



Guidelines for pharmacists providing smoking cessation support

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Contents

Executive summary	4
Acknowledgements	4
About the guidelines	5
Purpose	5
Scope	5
Terminology	6
Service overview	7
Smoking cessation in Australia	8
Health benefits of stopping smoking	8
Pharmacist's role in smoking cessation	9
Behavioural support	9
Smoking cessation in specific populations	9
Pharmacotherapy	11
Medicine interactions	12
Prescription stop smoking medicines	13
First-line pharmacotherapy	13
Second-line or other options	13
Pharmacist's role in supplying nicotine vaping products	16
Dispensing	16
Compounding	18
Appendix 1: Non-prescription medicine treatment guideline: nicotine replacement therapy for smoking cessation	19
Nicotine replacement therapy for smoking cessation	19
Meet legal and professional obligations	19
Gather patient information	20
Assess patient needs	20
Provide counselling	22
Follow up	24
Appendix 2: Historical access to nicotine vaping products	25
Appendix 3: Carbon monoxide monitors in smoking cessation	25
Appendix 4: Patient handout – Nicotine vaping products	26
Appendix 5: Patient support tools	27
Appendix 6: Further information	27
References	28

Executive summary

Tobacco use is the leading cause of premature death and disability in Australia.¹ Tobacco smoking rates in Australia have been declining over the past 30 years. This has been attributed to the public health strategies implemented in Australia to discourage smoking.² However, the use of nicotine vaping products and vaping devices has been increasing.¹

Pharmacists can support patients to stop smoking or vaping by:

- providing [brief advice](#) and [ongoing smoking cessation support](#)
- providing advice about [prescription](#) and [non-prescription](#) pharmacotherapy options
- [providing prescription and non-prescription pharmacotherapy](#) and counselling on appropriate use
- identifying and resolving pharmacotherapy-related problems (e.g. [interactions with medicines](#), adverse effects) during follow up.

First-line pharmacotherapy options for smoking cessation include bupropion, varenicline and nicotine replacement therapy (NRT).³ These pharmacotherapy options are subsidised on the Pharmaceutical Benefits Scheme (PBS).⁴

Nicotine vaping products are not a first-line option for smoking cessation. First-line pharmacotherapy options (in combination with behavioural intervention) should be trialled before using nicotine vaping products for smoking cessation.³ Nicotine vaping products can only be legally imported or supplied in Australia with a valid prescription.⁵ However, evidence for the use of nicotine vaping products as an effective aid to smoking cessation is inconclusive. Research in this area is continuing.

Dispensing nicotine vaping products involves special considerations, including:

- compliance with [Therapeutic Goods Order 110](#)
- compliance with [state and territory legislation](#)
- compliance with [advertising regulations](#)
- [access to unapproved products](#)
- access to [vaping devices](#) appropriate for the nicotine vaping product being dispensed
- [presence of ingredients other than nicotine](#) (e.g. flavouring, contaminants)
- [counselling](#) about appropriate use to stop smoking, safe storage and disposal.

Unapproved nicotine vaping products can be imported and held in stock by pharmaceutical wholesalers or pharmacies in anticipation of receiving a prescription that complies with the [authorised prescriber scheme](#) or [special access scheme](#). Patients who have a valid prescription can also import unapproved nicotine vaping products for personal use using the [personal importation scheme](#).⁵ However, the use of the personal importation scheme for nicotine vaping products is not recommended in prescribing guidelines.³

The scheduling conditions and access pathways for nicotine vaping products aim to⁶:

- prevent non-smokers (particularly adolescents) from using nicotine vaping products and developing nicotine dependence
- allow people who smoke to access these products to assist with smoking cessation in conjunction with medical advice.

These guidelines provide information for pharmacists about the key considerations for supporting patients to stop smoking, including the special considerations for nicotine vaping products.

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The work to develop the guidelines included review by experts, stakeholder feedback, and the consensus of organisations and individuals involved.

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About the guidelines

Purpose

This document describes the professional obligations of pharmacists when providing smoking cessation support. This guidance includes (where relevant):

- appropriate and effective processes
- desired behaviour or minimum standards of good practice
- how duties and responsibilities may best be fulfilled.

The guidance can be used as a tool to support balanced and professional decision making and ensure that patients' needs, beliefs and preferences are met. It can be used as an educational resource to inform quality assurance processes and to provide support when resolving legal disputes and ethical dilemmas.

Scope

These guidelines are applicable to all practice settings in which pharmacists provide smoking cessation support, including non-prescription medicines. Specific information about the general dispensing process is covered by other guidelines.

Guidelines produced by the Pharmaceutical Society of Australia (PSA) are not definitive statements of correct procedure but represent agreement by experts in the field. The guidelines do not set a prescribed course of action or a mandatory standard to which pharmacists must adhere.

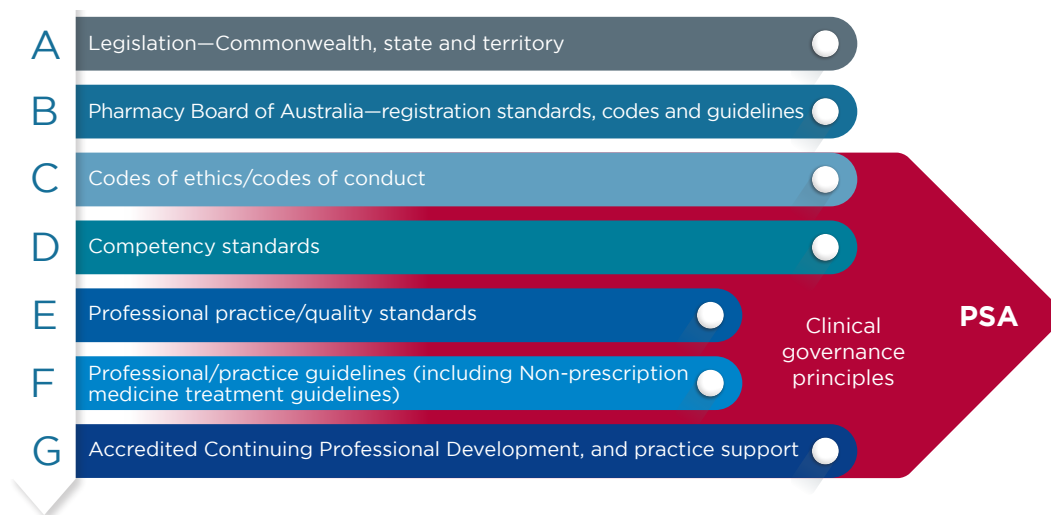
Pharmacists are expected to exercise professional judgement when adapting the guidance provided in these guidelines to specific circumstances. The guidelines sit within a broader hierarchy of guidance underpinning and supporting the practice of pharmacists (see Figure 1).

It is important to review these guidelines in conjunction with the current versions of the:

- Pharmacy Board of Australia *Code of Conduct for Pharmacists*⁷ and *PSA Code of Ethics*⁸
- relevant *PSA Professional Practice Standards*⁹, particularly Standard 3: Dispensing and Other Supply Arrangements
- Pharmacy Board of Australia *Guidelines for Dispensing of Medicines*¹⁰.

Details of legislative requirements are not addressed in these guidelines. At all times, pharmacists must comply with relevant Commonwealth and state or territory legislation. No part of the guidelines should be interpreted as permitting a breach of the law or discouraging compliance with legal requirements.

Figure 1: Broad hierarchy of guidance and regulation of pharmacy practice



- A. Commonwealth, state and territory **legislation** provides the legal framework governing pharmacy practice.
- B. The **Pharmacy Board of Australia's** registration standards define requirements to be met to be registered as a pharmacist in Australia. The Board's codes and guidelines may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacists.
- C. **Codes of ethics / conduct** articulate the values of the pharmacy profession and expected standards of ethical behaviour of pharmacists towards individuals, the community and society.
- D. **Competency standards** describe the skills, attitudes and other attributes (including values and beliefs) attained by an individual based on knowledge and experience which together enable the individual to practise effectively as a pharmacist.
- E. **Professional practice standards (or quality standards)** relate to the systems, procedures and information used by pharmacists to achieve a level of conformity and uniformity in their practice. Quality standards may be applicable to individuals or to organisations.
- F. **Professional guidelines** are generally service- or activity-specific and provide information on how best to deliver services consistent with expected professional standards.
- G. Accredited **Continuing Professional Development** and practice support activities; these support continuous quality improvement by pharmacists and assist pharmacists to maintain and enhance their competence in current and possible future roles.

