



Pharmacist workflow for dispensing therapeutic vapes

Note: this workflow is applicable when dispensing to a patient with a prescription.

KEY POINTS:

- Pharmacists must not dispense a prescription without verifying that it is appropriate, and lawful to supply the medicine. Where clarification is required, consult with the patient or their carer and contact the prescriber, if necessary.
- Therapeutic vapes must be listed on the TGA's list of notified vapes.
- Minors under 18 years of age cannot be supplied with vaping products in some states/territories. See **Prescribing and dispensing of prescription** only therapeutic vaping goods to patients under 18 years of age.
- Therapeutic vapes must only be supplied to patients in connection with an authority that is in force under the TGA's Authorised Prescriber (AP) pathway, an approval that is in force under the TGA's Special Access Scheme category B (SAS-B) pathway, or be authorised for supply to the patient in accordance with the TGA's Special Access Scheme category C (SAS-C) pathway (see below).

TGA Pathway	Description	Form submitted by	TGA Reference
AP	Established history of use pathway (for patients 16 years and older) or standard pathway (may be used for patients under 16).	Medical Practitioner	TGA reference on authorisation letter (MAP25-XXXXXXX)
SAS-B	TGA Approval for Category B: Case-by-case basis, generally for patients under 16 with appropriate clinical justification.	Prescribing medical or nurse practitioner or pharmacist (with permission)	TGA reference in approval letter (MB25-XXXXXXXX)
SAS-C	TGA Approval for Category C: For patients 16 years and older, used for smoking cessation or nicotine dependence management.	Prescribing medical or nurse practitioner or pharmacist (with permission)	TGA reference on submission receipt from SAS & AP Online System (MC25-XXXXXXXX)

1 Confirm product compliance

Compliance: Confirm that the therapeutic vapes you supply are included on the TGA's list of notified vapes and have not been flagged on the TGA website for supply to be stopped or discontinued.

Note: All therapeutic vapes on the TGA's notified vape list are unapproved goods that have not been evaluated by the TGA for quality, safety or efficacy. General dispensing requirements apply to prescription medicines, and state and territory regulations must be considered when sourcing and dispensing therapeutic vapes (e.g. retail licensing or notification mandates in specific jurisdictions).

Advertising Restriction: Do not advertise supply or stock of therapeutic vapes in pharmacy or online.

Receive prescription

Action: Obtain the prescription from the patient or prescriber, along with the TGA reference for the relevant SAS-B or AP approval or SAS-C authority.

Action: Where the prescribing health practitioner has not submitted a SAS-B or SAS-C form, the pharmacist may do so on behalf of the prescriber (with their permission). It is best practice for the prescriber to submit the SAS-B application or the SAS-C notification in case additional information is required. It is important to note, SAS-B applications require TGA approval before supply. Pharmacists are not obliged to submit the application or notification on behalf of the prescriber. Pharmacists must be registered with **TGA's SAS & AP Online System** to submit a SAS-B or SAS-C form.

Ensure SAS or AP submission is valid

Action: Before dispensing a therapeutic vape, pharmacists must check the validity of the SAS or AP submission by entering the TGA reference number in the validation tool of the TGA's SAS & AP Online System. Contact the prescriber if no reference number is provided on the prescription. For those unfamiliar with how to validate, click **here** to watch the guidance video.

4 Dispense the product

Action: Prepare and dispense the product as per the prescription in accordance with state/territory legislation. See PSA's Professional Practice Guidelines: Nicotine Dependence Support for further guidance.

Document the intervention

Action: Record the details of the prescription, TGA's reference for the relevant approval or authority and the clinical notes from your consultation with the patient in your dispensing records.

6 Notify the TGA (if necessary)

Action: Report any suspected adverse events to the **TGA**.

Note: Where a medical or nurse practitioner prescribes a therapeutic vape and provides the SAS-C notification to the TGA, a new notification does not need to be made each time the goods are dispensed to that patient. The initial notification is sufficient for the patient's course of treatment by that medical or nurse practitioner.

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