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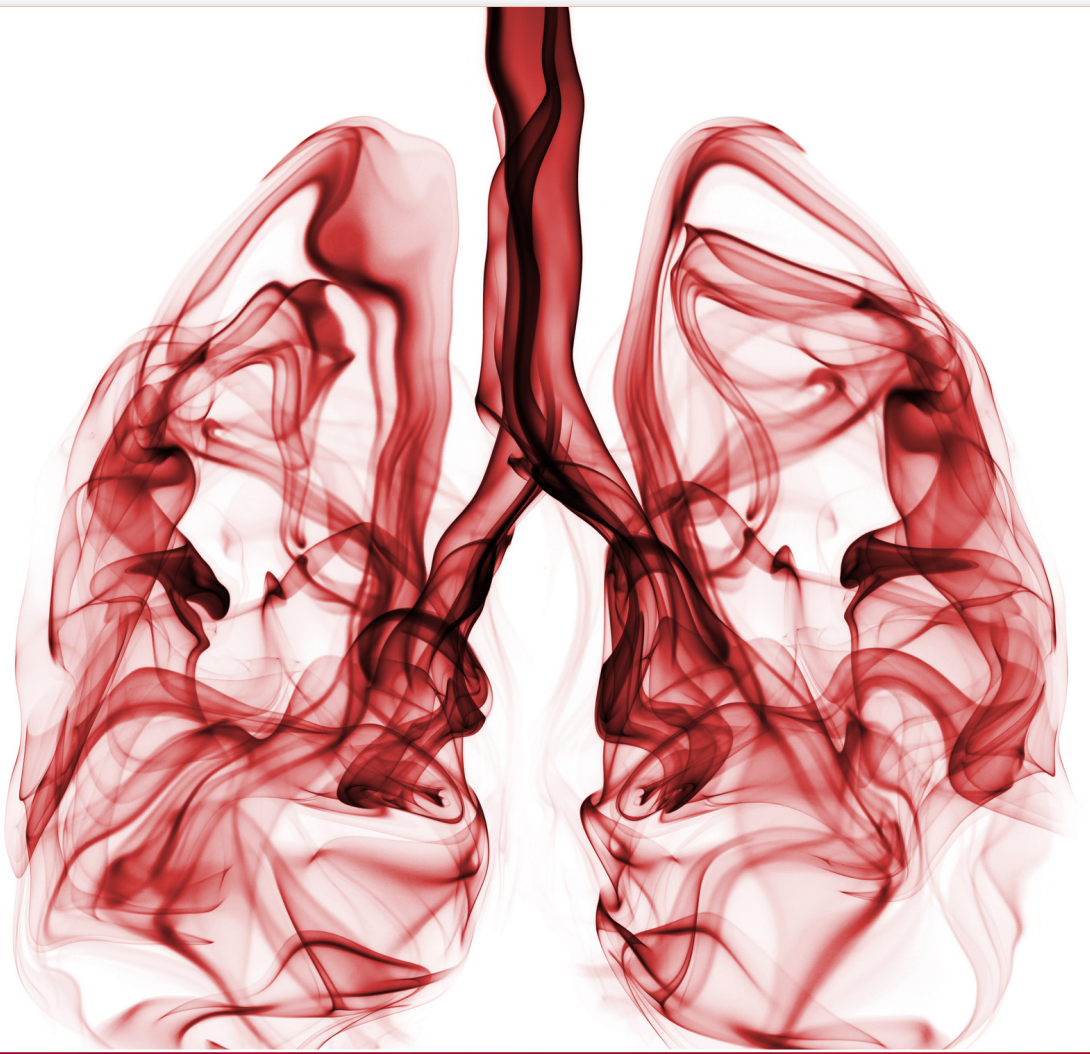

# Professional practice guidelines for pharmacists

# Nicotine dependence support

*PSA Connecting pharmacists*

# Acknowledgements

The development of the *Professional practice guidelines for pharmacists: nicotine dependence support* has been funded by the Australian Government Department of Health and Aged Care. The information and views in this document do not necessarily represent or reflect the views of the Australian Government Department of Health and Aged Care.

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

The Pharmaceutical Society of Australia thanks all those involved in the review process and gratefully acknowledges the contribution of the following individuals and organisations.

## Project Advisory Group 2024

- **Emma Dean**, Quit Centre
- **Nicholas Elmitt**, Australian Medical Association
- **Serena Hossain**, Royal Australian and New Zealand College of Psychiatrists
- **Jennifer Kyi**, Quit Centre
- **Alice Nugent**, National Aboriginal Community Controlled Health Organisation
- **Hester Wilson**, Royal Australian College of General Practitioners
- **Nick Yim**, Australian Medical Association
- Representatives for the Australian Government Department of Health and Aged Care

## PSA Project Team

- Claire Antrobus
- Chris Campbell
- Ness Clancy
- Tara Edmonds
- Nikita Grant
- Jarrod McMaugh
- Nena Nikolic
- Jacob Warner

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ISBN: 978-0-6486003-5-0

Date of Publication: September 2024, updated December 2025

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# Contents

# Executive summary

Tobacco smoking remains a leading cause of preventable death and disability in Australia, contributing significantly to diseases such as cancer (especially lung cancer), chronic obstructive pulmonary disease (COPD) and cardiovascular disease.[1,2] Nicotine-containing vapes have been used by people who have never smoked cigarettes.[1,2] Use of nicotine-containing vapes by never smokers can lead to nicotine dependence.[2] Nicotine dependence can be a chronic, relapsing condition.[3] Advice from pharmacists to patients about stopping smoking helps people to stop.[4]

These guidelines are applicable to all practice settings in which pharmacists provide nicotine dependence support, including providing medicines available without a prescription. These guidelines focus on the management of nicotine dependence that may have developed as a result of smoking or vaping.

Providing support to a patient with nicotine dependence can vary based on the service delivery model of the pharmacy or health service and the education and training of the pharmacy or health service staff. Regardless of the service delivery model of the pharmacy or health service, pharmacists should offer brief advice to all people who smoke or vape.

When providing nicotine dependence support consultations, pharmacists should establish the patient's needs and work with the patient to consider all options to develop the most appropriate management plan. Management plans should be tailored to the patient and their individual needs.

First-line pharmacotherapy options for smoking cessation include nicotine replacement therapy (NRT), bupropion and varenicline.[3] Pharmacotherapy for smoking cessation can also be considered to manage nicotine dependence from vaping.[5] Therapeutic vaping goods are not first-line pharmacotherapy for smoking or vaping cessation.[3]

Storing, prescribing, dispensing and compounding unapproved therapeutic vaping goods involves additional considerations relating to compliance with applicable legislation and access to therapeutic vaping substances and vaping devices. See **Pharmacist role and requirements in providing nicotine dependence support**.

References to legislation included in this document are current at the time of publishing.

# About the guidelines

## Purpose

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

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

These guidelines are not definitive statements of correct procedure. They are intended to provide advice and guidance to assist pharmacists to:

- meet their professional responsibilities
- exercise professional judgement in individual circumstances
- manage risks associated with providing nicotine dependence support.

Clinical guidance specific to providing nicotine dependence support is covered in **Appendix 1 Treatment guidelines for pharmacists: nicotine dependence**.

It is important that pharmacists read these guidelines in conjunction with relevant professional practice standards[6], particularly those mentioned in Table 1 (see next page).

## Relationship between the guidelines and professional practice standards

Professional practice standards are objective statements of the minimum performance expectations of professional behaviour of all pharmacists in Australia. Standards relate to the systems pharmacists should have in place for the delivery of a service and provide a benchmark against which performance can be assessed.

These guidelines provide practical guidance to support pharmacists to provide nicotine dependence support and meet the relevant standards (see Table 1. Professional practice standards relevant to providing nicotine dependence support). The health setting and context in which nicotine dependence support occurs will influence how the guidelines are applied to practice.

See Figure 1 for information about the relationship between documents that articulate, govern and guide pharmacist practice.

**Figure 1. Guidance and regulation of pharmacist practice in Australia**

## Table 1. Professional practice standards relevant to providing nicotine dependence support

| Domains | Standards | How the standard relates to the service or professional activity |
|---|---|---|
| FUNDAMENTAL | Person-centred care | Standards in the fundamental domain always apply to all aspects of a specific service or professional activity a pharmacist delivers |
| | Responsibility and accountability | |
| | Collaborative practice | |
| SERVICE DELIVERY | Service delivery | Develop and follow systematic procedures to maintain consistency and quality |
| PATIENT ASSESSMENT | Patient assessment | Identify the patient and assess their needs |
| PRESCRIBING | Prescribing | Decide to prescribe a medicine |
| DISPENSING AND PREPARATION | Dispensing | Dispense a medicine |
| | Compounding | Compound a medicine |
| | Medicine packing | |
| | Safe and secure handling of therapeutic goods | Store and dispose of the medicine |
| ADMINISTRATION | Administration of a medicine | |
| REVIEW AND MONITORING | Medication review | |
| | Medicine use evaluation | |
| | Patient monitoring | Review and monitor the patient and the prescribing decision |
| PROVIDING HEALTH INFORMATION | Providing health information (patient counselling) | Provide information about the medicine and smoking and/or vaping cessation |
| PUBLIC HEALTH | Screening, case-finding and risk assessment | Identify patients at risk of, or who may have, an undiagnosed health condition related to smoking or vaping |
| | Health promotion | Promote smoking and vaping cessation |

# Structure of the guidelines

These guidelines highlight relevant professional practice standards followed by a description of practical actions that contribute to the achievement of the standard (See Figure 2).

In this way, the guidelines can be viewed as a 'how to' guide for providing nicotine dependence support according to the relevant standards.

**Figure 2. Structure of the guidelines**

*Standard Statement*

**Background**

Information or statement to describe how the guidelines relate to the standard.

**Actions required**

A practical description of relevant tasks.

While not specifically referred to in the body of these guidelines, the fundamental standards (Person-centred care, Responsibility and accountability, Collaborative practice) apply to all aspects of pharmacy practice, and pharmacists can refer to the professional practice standards for actions required to meet these fundamental standards. The principles of the fundamental standards are included within the relevant actions listed in these guidelines.

# Scope of these guidelines

These guidelines are applicable to all practice settings in which pharmacists provide nicotine dependence support, including providing medicines available without a prescription. These guidelines focus on the management of nicotine dependence that may have developed as a result of smoking or vaping.

Nicotine dependence due to the use of other nicotine-containing products (e.g. nicotine pouches, heat-not-burn tobacco) is outside the scope of these guidelines as there is a lack of evidence to guide cessation of these products. Until evidence emerges, it may be reasonable to use the same strategies that are used for smoking cessation (e.g. brief advice, pharmacotherapy, multi-session behavioural intervention) to provide support to patients seeking to stop using other nicotine-containing products (see **Pharmacist role and requirements in providing nicotine dependence support**).

Specific information about general dispensing and compounding processes is covered by other guidelines, which are referred to in the relevant sections within these guidelines.

Legislative requirements are not addressed in detail in these guidelines due to the evolving nature. Information about legislation is correct at the time of publication. 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.

Pharmacists are expected to apply professional judgement when applying these guidelines in practice. They will need to make risk–benefit assessments from time-to-time based on the best available information and current evidence. Records of assessments should be kept, and all significant decisions should be documented.

# Background

## Tobacco smoking

Tobacco smoking remains a leading cause of preventable death and disability in Australia, contributing significantly to diseases such as cancer (especially lung cancer), chronic obstructive pulmonary disease (COPD) and cardiovascular disease.[1,2] Additionally, second-hand smoke exposure poses serious health risks, leading to cardiovascular and respiratory complications in adults and issues such as low birth weight and sudden infant death syndrome (SIDS) in infants.[2,7]

Over the last three decades, smoking rates in Australia have declined. This success is attributed to effective public health strategies, including tax increases, comprehensive smoke-free laws, plain packaging and targeted social marketing campaigns. However, further declines in tobacco smoking are needed to meet the 2030 smoking targets set in the National Tobacco Strategy. While smoking has declined in the general population, some patient populations continue to experience higher smoking rates than the general population (e.g. Aboriginal and Torres Strait Islander peoples, people living with mental illness, people living in low socio-economic circumstances). The rise in vaping has also introduced new challenges to public health.[1–3]

The health benefits of stopping smoking are widely recognised. See **Appendix 2 Health benefits of stopping smoking**.

## Nicotine dependence and vaping

Nicotine-containing vapes have been used by people who have never smoked cigarettes, including adolescents and adults under the age of 30. Use of nicotine-containing vapes by never-smokers can lead to nicotine dependence.[9] Evidence suggests that people who vape are more likely to take up smoking than those who do not vape.[10]

## Vaping-related risks and harms

Vaping exposes the user to a range of chemicals (e.g. flavours, solvents, humectants). These chemicals may be considered safe when ingested but may be harmful when inhaled.[9]

The long-term effects of exposure to vaping are unknown. Some of the harms associated with vaping that have been documented (mostly from short-term use) include[8]:

- adverse pregnancy and perinatal outcomes (e.g. preterm delivery, low birthweight)
- effects on adolescent brain development
- periodontitis.

It is suspected that an increase in vaping is contributing to the increasing rate of a condition characterised by respiratory and gastrointestinal symptoms including cough, shortness of breath, nausea and vomiting. This condition is known as E-Cigarette or Vaping Associated Lung Injury (EVALI). Most cases of EVALI have been linked to e-liquids containing THC (tetrahydrocannabinol) or vitamin E acetate, substances often found in illicit or unregulated vaping products.[8]

# Pharmacist role and requirements in providing nicotine dependence support

This section provides practical guidance on how to achieve the professional practice standards as they apply to providing nicotine dependence support. Information about the clinical aspects of providing nicotine dependence support can be found in **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

Providing support to a patient with nicotine dependence can vary based on the service delivery model of the pharmacy or health service and the education and training of the pharmacy or health service staff.

