacco.[14]
- 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.[14, 15, 16]

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.[17,18] 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.

NVPs as a smoking cessation aid for 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 319 participants and the outcome favoured NVP with risk ratio of 1.78 (95% CI 0.45 – 6.97). No difference in birth outcomes was found between groups. [19]

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 currently 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.

Aboriginal and Torres Strait Islander people are more likely than non-Indigenous people to live in households with children present [20] and to experience mental health illness, [21] and both of these factors can increase the risk of accidental and intentional poisoning from NVPs. Therefore, avoid prescribing high nicotine concentration liquids and/or open systems, and always inform patients about appropriate storage of NVPs, and the need to keep them out of the reach of children.

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 from the Tackling Indigenous Smoking program and the Aboriginal Quitline is recommended.

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.

Prescribing schemes

The following table shows the three prescribing schemes medical practitioners and nurse practitioners can currently use to prescribe NVPs:

Table 2 Prescribing pathways for NVPs

Scheme (click on the scheme for further information)	To use this scheme:	Recommend?
Authorised Prescriber Scheme	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.)	Yes
Special Access Scheme B	1. Apply online to the TGA for approval to prescribe an NVP for a single patient. 2. Re-apply for each patient.	Yes
Special Access Scheme C	1. A medical practitioner or nurse practitioner can use the online notification system to access the unapproved product immediately. 2. You must submit a form for each individual patient to notify the TGA within 28 days of use of the unapproved product. 3. A copy of the form 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.	**Yes. Available as at 1 Jan 2024**
Personal Importation Scheme	Provide the patient with a script (up to 3 months' supply) that allows them to import the product for their personal use. You do not need TGA approval or authority. Not recommended. The TGO 110 labelling and packaging requirements to do apply to imported NVPs	No. Closing Feb 2024

Also see NPS figure Accessing NVPs (pending updated information)

The recommended schemes

The Authorised Prescriber Scheme and Special Access Scheme (B or C) are recommended because they reduce the risks associated with imported products that may not meet all TGO 110 requirements.

This is because TGO 110 packaging and labelling requirements apply only to NVPs supplied in Australia and not to products imported via the Personal Importation Scheme.

Prescribing guidelines

Initial prescription

When you prescribe an NVP to a patient for the first time, attach a copy of the Authorised Prescriber or Special Access Approval (Category B) the TGA has issued to you. Under the current TGA reporting requirements, the pharmacist needs this before they can dispense the prescription.

From 1 January 2024 medical practitioners and nurse practitioners will be authorised under a new Special Access Scheme (Category C) to prescribe certain therapeutic vaping substances without pre-authority or approval from the TGA.

For SAS C you can access the unapproved product immediately, and do not require an approval letter for the pharmacist.

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

If prescribing nicotine pods, it is good practice to also prescribe the vaping device.

Clinical notes

You should document:

- a brief clinical justification for prescribing NVPs
- that you have explained the benefits and risks and obtained informed consent (preferably in writing)
- any adverse reactions to the NVP the patient reports during follow-up consultations so that you can report them to the TGA

Contents of each prescription

Each prescription should include:

- the brand and product (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 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

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.

If you are prescribing for a new user of NVPs, we recommend that 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. Vaping devices must comply with the new TGO 110 requirements.

From 1 March 2024 all vaping devices (including all unfilled cartridges, capsule, pod or other vessel) for use with a therapeutic vaping substance will be covered by TGO 110. More information can be accessed on the TGA website: https://www.tga.gov.au/resources/resource/guidance/vapes-information-prescribers

Specifying the brand and products

- Because different NVP brands have different nicotine concentrations, specifying the brand and product can reduce confusion or uncertainty during dispensing. It's therefore good to be aware of the available products and their nicotine concentrations. At the time of writing, there is a limited range available in Australian pharmacies and very few listed in the drug database of general practice software programs. Discuss availability of products with your local pharmacist.
- Consider prescribing products from manufacturers with certification of adherence to Good Manufacturing Practices and/or product liability insurance

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, 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 0.77 mg, whereas the amount of nicotine per combustible cigarette varies from 1.54 to 2.6 mg.[22] (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 that are similar to or greater than those from combustible cigarettes. [22, 23]

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.[24, 25, 26]

Starting doses

While acknowledging the lack of evidence about dosages, the 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. The following table will help you decide on a reasonable starting concentration. Less dependent smokers may require up to 50mg of nicotine per day while for more dependent smokers this may be as high as 75mg per day. (See also Assess Nicotine Dependence in Chapter 1 Introduction to smoking cessation). For example, if a more dependent smoker was using one 1.5ml pod per day of 35 mg/ml nicotine salt pod they would be consuming about 52.5mg of nicotine per day.