Note: Clinical governance principles, as outlined in *PSA's Clinical governance principles for pharmacy services* (2018), are integral to E and F with regards to implementation of safety, quality and consistency of pharmacist-delivered care and services

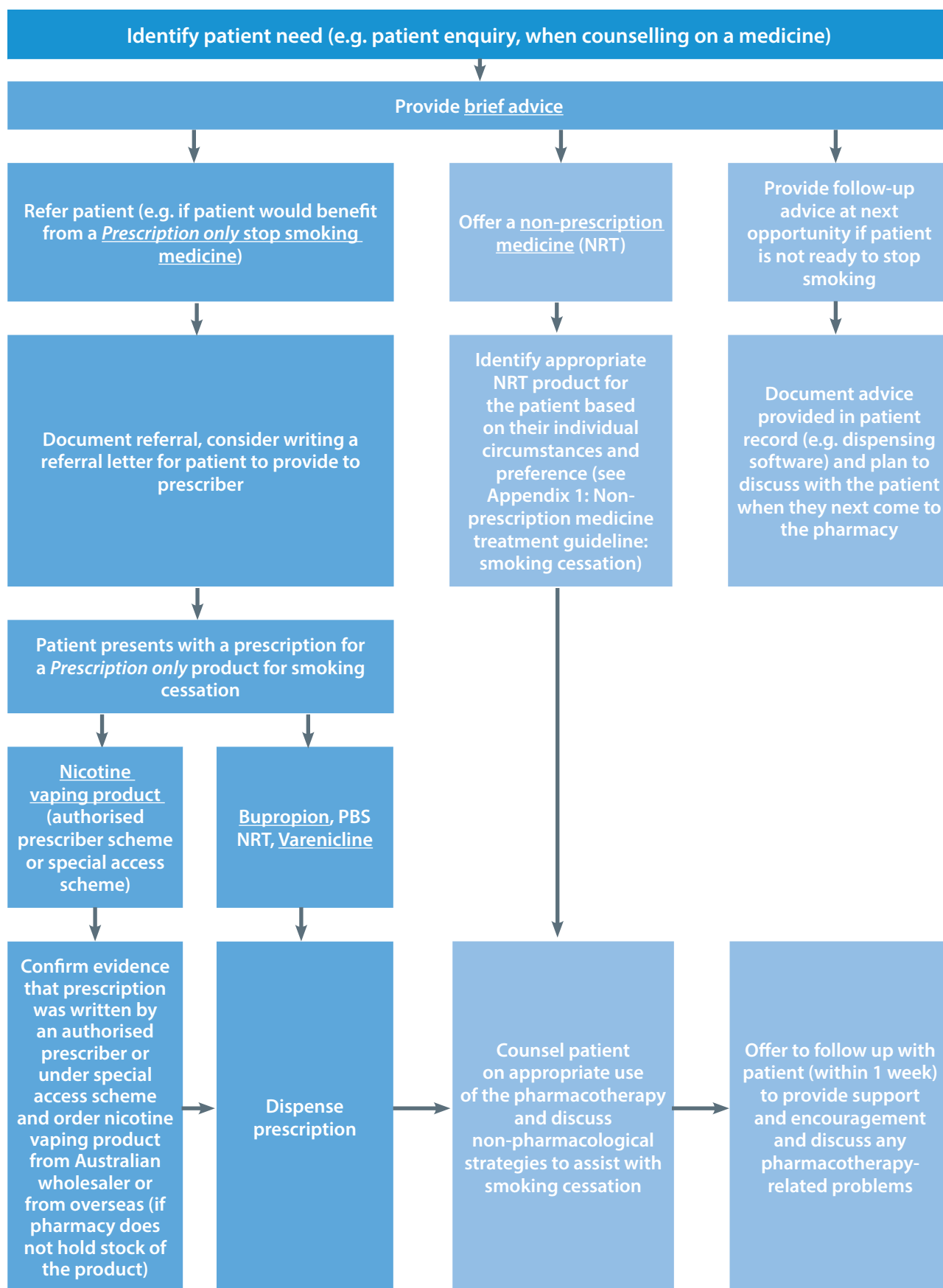
Terminology

Term	Definition
Authorised prescriber scheme	A scheme through the Therapeutic Goods Administration (TGA) that allows medical practitioners to prescribe therapeutic goods not included in the Australian Register of Therapeutic Goods (ARTG) to a group of patients with a specific medical condition
Nicotine replacement therapy (NRT)	Products containing nicotine and used to assist people to stop smoking. NRT products are included in the ARTG. Available in the form of gum, inhaler (inhalator), lozenge, patch or oral (mouth) spray
Nicotine vaping products	Products that contain nicotine (in salt or base form) in solution that are designed to be inhaled using a vaping device. Includes vape liquids, e-liquids and e-juices that contain nicotine. Nicotine vaping products may be pre-mixed in a ready to use form and contained in pods, cartridges or disposable vaping devices, or nicotine in solution that must be mixed with diluents prior to use in an open system vaping device
Patient	A person who uses, or is a potential user of, health services, including their family, carer(s) or agent. Also known as client, consumer, healthcare recipient, individual, person
Personal importation scheme	A scheme through the TGA that allows a patient to import a medicine that is not included in the ARTG for personal use
Prescriber	A health professional authorised to undertake prescribing within the scope of their practice
Special access scheme	A scheme through the TGA that allows access to therapeutic goods not included in the ARTG for a single patient
Unapproved medicine/product	A medicine or product that has not been assessed in Australia for its quality, safety or efficacy and is not included in the ARTG
Vaping device	An electronic device that is used to heat vaping products to release an aerosol that is inhaled. Includes e-cigarettes, e-cigars, e-hookahs, e-pens, e-pipes and vape pens

References: TGA¹¹; TGA¹²; TGA¹³; TGA¹⁴



Service overview



Smoking cessation in Australia

Tobacco smoking has a significant impact on the health and wellbeing of Australians. Cancer (particularly lung cancer), chronic obstructive pulmonary disease (COPD) and cardiovascular disease are key conditions contributing to this disease burden.² Tobacco use is the leading cause of preventable death and disability in Australia.²

Second-hand smoke exposure also impacts the health of Australians. In adults it can cause cardiovascular and respiratory complications. In infants and young children it can lead to low birth weight and sudden infant death syndrome, and exacerbate respiratory conditions.^{2,15}

Smoking rates in Australia have been declining over the past 30 years.² The reduction in smoking rates has been attributed to the success of public health strategies, including^{3,15}:

- tax increases
- comprehensive smoke free laws and policies
- plain packaging
- social marketing campaigns.

The use of nicotine vaping products and vaping devices has been increasing in Australia.¹ The long-term effects of vaping are unknown.

Health benefits of stopping smoking

There are major health benefits for everyone who stops smoking, with benefits beginning soon after ceasing cigarette use.¹⁵

Table 1. Examples of medical conditions and impacts of smoking

Medical condition	Consequences of smoking	Benefits of smoking cessation
Chronic obstructive pulmonary disease (COPD)	<ul style="list-style-type: none"> • More frequent COPD exacerbations than non-smokers • Increased risk of respiratory infections 	<ul style="list-style-type: none"> • Reduced rate of decline of lung function • Improved lung function • Reduced risk of hospitalisation
Cardiovascular disease	Higher risk of most types of cardiovascular disease	<ul style="list-style-type: none"> • Reduced risk of atherosclerotic cardiovascular disease • Reduced risk of coronary heart disease • Reduced risk of morbidity and mortality from stroke • Reduced risk of heart failure • May increase survival and reduce risk of hospitalisation in patients with left-ventricular dysfunction
Infertility	<ul style="list-style-type: none"> • Reduced fertility • Early-onset menopause • Shorter and more variable menstrual cycle • Premature ovarian failure • Decreased implantation rate 	<ul style="list-style-type: none"> • Improved fertility rate to be similar to non-smokers • Reduced risk of early-onset menopause
Diabetes	<ul style="list-style-type: none"> • Impaired glycaemic control • Increased risk of: <ul style="list-style-type: none"> - chronic kidney disease - neuropathy - retinopathy - peripheral vascular disease 	<ul style="list-style-type: none"> • Reduced risk of diabetes complications • Reduced risk of diabetic foot amputations • Improved glycaemic control

References: Greenhalgh¹⁵; eTG¹⁶; Rigotti¹⁷; Roelsgaard¹⁸; CDC¹⁹; Collins²⁰; RACGP²¹

Consumer resources that demonstrate the health benefits of stopping smoking are available from:

- Quitline: www.quit.org.au
- Lung Foundation: <https://lungfoundation.com.au>

Pharmacist's role in smoking cessation

Pharmacists should have a system in place to identify patients who smoke and to document their tobacco use. Everyone who smokes should be given brief advice on smoking cessation.³ See Brief advice.

See [Counselling](#) for information about the pharmacist's role in vaping cessation.

Behavioural support

Pharmacists can provide effective behavioural support to patients seeking to stop smoking.^{2,22} This can be in the form of brief advice when counselling patients about their medicines and management of medical conditions, through to providing ongoing smoking cessation support.^{3,22}

Pharmacists should provide advice on stopping smoking to all people who smoke. There are some situations where this advice may be even more relevant. For example, when a patient³:

- has a medical condition related to tobacco use
- has been diagnosed with a medical condition where treatment or outcome is affected by tobacco use
- has been hospitalised or recently discharged from hospital
- is preparing for surgery
- is pregnant/planning pregnancy or has recently given birth.

Advice from pharmacists to patients about stopping smoking helps people to stop. Both longer consultations (>10 minutes) and brief advice (up to 3 minutes) can be beneficial.^{3,22}

Written materials and other resources (e.g. videos, audio, websites) for patients may also be helpful to support smoking cessation.³

Brief advice

Ask, Advise, Help forms the basic structure for brief advice on smoking cessation³:

- **Ask** 'Do you smoke?' and record smoking status.
- **Advise** all people who smoke to stop. Establish rapport, and be clear and non-confrontational. Provide advice on the most effective methods available.
- **Help** by offering to arrange referral and encouraging use of behavioural interventions and appropriate pharmacotherapy.

Where possible, provide brief advice to all patients who smoke during routine counselling. Offer follow-up advice and support to people trying to stop smoking within one week of them stopping. Tailor advice and treatment recommendations for each patient's needs and experiences. Discuss behavioural strategies to help with smoking cessation and encourage patients to use support services such as Quitline (see [Appendix 5: Patient support tools](#)). Advise patients that the chance of successfully stopping smoking is increased if behavioural support is used in combination with other treatments (e.g. pharmacotherapy).³

Ongoing smoking cessation support

Pharmacists who have completed additional training in behavioural interventions for smoking cessation support, motivational interviewing or similar can provide ongoing multi-session smoking cessation support services. Consider referring patients to a dedicated smoking cessation support service (e.g. Quitline) for additional support.

The term 'stop smoking' (as opposed to 'quit smoking') is preferred by some people in priority populations (e.g. people living with a mental illness). 'Quit' can infer a loss, or giving up something, whereas 'stopping smoking' refers more to the action itself.