Regardless of the service delivery model of the pharmacy or health service, offer brief advice to all people who smoke or vape.

Ask, Advise, Help forms the basic structure for brief advice on smoking cessation[3]:

- Ask 'Do you smoke?' and record status.
- Advise all people who smoke to stop.
- Help by offering to arrange a referral and encouraging the use of behavioural interventions and appropriate pharmacotherapy.

Elements of Ask, Advise, Help are further developed in Patient assessment, Prescribing, Providing health information and Patient monitoring. See also **Appendix 3 Brief advice**.

**Note:** Evidence specifically addressing vaping cessation and dual smoking and vaping cessation is still emerging. While evidence emerges, it is reasonable to use the same strategies that are used for smoking cessation (e.g. brief advice, pharmacotherapy, multi-session behavioural intervention) to provide support to patients who are seeking to stop vaping.[5] This may also apply to cessation of other nicotine-containing products (e.g. nicotine pouches, heat-not-burn tobacco).

# Service delivery

*The pharmacist delivers a service to improve health outcomes*

A pharmacist in a senior clinical, managerial or organisational oversight role in the pharmacy or health service (e.g. community pharmacy owner, pharmacist manager, sole operator, director of pharmacy) has increased obligations to plan, resource, monitor and review the service.[6]

Quality systems are needed to deliver nicotine dependence support that is:

- safe and therapeutically appropriate for the patient
- consistent between different pharmacists
- aligned with evidence and scope of practice.

Actions required for service delivery are split into two categories:

- Those actions that apply to all pharmacists in an oversight role where nicotine dependence support is provided.
- Those actions that apply to all pharmacists providing nicotine dependence support.

## Actions required

### Pharmacist in an oversight role

Develop and maintain a standard operating procedure for providing nicotine dependence support, with a particular focus on:

- purpose and scope, including
  - the role of other health professionals and services involved in the provision of care
  - when to consult with or refer to other health professionals and services
- identifying patients who smoke and/or vape and documenting their use
- the nicotine dependence consultation (see **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**), including
  - providing in-person nicotine dependence consultations with the patient in a private consultation area/room
  - gathering patient information, including screening for undiagnosed conditions if appropriate (see **Screening, case-finding and risk assessment**)
  - assessing patient needs
  - agreeing on a management plan (including obtaining informed consent for unapproved products)
  - discussing the agreed management plan
  - documenting the details of the consultation (including documenting informed consent if an unapproved product is supplied; see **Appendix 4 Template written consent form for unapproved therapeutic vaping goods**)
- roles and responsibilities of staff involved (e.g. how pharmacy support staff will support the pharmacist)
- professional indemnity insurance coverage (e.g. coverage for supply of unapproved products)
- managing conflicts of interest
- managing pharmacist autonomy (i.e. the pharmacist practises and promotes patient-centred care, including informing the patient when exercising the right to decline supply of a medicine to the patient).[11] See **Prescribing**.
- education, training and qualification of staff members
- health and safety risks and applicable mitigating measures, including risks associated with
  - storage, handling and disposal of therapeutic vaping goods (see **Safe and secure handling of therapeutic goods**)
  - declining supply (see **Prescribing**)
- advertising and promotion, including
  - how patients will be advised of the nicotine dependence support available, noting
    - advertising Schedule 4 (*Prescription Only*) medicines and therapeutic vaping goods to the public is prohibited[12,13]
    - text-based signage can be used to alert patients if a type of pharmacotherapy is unavailable or not stocked by the pharmacy
- quality assurance, including
  - frequency of routine reviews of standard operating procedures
  - processes for collecting, documenting and reviewing feedback
  - method for documenting near misses or incidents associated with providing nicotine dependence support.

Provide appropriate facilities for providing nicotine dependence support, including:

- a private consultation area/room for consultations with
  - appropriate space and furnishings to accommodate the pharmacist, the patient and a support person for the patient, if needed

  - adequate protection of pharmacist and patient privacy such that the area/room layout and separators (e.g. screens, walls, doors) prevent
    - conversations at normal speaking volumes being overheard by people outside the consultation area/room (test whether conversations at normal speaking volumes can be heard outside the consultation area before the consultation area is used by patients)
    - unauthorised access to computer screens and documentation, including when the consultation area/room is not in use
  - required technology (e.g. computers, software) for the nicotine dependence support being delivered
  - required reference material, including guidelines
  - appropriately maintained and calibrated equipment as required (e.g. blood pressure monitor).

Meet legislative requirements if importing, stocking or supplying unapproved therapeutic vaping goods:

- Pharmacies can hold stock of unapproved therapeutic vaping goods in anticipation of supply under the Authorised Prescriber (AP) scheme or Special Access Scheme (SAS).[12] See **Appendix 5 Access to unapproved therapeutic vaping goods** and **Appendix 6 Vaping devices**.
- The unapproved therapeutic vaping goods must be confirmed to be included on the **Notified vape list**.[12]
- Australian sponsors of therapeutic vaping goods (see **Vapes: information for sponsors, importers and manufacturers**) are responsible for meeting import requirements, including[12,14]
  - import licences and import permits
  - ***Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023***[15] labelling, packaging requirements
  - reporting adverse events or device failures. See **Vapes: information for sponsors, importers and manufacturers**.
- Pharmacists are considered sponsors of therapeutic vaping goods if they[12]
  - import therapeutic vaping goods directly from an overseas supplier to supply to Australian patients
  - extemporaneously compound therapeutic vaping goods (with a section 41RC consent from the TGA). See **Compounding**.
- Legislation on the control of therapeutic vaping goods differs by state or territory.[12] See **Appendix 5 Access to unapproved therapeutic vaping goods**.

Review feedback from the community, patients and professional peers.

Use feedback to determine ways to improve service delivery.

## Pharmacist providing nicotine dependence support

Provide brief advice on smoking and/or vaping cessation to all patients that is tailored to their needs. See **Appendix 3 Brief advice**.

Provide nicotine dependence support consultations according to standard operating procedures.

Meet legislative, organisational and professional requirements, including requirements for:

- evidence-based medicine and patient-centred care
- informed consent, including informed financial consent (e.g. costs associated with nicotine dependence support in the pharmacy (e.g. any private consultation fee, product costs) and if subsidised support options are available)
- obtaining and recording patient personal details required to safely supply a therapeutic good
- professional indemnity insurance coverage for supplying unapproved products
- unapproved product access pathways requirements, including
  - validating the AP or SAS approval or notification using the Therapeutic Goods Administration (TGA) online validation tool. An AP or SAS-B approval or SAS-C notification submitted to the TGA by a prescriber will generate a reference number to use for validation. The reference number should be provided with the prescription or can be obtained by contacting the prescriber[12]
  - submitting a notification for each supply of a therapeutic vaping good as a Schedule 3 medicine under SAS-C using the TGA SAS and AP online system.[12] Although SAS-C must be submitted with 28 days of supply, best practice is to submit SAS-C notifications on the day of supply to minimise reporting errors.
- supply of therapeutic vaping goods (regardless of whether they are supplied with or without a prescription) directly to the patient or their carer (i.e. cannot be supplied to a third party unless they are the patient's carer)
- supply of therapeutic vaping goods (regardless of whether they are supplied with or without a prescription) in final dosage form (i.e. no mixing or dilution of the vaping substance is required). See **Compounding**.

Maintain personal competence and recency of relevant experience, including:

- cultural safety

- patient populations that may require additional support (see **Appendix 7 Patient populations that may require additional support**), for example
  - Aboriginal and Torres Strait Islander peoples
  - people with a co-existing medical condition (e.g. cardiovascular disease, diabetes, mental illness, substance use disorder)
  - adolescents
  - people who are pregnant or breastfeeding
  - lesbian, gay, bisexual, transgender, intersex, queer, asexual and other sexually or gender diverse (LGBTIQA+) people
  - people living with a disability
  - people from culturally and linguistically diverse backgrounds.

Conduct consultations consistent with personal competence and scope of practice:

- Pharmacists with additional training in behavioural interventions for smoking cessation can provide multi-session behavioural support services.
- Pharmacists practising in certain states or territories who have fulfilled the requirements for the scope of practice in that state or territory can prescribe bupropion or varenicline.

Encourage the patient to engage in the decision-making process to the extent they wish to participate (note that this will differ between patients and possibly along an individual patient's care journey).

Discuss with the patient relevant, evidence-informed information they need to make an informed decision.

Communicate relevant information about the nicotine dependence support being provided to the patient's regular general practitioner or practice (if they have one) with the patient's consent.

Document the details of the patient consultation in the patient's clinical record according to legislative, professional and organisational requirements, including details about:

- patient personal details
- patient assessment
- management plan
- informed consent
- prescribing
- dispensing
- patient monitoring (including follow-up schedule)
- health advice provided.

# Health promotion

*The pharmacist promotes health and preventive strategies to help people to increase control over and improve their health.*

Smoking and vaping cessation health promotion activities aim to increase awareness of the risks of smoking and vaping and the benefits of stopping. Delivering a health promotion activity over a defined period can assist pharmacists to open a conversation about smoking and vaping cessation with patients and learn more about the specific barriers to smoking and vaping cessation faced by their patient populations.

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.[3,4] Written materials and other resources (e.g. videos, audio, websites) for patients may also be helpful to support smoking cessation.[3]

Actions required for health promotion apply to all pharmacists delivering smoking and vaping cessation health promotion activities.

## Actions required

Plan the health promotion activity, including:

- setting specific, measurable, achievable, realistic and timely objectives for the health promotion activity according to organisational and professional requirements, for example,
  - to inform patients who smoke about the health impacts of continued smoking and the benefits of stopping smoking, over a 2-week period
  - to provide parents of teenage children advice and written materials over a 3-month period to assist them to talk to their children about smoking
  - to run a fortnightly drop-in clinic for breastfeeding people and their infants to talk about the benefits of smoking cessation
- identifying resource requirements (e.g. team member roles and responsibilities, written materials)
- developing or ordering written materials (e.g. posters, brochures) to complement the health promotion activity
- identifying special professional indemnity insurance requirements (e.g. for holding health promotion activities off site, engaging external providers)
- informing team members (e.g. hold a staff meeting to discuss the health promotion activity and roles and responsibilities)

- engaging with external organisations or health professionals to support the activity (e.g. state-based smoking cessation organisations)
- developing evaluation processes (e.g. team member and patient surveys).

Conduct team member training according to the roles and responsibilities of each team member.

Deliver the health promotion activity, including:

- displaying promotional materials about the health promotion activity; consider any advertising regulations
- approaching patients in the target audience
- tailoring the information provided according to the needs of the individual
- providing written resources to complement the health promotion activity.

Evaluate the health promotion activity to determine if the objectives have been met. Determine what worked well, what could be improved and how it can be done differently next time.

## Safe and secure handling of therapeutic goods

*The pharmacist provides safe and secure handling of therapeutic goods to enable access and safeguard the patient.*

The safe and secure handling of pharmacotherapy used for nicotine dependence support involves the same processes as for other TGA-approved medicines. Follow the guidance outlined in the *Professional Practice Standards*.[6]

Nicotine is a hazardous substance[16] and safe and secure handling of therapeutic vaping goods involves additional actions to meet legislative, professional and organisational requirements. See also **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

Actions required for safe and secure handling of therapeutic goods apply to all pharmacists handling therapeutic vaping goods.

### Actions required

Confirm the therapeutic vaping goods to be ordered are included in the **Notified vape list**.

Verify that therapeutic vaping goods ordered from a sponsor or wholesaler comply with the labelling, packaging, ingredient and record-keeping requirements outlined in the TGO110 prior to ordering.[12] See **Service delivery**.

Store therapeutic vaping goods in the dispensary out of the line of sight of the public.

Dispose of any containers with vaping liquid (e.g. cartridges, pods) or empty containers that may contain residual nicotine through the return of unwanted medicines (RUM) program.[17]

- Vaping devices cannot be disposed of in the RUM bin as they contain batteries that are a fire risk. Contact local councils for advice on the disposal of vaping devices.[17]

## Compounding

*The pharmacist prepares compounded medicines that are safe and appropriate for the patient.*

Compounding pharmacotherapy for smoking cessation or nicotine dependence involves the same processes as compounding other medicines (compounding therapeutic vaping goods requires consent from TGA). Follow compounding guidelines outlined in the Pharmacy Board of Australia *Guidelines on compounding of medicines*[18] and the Compounding section of *Australian Pharmaceutical Formulary and Handbook*.[16]

Therapeutic vaping goods must be supplied to the patient in the final dosage form (i.e. no mixing or dilution of the vaping substance is required). Mixing or dilution of a vaping substance (e.g. a prescriber recommends dilution of a freebase nicotine product that has concentration >20 mg/mL to avoid adverse effects) is considered compounding and therefore must be undertaken by a pharmacist with consent from the TGA.

Some additional processes are required when compounding therapeutic vaping goods.

Actions required for compounding apply to all pharmacists compounding therapeutic vaping goods.

### Actions required

Seek and be granted consent from the TGA to compound therapeutic vaping goods.[12]

Meet the requirements of TGO110 as an Australian sponsor of the therapeutic vaping good.[12] See **Service delivery** and Vapes: information for pharmacists.

# Patient assessment

*The pharmacist assesses the person's needs and determines appropriate management with them.*

Patient assessment involves gathering and assessing information to inform the provision of nicotine dependence support.