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. 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 ≤20mg/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.[27] 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

The TGA's TGO 110 prohibits certain ingredients being added to NVPs but does not assess the safety of ingredients used in unregistered NVPs. 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.[3, 28]

Strategies to reduce the risks of inhaling flavourings that may not be safe are:

- prescribe devices with closed systems so that users cannot purchase and add their own flavours.
- under the December 2023 amendment to TGO110 only mint or menthol flavours or tobacco flavour will be permitted.

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

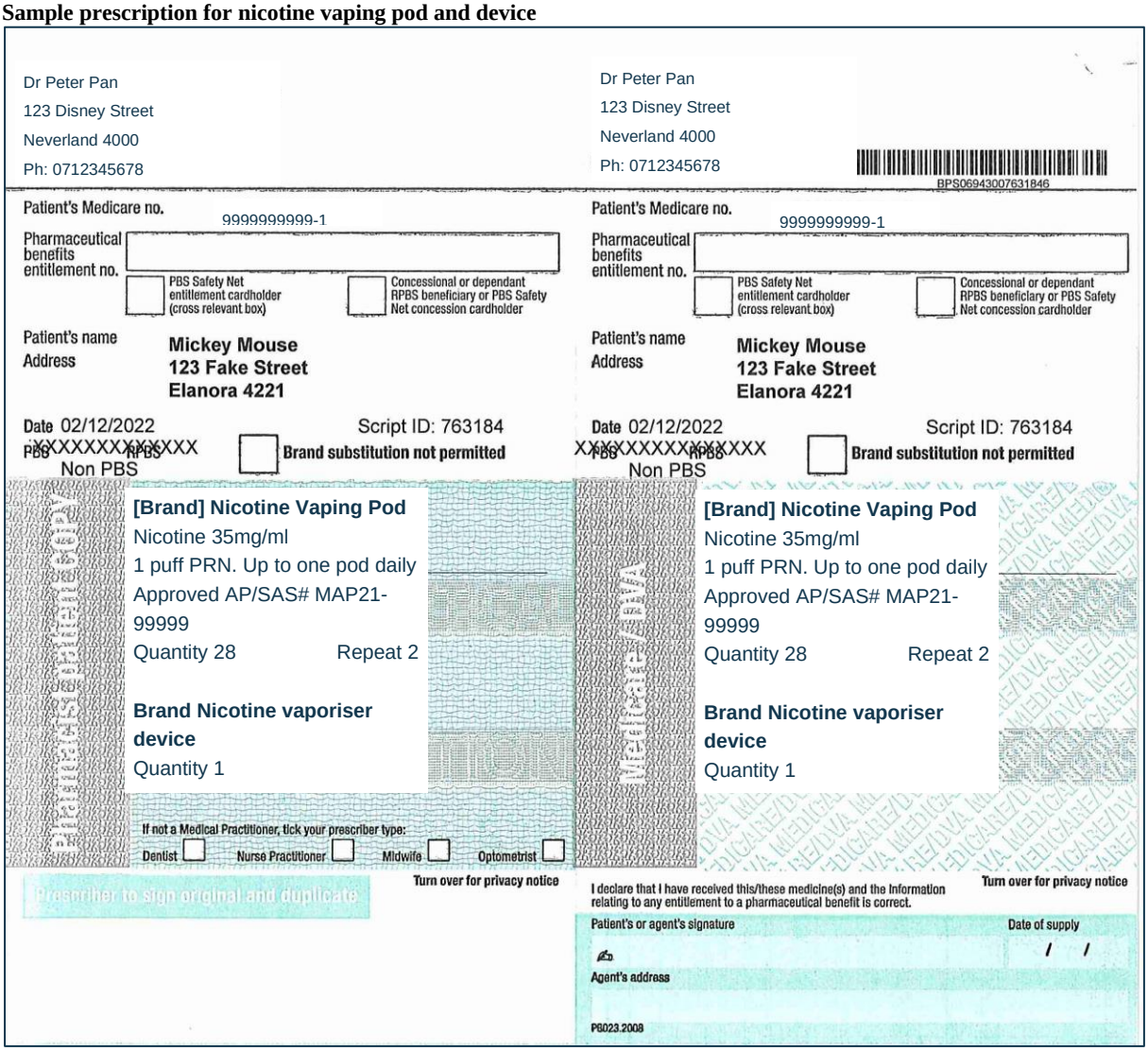
The severe respiratory illness known as E-cigarette or Vaping-Associated Lung Injury (EVALI) was first identified in the United States in early 2019. Investigations by the US Centers for Disease Control found that:

- 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.[29]

Sample prescriptions

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

Sample prescription for nicotine vaping pod and device



Dr Peter Pan
123 Disney Street
Neverland 4000
Ph: 0712345678

Patient's Medicare no. 9999999999-1
Pharmaceutical benefits entitlement no.
PBS Safety Net entitlement cardholder (cross relevant box)
Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder
Patient's name Mickey Mouse
Address 123 Fake Street Elanora 4221
Date 02/12/2022 Script ID: 763184
PBS RPBS Non PBS
Brand substitution not permitted

[Brand] Nicotine Vaping Pod
Nicotine 35mg/ml
1 puff PRN. Up to one pod daily
Approved AP/SAS# MAP21-99999
Quantity 28 Repeat 2

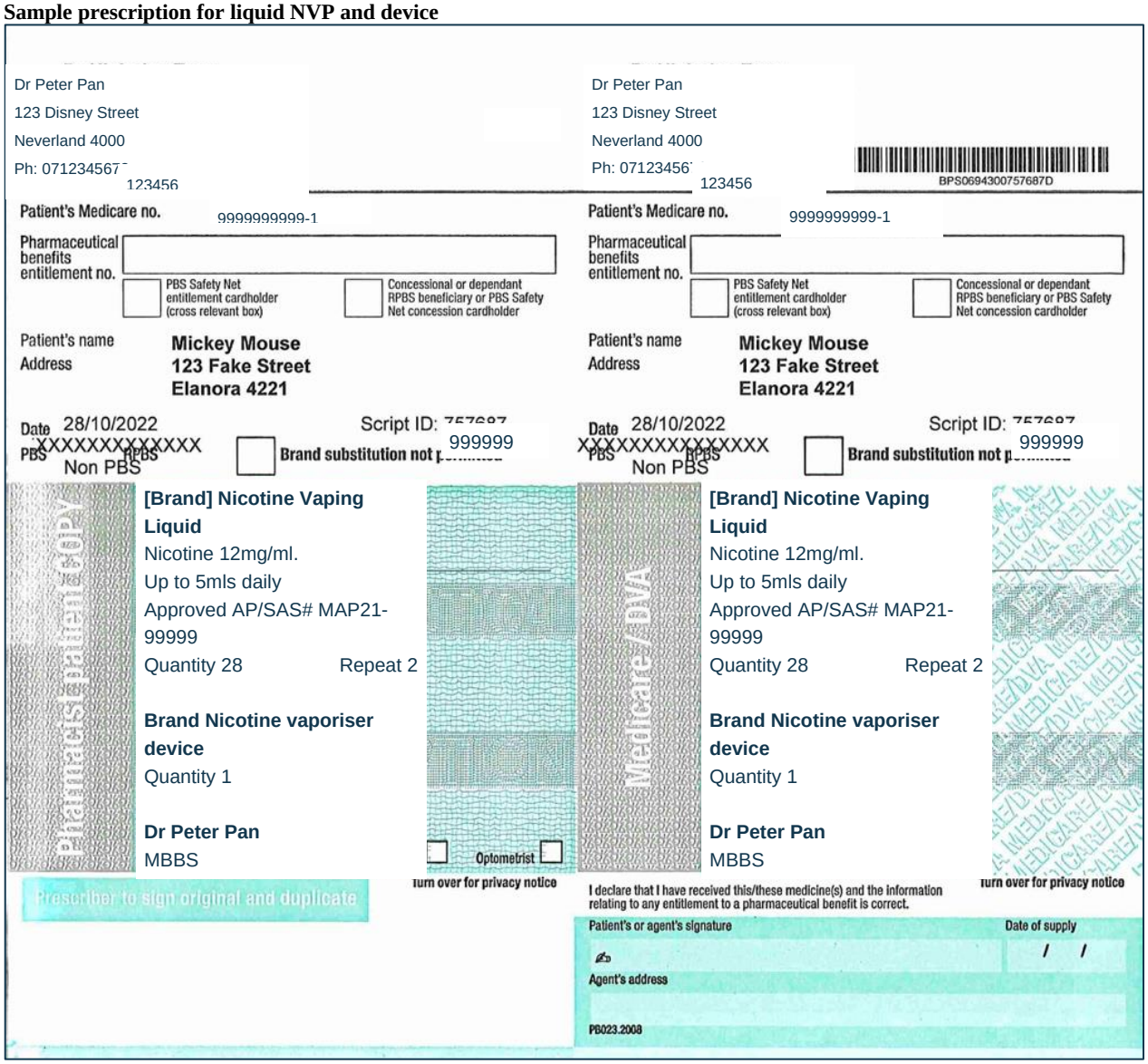
Brand Nicotine vaporiser device
Quantity 1