Smoking cessation in specific populations

Aboriginal and Torres Strait Islander people

Smoking-related conditions that contribute to Aboriginal and Torres Strait Islander morbidity and mortality include¹⁵:

- cardiovascular and respiratory conditions
- cancer
- diabetes
- pregnancy-related conditions.

Compared with non-Indigenous Australians, Aboriginal and Torres Strait Islander people are at a greater risk of¹⁵:

- being unemployed
- having lower levels of education
- having less access to facilities and services
- being over-represented in the prison system.

These factors affect how this population accesses services and support to help with stopping smoking.

Barriers to Aboriginal and Torres Strait Islander people accessing help to stop smoking include³:

- increased stress levels in these communities
- lack of culturally appropriate health services
- language barriers
- high rate of smoking amongst Aboriginal health workers.

Aboriginal and Torres Strait Islander people are just as likely to want to stop smoking as other patients.³ Strategies to overcome potential barriers include³:

- referring patients to a culturally specific smoking cessation service where available (e.g. programs run through a local Aboriginal health service, Aboriginal Quitline)
- providing information tailored for the patient's health literacy and cultural needs

- identifying cost-effective ways for patients to access treatment (e.g. referring patients for prescriptions for subsidised smoking cessation pharmacotherapies and ensuring they are registered for Closing the Gap, if eligible – see [Subsidised stop smoking medicines](#)).

Case study

A pregnant Aboriginal woman asks the pharmacist about getting nicotine for vaping, because she has heard it can help you stop smoking.

The pharmacist explains that you can get nicotine for vaping on a prescription from the pharmacy but it is not a first-line option for smoking cessation. This is because the safety and effectiveness of nicotine vaping products for smoking cessation aren't known, especially during pregnancy. The pharmacist suggests she call Aboriginal Quitline and refers the woman to her prescriber.

The patient attends her local Aboriginal health service and is connected to the families team and to the stop smoking team. She manages to cut down smoking using tips learned from Aboriginal Quitline and with suggestions from the Aboriginal health service team, including:

- going for a short walk to delay the urge to smoke
- replacing cigarettes with glasses of water
- eating vegetable sticks.

She is trying to completely stop smoking but is finding she is really craving a couple of cigarettes each day. She is worried she is getting cranky with her partner and other children. The stop smoking team suggested she try nicotine gum, so she returns to pharmacy. However, she is worried about the cost of the gum.

The pharmacy assistant makes her feel welcome and offers to have the pharmacist speak with her. The pharmacist explains that her GP or obstetrician should be involved if she wants to use NRT during pregnancy. The pharmacist phones her GP who knows she is attending the stop smoking program and organises an electronic prescription for nicotine 2 mg gum at reduced cost using Closing the Gap so she can try to stop smoking completely as soon as possible.

People living with mental illness

Compared with the general population, people living with a mental illness have^{3,15}:

- higher smoking rates
- lower rates of stopping smoking
- reduced life-expectancy (they are more likely to die from smoking than from their mental illness).

Stopping smoking can improve mental health, mood and quality of life amongst patients.¹⁵

Barriers to stopping smoking in people with a mental illness include¹⁵:

- misunderstandings about the safety of stopping smoking
- higher level of nicotine dependence
- reduced opportunity for participation in smoking cessation programs.

Strategies that pharmacists can use to support stopping smoking in this patient group include^{3,15}:

- discussing stopping smoking with patients as part of routine counselling
- monitoring patients' mental health when stopping smoking, and referring patients for further review if needed
- offering ongoing support and referring patients to specialised smoking cessation programs – Quitline has tailored protocols for people living with a mental illness.

Higher NRT doses, combination therapy and a longer duration of therapy may be needed in these patients.¹⁵ Varenicline is safe and effective for people with stable mental health or with past history of mental illness.³

When patients who are taking certain medicines for mental health conditions stop smoking, an adjustment to their medicine dose may be needed. See [Medicine interactions](#).

People living with a disability

Daily smoking rates are higher in people with a disability compared to those without. Smoking in people with a disability has been found to result in lower health-related quality of life, as well as increased mental and physical distress.²³

Barriers to stopping smoking in people living with a disability include^{24,25}:

- difficulty in obtaining, understanding or remembering smoking cessation advice
- difficulty in accessing services that meet their needs
- belief that smoking helps with symptoms of disability.

Strategies that pharmacists can use to support stopping smoking in this patient group include²⁶:

- providing information that is tailored to each patient's health literacy
- providing additional resources (e.g. written material) where appropriate
- providing support for patients to access and manage medicines (e.g. offering a delivery service, dose administration aid)
- referring patients to services designed for people living with their particular disability (e.g. intellectual disability)
- encouraging family members and/or support workers to be involved in the patient's plan to stop smoking, where appropriate.



Culturally and linguistically diverse backgrounds

Barriers to stopping smoking in patients from culturally and linguistically diverse backgrounds include^{3,15,27}:

- cultural resistance (e.g. smoking may be considered socially acceptable)
- lack of interest in telephone support services
- language barriers.

Strategies that could be implemented to support patients in this group to stop smoking include³:

- using culturally appropriate resources to support smoking cessation
- using an interpreter when communicating with patients
- providing information on stop smoking services available
- referring patients to services that offer programs in their local language (e.g. Quitline has resources in different languages and uses interpreters when necessary).

Pharmacotherapy

All patients who are nicotine dependent should be offered pharmacotherapy. First-line pharmacotherapy options for smoking cessation are NRT, bupropion and varenicline. Combining pharmacotherapy with behavioural support increases the rate of successfully stopping smoking compared to either intervention alone.³

First-line pharmacotherapy options reduce, but do not completely alleviate, symptoms of nicotine withdrawal. The rapid and high levels of nicotine obtained during tobacco smoking are not achieved by using the available forms of NRT.¹⁵ Nicotine withdrawal symptoms are more likely to occur in the first 3 weeks after stopping smoking.²⁸

Premature discontinuation of pharmacotherapy can lead to relapse.³ Planned follow up between the pharmacist and patient (within a week of the stop smoking date) to review pharmacotherapy can identify medicine-related problems (e.g. incorrect use, adverse effects, dose too high/low) and provide an opportunity to resolve them. See [Appendix 1: Non-prescription medicine treatment guidelines: nicotine replacement therapy for smoking cessation](#), [Subsidised stop smoking medicines](#) and [Prescription stop smoking medicines](#) for further information about addressing medicine-related problems.

Subsidised stop smoking medicines

Cost can be a barrier to continuation of pharmacotherapy. The Pharmaceutical Benefits Scheme (PBS) subsidises the use of bupropion, certain forms of NRT and varenicline for the management of nicotine dependence in certain situations.⁴ The current PBS requirements for subsidised treatments for smoking cessation are available at www.pbs.gov.au.

Medicine interactions

Tobacco smoking can affect a number of medicines through both pharmacokinetic and pharmacodynamic interactions. A change in dose may be required if a patient taking a medicine that is affected by smoking stops smoking.³

Pharmacokinetic interactions

Chemicals in tobacco smoke induce the metabolism of medicines metabolised by cytochrome P450 1A2 (CYP1A2), decreasing their plasma concentration.²⁹ Nicotine (in NRT or nicotine vaping products) does not induce CYP450 enzymes and therefore does not cause these pharmacokinetic interactions. The effects of diluents, flavours and other ingredients present in nicotine vaping products on other medicines are unknown.^{15,29}

Smoking cessation can increase plasma levels of medicines metabolised by CYP1A2. For medicines that have a wide therapeutic index, the impact of smoking cessation may not be clinically significant. However, for medicines that have a narrow therapeutic index (e.g. clozapine), monitoring and dose adjustment may be required.²⁹ Table 2 Pharmacokinetic interactions of high clinical significance outlines potential CYP1A2 pharmacokinetic interactions with tobacco smoking that are likely to be of high clinical significance.

Table 2 Pharmacokinetic interactions of high clinical significance

Medicine	Managing the impact when stopping smoking
Caffeine	Reduce caffeine by half
Clozapine	<ul style="list-style-type: none"> • Monitor trough concentrations (ideally before stopping smoking and for 2 weeks afterwards, sooner if there are adverse effects) • Monitor for increased adverse effects • Seek specialist advice • Reduce dose if clinically appropriate
Erlotinib	<ul style="list-style-type: none"> • Advise patients to stop smoking before starting treatment • Use recommended starting dose of erlotinib if patient stops smoking during treatment • Seek specialist advice
Theophylline	<ul style="list-style-type: none"> • Monitor theophylline levels, reduce dose if clinically appropriate • Monitor for adverse effects (e.g. palpitations, nausea, vomiting)

References: Preston²⁹; Quit Victoria³⁰; eMIMS³¹

Pharmacodynamic interactions

Pharmacodynamic interactions occur when the effects of tobacco smoking modify the physiological effects of a medicine.¹⁵

Potential pharmacodynamic interactions with tobacco smoking include^{15,29}:

- corticosteroids – reduced response to corticosteroids in patients with asthma
- oral contraceptives – increased risk of cardiovascular disease.

Patients taking these medicines should be advised to stop smoking.²⁹

Pharmacodynamic interactions associated with nicotine include^{15,29,30}:

- benzodiazepines – reduced effectiveness of benzodiazepines due to the stimulant effects of nicotine
- beta-blockers – nicotine opposes beta-blocker effects on blood pressure and heart rate
- insulin – slower insulin absorption (possibly due to nicotine-mediated peripheral vasoconstriction)
- methadone – nicotine affects the endogenous opioid system.

A dose reduction of the interacting medicine may be needed when a patient taking these medicines stops using NRT or a nicotine vaping product (or reduces their dose).



Prescription stop smoking medicines

Choice of pharmacotherapy is based on efficacy, suitability for an individual patient and patient preference.³ See Bupropion, Varenicline and Nicotine vaping products for further information about their use for smoking cessation. See [Appendix 1: Non-prescription medicine treatment guideline: nicotine replacement therapy for smoking cessation](#) for further information about NRT.