Actions required for patient assessment apply to all pharmacists providing nicotine dependence support.

## Actions required

Ask *all* patients if they smoke or vape when routinely gathering patient information (e.g. when a patient requests a Schedule 2 or 3 medicine, providing advice on managing a minor health condition, when a patient presents a prescription, providing immunisation services, prescribing a medicine). Nicotine use status can change over time. See **Appendix 1 Treatment guideline for pharmacists: nicotine dependence** and **Appendix 3 Brief advice**.

Record the patient's use of nicotine-containing products in their clinical record according to legislative, organisational and professional requirements.

Gather patient information in a confidential, respectful, systematic and non-judgemental manner, consistent with the principles of cultural safety. See also **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

Identify if any of the information gathered indicates an actual or potential medicine-related problem (e.g. medicine interaction) and take steps to address it.

Identify if any of the information gathered indicates a need for referral to another health professional. See **Appendix 7 Patient populations that may require additional support**.

# Prescribing

*The pharmacist judiciously and collaboratively prescribes therapeutic goods to treat the patient's health needs safely and effectively.*

After establishing the patient's needs, work with the patient to consider all options to develop the most appropriate management plan. Nicotine dependence can be a chronic, relapsing condition.[3] Management plans should be tailored to the patient and their individual needs. For detailed clinical information about prescribing pharmacotherapy for nicotine dependence, see **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

At the time of publishing this guideline, there were no therapeutic vaping goods in the Australian Register of Therapeutic Goods (ARTG). Therapeutic vaping goods not in the ARTG (and therefore unapproved products) can be accessed through the AP Scheme or the SAS.[12,19] Pharmacists prescribing unapproved therapeutic vaping goods as Schedule 3 (*Pharmacist Only*) medicines will need to use the SAS-C pathway.[12] See **Appendix 5 Access to unapproved therapeutic vaping goods**.

Actions required for prescribing apply to all pharmacists providing pharmacotherapy as part of nicotine dependence support.

## Actions required

Offer pharmacotherapy to patients who are nicotine dependent based on the outcome of patient assessment.

Choose pharmacotherapy based on[3]:

- efficacy, including
  - evidence for pharmacotherapy options (e.g. first-line therapies are recommended based on established evidence)
  - TGA approval status of pharmacotherapy (i.e. unapproved products have not been assessed by the TGA for quality, safety, efficacy, performance)[20]
- suitability for an individual patient, including:
  - current pharmacotherapy (if the patient wishes to continue using pharmacotherapy initiated previously)
  - level of nicotine dependence
  - impact of patient factors (e.g. contraindications, precautions, co-existing medical conditions) and medicine factors (e.g. potential adverse effects, drug interactions) on the safety of potential pharmacotherapy for the patient

  - cost, which can be a barrier to the continuation of pharmacotherapy (the Pharmaceutical Benefits Scheme (PBS) subsidises the use of some pharmacotherapies in certain situations.[21] See **www.pbs.gov.au**)
- patient preference and goals, for example
  - available dosage forms
  - past experience with pharmacotherapy for smoking or vaping cessation, which may influence their preference
  - harm reduction (as opposed to complete cessation) may be an interim goal for some patients (however, complete nicotine cessation remains the ultimate goal).

See **Appendix 1 Treatment guideline for pharmacists: nicotine dependence** for detailed clinical guidance on pharmacotherapy options.

Consider avoiding products that are manufactured by the tobacco industry or companies with links to the tobacco industry.[5]

Discuss any reasons why the pharmacist is choosing to decline to prescribe the patient's preferred pharmacotherapy (if applicable) with a focus on explaining:

- why the patient's preferred pharmacotherapy is not the preferred option for the patient (e.g. therapeutic indication, contraindications, interactions, co-existing medical conditions) or not able to be prescribed (e.g. pharmacy does not stock the pharmacotherapy, the pharmacotherapy is unavailable)
- why another pharmacotherapy option is more suitable
- other options available to support the patient (e.g. referral to a medical practitioner or other service provider).

Discuss when the patient should be referred to a medical practitioner or other service provider for additional support.

Discuss an appropriate duration of therapy and plan for cessation of pharmacotherapy.

Offer follow-up advice and support to people trying to stop smoking and vaping within one week of them stopping. See **Patient monitoring**.

Record the agreed management plan in the patient's clinical record.

# Dispensing

*The pharmacist facilitates the safe provision of a prescribed therapeutic good, according to a valid prescription or order, to treat a patient.*

Dispensing pharmacotherapy for nicotine dependence support involves the same processes as dispensing other medicines. Follow the guidance outlined in the *Dispensing practice guidelines*.[22]

Dispensing of therapeutic vaping goods involves additional actions to meet legislative, professional and organisational requirements. See also **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

Actions required for dispensing apply to all pharmacists dispensing therapeutic vaping goods.

## Actions required

Dispense therapeutic vaping goods that are prescribed by the pharmacist (under Schedule 3) using the same processes as dispensing Schedule 4 medicines.

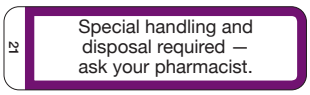
Determine the safety and therapeutic effectiveness of the therapeutic vaping goods for the individual patient. This may include assessing:

- prior use of first-line pharmacotherapy
- prior use of therapeutic vaping goods
- presence of co-existing conditions or medicine interactions
- appropriateness of prescribed concentration, dose and quantity of vaping substance
- appropriateness of vaping device
- risk of poisoning associated with the vaping device (Open systems carry a higher risk of nicotine poisoning than closed systems and are not recommended.[5] If an open system containing nicotine is prescribed, contact the prescriber to discuss the risks and alternative options)
- goals of therapy (i.e. smoking cessation or management of nicotine dependence)
- use of behavioural intervention by the patient.

Include dosing information for the therapeutic vaping goods on the dispensing label of therapeutic vaping goods.

Include the words 'Do not swallow' on the dispensing label of therapeutic vaping goods.

Use Cautionary Advisory Label 21 for all therapeutic vaping goods that contain nicotine to identify them as hazardous medicines.




Supply the therapeutic vaping goods directly to the patient or their carer (i.e. cannot be supplied to a third party unless they are the patient's carer).

# Providing health information

*The pharmacist critically appraises information to provide accurate, evidence-based, trusted and reliable medicines and health information to meet the needs of the patient, group of people and members of the healthcare team.*

Pharmacists can provide effective support to patients seeking to stop smoking.[4] This can be in the form of brief advice when providing health information to patients about their medicines and management of medical conditions through to providing ongoing smoking cessation behavioural support.[3,4]

There are some situations where smoking and vaping cessation care may be even more relevant. For example, when a patient[3]:

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

Pharmacists also have an important role in the multidisciplinary team providing, information on medicines to other health professionals.

Actions required for providing health information are split into two categories:

- Those that apply to all pharmacists providing health information to patients about nicotine dependence support.
- Those that apply to all pharmacists providing medicines information to other health professionals relating to smoking cessation or management of nicotine dependence.

## Actions required

### Providing health information to patients

Tailor advice for each patient's needs and experiences. See **Appendix 1 Treatment guideline for pharmacists: nicotine dependence** for detailed information.

Reinforce the management plan agreed to between the patient and prescriber (if the pharmacist providing health advice is not the prescriber). Confirm any changes to the management plan with the patient and the prescriber.

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]

Document the information provided according to legislative, organisational and professional requirements.

### Providing medicines information to other health professionals

Identify the information needs of the health professional.

Conduct a search of the literature and appraise the relevant information.

Tailor the medicines information provided according to the needs of the health professional.

Document the information provided according to legislative, organisational and professional requirements.

# Screening, case-finding and risk assessment

*The pharmacist uses evidence-based screening, case-finding and risk assessment methods to identify people at increased risk of, or who may have, an undiagnosed health condition.*

Consultations for nicotine dependence support provide an opportunity to identify if patients have, or are at risk of, undiagnosed health conditions.

Actions required for screening, case-finding and risk assessment apply to all pharmacists providing nicotine dependence support consultations.

## Actions required

Offer screening, case-finding and risk assessment to patients during an initial nicotine dependence support consultation.

Use an appropriate, evidence-based tool or device to obtain objective information about the patient. Some chronic health conditions that are more common in people who smoke include cardiovascular disease, COPD, diabetes, mental health conditions and substance use.[2,72] Reputable, validated risk assessment tools that can be used to identify people at risk of these conditions include[16,23]:

- Australian cardiovascular disease risk calculator (this may also involve measuring the patient's blood pressure)
- COPD case finding in the community
- Australian type 2 diabetes risk assessment tool (AUSDRISK)
- Alcohol use disorder identification test – consumption tool (AUDIT-C)
- Anxiety and depression test (K10).

Obtain information about the patient's immunisation history (e.g. from the patient or their health record).

Interpret and evaluate the risk assessment results in the context of the patient and the patient's condition.

Discuss the findings (including limitations) with the patient.

Refer the patient to a relevant health professional as required based on the findings.

# Patient monitoring

*The pharmacist collaboratively monitors patient outcomes and supports patients to self-monitor their condition and prevent complications.*

Relapse is common in the first few weeks after stopping smoking and may be related to the patient experiencing nicotine withdrawal.[3]

Review of patient progress and support provided by health professionals increases the likelihood of long-term abstinence. Follow-up should be offered to all people who are attempting to stop smoking and/or vaping.

Actions required for patient monitoring apply to all pharmacists providing nicotine dependence support.

## Actions required

Schedule reviews of the patient according to the agreed management plan. See **Prescribing** and **Appendix 1 Treatment guideline for pharmacists: nicotine dependence**.

Discuss the patient's smoking and vaping and treatments, such as pharmacotherapy and behavioural interventions.

Refer patients to a medical practitioner for additional advice and follow-up if required according to the agreed management plan.

Document the findings of the review according to legislative, organisational and professional requirements, including

- the details of any changes made to the management plan
- reasons for any change/s
- ongoing management goals and plan.

# Appendices

## Appendix 1 – Treatment guideline for pharmacists: nicotine dependence

This guideline focuses on the treatment of nicotine dependence that may have developed as a result of smoking or vaping.

Evidence specifically addressing vaping cessation is still emerging. While evidence emerges, it is reasonable to use the same strategies that are used for smoking cessation (e.g. brief advice, pharmacotherapy, multi-session behavioural intervention) to provide support to patients who are seeking to stop vaping.[1] This may also apply to cessation of other nicotine-containing products (e.g. nicotine pouches, heat-not-burn tobacco).

This guideline includes pharmacist management of nicotine dependence where prescribing of Schedule 4 *(Prescription Only)* bupropion and varenicline is within a pharmacist's scope of practice. See state or territory legislation and protocols for specific requirements.

**Meet legal and professional obligations**

- Poisons Standard schedules
- Therapeutic vaping goods

**Gather patient information**

- Clinical features
- Attitudes and barriers to smoking and vaping cessation
- Medical, medicines and lifestyle history
- Age
- Pregnant or breastfeeding

**Assess patient needs**

- The need to refer
- Make or understand diagnosis
- Treatments

**Refer**

Refer the patient to a medical practitioner and smoking or vaping cessation support service (e.g. Quitline) if:

- age <12 years
- pregnant (see 'Management in pregnancy and breastfeeding')
- most suitable (including financially suitable) pharmacotherapy for the patient requires a prescription from a medical practitioner (see 'Poisons Standard schedules', 'Management choice' and 'Using the treatments')
- a medicine the patient uses may require review or a dose change when they stop smoking or vaping (see 'Medical, medicines and lifestyle history' and 'Treatments')
- inadequate response to optimal treatment, including if the patient
  - continues to require vapes beyond 12 weeks (when initiated by a pharmacist)
  - has not ceased or reduced smoking since initiating nicotine vapes
  - requires more than 1 pod or cartridge (~2 mL) of a vape per day.

Supply initial treatment if clinically appropriate, and refer the patient to a medical practitioner and smoking or vaping cessation support service (e.g. Quitline) if:

- the patient has a chronic disease or medical condition that requires additional support or can complicate smoking or vaping cessation intervention (e.g. cardiovascular disease, diabetes, mental illness, substance use disorder, multiple comorbidities)
- breastfeeding (see 'Management in pregnancy and breastfeeding')
- age 12–17 years (vapes cannot be supplied as a Schedule 3 medicine to patients <18 years; see 'Poisons Standard schedules' and 'Management in adolescents').

**Agree on a management plan**

- Management goals
- Management choice
- Management in adolescents
- Management in pregnancy and breastfeeding
- Management in patients with co-existing conditions

**Discuss the agreed management plan**

- Using the treatments
- Adverse effects
- Non-pharmacological management
- Written information
- Review

**Document**

## Meet legal and professional obligations

Obligations in relation to the supply of a medicine by a pharmacist include[2,3]:

- complying with all appropriate standards, codes, guidelines and regulatory requirements
- respecting the patient's privacy and maintaining confidentiality
- recommending treatment that is safe for the patient and appropriate for their needs
- advising the patient on management of their condition
- referring the patient to other healthcare practitioners, if necessary
- documenting the supply (or refusal), and associated referral and advice provided, in accordance with relevant organisational and professional requirements
- following up patients at risk.

The *Code of Ethics for Pharmacists*[3] provides guidance on the ethical framework for the delivery of health services. The health and wellbeing of the patient is a pharmacist's first priority.

The *Professional Practice Standards* (PPS)[2] recommend that pharmacists follow a systematic process for gathering patient information, assessing the patient's condition(s), assessing potential management options and developing a management plan with the patient.

