CLINICAL RESOURCE

Nicotine vaping product guidelines

Contents

Disclaimer: *This document is intended for AHPRA registered healthcare practitioners and must not be distributed to the public. Therapeutic Nicotine Vaping Products discussed in these guidelines are not listed on the Australian Register of Therapeutic Goods (ARTG) and are therefore unapproved medicines. Unapproved medicines have not been assessed by the TGA for safety, quality or effectiveness. Prescribers must consider approved and available treatments prior to supplying an "unapproved" good to their patients. Estimated therapeutic effects and potential condition data is gauged by clinical experts through real patient feedback and supplier information.*

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Overview

Legislations and pathways

As of October 2021, the Australian government moved to a unique medical model for nicotine vaping products (NVPs), also known as vapes and e-cigarettes. This meant that nicotine vaping products could not be sold or imported into Australia without a prescription. In January 2024, the government introduced further restrictions by banning all disposable vapes and closing the personal importation scheme for these vapes. A new Special Access Scheme C was introduced to allow nurse practitioners to also prescribe nicotine vaping products. In March 2024, the personal importation scheme was completely closed for all vapes along with a ban on the importation and manufacture of all non-therapeutic vapes, with strict TGO (Therapeutic Goods Order) limits introduced to ingredients.

At the time of this version of this document, all nicotine vaping products in Australia may only be obtained from a pharmacy and require a prescription and TGA notification/approval prior to supply. Prescribers may use one of 2 pathways – Authorised Prescriber Pathway (for medical practitioners only) and the Special Access Scheme C (for medical and nurse practitioners).

Although the TGA does allow therapeutic nicotine vaping products to be prescribed for patients under the age of 18 (through the Authorised Prescriber pathway only), individual state regulations (except in Northern Territory and Western Australia) do not yet allow for the supply of these products to persons under the age of 18 – in line with the RACGP recommendations, these therapeutic products are not to be used in this patient cohort.

For nurse practitioners and prescribers using the Special Access Scheme C, a notification is required to the TGA within 28 days of supply of the therapeutic nicotine vaping product to the patient. Pharmacists may use the SAS/AP submission validation tool on the Special Access Scheme and Authorised Prescriber Scheme Online System.

From the **1 July 2024**, therapeutic vaping products (including nicotine and zero-nicotine products) are only accessible from a pharmacy. Until the **30 September 2024**, prescriptions are required for all therapeutic vaping products, prior to supply.

Flavours have also been restricted to mint, menthol and tobacco.

From the **1 October 2024**, nicotine vaping products under 20mg/mL will shift to schedule 3 medications, meaning a prescription will not be required for these products, provided the patient only requires 1 months' worth of product at a time and they over the age of 18. Any patients requiring a larger quantity, higher strength or patients under 18 years of age will require a prescription (subject to state or territory laws).

The pharmacology of nicotine

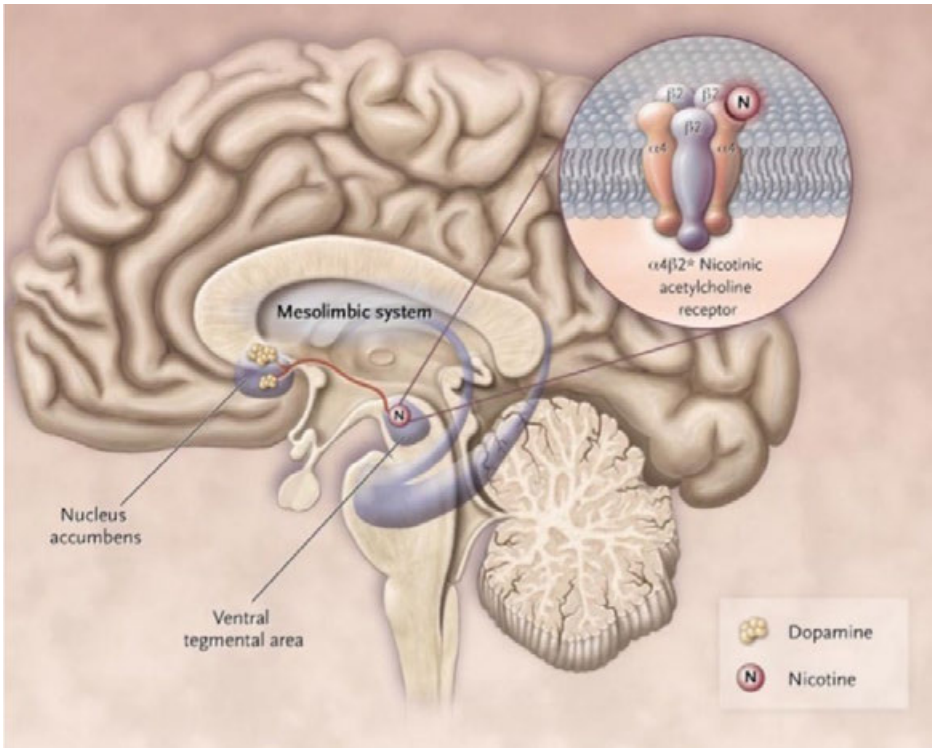
When a person inhales smoke from a cigarette, nicotine is distilled from the tobacco and is carried in smoke particles into the lungs, where it is absorbed rapidly into the pulmonary venous circulation.