First-line pharmacotherapy

Bupropion

Patients who use bupropion are 60% more likely to stop smoking long term than patients using placebo.^{3,2} However, it is less effective than either varenicline or combination NRT.³ It should be started at least 1 week before planned smoking cessation.²⁸

Considerations when using bupropion include^{3,28}:

- may be used in combination with NRT (e.g. a faster-acting product to manage nicotine cravings – blood pressure should be monitored if this combination is used)
- treatment with bupropion should be continued for 7–9 weeks
- tablets should be swallowed whole
- common adverse effects include insomnia (>40% of patients), gastrointestinal effects, dry mouth, dizziness, concentration difficulties, agitation
- taking once daily doses in the morning may reduce the chance of insomnia – when dosing increases to twice daily, separate doses by 8 hours and avoid bedtime doses
- alcohol consumption alters the seizure threshold and should be minimised (or avoided) in patients taking bupropion.

Varenicline

Varenicline more than doubles the chance of stopping smoking compared to placebo, and has similar efficacy to combination NRT (but is more effective than NRT monotherapy).^{3,28} It is more effective than bupropion. It should be started at least 1 week before planned smoking cessation. Alternatively, the patient can start using varenicline and then stop smoking anytime between day 8 and day 35 of treatment.³

Considerations when using varenicline include^{3,28}:

- use in combination with NRT patches improves effectiveness
- there is a risk of nicotine withdrawal symptoms and an urge to smoke after varenicline is ceased; reducing the dose gradually or using a faster-acting NRT product may minimise this
- tablets should be swallowed whole
- common adverse effects include gastrointestinal effects, increased appetite/weight, headache, insomnia, abnormal dreams, taste disturbance
- severe nausea may be relieved by taking with food or with a reduction in dose.

Second-line or other options

Second-line and other pharmacotherapy options that may be used for smoking cessation include^{3,4,33}:

- Nortriptyline: may be used as a second-line treatment. It is not currently indicated for use to assist with smoking cessation in Australia, and is not subsidised through the PBS for this purpose.
- Clonidine: has been found to be effective in assisting with smoking cessation in a small number of studies. It is not currently registered for use for smoking cessation in Australia.
- Cytisine: is chemically related to varenicline and has been used for smoking cessation in other countries. One study has found cytisine combined with behavioural support to be superior to NRT but with a higher incidence of adverse effects. It is not registered in the ARTG.

Nicotine vaping products

Legislative framework

Scheduling conditions

Nicotine in preparations for human use is a Schedule 4, *Prescription Only* product, except when in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking (i.e. NRT, which remains unscheduled) or in tobacco prepared and packed for smoking.³⁴ This means that supply, possession and use of nicotine vaping products (including those imported from overseas) without a valid prescription is illegal.⁶

The scheduling decision for nicotine vaping products aims to⁶:

- prevent non-smokers (particularly adolescents) from using nicotine vaping products and developing nicotine dependence by using these products or transitioning to tobacco smoking
- allow people who smoke to access these products to assist with smoking cessation in conjunction with medical advice.

State or territory legislation

The sale of nicotine vaping products and vaping devices is also regulated under state and territory legislation.

See the TGA website: [Nicotine vaping products information for pharmacists](#) for further information.

Therapeutic Goods Order: Standard for nicotine vaping products

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*¹² outlines the minimum safety, quality and record keeping requirements for nicotine vaping products (including imported products).

Australian sponsors (including pharmacists) who access unapproved nicotine vaping products for supply in Australia must adhere to the record keeping requirements of TGO 110. The Australian sponsor is responsible for confirming that the labelling and packaging requirements of TGO 110 are met for the imported unapproved nicotine vaping product. In the event these labelling and packaging requirements are not met, the Australian sponsor must re-package or re-label the product.¹¹ Pharmacists are considered a sponsor if¹¹:

- nicotine vaping products are imported directly from an overseas supplier to supply to Australian patients
- nicotine vaping products are exported from Australia (e.g. the product is sent to someone overseas)
- nicotine vaping products are extemporaneously compounded – record keeping requirements detailed in TGO 110 must be kept for each nicotine vaping product that is compounded (see also [Compounding](#)).

Prescribing pathways for unapproved products

Nicotine vaping products that are not included in the ARTG (and are therefore unapproved products) can be accessed with a valid prescription through one of several prescribing pathways³⁵:

- Authorised prescriber scheme
- Special access scheme
- Personal importation scheme.

See [Accessing unapproved products](#) for further information.

Authorised prescriber scheme

Medical practitioners can apply to the TGA for approval to become an 'authorised prescriber' of an unapproved product. Authorised prescribers do not require human research ethics committee approval to prescribe nicotine vaping products as an aid to smoking cessation. Authorised prescribers must provide a report to the TGA every 6 months outlining the number of patients they have treated during the 6 month period.³⁵

Pharmacists who dispense prescriptions for nicotine vaping products written by an authorised prescriber should request a copy of the prescriber's TGA approval letter to keep on file.

See the [TGA website, Nicotine vaping products: information for prescribers](#) for further information. The TGA website includes a list of prescribers who have approval to prescribe nicotine vaping products under the authorised prescriber scheme and their location. The authorised prescriber must consent for their details to be listed on the TGA website.

Special access scheme

The [special access scheme](#) allows an individual patient to access an unapproved product on a case-by-case basis. Prescribers (including prescribing health practitioners other than medical practitioners) can apply to the TGA for approval to prescribe nicotine vaping products through special access scheme Category B (SAS-B), subject to state or territory restrictions.^{14,35}

Pharmacists who dispense prescriptions for nicotine vaping products written under SAS-B should request a copy of the TGA approval.

See the [TGA website, Nicotine vaping products: information for prescribers](#) for further information.

Personal importation scheme

The [personal importation scheme](#)³⁶:

- allows patients to import nicotine vaping products directly from overseas (not through an Australian pharmacy) for their own personal use
- requires a valid prescription written by an Australian prescriber (TGA approval prior to writing the prescription is not required)
- enables importation of up to 3 months' supply at a time, and a maximum of 15 months supply in a 12 month period – if more than 3 months supply is required at one time, the prescriber will need to apply to the TGA to write a prescription under the authorised prescriber scheme or the special access scheme.

A copy of the prescription (scanned or photocopied) should be enclosed with the imported product to avoid the product being detained, seized or destroyed at the border.³⁶

The use of the personal importation scheme for nicotine vaping products is not recommended in prescribing guidelines because imported products for personal use are not required to meet the labelling and packaging requirements of TGO 110.

Advertising

Advertising prescription medicines to the general public is generally prohibited in Australia. However, pharmacies that stock nicotine vaping products to dispense on prescription may advertise that these products are available in their pharmacy. This advertising exemption is intended to allow people who have a prescription for nicotine vaping products to know where they can have the prescription filled.³⁷

See the [TGA website: Advertising nicotine vaping products to the Australian public](#) for specific details about acceptable and prohibited advertising of nicotine vaping products.

Use for smoking cessation

The evidence for use of nicotine vaping products for smoking cessation is inconclusive and there is a need for reliable, large-scale studies in this area.^{38,39} In 2020, the Health Research Board of Ireland concluded that nicotine vaping products were no more effective in assisting with smoking cessation than other therapies used for smoking cessation.⁴⁰ However, a Cochrane review concluded there was 'moderate-certainty' evidence that nicotine vaping products increase the rate of smoking cessation compared to using NRT.⁴¹ Research in this area is continuing.

Nicotine vaping products are not a first-line treatment to assist with smoking cessation. Nicotine vaping products in combination with ongoing behavioural support may be considered for patients who have not successfully stopped smoking using first-line pharmacotherapies combined with behavioural intervention and are still motivated to stop smoking.³

Scheduling nicotine vaping products as *Prescription Only* products aims to minimise the personal and public health risks associated with use of nicotine vaping products while maximising the benefits (increased opportunity to receive advice on their appropriate use and behavioural support from a health professional).³⁸ See [Safety considerations](#).

Consult the [Royal Australian College of General Practitioners](#) or the [Royal Australian and New Zealand College of Psychiatrists](#) guidelines for information about special considerations for use of nicotine vaping products in specific populations (e.g. patients with a chronic or mental illness, pregnant or breastfeeding women, adolescents, Aboriginal and Torres Strait Islander peoples).



Pharmacist's role in supplying nicotine vaping products

Dispensing

The standards and guidelines set out in the *Professional Practice Standards, version 5*,⁹ the Pharmacy Board of Australia's *Guidelines for dispensing of medicines*¹⁰ and the *Dispensing practice guidelines*⁴² must be followed when dispensing nicotine vaping products.

Accessing unapproved products

Patients who have a valid prescription written by an Australian prescriber may access unapproved nicotine vaping products through either the [personal importation scheme](#) or through a community pharmacy via the [authorised prescriber scheme](#) or [special access scheme](#), subject also to [state or territory legislation](#).³⁵

Pharmacies and pharmaceutical wholesalers can access unapproved nicotine vaping products and vaping devices from overseas suppliers. Pharmacies can hold stock of unapproved nicotine vaping products and vaping devices in anticipation of supply under the authorised prescriber scheme or special access scheme.

Pharmacies that order unapproved nicotine vaping products from overseas must confirm the imported products meet the requirements of TGO 110. Consider importing nicotine vaping products from countries with regulatory requirements that are similar to TGO 110 (e.g. UK, EU, Canada, US, NZ) and where there is evidence the imported product complies with the regulatory requirements of that country.

Safety considerations

Risks of using nicotine vaping products for the patient trying to stop smoking include³:

- unknown long-term health effects
- intentional and accidental poisoning
- acute nicotine toxicity, burns and lung injury
- unknown effects of dual use with continued smoking.

Public health risks associated with nicotine vaping products include³:

- intentional and accidental poisoning
- use by non-smokers acting as a gateway to tobacco use.

Nicotine vaping product ingredients

Nicotine vaping products contain nicotine in solution (either in salt or base form) and are designed to be vaporised and inhaled using a vaping device.¹² Nicotine in base form causes adverse effects (throat irritation) at relatively low concentrations (>20 mg/mL) and higher concentrations are diluted before use. See [Nicotine concentration and dilution](#). Nicotine salts combine base nicotine with an acid to reduce the pH and throat irritation of nicotine and to allow the nicotine to vaporise at lower temperatures.⁴³ Nicotine vaping products also contain carrier fluids (propylene glycol and glycerol).^{1,11}

Flavourings can be included in nicotine vaping products. Flavourings have not been assessed as being safe when inhaled. Different flavourings may have different safety profiles and ingredients. Diketone flavourings have been linked to the development of bronchiolitis. Unapproved nicotine vaping products must not contain any prohibited flavourings listed in [TGO 110](#).^{1,11}

Flavourings that are primarily designed to appeal to adolescents (or non-smokers) for non-therapeutic purposes (i.e. fruit or dessert flavours) should not be used in nicotine vaping products for smoking cessation purposes. Flavours should be avoided if possible. If a flavour is used, tobacco flavours are more appropriate.⁴⁴ If a prescription specifies a flavour other than tobacco, contact the prescriber to discuss the risks associated with use of flavours.

Contaminants

Known carcinogens have been found in nicotine vaping product aerosols. The extent to which nicotine vaping product use increases the risk of cancer is currently unknown.⁴⁵ The [TGO 110](#) recommends a maximum of 10 ppm for specified contaminants.¹¹ Pharmacists who are accessing unapproved nicotine vaping products from overseas suppliers are considered to be the sponsor of the product. As the sponsor of the product, pharmacists should ask the overseas supplier to supply information about¹¹:

- whether the contaminants specified in TGO 110 are present in their products
- the concentration of contaminants in their products
- methods of testing products for contaminants (including the device used for testing and the temperature the product was heated to).

Further information can be found in [Nicotine vaping products and vaping devices: Guidance for the Therapeutic Goods \(Standard for Nicotine Vaping Products\) \(TGO 110\) Order 2021 and related matters](#).



Vaping devices

Vaping devices are electronic devices used to heat nicotine vaping products to release an aerosol (mist or emission) for inhalation.¹¹ Vaping device designs vary, but they generally consist of a heating element or coil, a battery and a reservoir for the liquid (nicotine vaping product).⁴⁶

Different vaping devices deliver nicotine at different 'doses'. Devices with larger batteries or heating elements that heat the liquid to higher temperatures release more nicotine than those that heat the liquid to lower temperatures.⁴⁶

Vaping devices can be¹¹:

- open systems that have a refillable reservoir for the nicotine vaping product.
- closed systems
 - disposable devices, pre-filled with a vaping product that are disposed of when the battery runs out
 - non-refillable pods or cartridges, used with a rechargeable battery.

Prescribing guidelines recommend use of closed systems with non-refillable pods or cartridges rather than open systems (which increase the chance of inadvertent exposure by a person other than the patient) and disposable devices (which have adverse environmental consequences). Most closed system vaping devices contain nicotine salts.³

Most vaping devices are not regulated by the [TGO 110](#).

Nicotine concentration and dilution

The maximum concentration of nicotine vaping products that can be prescribed is 100 mg/mL. However, typical concentrations used for vaping are much lower (base nicotine concentrations typically do not exceed 18–20 mg/mL, concentrations up to 60 mg/mL of nicotine salts are used). Base nicotine >20 mg/mL must be diluted with diluents (e.g. propylene glycol, glycerol) prior to use.^{11,40} Nicotine vaping products that must be mixed or diluted prior to use in an open system vaping device are associated with a higher risk of poisoning and contamination.¹¹

At-home dilution of nicotine vaping products for use in open system vaping devices is not recommended due to the risk of³:

- errors in the dilution process
- poisoning from accidental exposure via ingestion, or absorption through skin or eyes
- addition of potentially toxic or illegal substances
- contamination.

Prescriptions for nicotine vaping products are likely to be for pre-filled cartridges or pods for use in a closed system vaping device.³ If a prescription is for a nicotine vaping product for an open system, contact the prescriber to discuss risk mitigation strategies (e.g. changing to a closed system device).

The evidence for starting concentrations of base nicotine for smoking cessation is limited. No studies have been performed to determine starting concentrations of nicotine salts for smoking cessation.³ The following are suggested reasonable starting concentrations for new users of nicotine vaping products.

Base nicotine³:

- 6–12 mg/mL for patients with low nicotine dependence.
- higher doses (18–20 mg/mL) may be needed for patients with high nicotine dependence.

Nicotine salts³:

- 18–30 mg/mL for patients with low nicotine dependence.
- higher doses (>30 mg/mL) may be needed for patients with high nicotine dependence.

Labelling

- Pharmacists must confirm the nicotine vaping product labelling follows the requirements set out in [TGO 110](#).¹²
- The dispensing label should include the information the patient needs to use the product safely and effectively.⁴⁷
- Inadvertent exposure to nicotine vaping products (ingestion or absorption through skin or mucus membranes) by a person other than the patient is a cause of poisoning. Cautionary advisory label 21 should be used for nicotine vaping products.⁴⁷ Include the words 'do not swallow' on the dispensing label.

Counselling

Pharmacists must provide patients with tailored information about the safe and effective use of nicotine vaping products. This information may include^{3,9,15,42,47,48}:

- how to use the vaping device (if supplied by the pharmacist) – some suppliers of vaping devices have instructions and/or videos about how to use the device
- avoiding smoking in combination with vaping – continued tobacco smoking while trying to stop smoking using nicotine vaping products can lead to increased nicotine dependence and/or cumulative cardiovascular adverse effects

- how much and how often to use the nicotine vaping product
 - the 'dose' of nicotine delivered from a nicotine vaping product and vaping device depends on the concentration of the nicotine vaping product, the device, and the inhalation technique
 - advise patients not to use the nicotine vaping product more often than they would usually smoke a cigarette. There is a risk of increased nicotine dependence if nicotine vaping products are used more frequently than a patient would usually smoke
- common adverse effects (e.g. cough, dry or irritated mouth and throat, nausea and headache)
- how to recognise signs and symptoms of nicotine overdose (e.g. nausea, vomiting, bradycardia, convulsions) – contact the Poisons Information Centre (13 11 26) if nicotine overdose is suspected
- duration of treatment – the long-term effects of nicotine vaping products are unknown, but may include respiratory and cardiovascular adverse effects. Nicotine vaping products should only be used short term for smoking cessation. Prescribing guidelines recommend a maximum treatment duration of 12 months. However, there may be instances where the prescriber and patient agree that longer-term use of a nicotine vaping product is needed to avoid relapse to tobacco use
- how to manage potential interactions with other medicines (discuss dose adjustment with prescriber) or caffeine (reduce caffeine intake by half when stopping tobacco smoking)
- how to store and dispose of the medicine and device, if applicable (see Safe storage and Safe disposal)
- availability of behavioural support and follow up.

Advise patients that unapproved nicotine vaping products have not been assessed by the TGA for their quality, safety or efficacy.

Pharmacists should reinforce the vaping cessation plan agreed to between the patient and prescriber. This may include weaning or ceasing the nicotine vaping product after 12 weeks of use or transition to NRT. If the patient is continuing to use nicotine vaping products for longer than the plan agreed to between the patient and prescriber, the pharmacist should confirm any changes to the vaping cessation plan with the prescriber and patient. Offer behavioural support (brief advice tailored to vaping cessation and referral to Quitline for multi-session behavioural intervention).

Adverse events experienced with the use of nicotine vaping products can be reported to the TGA.⁴⁹ This can be done online at: www.tga.gov.au/reporting-problems. The TGA will investigate significant safety concerns associated with the use of unapproved nicotine vaping products. Deficiencies or defects of nicotine vaping products that are believed to have occurred during the manufacture, storage or handling of these products should also be reported to the TGA.¹¹

Safe storage

Deaths have occurred in children who have inadvertently accessed and then consumed nicotine vaping products.¹ Nicotine is also rapidly absorbed through the skin. Advise patients to^{11,50}:

- keep nicotine vaping products and vaping devices in a place where children cannot see or reach them
- lock products away when they are not being used
- avoid using or discarding nicotine vaping products or vaping devices in front of children
- call 000 if inadvertent exposure or ingestion of nicotine vaping products has occurred in a child (or in an adult who is experiencing symptoms suggesting nicotine overdose)
- contact the Poisons Information Centre (13 11 26) and seek urgent medical assistance if inadvertent exposure or ingestion of nicotine vaping products has occurred in an adult.

Provide advice to patients about the child-resistant closure requirements for nicotine vaping products if they are importing nicotine vaping products using the [personal importation scheme](#).

Safe disposal

Nicotine vaping products and vaping devices are hazardous waste.

Open systems

Advise patients to return any unused nicotine vaping products (and empty nicotine vaping product containers that may contain residual nicotine) to the pharmacy for appropriate disposal through the return of unwanted medicines (RUM) program. Advise patients to switch vaping devices 'off' and remove rechargeable batteries prior to disposing in the household rubbish. Rechargeable batteries can be disposed of according to local council recommendations.

Closed systems

Contact your local council for information about disposal of household quantities of closed system 'disposable' vaping devices. If the waste must be stored prior to disposal, advise patients to store it securely and out of reach of children.