### Poisons Standard schedules

Treatments for smoking and vaping cessation include medicines listed in multiple poisons schedules.[4] See Table 1 for scheduling.

### Therapeutic vaping goods

The sourcing, supply and dispensing of vapes (including vaping devices and vapes with a zero-nicotine substance) are subject to specific vaping legislation in addition to the general requirements for the supply of scheduled medicines. This includes:

- *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*[5]
- *Therapeutic Goods (Medicines and OTG – Authorised Supply) Rules 2022*[6]
- *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Amendment (Vaping) Order 2023*[7]
- state and territory tobacco, smoking or e-cigarette legislation.[8]

**Requirements for the supply of a therapeutic vaping substance without a prescription**

Therapeutic vaping substances (containing nicotine or a zero-nicotine substance) can only be supplied without a prescription when[4,5,6,8]:

- supplied to patients ≥18 years
- the product is in the final dosage form (i.e. no mixing or dilution of vaping substance is required)
- it is being used for smoking cessation or management of nicotine dependence
- evidence of the patient's identity and age are sighted (cannot be supplied to a third party unless they are the patient's carer)
- advice is provided to the patient on alternative management options and appropriate use of the product (see 'Treatments', 'Management choice' and 'Using the treatments')
- contact details for smoking cessation support services are provided (e.g. Quitline)
- the quantity supplied does not exceed the quantity that is reasonably required for a patient's therapeutic use for 1 month and products are only supplied once a month (a smaller quantity can be supplied more frequently; e.g. a patient can be supplied with 7 days worth, four times in a month)
- the concentration of nicotine in the product is ≤20 mg/mL
- the patient is informed that vaping products are unapproved products
- informed consent is obtained from the patient for the use of an unapproved product (this can be written or verbal; see '*Professional practice guidelines for pharmacists: Nicotine dependence support; Appendix 4*' for sample template)
- supply is in accordance with good pharmacy practice (i.e. reputable and relevant guidelines are followed).

Additional requirements for the sourcing and supply of therapeutic vaping goods include the following:

- Therapeutic vaping goods are only available in pharmacies or pharmacy settings (e.g. aged care facilities, correctional facilities; subject to state and territory legislation), regardless of whether they contain nicotine or a zero-nicotine substance.[8]
- The dispensing of therapeutic vaping goods to patients <18 years is restricted in some jurisdictions even with a valid prescription (due to state and territory tobacco, smoking or e-cigarette legislation). See state or territory legislation and **Prescribing and dispensing of prescription only therapeutic vaping goods to patients under 18 years of age** for specific restrictions.[8]
- The supply of therapeutic vaping goods by a pharmacist without a prescription may be restricted in some jurisdictions. See state or territory legislation and the **PSA regulation hub**.
- Some of the patient's personal details will need to be obtained and recorded to satisfy legislative, organisational and professional requirements.
- A SAS-C notification must be submitted for each supply of a therapeutic vaping good (containing nicotine or a zero-nicotine substance) without a prescription.[8] It must be submitted within 28 days of supplying the therapeutic vaping good. Best practice is to submit it on the day of supply.[8] See '*Professional practice guidelines for pharmacists: Nicotine dependence support*; *Service delivery*'.
- All therapeutic vaping goods (including vaping substances containing nicotine or a zero-nicotine substance and vaping devices) must be supplied directly to the patient or their carer, regardless of whether they are supplied with or without a prescription.[5,8] See '*Professional practice guidelines for pharmacists: Nicotine dependence support; Glossary*' for details on who is considered a carer.
- Any vaping substance supplied by a pharmacist must be in final dosage form (i.e. no mixing or dilution of the vaping substance is required once supplied), regardless of whether it is supplied with or without a prescription.[5]
- See Table 2 for key requirements for the supply of therapeutic vaping goods depending on whether a medical or nurse practitioner or a pharmacist has prescribed them.

**Table 1 Scheduling of treatments for smoking and vaping cessation**

| Unscheduled | Schedule 3 *(Pharmacist Only)* medicine | Schedule 4 *(Prescription Only)* medicine |
|---|---|---|
| Nicotine replacement therapy (NRT) | | |
| | Nicotine in therapeutic vapes for smoking cessation or the management of nicotine dependence when the nicotine concentration is ≤20 mg/mL for patients ≥18 years. See 'Therapeutic vaping goods' for additional requirements for supply as a Schedule 3 medicine.[4] | Nicotine in therapeutic vapes that do not meet the requirements of Schedule 3 supply. See 'Therapeutic vaping goods' for full requirements for Schedule 3 supply.[4] |
| | | Bupropion |
| | | Varenicline |

**Table 2 Key requirements for the supply of therapeutic vaping goods**

| Health professional prescribing | Requirement | Therapeutic nicotine vaping substance | Therapeutic zero-nicotine vaping substance | Therapeutic vaping device (not packaged with a vaping substance) |
|---|---|---|---|---|
| When prescribed by a medical or nurse practitioner | Must be on the TGA **Notified vape list** | Yes | Yes | Yes |
| | Special access scheme (SAS) or Authorised prescriber (AP) authorisation required | Yes | Yes | No |
| | Pharmacist must validate the SAS or AP approval or notification prior to dispensing (by contacting the prescriber or using the **TGA's online validation tool**) | Yes | Yes | No |
| When prescribed by a pharmacist | Must be on the TGA **Notified vape list** | Yes | Yes | Yes |
| | Must comply with the requirements for supply of a therapeutic vaping substance without a prescription | Yes | Yes | No |
| | SAS-C notification required | Yes | Yes | No |
| | Pharmacist must independently determine whether it will be used for smoking cessation or managing nicotine dependence | Yes | Yes | Yes |

Reference: TGA[8]

# Gather patient information

Gather patient information in a confidential, respectful and non-judgemental manner. Ask the patient about their history of smoking, vaping and use of other nicotine-containing products, previous 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. Use additional sources of information (e.g. the patient's My Health Record), as applicable.

## Clinical features

Nicotine dependence is a chronic condition and relapse is common.[9,10]

Assess the patient's nicotine dependence by asking[1,9]:

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

Symptoms of nicotine withdrawal include[1,9]:

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

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[9]
- vapes within 30 minutes of waking, experiences withdrawal symptoms when they can't vape or has cravings to vape.[1,11]

* The number of cigarettes smoked a day is not a reliable indicator of nicotine dependence. However, it can be used to guide dosing of NRT and nicotine vapes.[1,9]

## Attitudes and barriers to smoking and vaping cessation

Identify and consider the patient's individual attitudes about smoking or vaping cessation and barriers they may be facing or have faced in previous attempts to stop smoking or vaping.[1,9]

Beliefs or attitudes that can prevent an attempt at, or affect the success of, smoking or vaping cessation include[9]:

- I'm not addicted.
- I don't need help to stop.

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

Beliefs or attitudes that affect vaping cessation can differ from those of smoking cessation. Additional barriers to vaping cessation can include[1]:

- belief that vaping is not harmful
- potential lower cost than smoking
- peer pressure
- fear of returning to tobacco smoking.

See 'Non-pharmacological management' for strategies to address the patient's attitudes or barriers.

Particular patient populations may face additional barriers to ceasing smoking or vaping. Health advice and behavioural interventions should be tailored to their individual needs.[9,12] These population groups include[1,9,12]:

- Aboriginal and Torres Strait Islander peoples
- people from culturally and linguistically diverse backgrounds
- lesbian, gay, bisexual, transgender, intersex, queer, asexual and other sexually or gender diverse (LGBTIQA+) people
- younger people.

See '*Professional practice guidelines for pharmacists: Nicotine dependence support; Appendix 7*' for strategies to overcome potential barriers in patient populations that may require additional support.

### Medical, medicines and lifestyle history

Tobacco smoking can modify the physiological effects of some medicines. Patients taking affected medicines should be advised to stop smoking.[13] These include[12,13,14]:

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

Medical conditions that can complicate smoking and/or vaping cessation interventions include[9,13,15]:

- cardiovascular disease
- diabetes
- mental illness, including substance use disorders
- pregnancy (see 'Management in pregnancy and breastfeeding').

The patient's medical, medicines and lifestyle history, including hypersensitivity reactions will influence management choice (see 'The need to refer', 'Treatments' and 'Formulation choice').

The patients smoking or vaping history can influence the dose of nicotine replacement therapy (NRT) or vape (see 'Using the treatments'). Ask the patient how many cigarettes they smoke a day and/or what their vape usage is (e.g. nicotine concentration used, whether it is nicotine free-base or salt, volume of vape liquid used per day).

If prescribing of Schedule 4 (*Prescription Only*) bupropion and varenicline is within a pharmacist's scope of practice, take the patient's blood pressure to screen for hypertension and have a baseline measurement.

**Impact of smoking/vaping cessation on medicines**

- CYP1A2 induction by tobacco smoke
  - Tobacco smoke contains aromatic hydrocarbons that induce cytochrome P450 isoenzymes, primarily 1A2 (CYP1A2) and can decrease concentrations of drugs that are metabolised by CYP1A2.[13,16]
  - Smoking cessation can, therefore, increase concentrations 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.
    - For some medicines metabolised by CYP1A2 (e.g. clozapine, erlotinib, olanzapine, pirfenidone, theophylline, warfarin), monitoring and dose adjustment may be required (see 'The need to refer').[13,15]
    - Caffeine is metabolised by CYP1A2 – intake should be reduced when stopping smoking. Maintaining pre-cessation caffeine intake may result in anxiety, restlessness and insomnia, which may be mistaken for nicotine withdrawal.[13]
    - Nicotine (including in NRT or nicotine vapes) does not induce CYP450 enzymes and, therefore, does not cause these pharmacokinetic interactions.[12,15]
- Nicotine
  - Nicotine interacts with some medicines (e.g. beta-blockers, benzodiazepines). Monitor for the need for a change in dose when a patient taking these medicines stops or reduces their smoking or vaping.[15] See 'Treatments'.
- Excipients in vapes
  - There is some evidence that aldehydes and carbonyls in some vapes can induce or inhibit CYP450 enzymes; however, the effects of this are unknown. Monitoring and dose adjustment of narrow therapeutic index medicines may be required.[17]

### Age

The patient's age will influence treatment choice. See 'The need to refer' and 'Management in adolescents'.

### Pregnant or breastfeeding

The patient's pregnancy or breastfeeding status will influence treatment choice. See 'The need to refer' and 'Management in pregnancy and breastfeeding'.

## Assess patient needs

### The need to refer

Refer the patient to a medical practitioner and smoking or vaping cessation support service (e.g. Quitline) if [9,14,17]:

- age <12 years
- pregnant (see 'Management in pregnancy and breastfeeding')
- most suitable (including financially suitable) pharmacotherapy for the patient requires a prescription from a medical practitioner (see 'Poisons Standard schedules', 'Management choice' and 'Using the treatments')
- a medicine the patient uses may require review or a dose change when they stop smoking or vaping (see 'Medical, medicines and lifestyle history' and 'Treatments')

- inadequate response to optimal treatment, including if the patient
  - continues to require vapes beyond 12 weeks (when initiated by a pharmacist)
  - has not ceased or reduced smoking since initiating nicotine vapes
  - requires more than 1 pod or cartridge (~2 mL of a vape per day).

Supply initial treatment, if clinically appropriate, and refer the patient to a medical practitioner and smoking or vaping cessation support service (e.g. Quitline) if [9,17]:

- the patient has a chronic disease or medical condition that requires additional support or can complicate smoking or vaping cessation intervention (e.g. cardiovascular disease, diabetes, mental illness, substance use disorder, multiple comorbidities)
- breastfeeding (see 'Management in pregnancy and breastfeeding')
- age 12–17 years (vapes cannot be supplied as a Schedule 3 medicine to patients <18 years; see 'Poisons Standard schedules' and 'Management in adolescents').

## Make or understand diagnosis

Use the patient information gathered to understand the patient's needs.

## Treatments

Pharmacotherapy for nicotine cessation includes NRT, bupropion, varenicline and vapes.

Varenicline is a partial agonist at nicotinic acetylcholine receptors.[10] NRT, vapes and varenicline assist in smoking or vaping cessation by reducing the impact of withdrawal symptoms. Bupropion is thought to assist in smoking cessation by inhibiting neuronal re-uptake of dopamine and noradrenaline.[10] See Table 3.

Nortriptyline or clonidine are sometimes prescribed off-label as second-line pharmacotherapy to support smoking cessation.[9]

Cytisine is currently used overseas for smoking cessation. At the time of publication, cytisine is an unapproved product in Australia and is only available through the SAS or AP scheme. A 2023 Cochrane meta-analysis concluded that it increases smoking cessation rates compared to control, however, its place in smoking cessation therapy in Australia is unclear.[19]

There is no evidence to support the use of zero-nicotine vapes for smoking or vaping cessation.[1]

Evidence suggests hypnotherapy is not any better than no treatment for smoking cessation.[9] The evidence for effectiveness of acupuncture is inconclusive and further research is needed.[9] However, individual patients may report success with hypnotherapy or acupuncture.

# Agree on a management plan

## Management goals

- Reduce cravings and symptoms of nicotine withdrawal.[9]
- Harm reduction.
- Aid long-term nicotine cessation.

