



# Accessing nicotine e-cigarettes and nicotine vaping products

From 1 October 2021, the Poisons Standard clarifies the regulation of nicotine as a Schedule 4 medicine. Nicotine vaping products are 'unapproved' therapeutic goods as they are not entered on the Australian Register of Therapeutic Goods. This information sheet outlines the established pathways for legal access to 'unapproved' nicotine vaping products, with a prescription.



Consumer seeks support to quit smoking using nicotine vaping products

If nicotine
vaping products
are appropriate
for smoking
cessation,
GP writes
prescription.

Will nicotine
vaping products
be purchased
from an Australian
pharmacy?



#### **Authorised Prescriber Scheme**

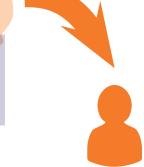
- ▶ GP prescribes directly to patients under their immediate care without requiring separate approval for individual patients.
- ▶ Apply to become an Authorised Prescriber using the SAS & Authorised Prescriber Online System, or downloadable form (there is no charge for applying). Prescribers submit their name, address and AHPRA number.
- ➤ This process has now been simplified so Human Research Ethics Committee (HREC) approval or specialist college endorsement is not required for nicotine in solution, salt or base form that is to be used for smoking cessation.
- ▶ The TGA does not need to be notified each time nicotine vaping products are prescribed during the period of approval (5 years). However, prescribers must report to the TGA the number of patients they treat every 6 months.

### **Special Access Scheme (SAS)**

- ► GP prescribes for a single patient on a case-by-case basis.
- Complete the SAS Category B application using the SAS & Authorised Prescriber Online System, or downloadable form.
- ▶ Include three patient identifiers, patient diagnosis and indication, product details and prescriber details. The application requires clinical justification for the use of the product.



Consumer fills prescription at Australian pharmacy



#### **Resources for GPs**

- ▶ RACGP Guidelines: **Supporting smoking cessation**
- ► TGA: Nicotine e-cigarettes hub
- ► TGA: Information for Authorised Prescribers
- ► TGA: **Special Access Scheme**

Telehealth smoking cessation MBS item numbers are in development, please see the Department of Health website for more information.

## **Personal importation Scheme**

- ➤ Any prescriber can write a script for a single patient to access nicotine vaping products for personal importation.
- ► TGA approval is not required.
- ▶ Patients are not permitted to import more than 3 month's supply via the personal importation scheme in any one importation. If a patient wants to access more than a 3-month supply in a single importation, prescribers will need to apply for approval through the Authorised Prescriber Scheme or Special Access Scheme before providing the prescription.



Consumer buys nicotine vaping products from an international seller.

The TGA strongly encourage consumers and health professionals to <u>report any suspected adverse events</u> involving e-cigarettes and nicotine vaping products.

This helps build a profile of the safety of an 'unapproved' product.