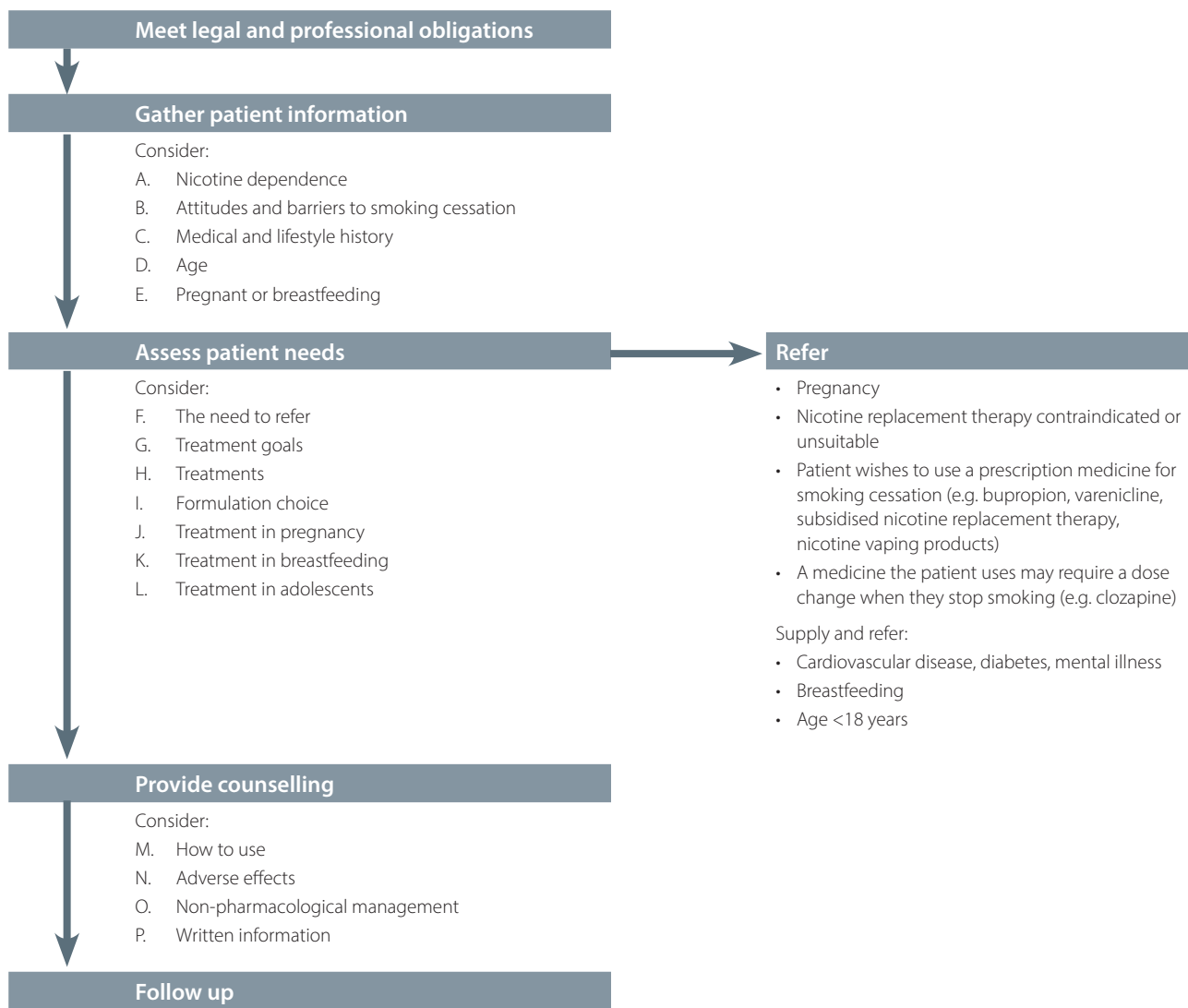
See [Vaping devices](#) for information about open and closed systems.

Compounding

Pharmacists can extemporaneously compound nicotine vaping products. When compounding nicotine vaping products, pharmacists must follow compounding standards and guidelines outlined in the *Professional Practice Standards*⁹, the Pharmacy Board of Australia's *Guidelines on compounding of medicines*,⁵¹ and the *Good compounding practice* chapter of *Australian Pharmaceutical Formulary and Handbook*.⁴⁷

Each nicotine vaping product that is extemporaneously compounded must meet the labelling, packaging, ingredient and record keeping requirements outlined in the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*.^{5,11,12}

Appendix 1: Non-prescription medicine treatment guideline: nicotine replacement therapy for smoking cessation



Meet legal and professional obligations

Obligations in relation to supply of a non-prescription medicine include^{8,9}:

- recommending treatment that is safe for the patient and appropriate for their needs (including when requested through a third party)
- complying with all appropriate standards, codes, guidelines and regulatory requirements
- respecting the patient's privacy and maintaining confidentiality
- counselling the patient (or the third party) on correct use of the medicine
- referring the patient to other health practitioners if necessary

- documenting the supply (or refusal), and associated referral and counselling, in accordance with relevant legislation and professional responsibilities
- following up patients at risk.

The *Code of Ethics for Pharmacists*⁸ provides guidance on the ethical framework for delivery of health services. The health and wellbeing of the patient is a pharmacist's first priority.

The *Professional Practice Standards (PPS)*⁹ recommend that pharmacists follow a systematic process for gathering patient information, assessing the nature and severity of the patient's condition(s), and providing potential solutions and reasons for referral.

Gather patient information

Ask the patient (or third party) about their nicotine dependence, tobacco smoking history, previous smoking cessation attempts, medical and lifestyle history, age, pregnancy or breastfeeding status, and current medicines.

Gather sufficient information to assess the safety and appropriateness of a medicine for the patient. If the third party cannot provide sufficient information, the patient may need to be contacted. Consider alternative sources of information (e.g. the patient's My Health Record), as applicable.

A. Nicotine dependence

Nicotine dependence is likely if a patient smokes within 30 minutes of waking, smokes more than 10 cigarettes a day and has a history of withdrawal symptoms with previous attempts to stop smoking.³

Assess the patient's nicotine dependence by asking³:

- How soon after waking do you have your first cigarette?
- Have you had cravings for a cigarette, urges to smoke or withdrawal symptoms if you have tried to stop smoking?
- How many cigarettes do you smoke each day?

Symptoms of nicotine withdrawal include³:

- cravings for nicotine
- anxiety
- depressed mood
- insomnia
- irritability, frustration, anger
- difficulty concentrating
- restlessness
- increased appetite.

B. Attitudes and barriers to smoking cessation

Identify and consider the patient's individual attitudes about smoking cessation and barriers they may be facing or have faced in previous attempts to stop smoking.³

Beliefs or attitudes that can prevent an attempt at, or affect the success of, smoking cessation include³:

- I'm not addicted.
- I don't need help to stop smoking.
- I'm too addicted.
- I won't benefit from stopping smoking.
- I don't have enough willpower to stop.
- I need cigarettes to help me relax.
- I will put on weight if I stop smoking.
- I won't be able to spend time with my friends who smoke.

See [O. Non-pharmacological management](#) for strategies to address the patient's attitudes or barriers.

C. Medical and lifestyle history

Medical conditions that can complicate smoking cessation interventions include³:

- smoking-related diseases (e.g. cardiovascular disease, respiratory disease)
- diabetes
- mental illness (see [O. Non-pharmacological management](#))
- pregnancy (see [J. Treatment in pregnancy](#)).

See F. The need to refer.

The patient's history of hypersensitivity or adverse reactions to medicines or excipients, and other medicines they are using will influence treatment choice (see F. The need to refer and [I. Formulation choice](#)).

Impact of smoking cessation on medicines

- Tobacco smoking induces cytochrome P450 isoenzymes, primarily 1A2 (CYP1A2), which can decrease levels of drugs that are metabolised by CYP1A2.
- Smoking cessation can therefore increase levels of drugs metabolised by CYP1A2 if the same dose regimen is maintained. For medicines metabolised by CYP1A2 that have a wide therapeutic index, the impact of smoking cessation may not be clinically significant. However, for medicines metabolised by CYP1A2 that have a narrow therapeutic index (e.g. clozapine), monitoring and dose adjustment may be required (see F. The need to refer).
- Caffeine is metabolised by CYP1A2 – intake should be reduced by half when stopping smoking. Maintaining pre-cessation levels of caffeine consumption may result in anxiety, restlessness and insomnia.
- Nicotine (in nicotine replacement therapy (NRT) or nicotine vaping products) has no effect on CYP1A2 activity.
- Nicotine may activate the sympathetic nervous system and oppose the effects of some medicines (e.g. blood pressure and heart rate-lowering effects of beta-blockers).^{3,29}

D. Age

The patient's age will influence treatment choice. See [L. Treatment in adolescents](#).

E. Pregnant or breastfeeding

The patient's pregnancy or breastfeeding status will influence treatment choice. See F. The need to refer, [J. Treatment in pregnancy](#) and [K. Treatment in breastfeeding](#).

Assess patient needs

F. The need to refer

Refer the patient to a medical practitioner in the following circumstances^{3,31}:

- Pregnancy (see [J. Treatment in pregnancy](#)).
- NRT contraindicated or unsuitable (see H. Treatments and [I. Formulation choice](#)).
- Patient wishes to use a prescription medicine for smoking cessation (e.g. bupropion, varenicline, subsidised NRT, nicotine vaping products).

- A medicine the patient uses may require a dose change when they stop smoking (e.g. clozapine – see C. Medical and lifestyle history).

Supply NRT and refer the patient to a medical practitioner in the following circumstances:

- Smoking-related diseases (e.g. cardiovascular disease, respiratory disease) – NRT can be used in stable cardiovascular disease, but patients may need additional support. Smoking cessation should be integrated into chronic disease management programs in conjunction with non-pharmacological management (see [O. Non-pharmacological management](#)).
- Diabetes – patients who have diabetes and who smoke may have poor glycaemic control. NRT can be used, but patients may need additional support. Additional blood glucose monitoring may be required when these patients cease smoking. Smoking cessation should be integrated into the patient's diabetes management program.
- Mental illness – NRT can be used, but patients may need additional support (see [O. Non-pharmacological management](#)).
- Breastfeeding (see [K. Treatment in breastfeeding](#)).
- Age <18 years (see [L. Treatment in adolescents](#)).

G. Treatment goals

- Reduce cravings and symptoms of nicotine withdrawal.³
- Aid long-term smoking cessation.

H. Treatments

NRT is the only non-prescription pharmacological treatment for smoking cessation. NRT is available in the following dosage forms³¹:

- transdermal patch
- gum
- inhaler (also known as inhalator)
- lozenge
- oral spray (also known as mouth spray).

NRT is safer than smoking, has low addictive potential and can be recommended to people with nicotine dependence who express interest in stopping smoking (see F. The need to refer and [J. Treatment in pregnancy](#)). NRT is contraindicated in children <12 years.³¹

Medicines to support smoking cessation available on prescription include varenicline, bupropion, nortriptyline, clonidine and nicotine vaping products. *The Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* sets out the safety and quality requirements for nicotine vaping products that are not registered in the Australian Register of Therapeutic Goods.¹²

There is limited evidence that complementary therapies, such as hypnotherapy and acupuncture, are effective for smoking cessation and they are not recommended in practice guidelines.³ However, individual patients may report success with these methods. There is no wrong way for a person to stop smoking.

Table 3. Nicotine replacement therapy

Formulation	Advantages	Disadvantages	Precautions
Long acting – maintains steady-state nicotine levels to reduce withdrawal symptoms			
Patch	<ul style="list-style-type: none"> • May be tolerated better than gum and easier to use • Once-daily application 	Dose adjustment is less flexible and may require different strength patch or multiple patches	Avoid in skin disorders (e.g. psoriasis, dermatitis)
Faster acting – flexible dosing that can be adjusted to reduce breakthrough cravings			
Gum	<ul style="list-style-type: none"> • Can be cut into smaller pieces or alternated with ordinary chewing gum to reduce dose • Different flavours available 	<ul style="list-style-type: none"> • Takes time to begin to relieve cravings; advise patients to use in anticipation of a trigger • Contains sorbitol; excess consumption may have a laxative effect 	Avoid in people with dentures, complicated dental work, oral/pharyngeal inflammation
Inhaler	Helpful for those who miss hand-to-mouth action of smoking	Takes time to begin to relieve cravings; advise patients to use in anticipation of a trigger	<ul style="list-style-type: none"> • Avoid in people with chronic throat disease, asthma, oral/pharyngeal inflammation • Contraindicated in patients with menthol hypersensitivity
Lozenge	<ul style="list-style-type: none"> • Different flavours available • Sugar free – suitable for patients with diabetes 	Takes time to begin to relieve cravings; advise patients to use in anticipation of a trigger	<ul style="list-style-type: none"> • Avoid in people with oral/pharyngeal inflammation • Contraindicated in patients with phenylketonuria
Oral spray	<ul style="list-style-type: none"> • Fastest acting of all of the faster-acting formulations • Can be used discreetly if patients are concerned about people knowing they are using NRT 	Contains alcohol	Avoid in people with oral/pharyngeal inflammation

References: Royal Australian College of General Practitioners³; eMIMS³¹; Quit Victoria^{53,54}

I. Formulation choice

- The choice of NRT depends on the level of nicotine dependence, the person's preference and the suitability of individual formulations.³ See [Table 3. Nicotine replacement therapy](#).
- All forms of NRT (at equivalent doses) have similar effectiveness in achieving long-term smoking cessation.^{3,52}
- Combination NRT (long-acting patch plus a faster-acting form) is safe and is more effective than NRT monotherapy.^{3,52} See M. How to use.
- The greatest benefit is seen when NRT (either combination therapy or monotherapy) is combined with regular counselling and support (e.g. Quitline).³ See O. Non-pharmacological management.

Using NRT before stopping smoking

Using a patch or a faster-acting NRT before stopping smoking completely can increase the chance of success. However, further research is needed.^{3,52} Options include³:

- using the highest-strength patch for 2 weeks before stopping smoking, then continuing the patch and adding faster-acting NRT
- replacing some cigarettes with faster-acting NRT to reduce the number of cigarettes smoked each day.

J. Treatment in pregnancy

- There is no safe level of smoking in pregnancy. Continued smoking during pregnancy leads to harmful effects for both the mother and fetus and pregnancy complications. Complete cessation of smoking (rather than simply cutting down) is recommended.³
- NRT is pregnancy category D.³¹
- Non-pharmacological smoking cessation strategies should be tried first (see O. Non-pharmacological management). If these are unsuccessful, refer the patient to a medical practitioner (see [F. The need to refer](#)).
- Faster-acting forms of NRT are preferred.³
- Advise partners of pregnant women to avoid smoking around them, and to encourage cessation.³

K. Treatment in breastfeeding

- Non-pharmacological strategies are preferred. NRT is considered safer than continuing to smoke.
- Minimise nicotine in breast milk by using a faster-acting form and breastfeeding just before using NRT.
- If unable to stop smoking completely, women should be encouraged to continue breastfeeding and use strategies to minimise potential harm to the child caused by second-hand smoke.^{3,31}

L. Treatment in adolescents

- The evidence of effectiveness of smoking cessation programs and pharmacological interventions for adolescents who smoke is limited.
- Interventions generally focus on preventing adolescents starting to smoke.

- NRT can be used by patients ≥ 12 years, but is more likely to be successful if combined with intensive, multi-session behavioural support. Referral to a medical practitioner is recommended (see [F. The need to refer](#) and O. Non-pharmacological management).^{3,31}

Provide counselling

M. How to use

See individual product information for how to use the different formulations of NRT. Australian guidelines recommend the following initial NRT doses^{3,55}:

- Smokes within 30 minutes of waking and smokes > 10 cigarettes a day
 - highest-strength patch + highest-strength gum OR highest-strength lozenge OR 1 mg oral spray OR 15 mg inhaler
- Smokes within 30 minutes of waking and smokes ≤ 10 cigarettes a day OR smokes more than 30 minutes after waking and smokes > 10 cigarettes a day
 - highest-strength patch + lowest-strength gum OR lowest-strength lozenge OR 1 mg oral spray OR 15 mg inhaler
- Smokes more than 30 minutes after waking and smokes ≤ 10 cigarettes a day
 - lowest-strength gum OR lowest-strength lozenge OR 1 mg oral spray OR 15 mg inhaler.

Titrate the dose according to the patient's withdrawal symptoms. Underdosing can undermine a patient's confidence in treatment. Patients with high nicotine dependence may benefit from use of two patches at the same time (see [A. Nicotine dependence](#)). However, the evidence supporting the use of two patches is inconclusive.^{3,52}

Tapering the dose of NRT at the completion of a course of treatment does not influence successful long-term smoking cessation. Patients who have successfully stopped smoking after an initial 8-week course of NRT should consider a follow-up course followed by abrupt cessation, rather than tapering the dose. The optimal duration of NRT has not been established.^{3,52}

Food and drink can reduce buccal absorption of nicotine. Avoid acidic beverages (e.g. coffee, soft drinks) for 15 minutes before use of sublingual/buccal NRT formulations, and avoid eating or drinking while using sublingual/buccal NRT formulations.³¹

N. Adverse effects

- Adverse effects of NRT are usually minor and transient, and some may be related to smoking cessation (e.g. sleep disturbance, dizziness, weight gain, headache).³¹ See O. Non-pharmacological management.
- Signs of nicotine overdose include nausea, vomiting, bradycardia and convulsions.^{31,56}
- NRT is intended for transdermal or sublingual/buccal absorption. Swallowed nicotine may exacerbate symptoms of oesophagitis, gastritis and gastric ulcers.³¹

Table 4. Adverse effects of NRT

Formulation	Adverse effects	Mitigation strategies
Patch	Application-site skin reactions	Rotate application site daily
	Vivid dreams	Remove patches at night
	Patch adhesive not sticking	Use adhesive skin tape to provide extra adhesion
Gum, inhaler, lozenge, oral spray	Throat or mouth irritation, hiccups, cough (may be a result of swallowed nicotine)	Check and correct any problems with using the formulation. If adverse effects persist, consider alternative formulation

References: Royal Australian College of General Practitioners³; eMIMS⁵¹; Quit Victoria⁵⁷

O. Non-pharmacological management

Provide all patients with behavioural strategies to assist them to stop smoking. Successful long-term smoking cessation is more likely if NRT is combined with evidence-based, multi-session behavioural intervention. Patients can also be referred to Quitline or apps, such as My QuitBuddy, for ongoing support. Best practice smoking cessation support (including both pharmacotherapy and multi-session behavioural intervention) is especially important for achieving long-term smoking cessation in patients with a mental illness.^{3,58}

Address barriers to smoking cessation

- Consider the patient's individual barriers, motivation, confidence and previous attempts to stop smoking. Discuss what strategies have been helpful in past attempts and what could be done differently.
- Explain success rates with and without assistance (3–5% successfully stop smoking without assistance; rates are substantially higher with assistance) and encourage use of the assistance that is available (e.g. pharmacotherapy together with counselling services).
- Discuss the health and financial benefits of smoking cessation specifically for the person. The Quitline website has useful information about the benefits of smoking cessation that can be tailored for the patient.
- Discuss the health implications of continuing to smoke (e.g. chronic obstructive pulmonary disease).
- Provide information about relaxation techniques (e.g. mindfulness, meditation, breathing exercises).
- Discuss strategies to minimise weight gain (e.g. healthy eating, exercise) and advise that the health benefits of stopping smoking outweigh the risks of weight gain.
- Suggest avoidance of high-risk social situations when first stopping smoking and practising ways of saying no when a cigarette is offered.^{3,58,59}