## Management choice

### General notes

- Pharmacotherapy is indicated for smoking cessation when the patient is nicotine dependent.[9] Smoking cessation pharmacotherapy can also be considered to manage nicotine dependence from vaping.[1] See 'Clinical features'.
- The greatest benefit for nicotine cessation is seen when pharmacotherapy is combined with behavioural support (e.g. Quitline) and follow-up.[9] See 'Non-pharmacological management'.
- Choice of treatment depends on the nicotine product the patient is dependent on (e.g. tobacco smoking, nicotine vapes), treatment effectiveness, level of dependence, patient preference, other medicines being used and co-existing conditions.[20]

**Table 3 Pharmacotherapy for smoking cessation**

| Treatment | Possible drug interactions* | Contraindications and precautions* |
|---|---|---|
| NRT | • Nicotine in NRT or nicotine vapes has no effect on CYP1A2 activity[13]<br>• Nicotine activates the sympathetic nervous system and may oppose the effects of some medicines including:<br>– beta-blockers (blood pressure and heart rate lowering effects)[13#]<br>– benzodiazepines (sedation effects)[15,20#]<br>• Insulin[13,15#] | <12 years[9,14] |
| Nicotine vapes† | | <18 years[1,9] |
| Bupropion | • CYP2B6 inhibitors or inducers and CYP2D6 substrates (see Australian Pharmaceutical Formulary and Handbook: Drug interactions; Cytochrome P450 substrates, inhibitors and inducers)[10]<br>• Monoamine oxidase inhibitors (MAOIs)[10]<br>• Medicines that increase the risk of seizures[10] | • <18 years[9,14]<br>• Older people[10]<br>• Alcohol misuse[10]<br>• Bipolar disorder[10]<br>• Bulimia or anorexia nervosa[10]<br>• Epilepsy or increased risk of seizures[10]<br>• Hepatic impairment[10]<br>• Hypertension[10]<br>• Renal impairment[10] |
| Varenicline | No clinically significant interactions[14] | • <18 years[9]<br>• Epilepsy or increased risk of seizures[10,14]<br>• Mental illness[14]<br>• Severe renal impairment CrCl <30 ml/min)[9,10,14] |

* This table does not list all possible drug interactions, contraindications or precautions. The listing of a class of interacting medicines does not imply that all medicines within the class will interact. Consult specialised references for further information.

† The effects of other ingredients in nicotine vapes on other medicines are unknown.

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

- Pharmacotherapy options reduce, but do not always completely alleviate, symptoms of nicotine withdrawal.
- Nicotine withdrawal symptoms are usually strongest in the first week after stopping smoking, decline steadily over time and rarely last more than one month.[9,10]

**Smoking cessation**

- See Table 4.
- Pharmacists in some jurisdictions may be able to prescribe Schedule 4 *(Prescription Only)* bupropion or varenicline for smoking cessation depending on state or territory legislation.
- Varenicline, NRT and bupropion are first-line pharmacotherapies for smoking cessation.[9,20]
- Nicotine vapes are not a first-line option for smoking cessation. They may be considered for patients who have failed to stop smoking with first-line pharmacotherapy combined with behavioural support.[9]
- All pharmacotherapy for smoking cessation should be used in combination with behavioural support.[9]
- NRT
  - Combination NRT (long-acting patch plus a faster-acting formulation) is equally as effective as varenicline and more effective than NRT monotherapy.[9,21] See 'Using the treatments'.
  - NRT is safer than smoking, has low addictive potential and can be recommended to patients with nicotine dependence who are motivated to stop smoking.[9] See 'The need to refer' and 'Management in pregnancy and breastfeeding'.
  - All formulations of NRT (at equivalent doses) have similar effectiveness in achieving smoking cessation.[9,21]
- Varenicline
  - Most effective monotherapy option available.[9,22]
  - Equally as effective as combination NRT.[22]
  - Can be used in combination with NRT. Combining with NRT may improve effectiveness.[9]
    - There is some evidence that varenicline combined with a NRT patch is more effective than varenicline alone.[9]
    - There is insufficient evidence that varenicline combined with oral NRT is more effective than varenicline alone; in practice they are sometimes used together.[9]
- Bupropion
  - Less effective than varenicline or combination NRT.[9]
  - Equally as effective as NRT monotherapy.[9]
  - Bupropion can be used first-line if varenicline and combination NRT are not suitable.[9,20]
  - The use of bupropion in combination with NRT has not shown an additive benefit.[9]
- Nicotine vapes
  - The current evidence for the use of nicotine vapes for smoking cessation is uncertain.[1,23]
    - There is evidence that nicotine vapes increase smoking cessation rates compared to NRT, behavioural intervention or no treatment.[24]
    - The evidence for serious harm from vapes is unknown as the longest follow-up after use is 2 years.[24]
  - There are currently no TGA-approved vapes. Unapproved vapes have not been assessed for safety, quality or efficacy.
  - Nicotine vapes are an option, if the patient has failed to cease smoking after an appropriate trial of first-line therapy (e.g. 2 weeks of correct use of NRT at a dose appropriate to their level of nicotine dependence in combination with behavioural intervention).[9,20]
  - If the patient has not had an appropriate trial of first-line therapy, recommend appropriate first-line therapy (e.g. correct use of NRT at a dose appropriate to their level of nicotine dependence in combination with behavioural intervention) before recommending vapes.
  - The decision to use vapes (an unapproved treatment) for smoking cessation must be made through an evidence-informed, shared decision-making process with the patient where the patient is made aware of the current evidence for their safety and efficacy.[9]
  - Closed system vapes (e.g. pre-filled cartridges or single-use pods) are recommended to reduce the risk of accidental poisoning and prevent the addition of other substances to the vaping substance.[1]
  - If a prescription for an open system vape is received, contact the prescriber to discuss risk mitigation strategies (e.g. changing to a closed system device).
  - Vapes can only be supplied directly to the patient or their carer, regardless of whether they are supplied as a Schedule 3 or Schedule 4 medicine.[5]

**Nicotine vaping cessation**

- Evidence for the treatment of nicotine dependence is primarily based on studies of smoking cessation. Evidence for nicotine vaping cessation is emerging.[1]
  - Inform patients seeking treatment to aid nicotine vaping cessation that evidence to guide management is emerging and current recommendations are largely based on evidence for smoking cessation.
- The use of some smoking cessation pharmacotherapies for vaping cessation is off-label.
- NRT, varenicline or short-term use of vapes, combined with behavioural support (e.g. Quitline), are considered reasonable options for vaping cessation.[1]
  - Always recommend first-line pharmacotherapies (NRT or varenicline) first.
- Combination NRT may be useful for patients with a high level of nicotine dependence, while NRT monotherapy may be sufficient for patients with a low level of nicotine dependence.[1]
- If short-term use of vapes is being trialled for vaping cessation, balance the aim of complete nicotine cessation with reducing the risk of the patient relapsing to or initiating tobacco smoking.[1]
- All pharmacotherapy for vaping cessation should be used in combination with behavioural support.

**Dual smoking and vaping cessation**

- There is a lack of evidence to guide nicotine cessation in patients who are dual users of cigarettes and vapes.
- It may be reasonable to recommend smoking cessation pharmacotherapy. Always recommend first-line pharmacotherapy first.
- If first-line pharmacotherapy is unsuitable, advise patients to initially switch completely to vaping and cease smoking, with the intention of ceasing vaping after an agreed treatment period.[1]

### Table 4 Some factors influencing choice of treatment for smoking cessation

| Factor* | Treatment choice for smoking cessation# | Notes |
|---|---|---|
| Patients ≥18 years | • NRT, varenicline or bupropion are first-line[9,20]<br>• Nicotine vapes can be considered for patients who have failed to stop smoking after an appropriate trial of first-line therapy[9,20] | • Bupropion can be used first-line if varenicline and NRT are not suitable[9]<br>• Nicotine vapes can be considered if first-line pharmacotherapy plus behavioural support is unsuccessful[9,20]<br>• Nicotine vapes are unapproved |
| Adolescents | • Insufficient evidence:<br>– NRT can be trialled by patients ≥12 years[9]<br>– Intensive, multi-session behavioural support is important[9] | • Varenicline, bupropion and vapes are not recommended in patient's <18 years[1,9,14] |
| Pregnancy | • Non-pharmacological strategies are first line[9,25]<br>• NRT can be tried (on a medical practitioner's recommendation) if non-pharmacological strategies are not successful[9,25] | • If NRT is recommended by a medical practitioner, faster-acting formulations are preferred [9,25]<br>• See 'Management in pregnancy and breastfeeding' |
| Breastfeeding | • Non-pharmacological strategies are first line[9,25]<br>• NRT is considered safer than continuing to smoke.[9,25] | • Minimise nicotine in breast milk by using a faster-acting formulation and breastfeeding just before using NRT [9,25]<br>• See 'Management in pregnancy and breastfeeding' |
| Mental illness | • NRT, varenicline or bupropion are first-line[9]<br>• Nicotine vapes can be considered for patients who have failed to stop smoking after an appropriate trial of first-line therapy[1] | • Bupropion can be used first-line if varenicline and NRT are not suitable[9]<br>• Varenicline can be used if the patient's mental illness is stable[26]<br>• Bupropion should be used with caution in patients with bipolar disorder[26]<br>• Bupropion is contraindicated if [10]:<br>– patient has a current or previous diagnosis of bulimia or anorexia nervosa<br>– a MAOI has been taken within the previous 14 days<br>• Avoid or minimise alcohol use during treatment with bupropion[14]<br>• Alcohol intake may increase the risk of neuropsychiatric adverse events during treatment with varenicline[14]<br>• Nicotine vapes can be considered if first-line therapy (pharmacotherapy plus behavioural support) is unsuccessful[9,20]<br>• Neuropsychiatric symptoms during quitting are more common; close monitoring by a medical practitioner is required[9]<br>• The dose of medicines metabolised by CYP1A2 (e.g. clozapine, olanzapine) may need to be reduced when smoking is reduced or ceased[9] |

* This table does not list all factors that influence the choice of treatment. Consult specialised references for further information.
# Pharmacological therapy should be used in conjunction with behavioural support (e.g. Quitline).

### Table 5 Nicotine replacement therapy

| Formulation | Advantages | Disadvantages | Precautions |
|---|---|---|---|
| **Long-acting – maintains steady-state nicotine levels to reduce withdrawal symptoms** | | | |
| Patch | • Easy to use<br>• Once-daily application | Dose adjustment is less flexible and may require a 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 | • Can be cut into smaller pieces to reduce dose<br>• Different flavours available | Takes time to begin to relieve cravings; advise patients to use in anticipation of a trigger | Avoid in patients with dentures, complicated dental work, oral/pharyngeal inflammation |
| Lozenge | Different flavours available | Takes time to begin to relieve cravings; advise patients to use in anticipation of a trigger | • Avoid in patients with oral/pharyngeal inflammation<br>• Lozenges containing aspartame are contraindicated in patients with phenylketonuria |
| Oral spray | • Fastest acting of all of the faster-acting formulations<br>• Can be used discreetly if patients are concerned about people knowing they are using NRT | • Contains alcohol<br>• Can be difficult to use by some patients with dexterity concerns | Avoid in patients with oral/pharyngeal inflammation |

References: RACGP[9]; AMH[10]; eMIMS[14]; Alfred Health[27]

**NRT formulation choice**

- The choice of NRT depends on the level of nicotine dependence, the patient's preference and the suitability of individual formulations.[9] See Table 5 and individual product information.
- If NRT is clinically appropriate, Quit Centre has an online tool to guide initial dosing. See **quitcentre.org.au/nrt-tool**

**Using NRT before stopping smoking**

Using the highest-strength patch for 2 weeks before stopping smoking completely can increase the likelihood of success. However, further research is needed.[9,21]

Faster-acting NRT can be used to reduce the number of cigarettes smoked each day. However, the evidence of the effectiveness of this approach is uncertain.[9,14]

## Management in adolescents

- There is insufficient evidence that smoking cessation programs and pharmacological interventions for adolescents who smoke are effective.[9]
- There is also insufficient evidence on how to support adolescents to cease vaping.[1]
- Success rates of smoking cessation are lower in people who start smoking at a younger age.[9]
- Interventions generally focus on preventing adolescents from starting to smoke or vape.[9]
- Intensive, multi-session behavioural support is important in this age group.[9]
- NRT can be used by patients ≥12 years (for both tobacco smoking and vaping cessation), but adherence is likely to be an issue in adolescents.[9,14]
- Bupropion and varenicline are not approved for use in patients <18 years.[9]
- Nicotine vapes are not recommended for use in patients <18 years. There have been no studies on their efficacy or safety in this population.[9]
- See 'The need to refer' and 'Non-pharmacological management'.

## Management in pregnancy and breastfeeding

See Table 6.

**Pregnancy**

- There is no safe level of smoking in pregnancy. Continued smoking during pregnancy leads to pregnancy complications and harmful effects for both the pregnant person and the fetus. Complete cessation of smoking (rather than simply cutting down) is recommended.[9]
- Non-pharmacological smoking cessation strategies should be tried first (see 'Non-pharmacological management').[9,25]
- If non-pharmacological strategies are unsuccessful, NRT may be recommended by a medical practitioner.[9] See 'The need to refer'.
  - Evidence for the safety of NRT in pregnancy is limited. It may be a safer alternative to cigarette smoking as it provides a clean source of nicotine (without the other chemicals) and generally delivers a lower level of nicotine.[25]
- If NRT is recommended by a medical practitioner, faster-acting formulations are preferred.[9,25]
- Bupropion, varenicline and vapes are not recommended for nicotine dependence in pregnancy; there is currently insufficient evidence for their safety and efficacy in this population.[1,9,25]
- Advise people living with a pregnant person to avoid smoking around them. Encourage them to also cease smoking as this can help the pregnant person to stop smoking.[9]

**Breastfeeding**

- Non-pharmacological strategies are preferred. NRT is considered safer than continuing to smoke.[9,25]
- Minimise nicotine in breast milk by using a faster-acting formulation and breastfeeding just before using NRT.[9,25]
- If unable to stop smoking completely, encourage continued breastfeeding and minimisation of the infant's exposure to second-hand smoke.[9]
- Bupropion, varenicline and vapes are not recommended for nicotine dependence in breastfeeding. There is currently insufficient evidence for their safety and efficacy in this population.[1,9,25]

## Management in patients with co-existing medical conditions

Smoking cessation pharmacotherapy options are available for patients with cardiovascular disease, diabetes, mental illness and substance use disorder (see 'Treatments').[9] However, patients may need additional support (see 'The need to refer' and 'Non-pharmacological management'). Smoking and vaping cessation should be integrated into the patient's chronic disease management program.[9]

# Discuss the agreed management plan

## Using the treatments

See individual product information and specialised references.

