

# Prescribing of Nicotine Vaping Products from 1 January 2024

Reading time:

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## What are the changes?

On 26 June 2024, the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 passed the Senate. The Bill restricts the manufacture, supply, advertisement, and possession of commercial quantities of NVPs and, in addition to earlier bans on the importation of NVPs into Australia, will likely lead to increased patient demand for prescriptions from medical practitioners.

During a transition period from 1 July until 1 October 2024, anyone wanting to access an NVP will require a prescription from a medical practitioner. From 1 October 2024, anyone over 18 years who wants to access an NVP will be able to discuss their quit options with a pharmacist who can provide an NVP to a patient without a prescription as a Schedule 3 medication. Anyone under the age of 18 years will continue to require a prescription from a medical practitioner.

## What impact will these changes have on members?

NVPs are currently “unapproved goods”, which means that they have not been included by the TGA in the Australian Register of Therapeutic Goods (ARTG) for use in smoking cessation or nicotine dependence. Therefore, a valid prescription is required before a pharmacist can supply an NVP to a patient for a therapeutic purpose. The need for a prescription is likely to generate a substantial number of requests from patients in the coming weeks and months, and it is important for members to understand their rights and responsibilities.

## What are the requirements for prescribing a nicotine vaping product?

There are three ways in which medical practitioners may prescribe NVPs.

First, the **Authorised Prescriber scheme** allows practitioners to apply online to prescribe NVPs without the need for individual approvals for every patient. The approval lasts for five years, but practitioners must report numbers of patients prescribed NVPs every six months.

Second, the **Special Access Scheme B** allows practitioners to apply online to prescribe NVPs for each patient. A copy of the application and approval should be kept in the patient's medical record.

Third, a new streamlined **Special Access Scheme C** allows practitioners to prescribe NVPs provided they notify the TGA within 28 days. The notification generates a unique number that allows pharmacists to verify if the NVP has been supplied. No approval is required, but a copy of the notification should be kept in the patient's medical record.

More information about these processes and how to apply/notify can be found on the TGA website [here](#).

## Are there guidelines for the prescribing of nicotine vaping products?

MIPS does not provide clinical advice to its members, nor does it endorse currently available guidelines. Members should thoroughly assess patients who request prescriptions for NVPs and only prescribe NVPs if they consider it to be safe and clinically appropriate. The Royal Australian College of General Practitioners is currently consulting on clinical guidelines for the use of NVPs, which can be found [here](#).

This provisional guideline suggests that NVPs may be appropriate in conjunction with behavioural support if a patient has failed to achieve smoking cessation with approved first-line therapies.

However, the provisional guideline recommends that prescribers inform patients that, due to the lack of available evidence, the safety and quality of NVPs have not been established, and their long-term health effects are unknown.

The provisional guideline also recommends that patients prescribed NVPs be regularly reviewed and monitored.

## What else should I consider when prescribing unapproved goods?

You should exercise caution when prescribing any unapproved goods, including NVPs.

First, you are not under an obligation to prescribe them and should only do so if you believe that you have the appropriate knowledge, skills, and training to do so. If you are unsure, you could decline the patient's request or refer them to another more experienced colleague for further assessment and advice.

Second, you should clearly explain the benefits and risks of NVPs with the patient, including that they are unapproved for use, and any gaps in our knowledge about longer terms risks and safety. This will facilitate patients making informed choices.

Third, it is important to maintain accurate and contemporaneous medical records of the NVPs prescribed, your clinical reasons for prescribing them, your discussions with the patient, and the patient's verbal consent.

## Can I advertise that I prescribe nicotine vaping products?

Direct-to-consumer advertising of prescription-only medicines remains banned in Australia, under the Therapeutic Goods Act 1989 (Cth). This includes NVPs. One of the [TGA's 2024 priorities](#) is to monitor compliance with the unlawful advertising of NVPs.

## Am I covered by MIPS for prescribing nicotine vaping products?

Subject to the terms and conditions of the current MIPS Indemnity Insurance Policy, members are covered for their prescribing of NVPs. There is a general requirement in the Policy that members have the appropriate and recognised training, qualifications, and experience for any healthcare provided.

## Where can I access further information?

[Australian Government. Guidance on the use of vapes for smoking cessation or the management of nicotine dependence 1 January 2024. Therapeutic Goods Administration.](#) (accessed 22 January 2024).

[Australian Government. Vapes: information for prescribers. 11 January 2024. Therapeutic Goods Administration.](#) (accessed 22 January 2024).

[Australian Government. Import, advertising and supply compliance priorities 2023-24. 25 July 2023. Therapeutic Goods Administration.](#) (accessed 22 January 2024).

[Royal Australian College of General Practitioners. Supporting smoking cessation: a guide for health practitioners. Guidance updates on smoking and vaping cessation support related to changes to Australia's vaping regulation. Provisional draft for consultation. December 2023.](#) (accessed 22 January 2024).

## Who can I call if I need further information from MIPS?

If you have any further questions, please do not hesitate to contact MIPS on 1800 061 113.

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The information on this page is a summary and of a general nature and it does not constitute legal, health or professional advice. You should seek your own professional advice before relying on it. It does not take into account your healthcare practice or needs. You should consider the appropriateness of the information and read the Member Handbook Combined PDS and FSG before making a decision on whether to join MIPS.

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