Behavioural strategies

- Write a list of reasons that you want to stop smoking and things you will look forward to as a non-smoker.
- Make a plan and set a date to stop smoking. Decide what support options will work best for you.
- Tell family and friends of the plan to stop smoking, and explain how they can help (e.g. stopping together, not offering a cigarette).
- Practise stopping (e.g. experiment with not smoking at usual times, make home and car smoke-free, stop carrying a lighter).
- Identify situations and triggers that make you want to smoke (e.g. coffee, alcohol, friends who smoke), and plan for these.
- Prepare for healthy eating (e.g. buy healthy snacks before stopping day).
- Reduce coffee and tea intake by half when you first stop smoking, to prevent caffeine-induced anxiety and restlessness. See [Impact of smoking cessation on medicines](#).
- The '4Ds' can help to deal with cravings
 - Delay acting on the urge to smoke for at least 5 minutes (the urge will pass).
 - Deep breathe, slowly and deeply.
 - Drink water, to take time out; sip slowly.
 - Do something else, to keep your hands busy.
- Exercise every day. This will help to reduce stress and reduce weight gain.
- Reward yourself with the money that has been saved.
- If you have a cigarette, it does not mean the attempt has failed. Keep trying to stop smoking. Remind yourself of all the times you have resisted the urge to have a cigarette, follow the '4Ds' and adjust your stop smoking plan.^{3,59}

Quitline

Refer patients to Quitline for free evidence-based, multi-session behavioural intervention. Quitline counsellors assess the patient's smoking history and use motivational interviewing to help them develop a plan to stop smoking. There are tailored programs for people living with a mental illness, pregnant women and young people. There is also an Aboriginal and Torres Strait Islander Quitline service.⁵⁸

Pharmacists can refer patients to Quitline directly by submitting a secure, online referral. See quit.org.au for details of local Quitline services. Alternatively, patients can contact Quitline by phone on 13 78 48.⁵⁸

P. Written information

- Provide the patient with *Smoking, Nicotine Replacement Therapy* and *Staying a Non-smoker Self Care Fact Cards* or other consumer information.
- Quitline can provide patient brochures, the *Quit Because You Can* booklet and appointment cards.⁵⁸ Quit resources can be ordered from quit.org.au/resource-order-form.

Follow up

Planned follow-up increases cessation rates. Suggest that patients return for follow-up within 1 week of the stop smoking date and for additional planned follow-up visits to review progress.³ Invite the patient (directly or through the third party) to contact the pharmacy if they have any questions about NRT or the advice provided.

Advise the patient to return to the pharmacy or consult a doctor if they experience:

- adverse effects from treatment
- inadequate response to treatment.

If relapse occurs, offer support and encourage further attempts. Acknowledge that it often takes numerous attempts to stop smoking.

Patient follow-up supports ongoing patient relationships, quality use of medicines and collaboration between healthcare providers. Follow-up is facilitated by documentation of non-prescription medicine consultations. Documentation is especially important for:

- patients with an established relationship with the pharmacy
- patients who make repeated requests involving the same condition
- patients who are at high risk of adverse events
- supply and refer situations.

Record supply of any medicine, and details of referral and counselling information provided, according to relevant legislation and professional responsibilities.⁹

Appendix 2: Historical access to nicotine vaping products

Prior to 1 October 2021, nicotine vaping products were imported from overseas (in most cases without a prescription from a medical practitioner). Prior to the October 2021 change to legislation, Australian Border Force did not have powers to intercept these products at the border. See [Personal importation scheme](#).

Appendix 3: Carbon monoxide monitors in smoking cessation

Carbon monoxide monitors measure carbon monoxide (CO) levels in a person's body via a breath test and provide an indirect measure of the person's blood levels of CO.⁶⁰ They can indicate the level of tobacco smoking.⁶¹ CO monitors can provide CO readings for both people who smoke and passive smokers.⁶⁰

In addition to tobacco smoking, CO exposure may come from vehicle exhaust fumes, leaking of a faulty gas appliance, or workplace exposure. A person's CO levels will rarely be zero.^{60,61} People who smoke are exposed to much higher CO concentrations. CO is absorbed through the lungs into the bloodstream, and increases the risk of cardiovascular conditions such as heart attack, stroke and deep vein thrombosis. CO may remain in the body for 24–48 hours.⁶⁰

CO monitoring can help to engage and motivate patients and monitor progress during a patient's smoking cessation journey.^{60,62}

Infection control is a key consideration when using CO monitors as part of smoking cessation support. Documented procedures for cleaning CO monitors and equipment between patients must be developed and followed.⁹

Appendix 4: Patient handout – Nicotine vaping products



Nicotine vaping products

This fact sheet contains information for patients, families and carers about the use of nicotine vaping products

Nicotine vaping products contain liquid nicotine. Liquid nicotine is often referred to as vape liquid, e-liquid and ejuice. Liquid nicotine is inhaled using a vaping device. Nicotine vaping products may help some people to stop smoking tobacco. In Australia, most medicines and other therapeutic goods have been approved by the Therapeutic Goods Administration (TGA). However, your nicotine vaping product may not be approved by the TGA. It may be an unapproved therapeutic good.

What are unapproved nicotine vaping products?

Unapproved nicotine vaping products have not been assessed by the TGA for quality, safety or effectiveness. This means you cannot be sure about the safety and effects of unapproved vaping products. Ask your doctor or pharmacist for advice. You can help the TGA to monitor the safety of unapproved vaping products by reporting any side effects or problems you have to:

- the TGA at www.tga.gov.au/reporting-problems
- your doctor or pharmacist.

Why do I need a prescription?

The TGA has strengthened the regulation of nicotine vaping products to minimise the risk of harm from nicotine vaping. You need a prescription from an Australian-registered prescriber (e.g. medical practitioner (doctor), nurse practitioner, midwife) to access nicotine vaping products, even if you order them over the internet from an overseas supplier. Possession and use of nicotine vaping products without a prescription is illegal.

Are there any side effects?

Common side effects of nicotine vaping products include:

- cough
- throat irritation
- nausea and vomiting
- headache
- dizziness

Cautions with nicotine vaping

- There is no proof that any nicotine vaping products are safe to use.
- Aerosol from vaping may cause harm to non-smokers.
- Liquid nicotine can cause serious harms if misused, swallowed or absorbed through the skin.
- Nicotine vaping can lead non-smokers into tobacco smoking.

Ask your doctor or pharmacist how to reduce the risks of harm from nicotine vaping.

Your vaping product may cause harm to others

- Don't vape in front of children
- Never share your nicotine vaping product with another person
- Keep your nicotine vaping product and vaping device in a secure place to prevent others using them
- Keep your nicotine vaping product and vaping device out of reach of children and pets
- Take expired, left over or empty nicotine vaping products and devices to a pharmacy for safe disposal.

Ask your doctor or pharmacist for advice if you think you have any side effects from your nicotine vaping product.

If you suspect a person has swallowed, or come into direct skin or eye contact with liquid nicotine:

- phone **000** for an ambulance
- phone Poisons Information Centre 24/7 hotline on **13 11 26** for advice

Swallowed liquid nicotine can be life-threatening, especially in children.

Where can I find more information?

Nicotine vaping products: information for consumers: www.tga.gov.au/nicotine-vaping-products-information-consumers

Quitline: **13 78 48** or www.quit.org.au

Appendix 5: Patient support tools

- *Nicotine vaping products: information for consumers* provides information for patients about nicotine vaping products and how to access these: www.tga.gov.au/nicotine-vaping-products-information-consumers
- *Quitline*: ph 13 78 48, provides free multi-session behavioural interventions and Aboriginal Quitline
- *My Quitbuddy* app
- *Quit Now* app
- *QuitCoach* provides advice on developing a personalised quit plan: www.quitcoach.org.au/
- *iCanQuit* provides information and advice to help with quitting smoking: www.icanquit.com.au/
- *QuitTxt* is an SMS program that sends text messages to patients to support them while stopping smoking: www.quitcoach.org.au/QuitTextInformation.aspx
- Local stop smoking programs may also be provided in some areas by hospitals, Aboriginal and Torres Strait Islander Health Services and community health facilities.

Appendix 6: Further information

- *Nicotine vaping products* provides information from the TGA on accessing nicotine vaping products and the regulations surrounding these, and contains links to information for patients, prescribers and pharmacists. Available at: www.tga.gov.au/nicotine-vaping-products
- *Nicotine vaping products: information for pharmacists* provides information from the TGA about nicotine vaping products relevant to pharmacists. Available at: www.tga.gov.au/nicotine-vaping-products-information-pharmacists
- *Nicotine vaping products: information for prescribers* provides information from the TGA about prescribing nicotine vaping products. Available at: www.tga.gov.au/nicotine-vaping-products-information-prescribers
- *Nicotine vaping products and vaping devices: frequently asked questions* provides answers to common questions about nicotine vaping products and how to access them in Australia. Available at: www.tga.gov.au/nicotine-vaping-products-frequently-asked-questions
- *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* outlines the minimum safety and quality standards for unregistered nicotine vaping products, particularly in relation to ingredients, nicotine concentration, labelling requirements and record keeping. Available at: www.legislation.gov.au/Details/F2021L00595
- *Supporting smoking cessation: A guide for health professionals* from the RACGP provides guidance for primary care health professionals on smoking cessation, including strategies to provide stop smoking advice, treatments available and their place in therapy. Available at: www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation
- *Quitline* has various resources for health professionals, including a table on drug interactions with smoking, resources for the workplace and patient resources. Available at: www.quit.org.au/resources/general-practice/resources-general-practitioners/
- *NPS Medicinewise* provides resources for health professionals about how to access nicotine vaping products in Australia. Available at: www.nps.org.au/professionals/prescribing-nicotine

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