Advise patients to reduce their caffeine intake by half when stopping tobacco smoking.[15]

**Table 6 Management in pregnancy and breastfeeding**

| Medicine | Pregnancy* | Breastfeeding* |
|---|---|---|
| NRT[25] | Category D; consider alternative – see 'Management in pregnancy and breastfeeding' for information on when it may be considered appropriate | Consider alternative – see 'Management in pregnancy and breastfeeding' for information on when it may be considered appropriate |
| Vapes[9] | Insufficient data; not recommended | Insufficient data; not recommended |
| Bupropion[25] | Category B2; consider alternative | Consider alternative |
| Varenicline[25] | Category B3; consider alternative | Consider alternative |

* Consult specialised references for further information about safety in pregnancy and breastfeeding.

### NRT

Australian guidelines recommend the following initial NRT doses for smoking cessation[9]:

- 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
- 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
- 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.

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 the use of two patches at the same time (see 'Clinical features'). However, the evidence supporting the use of two patches is inconclusive.[9,21]

Premature discontinuation of NRT can lead to relapse. 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 may consider a follow-up course. The optimal duration of NRT has not been established.[9,21]

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.[14]

### Vapes

Advise the patient of the evidence for vapes and how to use them. This may include[1,12]:

- evidence
  - vapes are unapproved products that have not been assessed by the TGA for their quality, safety and efficacy or performance
  - nicotine vapes are not first-line pharmacotherapy for smoking or vaping cessation; there are other smoking cessation medicines that have been approved by the TGA for quality, safety and efficacy
- how to use the vaping device
  - some suppliers of vaping devices have instructions about how to use the device
- avoiding smoking in combination with vaping
  - continued tobacco smoking while trying to stop smoking using vapes may lead to increased nicotine consumption and/or cumulative cardiovascular adverse effects[1,28,29]
- how much and how often to use vapes
  - the 'dose' of nicotine delivered from a vape depends on a number of factors including the nicotine concentration, the device used, and the inhalation technique
  - there is no distinct end-point as there is with smoking (i.e. finishing and stubbing out a cigarette); the volume of vaping substance in a single pod or cartridge is far more than would typically be used in a single vape session
- duration of treatment
  - the long-term effects of vaping are unknown
  - vaping should only be used short-term for smoking cessation – the optimal duration of nicotine vapes has not been established
  - do not continue supplying vapes for longer than 12 weeks without review by a medical practitioner
  - current Australian 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 vape is needed to avoid relapse to tobacco use
- weaning strategies
  - the optimal strategy to titrate down nicotine vaping use to achieve cessation has not been established. Suggestions include:
    - attempting weaning or cessation after 12 weeks
    - transitioning from nicotine vapes to NRT
    - limiting vaping to particular times or places
    - increasing the time between vapes
    - tapering the dose (e.g. reducing the nicotine concentration every 2–4 weeks as well as the number of vape session per day)
- how to store and dispose of the medicine and device
  - return any containers with vaping liquid (e.g. cartridges, pods) or empty containers that may contain residual nicotine to the pharmacy for disposal through the return of unwanted medicines (RUM) program
  - contact local council for advice on disposal of vaping devices
- how to reduce the risk or impact of accidental nicotine poisoning
  - using nicotine vapes with a nicotine concentration of ≤20 mg/mL
  - using a closed system device
  - keeping vapes out of reach of children and avoiding use of vapes in front of children
  - call 000 if inadvertent exposure or ingestion of a nicotine vaping substance has occurred in a child (or adult who is experiencing signs and symptoms suggestive of nicotine overdose)[30]
  - contact the Poisons Information Centre (13 11 26) and seek urgent medical assistance if inadvertent exposure or ingestion of a nicotine vaping substance has occurred in an adult.

### Nicotine vape doses

There is limited evidence for starting nicotine concentrations for the treatment of nicotine dependence. Nicotine vapes contain nicotine in either free-base (bioactive form) or salt form. Free-base and salt products with the same nicotine concentration are not directly interchangable.[1] See Table 7 for suggested reasonable starting concentrations for new and current users of nicotine vapes. Review the appropriateness of the nicotine vape concentration at all follow-ups and adjust according to the patient's needs.

There is limited evidence for the volume of nicotine vape liquid that should be used for the treatment of nicotine dependence. The following factors should be considered when determining an appropriate quantity for the patient:

- The dose of nicotine received by a patient using a nicotine vape varies depending on the device, type of nicotine (free-base or salt), concentration and the length and intensity of inhalation.[1,31]
- Patients will self-titrate to achieve the nicotine level required to satisfy their craving.[1]

- The safety of vapourised chemicals (including excipients, chemicals originating from devices and chemicals formed by chemical reactions with the heating element) in vapes is currently unknown.[31] There are concerns that inhaling high volumes of vape liquid in low concentration products could increase risk of adverse effects due to an increased quantity of inhaled chemicals.[1,24]
- If the concentration of nicotine vape is too low for the patient, they may use a higher volume of vaping substance, which will increase the cost to the patient.
- A suggested reasonable quantity of nicotine vape liquid to use is 1 pod or cartridge (~2 mL) per day. If a patients usage exceeds this, they should be referred to a medical or nurse practitioner for a higher concentration product.[32]

**Varenicline**

- Start 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.[14]
- Continue treatment to a total of 12–24 weeks.[10,14]
- Swallow tablets whole.[14]
- 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.[10]

**Bupropion**

- Start at least 1 week before planned smoking cessation.[10,14]
- Continue treatment for 7–9 weeks.[10,14]
- A faster-acting NRT product can be added to bupropion to manage nicotine cravings. However, evidence supporting the effectiveness of this combination is lacking. Blood pressure should be monitored if this combination is used.[9,10,14]
- Swallow tablets whole.[10]
- Alcohol consumption should be minimised (or avoided) as it alters the seizure threshold and increases the risk of other adverse effects.[10,14]

## Adverse effects

Advise the patient of the following potential adverse effects of treatment.

**NRT**

- 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).[14] See Table 8 and 'Non-pharmacological management'.
- Signs of nicotine overdose include nausea, vomiting, bradycardia and convulsions.[14,33]
- NRT is intended for transdermal or sublingual/buccal absorption. Swallowed nicotine may exacerbate symptoms of oesophagitis, gastritis and gastric ulcers.[14]

**Nicotine vapes**

- cough, dry or irritated mouth and throat (irritation particularly occurs with free-base form at concentrations >20 mg/mL)[1]
- headache[1,12]
- nausea[1]
- lung injury[1]
- burns[1]
- intentional or accidental poisoning[1]
  - nicotine overdose – signs and symptoms include nausea, vomiting, bradycardia, convulsions
  - see 'Using the treatment' for guidance on actions to take if intentional or accidental poisoning is suspected
- long-term adverse effects are unknown[9]
- adverse effects from carrier fluids (propylene glycol and glycerol), flavourings and contaminants
  - flavourings have not been assessed as being safe when inhaled. Different flavourings may have different safety profiles and ingredients (e.g. the 'mint' flavour in two different products may be made of different ingredients)[34]
  - known carcinogens have been found in vape aerosols.[34] The extent to which vape use increases the risk of cancer is currently unknown.[12] The TGO 110 recommends a maximum of 10 ppm for specified contaminants.[34]

**Table 7 Nicotine vape suggested starting concentration**

| Type of product | New nicotine vape users* | | Current nicotine vape users* |
|---|---|---|---|
| | Lower nicotine dependence (Smokes more than 30 minutes after waking and smokes ≤10 cigarettes a day) | Higher nicotine dependence (Smokes within 30 minutes of waking or smokes >10 cigarettes a day) | |
| Nicotine free-base | 6–12 mg/mL | 18–20 mg/mL | Base on current usage<br>• if currently using an open system, switch to a closed system<br>• nicotine free-base and nicotine salt products with the same concentration are not directly interchangeable, carefully consider appropriate dose for the patient if switching between free-base and salt |
| Nicotine salt | 18–30 mg/mL | >30 mg/mL | |

Reference: RACGP [1]

* Only vapes with a nicotine concentration ≤20 mg/ml can be supplied as a Schedule 3 *(Pharmacist Only)* medicine. See 'Poisons Standard schedules' and 'Therapeutic vaping goods' for full list of requirements for supply of therapeutic vaping goods without a prescription.

**Varenicline**[10]

- gastrointestinal effects – severe nausea may be relieved by taking with food or with a reduction in dose
- increased appetite/weight
- headache
- insomnia
- abnormal dreams
- taste disturbance

**Bupropion**[10]

- gastrointestinal effects
- insomnia – 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
- dry mouth
- dizziness, concentration difficulties – be careful driving or operating machinery if affected
- agitation

This guideline does not list all possible adverse effects. Consult specialised references for further information.

## Non-pharmacological management

Advise patients about behavioural strategies to assist them to stop smoking or vaping. Successful long-term smoking cessation is more likely if pharmacotherapy is combined with evidence-based, multi-session behavioural intervention (e.g. Quitline).[9] Behavioural intervention (e.g. Quitline) is also recommended for vaping cessation.[1] Patients can also use 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.[9,35]

### Addressing barriers to smoking and vaping cessation

Discuss the patient's individual barriers and previous attempts to stop smoking or vaping. Discuss what strategies have been helpful in past attempts.

- Explain the benefits, costs, options and accessibility of assistance that is available (e.g. pharmacotherapy, counselling services).[9,36]
- Discuss the health and financial benefits of smoking and vaping cessation specifically for the patient. The National Cessation Platform (quit.org.au) has useful information about the benefits that can be tailored for the patient.[9,35]
- Discuss the health implications of continuing to smoke or vape (e.g. possible lung damage).[9,35]
- Provide information about relaxation techniques (e.g. mindfulness, meditation, breathing exercises).[9,35]
- 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.[9]
- Suggest ways to manage high-risk social situations when first stopping smoking or vaping and practising ways of saying no when a cigarette or vape is offered.[9,35]

### Behavioural strategies

Discuss some practical tips for stopping smoking or vaping:

- Write a list of reasons that you want to stop smoking or vaping and things you will look forward to when you stop.[35]
- Make a plan and set a date to stop smoking or vaping. Decide what support options will work best for you.[35]
- Tell family and friends of the plan to stop smoking or vaping, and explain how they can help (e.g. stopping together, not offering a cigarette or vape).[35]
- Practise stopping (e.g. experiment with not smoking or vaping in situations you normally would, make home and car smoke and vape-free, stop carrying a lighter).[35]
- Identify situations and triggers that make you want to smoke or vape (e.g. coffee, alcohol, friends who smoke or vape), and plan for these.[9,35]
- Prepare for healthy eating (e.g. buy healthy snacks before stop day).[35]
- Reduce coffee and tea intake when you first stop smoking, to prevent caffeine-induced anxiety and restlessness.[15] See 'Medical, medicines and lifestyle history'. (This only applies to smoking cessation)
- The '4Ds' can help to deal with cravings[35]
  - Delay for at least 5 minutes, the urge will pass.
  - Deep breathe, slowly.
  - 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 weight gain.[35]
- Reward yourself with the money that has been saved.[9,35]
- If you have a cigarette or vape, it does not mean the attempt has failed. Keep trying to stop. Remind yourself of all the times you have resisted the urge to smoke or vape, follow the '4Ds' and adjust your stop smoking or vaping plan.[35]

**Table 8 Adverse effects of NRT**

| Formulation | Adverse effects | Mitigation strategies |
|---|---|---|
| Patch | Application site skin reactions | Rotate application site daily<br>Apply 1% hydrocortisone cream to the affected area (short-term use only) |
| | Vivid dreams affecting daytime functioning | Remove patches at night |
| | Patch adhesive not sticking | Use adhesive skin tape to provide extra adhesion |
| Gum, 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: RACGP[9]; eMIMS[14]

**Support services**

Refer patients to smoking and vaping cessation support services for additional support.

Quitline provide free, multi-session behavioural intervention. Quitline counsellors assess the patient's smoking or vaping history and use motivational interviewing to help them develop a plan to stop smoking or vaping. Quitline is tailored to meet the needs of priority populations including patients living with mental illness, pregnant patients and young people. Quitline also provides Aboriginal and Torres Strait Islander counsellors, and is able to assist people with hearing or speech impairment, or people needing an interpreter.[35]

Pharmacists can refer patients to Quitline at **www.quitcentre.org.au/referral-form**. Alternatively, patients can contact Quitline by phone on 13 78 48.[35]

### Written information

- Provide the patient with *Smoking, Vaping, Nicotine Replacement Therapy and Staying a Non-smoker* Self Care Fact Cards or other consumer information.
- Resources can be ordered from **quit.org.au/resource-order-form**

**Labelling of nicotine vaping products**

- It is recommended that pharmacists dispense supplies of therapeutic vaping substances prescribed by a pharmacist under Schedule 3 supply using the same processes as dispensing Schedule 4 medicines. See '*Professional practice guidelines for pharmacists: Nicotine dependence support; Dispensing*'.
- Attach cautionary advisory label 21 to therapeutic vaping goods that contain nicotine. See *'Australian Pharmaceutical Formulary and Handbook: Cautionary advisory labels'*.
  - Inadvertent exposure to nicotine vape liquid (ingestion or absorption through skin or mucus membranes) by a person other than the patient is a cause of poisoning. See 'Using the treatments'.
- Include the words 'do not swallow' and dosing information on the dispensing label.

### Review

Invite the patient to contact the pharmacy if they have any questions or concerns about the medicine or advice provided.

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

- concerning or unexpected adverse effects from treatment
- inadequate response to treatment
- difficulty using the treatment.

Suggest that patients return for follow-up within 1 week of the stop use date and for additional planned follow-up visits to review progress.[9] Review can include:

- enquiring about the patient's perspective on their progress
- identifying and addressing any concerns the patient has regarding the management plan
- working with the patient to determine whether pharmacotherapy should be continued, ceased or modified (e.g. dose titration of nicotine vapes)
- discussing behavioural strategies to help with smoking or vaping cessation and encouraging patients to use support services such as Quitline
- encouraging patients to avoid dual smoking and nicotine vaping
- reaffirming that the long-term risks of nicotine vapes are unknown (if patient is using nicotine vapes)
  - discuss switching to approved smoking cessation pharmacotherapy to maintain their nicotine cessation progress and prevent relapse.

For varenicline or bupropion supplied via pharmacist prescribing:

- advise patient to return for review 2 weeks after commencing the pharmacotherapy (or shortly after quit date if more than 3 weeks after starting the pharmacotherapy) and at the end of the treatment course
- encourage ongoing support (e.g. from Quitline)
- measure the patient's blood pressure at each review.

If relapse occurs, offer support and encourage further attempts. Acknowledge that it may take numerous attempts to stop smoking or vaping.

## Document

Document the interaction with the patient, including patient details, assessment, the agreed management plan (e.g. medicines, recommendations, education, advice), adverse events and any communication with other healthcare professionals (e.g. referral), according to relevant legislative, organisational and other professional requirements.[2]

To facilitate multi-session behavioural support, it is recommended that:

- all patient interactions regarding smoking or vaping cessation are documented in the patient's clinical record and,
- relevant information about the smoking or vaping cessation support being provided to the patient is communicated to the patient's regular general practitioner or practice (if they have one), with the patient's consent.

Documentation also supports ongoing patient relationships, quality use of medicines and collaboration between healthcare providers. 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 referral situations
- decline to supply situations
- supply of Schedule 4 *(Prescription Only)* medicines
- supply of unapproved medicines or medicine for off-label use.

When nicotine vapes are supplied as a Schedule 3 *(Pharmacist Only)* medicine or zero-nicotine vapes are supplied without a prescription:

- complete a SAS-C notification according to legislative requirements
- obtain and document informed consent from the patient (as vapes are an unapproved product) – See '*Professional practice guidelines for pharmacists: Nicotine dependence support; Appendix 4 Template written consent form for unapproved therapeutic vaping goods*'.

Report adverse effects to the **Therapeutic Goods Administration** (TGA) as appropriate.[2] Report deficiencies or defects of therapeutic vaping goods that are believed to have occurred during the manufacture, storage or handling of these products to the TGA.[34]

**Additional documentation requirements for pharmacist prescribing of Schedule 4 *(Prescription Only)* medicines**

Documentation requirements for pharmacist prescribing of Schedule 4 *(Prescription Only)* medicines include:

- date of consultation
- pharmacist who provided the consultation
- any relevant patient consent obtained (e.g. to communicate with patient's medical practitioner)
- relevant medical, medicines and lifestyle history
- information relevant to diagnosis or treatment (e.g. symptoms, assessment results)
- clinical opinion reached by the pharmacist
- agreed management plan
- details of any medicines supplied (name, strength, formulation, instructions, quantity)
- treatment information offered to the patient.

When prescription medicines are supplied via pharmacist prescribing, provide a copy of the clinical record to the patient and, with the patient's consent, to their usual medical practitioner or medical practice.

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# Appendix 2 – Health benefits of stopping smoking

There are major health benefits for everyone who stops smoking, with benefits beginning soon after ceasing.[7]

| Medical condition | Consequences of smoking | Benefits of smoking cessation |
|---|---|---|
| Chronic obstructive pulmonary disease (COPD) | • More frequent COPD exacerbations than non-smokers<br>• Increased risk of respiratory infections | • Reduced rate of decline of lung function<br>• Improved lung function<br>• Reduced risk of hospitalisation |
| Cardiovascular disease | Higher risk of most types of cardiovascular disease | • Reduced risk of atherosclerotic cardiovascular disease all-cause mortality<br>• Reduced risk of coronary heart disease<br>• Reduced risk of morbidity and mortality from stroke<br>• May reduce risk of heart failure<br>• May increase survival and reduce risk of hospitalisation in patients with left-ventricular dysfunction |
| Infertility | • Reduced fertility<br>• Early-onset menopause<br>• Shorter and more variable menstrual cycle<br>• Premature ovarian failure<br>• Decreased implantation rate | • Improved fertility<br>• Reduced risk of early-onset menopause |
| Diabetes | • Impaired glycaemic control<br>• Increased risk of:<br>– chronic kidney disease<br>– neuropathy<br>– retinopathy<br>– peripheral vascular disease | • Reduced risk of diabetes complications<br>• Reduced risk of diabetic foot amputations<br>• Improved glycaemic control |

References: Greenhalgh[7]; eTG[24]; Rigotti[25]; Roelsgaard[26]; CDC[27]; Collins[28]; RACGP[29]

# Appendix 3 – Brief advice

Health professionals report that lack of time can be a barrier to providing nicotine dependence support. However, brief advice using the 3-step model Ask, Advise, Help can be used to initiate discussions about smoking cessation and link patients to more comprehensive support.[3]

The Ask, Advise, Help model outlined below is focused on smoking cessation. This model can be adapted for use in conversations about vaping cessation. When asking patients about vaping, follow-up questions are needed to find out if the patient is using vaping as a smoking cessation strategy so advice and help can be tailored accordingly.

## Ask

Ask *all* patients if they smoke when routinely gathering patient information. Pharmacists gather patient information when:

- prescribing medicines (including Schedule 2 and Schedule 3 medicines)
- dispensing medicines
- providing professional services (e.g. screening, case finding and risk assessment, medicine review, wound management)
- administering medicines (e.g. vaccines, injectable medicines).

Gathering patient information about the patient's medicines and medical conditions provides an opportunity to ask if the patient smokes.

Ask the person if they smoke, then:

- if they say yes, progress to 'Advise'
- if they say no, congratulate them (e.g. 'That's great!') and consider asking follow-up questions about prior smoking history, if applicable.

## Advise

Advise all patients who smoke to stop using a personalised, non-confrontational approach. Tailor the advice to the patient's reason for presentation. For example:

- If the patient is requesting a medicine for a cough, discuss the respiratory effects of smoking.
- If the patient is getting their blood pressure checked, discuss the cardiovascular risks of smoking.
- If the patient is having a wound dressing changed, discuss how smoking can delay wound healing.
- If the patient is getting a flu vaccination, discuss how smoking increases susceptibility to acute respiratory infections.

Provide advice about ways to stop smoking (e.g. behavioural interventions, pharmacotherapy).

## Help

Determine the best way for you to provide help to the patient to stop smoking, considering your scope of practice and availability, individual patient factors (e.g. medicine interactions, co-existing medical conditions) and the patient's availability. Help may include:

- arranging referral to a behavioural intervention program (e.g. Quitline) on behalf of the patient
- providing a nicotine dependence support consultation to encourage the use of first-line pharmacotherapy options for smoking cessation (e.g. NRT)
- arranging referral to the patient's regular medical practitioner to discuss smoking cessation strategies.

Arrange follow-up with the patient to discuss progress or next steps.

Record the patient's smoking status in their clinical record (if they have one), along with any notes about the advice or help provided.

## Appendix 4 – Template written consent form for unapproved therapeutic vaping goods

### Confirmation of informed consent to use unapproved therapeutic vaping goods

I confirm the pharmacist has informed me:

- that the therapeutic vaping goods are unapproved therapeutic goods and not evaluated by the Therapeutic Goods Administration (TGA) for quality (how well it is made), safety, efficacy (how well it works) or performance
- that therapeutic vaping goods are not first-line therapy for smoking cessation or management of nicotine dependence and I have been offered first-line therapy
- of the short- and long-term risks versus potential benefit of using the therapeutic vaping good
- how to use the therapeutic vaping goods, including what to do if I experience a side effect
- about nicotine poisoning and what to do if I think that I (or someone else) has been exposed to a vaping substance
- of contact details for a support service (e.g. Quitline).

.....  .....

Patient name  Date

.....

Patient signature

# Appendix 5 – Access to unapproved therapeutic vaping goods

Individuals under the age of 18 require a prescription written by a medical or nurse practitioner to access unapproved therapeutic vaping goods for the treatment of nicotine dependence (subject to state or territory legislation).

A prescription is also required if a patient requires a therapeutic vaping good with a concentration >20 mg/mL.

See the TGA website, Vapes: information for prescribers and Vapes: information for pharmacists for further information.

## Authorised Prescriber (AP) scheme

Medical practitioners can apply to the TGA for approval to become an 'authorised prescriber' of an unapproved product.[19]

Pharmacists who dispense prescriptions for therapeutic vaping goods written by an authorised prescriber can confirm the validity of the prescription using the TGA online validation tool or by contacting the prescriber.

## Special Access Scheme

The Special Access Scheme (SAS) allows an individual patient to access an unapproved product.[30]

The SAS-C pathway facilitates patient access to therapeutic vaping substances for patients 16 years or over. SAS-C is a notification system only, and no TGA pre-approval is needed. The SAS-C notification can be submitted online.

The SAS-B pathway can be used if an unapproved product cannot be accessed through SAS-A or SAS-C pathways (e.g. therapeutic vaping goods for patients <16 years). Medical and nurse practitioners must submit a new application for each patient for whom they prescribe therapeutic vapes. Under SAS-B, an approval letter from the TGA must be obtained prior to prescribing.

Pharmacists who dispense prescriptions for nicotine vaping products written under SAS-B and SAS-C can confirm the validity of the prescription using the TGA online validation tool or by contacting the prescriber.

## State or territory regulations for therapeutic vaping goods

Legislation covering control of therapeutic vaping goods differs in each state and territory. Information about state or territory legislation relating to therapeutic vaping goods is available **here**.

# Appendix 6 – Vaping devices

Vaping devices are battery-operated devices that heat vaping substances to form a vapour that is inhaled.[15]

Vaping devices can be[15]:

- open systems that have a refillable reservoir for the vaping substances (could be a refillable cartridge or pod)
- closed systems that have non-refillable pods or cartridges.

## Access to vaping devices

Therapeutic vaping devices that do not contain, and are not packaged with, a therapeutic vaping substance do not require a prescription and do not need authorisation for supply under Authorised Prescriber or Special Access Scheme. However, a pharmacist must be satisfied the device will only be used for smoking cessation or the management of nicotine dependence prior to supply (i.e. if the therapeutic vaping device is being sold without a therapeutic vaping substance, the pharmacist needs to discuss the intended use with the patient).[12]

Only therapeutic vaping devices that are included in the TGA Notified vape list can be supplied.[12]

## Standards for vaping devices

Therapeutic vaping devices must comply with either the Essential Principles or the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (MDSO)*.[12] See **Understanding requirements for unapproved therapeutic vaping devices and accessories in Australia** and **Product standards: unapproved therapeutic vapes.**

Sponsors of therapeutic vaping devices that are included in the TGA Notified vape list have stated that their devices comply with the applicable standards. However, the devices on the list have not been assessed by the TGA for quality, safety, efficacy or performance.[20]

## Storage of vaping devices

As with other therapeutic vaping goods, therapeutic vaping devices that do not contain therapeutic vaping substances should be stored in the dispensary out of the line of sight of the public.[12]

# Appendix 7 – Patient populations that may require additional support

| Patient populations | Barriers to smoking cessation | Strategies to overcome potential barriers |
|---|---|---|
| Aboriginal and Torres Strait Islander peoples[3,31] | • Lack of access to culturally appropriate health care<br>• Exposure to smoking behaviour in social and cultural contexts | • Refer patients to a culturally specific smoking cessation service where available (e.g. programs run through a local Aboriginal health service, Quitline)<br>• Identify cost-effective ways for patients to access treatment (e.g. referring patients for prescriptions for subsidised smoking cessation pharmacotherapies and checking they are registered for Closing the Gap, if eligible) |
| People with a co-existing medical condition[3,32] | • Belief it is too late to stop or lack of benefit of stopping | • Highlight the health benefits of stopping specific for their health condition<br>• Integrate smoking cessation into the patient's chronic disease management program |
| People living with mental illness[11] | • Misunderstandings about the impacts of stopping smoking on mental health<br>• Higher levels of nicotine dependence<br>• Reduced opportunities for participation in smoking cessation programs | • Use higher NRT doses, combination therapy and a longer duration of therapy<br>• Adjust doses of the medicines they take for their mental health condition, if necessary<br>• Discuss stopping smoking with patients when providing advice or information about prescribed medicines<br>• Monitor patients' mental health when stopping smoking and refer them for further review if needed<br>• Offer ongoing support and refer to specialised smoking cessation programs – Quitline has tailored protocols for people living with mental illness |
| Adolescents[3] | • Fear of weight gain<br>• Stress<br>• Peer influence<br>• Parental smoking status | • Aim to prevent starting to use nicotine-containing products<br>• Intensive, multi-session behavioural intervention is important in this age group<br>• Provide messaging that smoking is not 'cool' and highlight immediate effects of smoking (e.g. bad breath, costs, reduced fitness, wrinkles)<br>• Refer to specialised smoking cessation programs<br>• Encourage parental smoking cessation |
| People who are pregnant[3] | • Lack of understanding of the risks to the fetus and themselves<br>• Household members smoking status<br>• Stigma<br>• Stress | • Highlight risks to the fetus and mother<br>• Complete cessation (rather than cutting down) is recommended<br>• Encourage other household members to also stop smoking |
| LGBTIQA+ people[3] | • Stress<br>• Anxiety<br>• Social pressure | Refer to specialised smoking cessation programs tailored to their needs (e.g. Quitline has LGBTIQA+ inclusive practices) |

