



Nicotine Vaping Products: A Quick Guide for Pharmacists

Current as at 24 September 2021

From 1 October 2021, consumers will require a prescription for all purchases of nicotine vaping products (NVPs), regardless of whether these products are purchased in Australia or from overseas. These regulatory changes will mean that it will be illegal for retailers such as vape stores and tobacconists to sell NVPs.

NVPs include nicotine e-cigarettes, nicotine pods and liquid nicotine. There are currently no TGA approved NVPs in the Australian Register of Therapeutic Goods, making these products unapproved medicines that have not been assessed by the TGA for safety, quality and efficacy.

Access pathways

There will be two main ways in which consumers will be able to legally access unapproved NVPs, with a valid prescription, that utilise the already established [access pathways for unapproved medicines](#).

At a pharmacy (in person or online)

If the consumer intends to fill their prescription at a pharmacy, their medical practitioner will need to use either the Authorised Prescriber (AP) Scheme or Special Access Scheme (SAS) Category B to obtain approval to prescribe these products. Pharmacists will require evidence of an AP or SAS B approval prior to dispensing.

Using the Personal Importation Scheme

Consumers can continue to order and import NVPs from an overseas online retailer using the Personal Importation Scheme. Consumers will require a valid prescription to be able to order NVPs via this pathway.

Sourcing stock

Unapproved NVPs may be sourced from an Australian sponsor and/or wholesaler, or directly from an overseas supplier. Pharmacies are allowed to keep NVP stock in anticipation of receipt of a valid prescription. As there are a large number of NVPs available, including many different strengths and flavours, it may be prudent to determine consumer demand prior to ordering stock in anticipation of a prescription.

Standard for Nicotine Vaping Products (TGO 110) Order 2021

The TGA has introduced a [standard for unapproved NVPs](#) that sets out the minimum safety and quality requirements for unapproved NVPs. The [Guidance on TGO 110](#) helps to explain the requirements of TGO 110 as well as other matters related to NVPs such as vaping devices and advertising. It is the responsibility of the product sponsor to ensure products dispensed and supplied to patients meet the requirements of TGO 110.

Pharmacists are considered the product sponsor for extemporaneous compounds and are likely to be considered the sponsor for products ordered by the pharmacy directly from an overseas supplier. The TGO 110 requirements applicable to NVPs supplied through pharmacy are summarised below.

Ingredients

- » Nicotine must be the only active ingredient
- » Nicotine concentration/content must be within 90-110% of what is stated on the label
- » Nicotine concentration must be 100mg/mL or less (expressed as base form)
- » NVPs must not contain any prohibited ingredient listed in TGO 110

Packaging

NVPs must have child-resistant packaging unless exempt by TGO 110.

Labelling

NVPs must include on the container, primary pack or information sheet:

- » An ingredient list in English
- » Nicotine concentration (mg/mL)
- » Specified warning statements

Record-keeping obligations for Australian sponsors

Sponsors must maintain records that demonstrate conformance with TGO 110.

State and Territory considerations

Each state and territory has tobacco/smoking product or e-cigarette control legislation that may apply to pharmacists seeking to dispense NVPs or supply vaping devices. Some jurisdictions may require pharmacies to obtain a retail licence for tobacco products/e-cigarettes before dispensing and supplying NVPs; other jurisdictions may require health department notification before dispensing and supply NVPs. Further information including the contact details for each state and territory can be found on the [TGA website](#).

Pharmacist Guidelines

The professional *Guidelines for pharmacist providing smoking cessation services* are being updated to include information on NVPs. Pharmacists should familiarise themselves with the guidelines when they become available.

Additional Resources

TGA Nicotine vaping products webpage: <https://www.tga.gov.au/nicotine-vaping-products>

Department of Health & NPS MedicineWise access flowchart: https://www.nps.org.au/assets/NPS2364_Nicotine_eCigs_Flowchart_v8.pdf

Australian Government Department of Health website: <https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes>