



Australian Government

Department of Health  
Therapeutic Goods Administration

## Regulatory changes to importing, supplying and advertising

From 1 October 2021, all nicotine vaping products, such as nicotine e-cigarettes, nicotine pods and liquid nicotine, will be prescription only medicines. Because there are presently no nicotine vaping products registered in the Australian Register of Therapeutic Goods (ARTG), *any* importation of nicotine vaping products must comply with the *Therapeutic Goods Act 1989* obligations for 'unapproved' medicines. This fact sheet explains how nicotine vaping products can be lawfully imported, supplied and advertised in Australia and the requirements of the TGA standard for ingredients, packaging and labelling of unapproved products.

### International supply to the Australian market for personal use

If you are a retailer of nicotine vaping products outside of Australia who would like to keep supplying the Australian market after 1 October 2021, there are a number of ways you can do this and ensure your customers comply with Australian law and receive their goods.

If you have customers who are purchasing a personal supply of nicotine vaping products, they will require a valid prescription from an Australian doctor at the time of import. Under the TGA's personal importation scheme, Australian consumers with a prescription can order a maximum of 3 months' supply at one time and a maximum of 15 months' supply in a 12-month period.

We encourage you to ask your Australian customers for a copy of their prescription to finalise their order from you and that you provide a copy of the prescription to your logistics provider and/or include a copy in the package when you ship the products. Having a valid prescription available at the time of import will assist in the assessment and clearance of goods by the Australian Border Force. Without it included, the customer risks delivery delays and, if there is no prescription, loss of product and fines.

If your customers require more than a 3 months' supply in a single order they will need to order it through an Australian pharmacy who can import on their behalf under the [Special Access Scheme](#) or the [Authorised Prescriber Scheme](#).

### International supply to the Australian market for commercial purposes

Generally, prescription medicines, such as nicotine vaping products, must be approved by the TGA and registered in the ARTG before they can be lawfully imported into, or supplied in, Australia. Pharmacists can dispense nicotine vaping products to consumers within Australia on prescription, but general retail sale to consumers within Australia is not permitted.

To obtain ARTG entry for a nicotine vaping product, an Australian sponsor can apply to the TGA to register the product as a prescription medicine. Further information about the process for product registration can be found at [Prescription medicines](#).

Nicotine vaping products not registered in the ARTG are unapproved medicines. Unapproved nicotine vaping products can only be imported into Australia by consumers under the [Personal Importation Scheme](#).

When importing for commercial supply, the Australian sponsor (supplier) must have a reasonable expectation that the unapproved nicotine vaping product will ultimately be supplied to a consumer under the Authorised Prescriber scheme, the Special Access Scheme, the Clinical Trial Approval Scheme, or another relevant exemption.

The sponsor should ensure that they (or their logistics service provider/s), and any wholesale supplier they sell to, has a wholesale licence for prescription only medicines, including nicotine vaping products, from the relevant state or territory health department.

### Nicotine vaping product standard

The TGA has made a [standard for unapproved and export only nicotine vaping products](#), known as the [Therapeutic Goods Standard for Nicotine Vaping Products \(TGO 110\) Order 2021](#) (TGO 110), that comes into effect on 1 October 2021. TGO 110 includes minimum safety and quality requirements for unapproved nicotine vaping products. It includes rules about:

- product labelling (including an over sticker or in an information sheet provided with the product)
- child resistant packaging
- maximum nicotine concentration (although people will still only be able to access the nicotine concentration in their prescription)
- requiring actual nicotine concentration/content to reflect what the product's label says

- prohibited ingredients
- records that need to be kept by the Australian sponsor for the product.

Some, but not all, of the requirements of TGO 110 apply at the time a product is imported into, or exported from, Australia. All of the requirements of TGO 110 apply when the products are supplied within Australia. Australian sponsors of unapproved and export only nicotine vaping products must maintain records demonstrating conformance to the requirements of TGO 110.

Further information on the requirements of TGO 110 is available in our [Guidance for Therapeutic Goods \(Standard for Nicotine Vaping Products\) Order 110 2021 \(TGO 110\) and related matters](#) (Guidance on TGO 110). This guidance will assist Australian sponsors to understand their obligations in relation to TGO 110. Overseas suppliers of Australian consumers through the personal importation scheme might also find it helpful to review the Guidance on TGO 110 when responding to enquiries from Australian doctors and consumers, who are encouraged to check with overseas suppliers about whether their products meet the requirements of TGO 110 and otherwise have appropriate packaging, labelling and manufacturing controls.

### Advertising requirements

Advertising prescription medicines, including nicotine vaping products, to consumers is generally prohibited in Australia. However, a TGA permission authorises pharmacies and pharmacy marketing groups, in limited circumstances, to advertise the availability of product. A number of states and territories also restrict the promotion of nicotine vaping products and / or vaping devices.

Further information on how you can lawfully refer to nicotine vaping products and vaping devices and promote your services is available in our guidance on [Advertising nicotine vaping products to the Australian public](#).

### Consequences for unlawfully importing, supplying and advertising nicotine vaping products

Imported nicotine vaping products may be intercepted by the ABF and assessed for compliance with Australian law including, for individuals, whether there is prescription and, for businesses, whether there is a reasonable expectation the product will be supplied to the ultimate consumer in accordance with a TGA approval or authorisation or other relevant exemption. The TGA can request the ABF seize any imports it assesses to be unlawful.

The bottom line – Australian customers importing nicotine vaping products for personal use must have a valid prescription at the time of import. Where an Australian business imports for subsequent supply, they must have a reasonable expectation that the unapproved nicotine vaping product will ultimately be supplied to a consumer in accordance with a TGA approval or authorisation, or other relevant exemption. Imported products must comply with the ingredient requirements of TGO 110 and, if supplied within Australia, the packaging and labelling requirements in TGO 110 also. Furthermore, nicotine vaping products must not be advertised in Australia unless subject to the [nicotine advertising permission](#). Failure to do this may result in customers not receiving their goods and exposure to criminal offences or civil penalties.

The TGA investigates unlawful import, supply and advertising of nicotine vaping products in Australia and encourages compliance with Australian laws by providing education and guidance in the first instance. For repeated and deliberate non-compliance, the TGA takes escalated regulatory action which can include injunctions, infringement notices, civil court proceedings and criminal prosecution.

### Further information

Further information about the regulation of nicotine vaping products can be found at <https://www.tga.gov.au/nicotine-vaping-products>.

### Contact us

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