If not a Medical Practitioner, tick your prescriber type:
Dentist Nurse Practitioner Midwife Optometrist
Turn over for privacy notice
Prescriber to sign original and duplicate

Dr Peter Pan
123 Disney Street
Neverland 4000
Ph: 0712345678
BPS06943007631846
Patient's Medicare no. 9999999999-1
Pharmaceutical benefits entitlement no.
PBS Safety Net entitlement cardholder (cross relevant box)
Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder
Patient's name Mickey Mouse
Address 123 Fake Street Elanora 4221
Date 02/12/2022 Script ID: 763184
PBS RPBS Non PBS
Brand substitution not permitted
[Brand] Nicotine Vaping Pod
Nicotine 35mg/ml
1 puff PRN. Up to one pod daily
Approved AP/SAS# MAP21-99999
Quantity 28 Repeat 2
Brand Nicotine vaporiser device
Quantity 1
Turn over for privacy notice

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

Sample prescription for liquid NVP and device



Dr Peter Pan
123 Disney Street
Neverland 4000
Ph: 071234567
123456

Patient's Medicare no. 9999999999-1
Pharmaceutical benefits entitlement no.
PBS Safety Net entitlement cardholder (cross relevant box)
Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder
Patient's name Mickey Mouse
Address 123 Fake Street Elanora 4221
Date 28/10/2022
Script ID:
PBS XXXXXXXXXXXX RPBS 999999
Non PBS
Brand substitution not p...

[Brand] Nicotine Vaping Liquid
Nicotine 12mg/ml.
Up to 5mls daily
Approved AP/SAS# MAP21-99999
Quantity 28 Repeat 2

Brand Nicotine vaporiser device
Quantity 1

Dr Peter Pan
MBBS

Optometrist
Turn over for privacy notice
Prescriber to sign original and duplicate

Dr Peter Pan
123 Disney Street
Neverland 4000
Ph: 07123456
123456
BPS0694300757687D
Patient's Medicare no. 9999999999-1
Pharmaceutical benefits entitlement no.
PBS Safety Net entitlement cardholder (cross relevant box)
Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder
Patient's name Mickey Mouse
Address 123 Fake Street Elanora 4221
Date 28/10/2022
Script ID:
PBS XXXXXXXXXXXX RPBS 999999
Non PBS
Brand substitution not p...
[Brand] Nicotine Vaping Liquid
Nicotine 12mg/ml.
Up to 5mls daily
Approved AP/SAS# MAP21-99999
Quantity 28 Repeat 2
Brand Nicotine vaporiser device
Quantity 1
Dr Peter Pan
MBBS
Turn over for privacy notice

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

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. 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 is consistent with when 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.

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.

A maximum duration of 12 months' use of NVPs is a reasonable consideration.

Practice points

NVPs are unregistered products and it is valid and reasonable for medical practitioners to choose not to prescribe them.

Overseas nicotine vaping products are not required to meet all of the TGO 110 safety requirements.

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).

   Also avoid disposable devices: their high concentration of nicotine salt presents a safety concern and a high risk of diversion; and the non-rechargeable battery in a single unit that is designed to be discarded after use creates environmental waste.[17, 30]

2. **Use the Authorised Prescriber and Special Access prescribing schemes** instead of the Personal Importation Scheme in order to minimise the risk of the patient accessing NVPs that do not comply with TGO 110's labelling and packaging requirements. **The personal importation scheme for therapeutic vapes will cease from 1 January 2024 for disposable vapes and 1 March 2024 for all other vapes**.

3. **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.
4. **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.
5. **Where possible, avoid flavours or limit to mint, menthol or tobacco flavour.**
6. **Provide follow-up and behavioural support.**

Preventing tobacco relapse

Although cessation of 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 users [31]
- 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.

Legislation relating to vaping

As of 1 October 2021, it is illegal to import nicotine vaping products without a prescription.

The Commonwealth Department of Health is currently revising legislation relating to the manufacture, labelling and packaging of vaping products. The aim is only to have NVPs available via the Medical Access Framework. The proposed regulatory revisions are complex.

The proposed reforms are being implemented in stages. The key changes will:

- Tighten importation controls:
  - ban the importation of vapes (including devices, e-liquids and pods, whether they contain nicotine or not), except therapeutic vapes that comply with requirements of the Therapeutic Goods Act for supply in pharmacy settings by registered pharmacists or other persons authorised to supply prescription medicines under state or territory law.

- Alter Therapeutic Goods Order (TGO) limits:
  - introduce minimum quality standards for NVPs (therapeutic vapes), including restricting flavours and other ingredients
  - require all therapeutic vapes to have pharmaceutical-like packaging
  - reduce permissible nicotine concentrations and volumes.

- Implement changes to the Prescribing Pathway
  - allow all medical practitioners and nurse practitioners to write prescriptions for therapeutic vapes containing nicotine without applying for authority or approval under the Authorised Prescriber or Special Access (Category B) Schemes
  - closure of the personal importation pathway.

- Ban all single-use disposable vapes.

Due to the complexity of these reforms, only an indicative timeframe (Table 1) can be provided at this stage. This guide will be updated once the changes become law.

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

Due to the complexity of these reforms, only an indicative timeframe (Table) can be provided at this stage. This guide will be updated again once the changes become law.

Table 1 Vaping regulatory reforms: indicative timeframe for date of effect

Regulatory Reform	Dec 2023	Jan 2024	Feb 2024	Mar 2024	Jun 2024	Dec 2024
Tighter importation controls (disposable vapes)		✓				
Tighter importation controls (all other vapes)				✓		
Implementation of SAS C prescribing pathway – new option by which medical and nurse practitioners can prescribe therapeutic NVPs		✓				
Closure of the personal importation pathway (disposable vapes)		✓				
Closure of the personal importation pathway (all other vapes)				✓		
Importation and manufacture of non-therapeutic vapes banned (all vapes imported or manufactured in Australia irrespective of nicotine content must comply with the Therapeutic Goods Act)				✓		
Therapeutic Goods Order (TGO) limits to ingredients introduced:				✓		
• Any formulation changes eg. restrictions to flavours, nicotine dose etc to take effect in late 2024						✓

Note: The implementation of these regulatory changes, particularly the domestic bans on certain types of vaping products, is likely to result in an influx of people who use NVPs seeking help from their doctor or another health professional.

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.

In most jurisdictions across Australia the dispensing of NVPs to people younger than 18 years is permitted under the medical access scheme, except for Tasmania where NVPs are classified as smoking products and may not be supplied to persons aged under 18 years. In Victoria, the Tobacco Act prohibits the sale of NVPs, however the Drugs Act, which regulates the prescribing and dispensing of Schedule 4 poisons does not contain any restrictions relating to the prescribing and dispensing to minors. Guidance by the Victorian Department of Health confirms that the Drugs Act prevails: https://www.health.vic.gov.au/sites/default/files/2022-11/the-retail-sale-of-e-cigarettes-guidance-for-e-cigarette-vape-retailers.pdf. In the Northern Territory the vaping device is considered a tobacco product and may only be sold when included on a prescription.

For people 16 years and above, the SAS C pathway may be used. For people younger than 16 years, the SAS B pathway is available.

