

## **Information for Pharmacists - Nicotine Vaping Products**

### **Nicotine Vaping products are Schedule 4 Prescription medicines**

**From 1 October 2021** nicotine for human use, apart from that in tobacco for smoking, or oromucosal or transdermal nicotine replacement therapy (NRT) treatments, is a Schedule 4 prescription medicine. For consumers to obtain e-liquids and e-cigarettes containing nicotine, they will need to consult with a medical practitioner to obtain a prescription if the medical practitioner decides the products are clinically appropriate. If prescribed, consumers can obtain their nicotine vaping product either dispensed in an Australian pharmacy (only for persons aged 18 years and over), or import it from overseas websites using the Personal Importation Scheme.

### **Nicotine vaping products are 'unapproved' therapeutic goods**

Currently there are no nicotine vaping products included in the Australian Register of Therapeutic Goods (ARTG). Medicines that are not in the ARTG are known as 'unapproved' medicines and have not been assessed by the Therapeutic Goods Administration (TGA) for quality, safety or efficacy.

However, there are a range of evidence based smoking cessation aids available to consumers that are included in the ARTG, including various nicotine replacement therapy (NRT) products and some prescription medicines. NRT, varenicline and bupropion are approved to aid smoking cessation. There is also evidence for effectiveness of nortriptyline although smoking cessation is not an approved indication.

### **Requirements for NSW pharmacies that supply nicotine vaping products**

In NSW, if a pharmacist chooses to dispense nicotine vaping products on prescription, he/she will need to comply with all of the legal requirements under the NSW *Poisons and Therapeutic Goods Act 1966*, NSW *Public Health (Tobacco) Act 2008* and the Commonwealth *Therapeutic Goods Act 1989*.

### **Restrictions on retailing and advertising nicotine vaping products**

Any retailing of e-cigarettes and e-liquids, regardless of whether the product contains nicotine or not, must meet the requirements set out under the NSW *Public Health (Tobacco) Act 2008*. This means, to dispense nicotine vaping products in pharmacies, the following must be complied with:

- Notify NSW Health of their intention to retail e-cigarettes and e-liquids through Service NSW before commencing retailing of these products. Register at: [www.service.nsw.gov.au/transaction/apply-be-tobaccoe-cigarette-retailer](http://www.service.nsw.gov.au/transaction/apply-be-tobaccoe-cigarette-retailer)
- E-cigarettes or e-liquid must not be supplied to anyone aged under 18 years, (with or without nicotine).
- The sale of e-cigarettes and e-cigarette accessories must be from a single point of sale – meaning only one cash register can sell these products in each pharmacy.
- Ensure that e-cigarettes are not part of any shopper loyalty program.
- Display the notice regarding sales to minors at the point of sale. Compulsory signs are provided at the time of registering through Service NSW.

Further information and resources for e-cigarette retailers are available from the NSW Health website at [www.health.nsw.gov.au/tobacco/Pages/ecig-retailers.aspx](http://www.health.nsw.gov.au/tobacco/Pages/ecig-retailers.aspx) or you can contact the Tobacco Information Line on 1800 357 412.

## Restrictions on the supply of prescription nicotine

Schedule 4 medicines containing nicotine must be dispensed as a Schedule 4 medicine, in accordance with the *Poisons and Therapeutic Goods Act 1966* and *Poisons and Therapeutic Goods Regulation 2008* (PTGR), with additional requirements that apply to unapproved medicines.

The nicotine product in NSW:

- must only be supplied on the valid prescription of an authorised practitioner
- must be supplied on the prescription of an authorised practitioner who is approved or authorised by the TGA under the Special Access Scheme, Authorised Prescriber scheme or Clinical Trial schemes to supply the unapproved good
- must only be supplied in a quantity and for a purpose that accords with the recognised therapeutic standard of what is appropriate in the circumstances
- record of supply must be kept in accordance with the PTGR
- must be labelled as a dispensed medicine
- must be packaged with a child resistant closure
- must be stored in a room or enclosure to which the public does not have access, and apart from food. In addition, e-cigarettes and e-cigarette accessories must not be seen by the public from inside or outside the pharmacy.
- must not be used or disposed of in any place or in any manner likely to constitute a risk to the public. Unsafe disposal of nicotine may place people at high risk of poisoning.

## Advertising and promotion restrictions and therapeutic claims

It is unlawful to promote or publicise an e-cigarette product, trademark or brand name through a sponsorship; include e-cigarettes in shopper loyalty programs; give out free samples of e-cigarettes; and sell confectionery or toys that resemble e-cigarettes.

It is also unlawful to make false or misleading representations that goods have a standard or quality which they do not have. For example, making unsubstantiated claims about the therapeutic properties of e-cigarettes and e-liquids.

For more information see:

- The NSW Health [Pharmaceutical Services](#) webpage
- The NSW Health [Electronic Cigarettes](#) webpage
- The TGA webpage on [Nicotine vaping products: Information for pharmacists](#)