It then enters the arterial circulation and moves quickly to the brain where it readily diffuses through brain tissue.[1]

Nicotine binds to and activates neuronal nicotinic cholinergic receptors (nAChRs) which stimulates the release of several neurotransmitters in the brain (nucleus accumbens) including dopamine, the pleasurable effects of which contribute significantly to the reinforcing effects of nicotine intake1. The nAChRs that contain the α4 and β2 subunits, often in combination with the α6 subunit, are particularly important for nicotine's ability to increase midbrain dopamine neuron firing rates and phasic burst firing. Alpha4 beta2 receptor in the brain is responsible for reducing appetite and increasing metabolism. Nicotine can pass through the Blood Brain Barrier (BBB) which can have rapid effects on the brain.

Although most of the toxicity of smoking is related to other components of cigarette smoke, it is primarily the pharmacologic effects of nicotine that produce addiction to tobacco.[1]

Tobacco is carcinogenic – however, whilst nicotine is addictive, studies are unable to determine if it is a carcinogen in isolation.[2]



Role of the mesolimbic dopamine system in nicotine activity.

Image source: https://link.springer.com/chapter/10.1007/978-981-10-8144-6_5

When to consider therapeutic nicotine vaping products

According to recommendation 1 of the RACGP smoking cessation guidelines, all patients who smoke should be offered brief smoking cessation advice.

Pharmacotherapy should be recommended to all people who smoke with nicotine dependence.

The most successful approach to quitting for people who smoke with nicotine dependence is behavioural support combined with first-line pharmacotherapy and follow-up.

Nicotine replacement therapy (NRT), varenicline and bupropion are licensed and available in Australia to assist smoking cessation.

Varenicline is the most effective single-form pharmacotherapy for smoking cessation.

Combination NRT is as effective as varenicline and more effective than single types of NRT.

Considerations guiding choice of pharmacotherapy for people who want to quit smoking are based on evidence of effectiveness, clinical suitability, and patient choice.

Recommendation 15 of the RACGP smoking cessation guidelines states the following:

Recommendation 15

"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 OR patients with nicotine dependency, NVPs may be a reasonable intervention to recommend along with behavioural support. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following caveats:

- Due to the lack of available evidence, the long-term health effects of NVPs are unknown.
- NVPs are not registered therapeutic goods in Australia and therefore their safety, efficacy and quality have not been established.
- There is a lack of uniformity in vaping devices and NVPs, which increases the uncertainties associated with their use.
- To maximise possible benefit and minimise risk of harms, dual use should be avoided and long-term use should be minimised.
- It is important for the patient to return for regular review and monitoring."

Therapeutic nicotine vaping products are reserved for last-line therapy, when all other TGA-approved pharmacotherapy has failed.

Nicotine vaping products may be considered in patients seeking smoking cessation support as it may mimic behavioural aspects of smoking, whilst minimising the effects of nicotine withdrawal. HCPs may also consider supplementing NVP therapy with conventional NRT (patches, gums, lozenges) to provide baseline nicotine plasma concentrations and for nicotine replacement in instances where an NVP may not be used (aeroplanes, office settings etc).

Potential patient cohorts

Patients with alcohol and drug dependence, a personal history of mental health disorders, from a low socio-economic background, blue collar workers and Aboriginal and Torres Strait Islanders are at a higher risk of nicotine dependence and smoking.[3]

Contraindications and interactions

Prescription of NVPs does not add any new pharmaceutical agent to the body – for most patients who have nicotine dependence, there will be no contraindications. Harm minimisation in pregnancy and breastfeeding – where possible, avoid use, however if patient is smoking and other NRT has failed then NVP use is preferrable.