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 less than 9% of people who had vaped in the past year had a prescription for nicotine from their doctor.[32]

In most states and territories retail outlets such as convenience stores and tobacconists can 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.[33, 34] Consequently, people may be 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. [35]

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%).[36]

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. [36]

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. [36] Use by people who have never smoked is most common in children and adolescents.[36] 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.[37]

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.[38] 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.[39]

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. [39]

There are numerous shorter-term potential adverse health effects of vaping, including: acute lung injury; mouth and airway irritation; cough; nausea; dizziness and headache.[39]

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.[40] The extension 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. [41]

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.[42]

In the context of frequent and sustained vaping, e-cigarettes can deliver as high or higher nicotine concentrations than combustible cigarettes.[43]

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. [44]

Supporting vaping cessation

Currently there is a lack of research on interventions specifically targeting vaping cessation.[45] [46] 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[46] [47] [49] [48]

There are specific challenges to treating vaping addiction in youth, particularly for those who are quite young,[46] [47] and dual users for which there is even less evidence currently available.[46]

A scoping review of cessation interventions for e-cigarettes reported behavioural support interventions based on the 5As approach, motivational interviewing, individual or group counselling, cognitive behavioural therapy and mindfulness as most recommended.[46] [49]

Novel interventions targeting youth included the "SmokeSCREEN" video game,[50] [51] smart phone apps and the "This is Quitting" text messaging program. These have demonstrated positive early results in reducing vaping among youth.[52]

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. [53]

Many people quit vaping without assistance or going 'cold turkey'. [54] 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.[63]

Impact of regulatory changes on vaping behaviours and seeking assistance

As outlined previously (

Table 1), a domestic ban on single-use disposable vaping products will take effect from 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, it is likely that a large proportion of people who currently vape will seek assistance from a GP 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, distraction techniques, and when necessary, a registered pharmacotherapy licenced for smoking cessation.

There may be a sub-group of 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 prescribing NVPs for a limited period on the understanding that the aim is for the patient to transition off these and become nicotine free.

The supply of NVPs to patients aged under 18 years is legal in all states and territories except for Tasmania.

For patients under 16 years of age, SAS B must be used.

It is also important to note that there is currently a lack of research on this approach and that, 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: 3As 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 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. [48] 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. [55] It is vital to ensure confidentiality for young people, so they feel safe to disclose the behaviour to a health professional. [55] 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. It is reasonable to think that this would also apply to vaping.

Assess nicotine dependence, barriers to quitting and psychosocial context

The level of nicotine dependence impacts cessation success. [56]

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.[57]

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.[57]

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 now 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,[58] as are factors related to convenience of use, the discreetness of e-cigarettes and the enjoyment of different flavours. [59]

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. [60] It is not known if this applied 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.[34] [39] [61] 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.[62]

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 smoking [63] which includes behavioural support (eg. Quitline) and consideration of pharmacotherapy for management of nicotine dependence.

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 is a reasonable pathway. [63]

Youth and adolescents

How best to support young people to stop vaping is uncertain given the lack of evidence.[56]

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.[57]

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 in young people may be considered from age 12 years.[57]

Dual users

Advise dual users to switch completely from smoking to vaping only, and then implement intervention strategies. 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).

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 and bupropion 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 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. This may change as new regulations come into effect.

The use of pharmacotherapies, including among younger people, is increasingly being included as part of the treatment for vaping cessation.[64] [65] [66] 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. [67]

The use of pharmacotherapy may be considered from age 12, however this is based on evidence from studies for smoking cessation.[20] In patients aged 12-17 years NRT is the preferred pharmacotherapy option for vaping cessation given the greater evidence of safety.

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).[68]

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. This may change as new regulations come into effect.

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 evidence on the use of varenicline to support vaping cessation. A recent randomised controlled trial 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.[69]

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

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. [46] [70] 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 titrating down 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.

The supply of NVPs to patients aged under 18 years is legal in all states and territories except for Tasmania.

For patients under 16 years of age, SAS B must be used.

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. [71] [72]

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: [70]

- 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 such diacetyl and are increasingly being shown to be linked to gum disease and poor oral health [73]
- avoid disposable devices that are both low quality and cause environmental damage
- 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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