

Question	Answers
How can I find a list of available vaping products to prescribed? How do I prescribe an authorised script? It seems overly complex	Nicotine vaping products (NVPs) are not listed on the Australian Register of Therapeutic Goods (ARTG) and are therefore unapproved products. There is no specific list of NVPs to be prescribed. A broad range of NVPs and vaping devices are available on the market. The steps required become an Authorised Prescriber can be found on the TGA website https://www.tga.gov.au/form/authorised-prescribers
What are the obligations of being an Authorised Prescriber again?	These details can be found on the TGA website https://www.tga.gov.au/form/authorised-prescribers or https://www.tga.gov.au/nicotine-vaping-products-information-prescribers
Any recommendations on prescribing varenicline whilst recall is in place?	<p>Champix (varenicline) was recalled by Pfizer Australia in July 2021 due to a potential contamination issue with the nitrosamine impurity, N-nitrosovarenicline.</p> <p>Information on the recall can be found at https://www.tga.gov.au/alert/varenicline.</p> <p>The supply impact dates are currently listed to 31 December 2021.</p> <p>Currently, there are no other brands of varenicline available in Australia. Combination nicotine replacement therapy is as effective as varenicline for smoking cessation (as an alternative) if clinically appropriate.</p>
Is there a place for entering the patient into a contract that your prescription is conditional on them engaging in a quit program with a view to cessation by week 12? In this instance, can pharmacotherapy such as Champix be prescribed at the same time?	<p>Support for patients should be individualised, according to evidence-based guidelines. NVPs should be used in combination with behavioural support (such as Quitline). Further information can be found in the RACGP guidelines.</p> <p>There is currently limited evidence for combination use involving NVPs. According to a 2021 UK briefing paper on NRT combination therapy, there may be benefit from the rapid delivery of nicotine from NVPs alongside steady state nicotine from nicotine patches.</p>
If patients use nicotine vaping products for 12 weeks and aim to completely stop but find it difficult, is it better for them to continue using nicotine vaping products or go back to smoking cigarettes? In other words, why is there a recommendation for patients to stop using vaping products at 12 weeks?	<p>The long-term health effects of NVPs are currently unknown. Cessation of both tobacco smoking and use of other forms of nicotine is always the preferred option. There may be instances in selected patients where the doctor and patient agree that a longer-term use of NVP is needed to avoid a relapse to tobacco use. The patient should be counselled on the risks and benefits versus re-trying other approved smoking cessation pharmacotherapies.</p> <p>Transfer to NRT is an option for transitioning from NVPs to a form of nicotine less associated with long-term use.</p>
Do we know what products will be available in pharmacies?	Discussion with your local pharmacist is advised. Australian Pharmacies can source unapproved nicotine vaping products from an Australian sponsor and/or pharmaceutical wholesalers or directly from overseas suppliers. Pharmacies can hold stock of unapproved nicotine vaping products in anticipation of supply under the Authorised Prescriber Scheme or Special Access Scheme (subject to any state or territory restrictions or requirements). Products must be compliant with TGO 110.
Are any NVPs in prescribing software?	<p>NVPs will increasingly become listed in prescribing software, but this does not guarantee alignment with the recommendations in the RACGP guidelines or compliance with TGO 110. In some cases, the prescriber will need to manually add the product into the software. Prescriptions are non-PBS and can be handwritten.</p> <p>It is important to remember that an Authorised Prescriber must report to the TGA the number of patients treated every six months and records must be kept for this reporting.</p>

How does the authorised prescriber system work if there are no authorised nicotine vaping products in Australian pharmacies? Doesn't everyone need to import?	Australian Pharmacies can source unapproved NVPs from an Australian sponsor and/or pharmaceutical wholesalers or directly from overseas suppliers. Pharmacies can hold stock of unapproved NVPs in anticipation of supply under the Authorised Prescriber Scheme or Special Access Scheme (subject to any state or territory restrictions or requirements). Products must be compliant with TGO 110.
How do we assess risks of flavours if we don't know the ingredients of the flavours (not required by TGO 110)?	Flavourings have not been assessed as being safe when inhaled. Different flavourings may have different safety profiles and ingredients.
What standards apply to the vaping devices themselves?	Vaping devices are not considered medical devices and are therefore not regulated by the TGA. These devices are considered to be consumer goods. The Australian Competition and Consumer Commission (ACCC) and state and territory consumer agencies regulate product safety issues with these devices. State and territory tobacco legislation may also apply to the sale of these devices.
What are the approximate costs?	The cost of the NVP or vaping device will be set by the pharmacy or retailer (depending on the place of purchase and pathway of access). Unapproved products are not eligible to be subsidised under the Pharmaceutical Benefits Scheme. Discussion with your local pharmacist is advised.
Are repeats permitted? I can imagine the upfront cost may be exorbitant (especially for 3 months supply)	The prescription is a private prescription and the decision to provide repeats or not is at the discretion of the prescriber. The RACGP guidelines recommend limiting the quantity of NVPs per prescription to a maximum of 3 months' supply or aligning the duration of supply with the timing of follow-up).
if a patient needs a script for the personal importation pathway, does the prescriber need to be an authorised prescriber on the TGA register as they would if writing for a local pharmacy?	Any medical practitioner who considers it appropriate for their patient to use NVPs for smoking cessation can prescribe those products for personal importation (note that the labelling and packaging requirements within the TGO 110 do not apply to products that are personally imported). Medical practitioners do not need TGA authorisation or approval to prescribe unapproved nicotine vaping products for access through the Personal Importation Scheme.
On the prescription do we just need to write for example 'Nicotine liquid for vaping 20mg/ml, 100ml' ... or do we need to specify a particular product and write something like 'Odin's Raven Nicotine liquid for vaping 18mg/ml, 30ml'. It seems like the nicotine guidelines recommend specifying a particular product to ensure it is reputable and follows the designated requirements, but now in Australia we're only meant to write prescriptions using the generic name of the drug -> ie. 'Nicotine'.	NVP prescriptions should specify: nicotine concentration (in mg/mL), recommended daily dose and quantity. The RACGP guidelines suggest that the prescriber may wish to specify a product brand to reduce confusion or uncertainty during dispensing. Pharmacies can hold stock of unapproved NVPs, discussion with your local pharmacist may assist with advice regarding available products.
Duration of use? Is there any role for harm minimisation akin to Buprenorphine or Methadone in opioid prescription in individuals who indicate after 3-6 months of NVP they will go back to cigarettes if they don't continue to get NVP's?	<p>There is currently a lack of evidence about the optimal length of use or how to titrate NVPs to achieve nicotine cessation, A suggested approach is to attempt weaning or cessation after 12 weeks. Consider a maximum duration of 12 months.</p> <p>If considering ongoing use of NVPs, counsel the patient on the risks and benefits versus re-trying other approved smoking cessation pharmacotherapies. This discussion includes that the long-term safety of NVPs is unknown, that there is a lack of high quality evidence of the health benefit from a tobacco harm reduction approach using NVPs, and that people who use NVPs have an approximately double the risk of relapse to combustible tobacco smoking compared with non-NVP users.</p>

<p>1. Where are the prescription forms and how do I fill them out ? The only nicotine on BP is gums , patches etc 2. What about pre existing 'vapers' . Are they eligible if they want to stop over time 3 . Approximate costs per month average smoker ? Will imports be cheaper ?</p>	<p>Regarding prescription forms and electronic prescribing software, see above.</p> <p>Regarding patients appropriate for prescription of NVP's, consider RACGP recommendation "For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along with behavioural support.</p> <p>The cost of cigarettes is dependent on the brand and number smoked, but is estimated to be in the region of \$390 per month (for a half-a-pack a day smoker). The costs of NVPs will be entirely dependent on the cost of the chosen products and the rate at which they are used.</p>
<p>How does one write a prescription and what needs to be specified if a patient is going to import it for personal use? For example primary ingredient or brand? dose? and amount? Did you have an example of what a script would specify? thanks!</p>	<p>See answers regarding prescription requirements and product choice above</p>
<p>Does the patient need to be in my personal care or can they a practice patient?</p>	<p>If you are referring to patient eligibility for MBS subsidised smoking cessation services, refer to the MBS facts sheet http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/FAQ-SmokCess</p>