Prescribers who switch patients from smoking to nicotine vaping need to consider drug interactions, even though new pharmaceutical agent is not being introduced to the body.

The smoke from a cigarette itself can influence drug metabolism in the liver. When patients stop smoking, this can cause an increase in other drug plasma concentrations – prescribers should monitor patients for adverse effects of other drugs during the initial cessation period (up to 1 month).

Adverse events

Adverse events related to NVPs are rare. These events include:

- Cough
- Nausea
- Dry mouth
- Throat irritation
- Other nicotine AEs

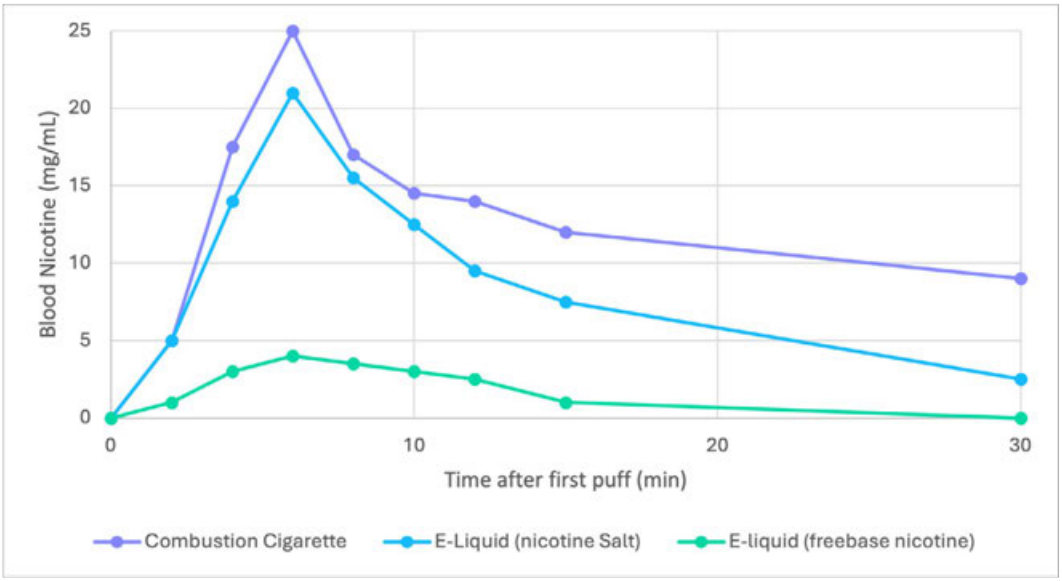
Healthcare professionals are required to report any suspected adverse effects to the TGA as soon as they are made aware of the side effect.

Product considerations

Nicotine salt vs freebase nicotine

Nicotine is delivered in therapeutic vaping products either as freebase nicotine or nicotine salts. The below diagram details the pharmacokinetic profile of the two delivery forms of nicotine compared to that of a combusted cigarette:

- Nicotine Salt: For patients who are transitioning from cigarettes to NVP (more closely mimics the plasma concentration of a cigarette)
- Freebase Nicotine: For patients who are transitioning from nicotine salt NVPs to zero-nicotine vaping products to begin to combat behavioural aspects of addiction



Closed vs open systems[4]

Closed systems are better options to consider for patients who are less experienced with vaping. Closed systems are available as pre-filled disposable pods that are to be used with a rechargeable device which is brand specific (prescription not required). Pods may be up to a maximum of 2mL capacity, depending on brand. Closed systems are generally considered safer than open systems due to the lower risk of contact with nicotine liquid through accidental oral or dermal absorption. Some brands have refillable pods, which can be used with eLiquids for open systems.

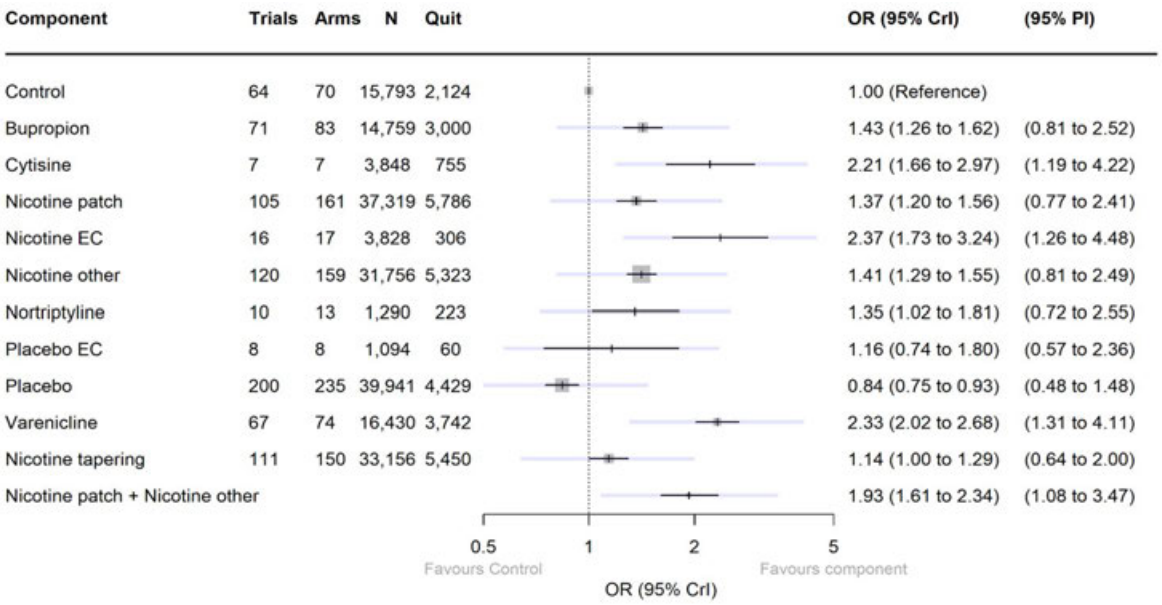
Open systems are better options to consider for patients who are experienced with vaping. They require eLiquids which can be used in any open tank system which have varying capacities from 5-20mL. eLiquids may contain nicotine salts or freebase nicotine.

Evidence for use, contraindications and interactions

Cochrane Review, September 2023

In September 2023, the Cochrane Library conducted a systematic review comparing the efficacy and safety of nicotine vaping products to conventional NRT and pharmaceutical therapy for smoking cessation.[5]

The primary outcome of the review showed that varenicline, NVPs and combination NRTs resulted in higher quit rates than bupropion and single form NRT at the 6-month smoking cessation mark, suggesting that single form NRT should not be favoured over NVPs or combination NRT.



Cochrane Review, January 2024

In January 2024, the Cochrane Library updated the systematic review originally conducted in 2022. A total of 88 studies were reviewed, of which 47 were RCTs. The overall results of the review showed high-certainty evidence that nicotine vaping products increased quit rates compared to conventional NRT – in absolute terms, translating to an additional 4 quitters per 100. Data from non-randomised trials were consistent with randomised results. The most reported side effects were throat/mouth irritation, headache, cough and nausea, which tended to dissipate with continued NVP use.[6]

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Public Health England, February 2021

The 2015 evidence update by Public Health England estimates that NVPs are 95% less harmful to health than cigarettes.[7]

For further evidence, we can look at data collected by Public Health England as the English market provides a very comparable model to Australia for how NVPs may be used to facilitate smoking cessation.

Public Health England provided an evidence update in February 2021, discussing possible evidence for NVPs as a smoking cessation tool.

It was determined that vaping is positively associated with quitting smoking successfully. In 2017 50,000 smokers successfully stopped smoking after transitioning to a vaping product. Highest quit rates (74%) were seen when the attempt involved pharmaceutical therapy and a vaping product, one after another. Quit rates were also the same when comparing NVP only, NVP and pharmaceutical therapy and varenicline. Quit rates involving a vaping product were higher than any other method in all regions in England.[8]

Determining the correct therapeutic nicotine vaping product for your patient[4]

NAÏVE VAPER (SMOKING CESSATION) – CLOSED SYSTEM (POD) Low-medium vapour production							
Smoking status (Cigarettes/day)	**0**	**1–6**	**6–12**	**12–20**	**20–25**	**25+**	**2+ packs**
Starting strength (Freebase) mg/mL	0	3	6	9	12	18	24-36
Starting strength (Nicotine Salt) mg/mL	0	≤ 10	20	25	30	35	50-60

Supply: *1 pod (1-2mL depending on brand) per day*

EXPERIENCED VAPER (NICOTINE DEPENDENCE AND BEHAVIOURAL MANAGEMENT) Medium-high vapour production				
Vaping status (NVP strength)	**Nicotine-free**	**Low NVP strength**	**Average usage**	**High NVP strength**
Open systems	0 mg/mL	Use known strength and option of freebase vs salt	**Freebase** › 3 – 6mg/mL › 4 – 6mL daily	**Freebase** › 6 mg/mL › 4 – 6 mL daily
Closed (Pod) systems	0 mg/mL	Use known strength and option of freebase vs salt	**Salt** › 30mg/mL › 1 pod daily	**Salt** › 35mg/mL › 1 pod daily

Flavour: *Mint, menthol, tobacco and unflavoured*

Allow patients to choose flavour – taste preferences may change after a patient quits smoking, so patients may wish to change flavours as they progress.

Ensure patient has compatible nicotine vaping device to use with pods/appropriate open tank system.

Suggest lowering dose where possible. If titrating down, consider increasing prescribed volume to compensate for potential increase in vaping due to cravings.

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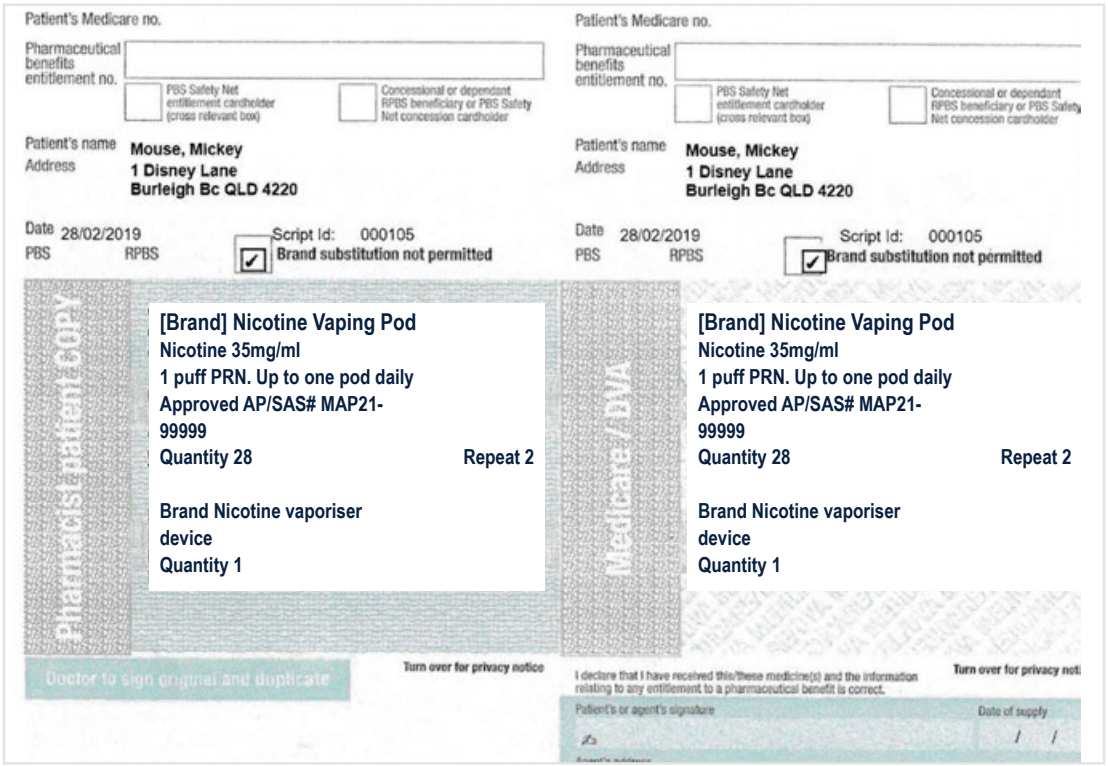
Below is a sample prescription written for a nicotine vaping product and compatible device:



Patient's Medicare no.

Pharmaceutical benefits entitlement no.