# Appendix 7 – Patient populations that may require additional support - continued

| Patient populations | Barriers to smoking cessation | Strategies to overcome potential barriers |
|---|---|---|
| People living with a disability | • Difficulty obtaining, understanding or remembering smoking cessation advice<br>• Difficulty accessing services that meet their needs<br>• Belief that smoking helps with their symptoms of disability | • Provide additional resources (e.g. written material) where appropriate<br>• Provide support for patients to access and manage medicines (e.g. offering a delivery service, dose administration aid)<br>• Refer patients to services designed for people living with their particular disability (e.g. intellectual disability)<br>• Encourage family members and support workers to be involved in the patient's plan to stop smoking, where appropriate |
| People from culturally and linguistically diverse backgrounds | • Cultural resistance (e.g. if smoking is considered socially acceptable in their culture)<br>• Lack of interest in telephone support services<br>• Language barriers | • Use culturally appropriate resources to support smoking cessation<br>• Use an interpreter when communicating with patients (see the Translating and Interpreting Service **www.tisnational.gov.au**)<br>• Provide information on stop-smoking services available<br>• Refer patients to services that offer programs in their local language (e.g. Quitline uses interpreters when necessary) |

# Glossary

| Term | Definition |
|---|---|
| Authorised Prescriber (AP) scheme[33] | A scheme through the Therapeutic Goods Administration (TGA) that allows medical practitioners to prescribe therapeutic goods that are not included in the Australian Register of Therapeutic Goods (ARTG) to a group of patients with a specific medical condition. |
| Carer | For the purpose of this guideline and in relation to supplying therapeutic vaping goods only, a 'carer' has its ordinary dictionary meaning, and may include a paid or unpaid person who looks after someone who needs help with their day-to-day living. |
| Dispensing[6] | The safe provision of a medicine to a patient, which involves reviewing an order for a medicine (e.g. prescription, medication chart, patient request) in the context of the patient's medical history, and the preparation, packaging, labelling, documentation and transfer of the prescribed medicine. It includes providing advice to the patient. |
| Informed consent[6] | Permission granted voluntarily by a patient or person who has been adequately informed (e.g. of options, risks, benefits) and has the capacity to understand, provide and communicate their permission. Consent can be verbal, written or implied (e.g. patient providing a prescription to the pharmacist, patient holding their arm out to have their blood pressure taken). |
| Management plan[6] | A plan of systematic care outlined for the patient, reflecting shared decisions made with patients, families, carers and other support people about tests, interventions, treatments and other activities needed to achieve the goals of care provided by the pharmacist in collaboration with the patient and other healthcare professionals.<br><br>For the purpose of these guidelines, the management plan includes an assessment of nicotine dependence, recommendations for pharmacological and non-pharmacological interventions, duration of intervention, monitoring, therapeutic goals, education and advice provided, required follow-ups to monitor the patient's progress and when to refer to other healthcare professionals or return to the pharmacist. |
| Multi-session behavioural intervention[3] for smoking or vaping cessation | Counselling provided by a smoking and vaping cessation professional (can be a pharmacist) who uses behaviour change techniques to help guide people through the quitting process (i.e. building motivation and confidence to make a quit attempt, coping with cravings and withdrawal, and adjusting to life without smoking or vaping). Formats can include one-to-one delivery either by phone (e.g. Quitline) or face-to-face as well as group programs. |
| Nicotine-containing products | A product that contains nicotine – can include tobacco products (e.g. cigarettes, cigars, pipe tobacco, chewing tobacco, shisha, snuff, heat-not-burn), vaping substances, nicotine pouches. |
| Nicotine dependence support | Pharmacists providing support to patients to manage nicotine dependence, which may include activities such as health promotion and screening and risk assessment as well as smoking or vaping cessation strategies (e.g. brief advice, behavioural intervention, pharmacotherapy). |
| Nicotine replacement therapy (NRT)[3] | Medicines included in the ARTG that are used to support smoking cessation by providing lower doses of nicotine at a slower rate than tobacco smoking. Available in a variety of dose forms, such as gum, lozenges, mouth spray and patches. |
| Off-label use[34] | A medicine or medical device is being used for an indication, route of administration or patient group that differs from the TGA-approved indication. |

## Glossary - continued

| Term | Definition |
|---|---|
| Patient[6] | A person who is receiving care in a healthcare service organisation. 'Patient' also extends to the person's support network, which can include authorised representatives, carers (including kinship carers), families, support workers and groups or communities.<br><br>For the purpose of these guidelines and in relation to supplying therapeutic vaping goods, 'patient' refers only to the person receiving care (i.e. not to the person's support network). See also 'Carer'. |
| Prescriber[6] | A health professional authorised to undertake prescribing within the scope of their practice. |
| Prescribing[6] | An iterative process involving the steps of information gathering, clinical decision-making, communication and evaluation that results in the initiation, continuation or cessation of a medicine. |
| Special Access Scheme (SAS)[30] | A scheme through the TGA that allows access to therapeutic goods not included in the ARTG for a single patient. |
| Therapeutic vaping device[35] | A therapeutic good that is a vaping device other than a disposable therapeutic vape or a therapeutic cannabis vaping device. |
| Therapeutic vaping device accessory[35] | A therapeutic good that is an unfilled cartridge, capsule, pod or other vessel that is designed or intended for use in or with a therapeutic vaping device and that is designed or intended to contain a therapeutic vaping substance and whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled but does not include a therapeutic cannabis vaping device accessory. |
| Therapeutic vaping good[36] | A therapeutic vaping device, or a therapeutic vaping device accessory, or a therapeutic vaping substance, or a therapeutic vaping substance accessory. |
| Therapeutic vaping substance[36] | A therapeutic good that is a liquid or other substance designed or intended for use in or with a vaping device. |
| Therapeutic vaping substance accessory[36] | A vaping accessory that is designed or intended for use in, or with, a therapeutic vaping device and contains a therapeutic vaping substance. |
| Unapproved medicine/ product[37] | A medicine or product that has not been assessed in Australia for its quality, safety or efficacy and is not included in the ARTG. |
| Vape | See 'Therapeutic vaping good'. |

# Further information

## Health professional resources

- Vaping hub – provides information from the TGA on the regulations for accessing therapeutic vaping goods and links to information for patients, prescribers and pharmacists. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/therapeutic-vaping-goods/vaping-hub**
- Navigating vaping reforms – provides information from PSA about the support available for pharmacists about the changes to vaping regulations. At: **www.psa.org.au/career-and-support/navigating-vaping-reforms**
- Vapes: information for pharmacists – provides information from the TGA about therapeutic vaping goods relevant to pharmacists. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-pharmacists**
- Vapes: information for prescribers – provides information from the TGA about prescribing therapeutic vaping goods. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers**
- About vaping and e-cigarettes – provides answers to common questions about therapeutic vaping goods and how to access them in Australia. At: **www.health.gov.au/topics/smoking-vaping-and-tobacco/about-vaping**
- Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 – outlines the minimum safety and quality standards for unregistered nicotine vaping products, particularly in relation to ingredients, nicotine concentration and labelling requirements. At: **www.legislation.gov.au/Details/F2021L00595**
- Notified vape list - a list of therapeutic vaping goods that can be prescribed and dispensed in Australia. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/table/list-notified-vapes**
- Prescribing and dispensing therapeutic vapes to patients under 18 years – summarises the regulations that apply to supply of vapes to patients under 18 years in each jurisdiction. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-prescribers/prescribing-and-dispensing-therapeutic-vapes-patients-under-18-years**
- Product standards: unapproved therapeutic vapes - provides information about product standard that apply to unapproved therapeutic vapes. At: **https://www.tga.gov.au/products/unapproved-therapeutic-goods/therapeutic-vaping-goods/vaping-hub/product-standards-unapproved-therapeutic-vapes**
- Royal Australian College of General Practitioners. Supporting smoking cessation: a guide for health professionals – provides guidance for primary care health professionals on smoking cessation, including support strategies, treatments and their place in therapy. At: **www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation**
- Quit Centre – has resources for health professionals, including clinical tools, online training, links for referring patients to Quitline. At: **www.quitcentre.org.au**
- Tobacco in Australia: facts and issues – a comprehensive review of major issues in smoking and health in Australia compiled by the Cancer Council Victoria. At: **www.tobaccoinaustralia.org.au**
- Vapes: advertising and promotion - provides information about the restrictions on advertising and promotion that apply to vapes. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/therapeutic-vaping-goods/vaping-hub/vapes-advertising-and-promotion**
- Reporting adverse events for health professionals - outlines how a health professional can report an adverse event or problem related to a medicine, vaccine or medical device. At: **www.tga.gov.au/safety/report-problem/report-adverse-event-or-safety-problem/reporting-adverse-events-health-professionals**
- World Health Organization. Clinical treatment guideline for tobacco cessation in adults – international guidance for health care providers, policy makers and health service managers. At: **www.who.int/publications/i/item/9789240096431**
- World Health Organization. Framework convention on tobacco control, guidelines for the implementation of article 14 – guidance relating to tobacco cessation support. At: **https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-14**
- Using a carbon monoxide monitor – provides information about using carbon monoxide monitoring as a motivational tool in smoking cessation. At: **www.cancer.nsw.gov.au/getmedia/2bfdf618-34c9-4b01-b705-7ab3dd1337d9/Using-a-Carbon-Monoxide-Monitor-Factsheet.PDF**
- Pathology tests explained: nicotine/cotinine – provides information about cotinine testing, which is sometimes used to determine compliance with smoking cessation. At: **https://pathologytestsexplained.org.au/ptests-pro.php?q=Nicotine**

## Patient resources

- Vapes: information for individuals and patients – provides information for patients about therapeutic vaping goods and how to access them. At: **www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/vapes-information-individuals-and-patients**
- National Cessation Platform Quit – has various resources for people who smoke or vape. At: **www.quit.org.au**
- Quitline: Phone 13 78 48 – provides free, multi-session behavioural interventions with personalised and culturally appropriate support tailored to individual needs. Quitline also provides counsellors who are Aboriginal or Torres Strait Islanders.
- My QuitBuddy app – provides quit plans, tips for overcoming cravings and tracking systems to chart progress. At: **www.health.gov.au/resources/apps-and-tools/my-quitbuddy-app**
- Disposal of vapes – provides information about how to dispose of vapes. At: **https://recyclingnearyou.com.au/material/home/vapes**
- Local stop smoking programs may be provided in some areas by hospitals, Aboriginal and Torres Strait Islander Health Services and community health facilities
- Reporting adverse events for consumers - outlines how consumers can report adverse effects related to a therapeutic good. At: **www.tga.gov.au/safety/report-problem/report-adverse-event-or-safety-problem/reporting-adverse-events-consumers**

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# Notes

**PHARMACEUTICAL SOCIETY OF AUSTRALIA LTD.**
ABN 49 008 532 072

**NATIONAL OFFICE**
Ngunnawal and
Ngambri Country
Level 1, Pharmacy House
17 Denison Street
Deakin ACT 2600

PO Box 9464
Deakin West ACT 2600

**P: 02 6283 4777**
**F: 02 6285 2869**
**E: psa.nat@psa.org.au**

**BRANCH CONTACT DETAILS**
**P: 1300 369 772**

**AUSTRALIAN CAPITAL TERRITORY**
Ngunnawal and
Ngambri Country
Level 1, Pharmacy House
17 Denison Street
Deakin ACT 2600

PO Box 9464
Deakin West ACT 2600
**E: act.branch@psa.org.au**

**NEW SOUTH WALES**
Cammeraygal Country
32 Ridge Street
North Sydney NSW 2060

PO Box 162
St Leonards NSW 1590
**E: nsw.branch@psa.org.au**

**QUEENSLAND**
Turrbal and Yuggera Country
Level 2, 225 Montague Road
West End QLD 4101

PO Box 6120
Woolloongabba QLD 4102
**E: qld.branch@psa.org.au**

**SOUTH AUSTRALIA**
Kaurna Country
Suite 7/102 Greenhill Road
Unley SA 5061
**E: sa.branch@psa.org.au**

**TASMANIA**
Nipaluna Country
161 Campbell Street
Hobart TAS 7000
**E: tas.branch@psa.org.au**

**VICTORIA**
Wurundjeri Country
Level 1, 381 Royal Parade
Parkville VIC 3052
**E: vic.branch@psa.org.au**

**WESTERN AUSTRALIA**
Whadjuk Noongar Country
136 Stirling Highway
Nedlands WA 6009
**E: wa.branch@psa.org.au**

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Pharmaceutical Society of Australia