PBS Safety Net entitlement cardholder (cross relevant box)

Concessional or dependant RPBS beneficiary or PBS Safety Net concession cardholder

Patient's name
Address

Mouse, Mickey
1 Disney Lane
Burleigh Bc QLD 4220

Date 28/02/2019
PBS RPBS

Script Id: 000105
Brand substitution not permitted

Pharmacist's prescription copy

[Brand] Nicotine Vaping Pod
Nicotine 35mg/ml
1 puff PRN. Up to one pod daily
Approved AP/SAS# MAP21-99999
Quantity 28 Repeat 2

Brand Nicotine vaporiser device
Quantity 1

Doctor to sign original and duplicate

Turn over for privacy notice

Medicare/ARIA

I declare that I have received this/these medicine(s) and the information relating to any entitlement to a pharmaceutical benefit is correct.

Patient's or agent's signature

Date of supply

Dispensing considerations

Certain states and territories require pharmacies to hold a licence to supply NVPs. Check your local state or territory laws to ensure you hold the correct licences prior to supply.

Ensure a SAS C notification number or MAP (Authorised Prescriber) number is supplied with the prescription – use the SAS/AP Submission Validation tool on the SAS Compliance Portal to check for approval validity.

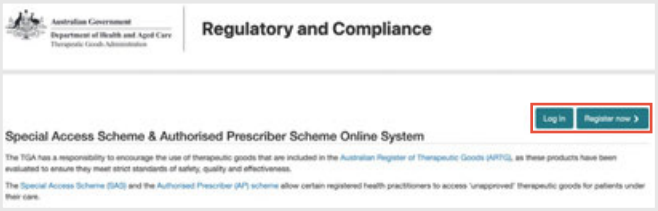
Ensure all NVP products are stored in the dispensary with other prescription medications. Unapproved medications must not be visible to patients as this may be deemed as advertising.

From the 1st of October, pharmacists will need to register with the SAS compliance portal to submit SAS-C notifications. Contact your Canview Pharmacy Account Manager for guidance on licences, SAS portal registration and submitting your first notification.

Authorised prescriber application guideline

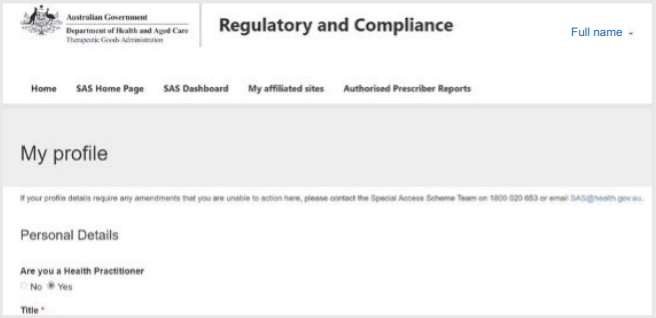
Step 01

Visit compliance.health.gov.au/sas to register. If you are already registered, log in to the portal and skip to step 3.



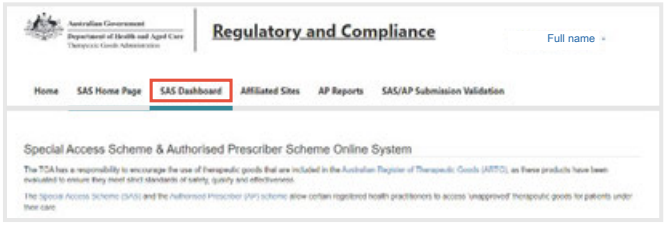
Step 02

Once you have created an account, log into your profile and update your health practitioner details under “My Profile”



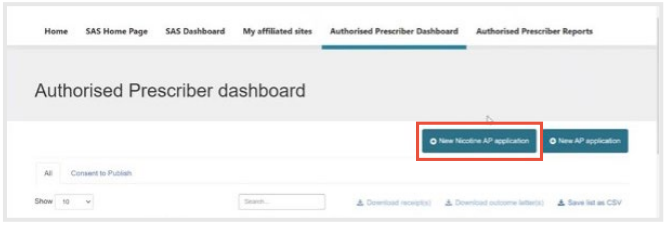
Step 03

Once fully set up navigate to the Authorised Prescriber Dashboard



Step 04

Click on “New Nicotine AP application”



Step 05

Review the pre-filled information regarding dosage form and indication.

Step 06

Read the ARTG product consideration and privacy statement – if you agree with both, select “Yes” for both.

Step 07

Submit your application by clicking “Submit” – the TGA will review your application and will provide you with a letter (via email or available for download in your Authorised Prescriber Dashboard) which will contain your approval number (required to be supplied to pharmacies with prescriptions).

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