RACGP
Royal Australian College of General Practitioners

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16 January 2023

Secretariat
Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Email: NVP@health.gov.au and via Consultation Hub – online submission

Dear Secretariat,

Re: Potential reforms to the regulation of nicotine vaping products: Consultation paper, November 2022

The Royal Australian College of General Practitioners (RACGP) thanks the Therapeutic Goods Administration (TGA) for the opportunity to respond to the public consultation on *Potential reforms to the regulation of nicotine vaping products*. Considering the recent legislative change to the supply of nicotine e-liquids to prescription only, along with emerging public health challenges particularly for young Australians, the RACGP recognises the urgent need to review the existing regulation of Nicotine Vaping Products (NVPs).

General practitioners (GPs) are the backbone of Australian healthcare with almost nine in ten Australians visiting a GP each year.[1] The RACGP produces evidence-based clinical guidelines and resources relevant to all healthcare professionals who provide support for people wishing to quit smoking. The guideline *Supporting smoking cessation: A guide for health professionals (Smoking cessation guidelines)*, reflects the rescheduling of nicotine e-liquids in response to the Therapeutic Goods (Standard for Nicotine Vaping Products) TGO 110 which came into effect on 1 October 2021, making the supply of nicotine e-liquids prescription only.

The potential reforms outlined by the TGA have been carefully reviewed by the RACGP and its Smoking Cessation Expert Advisory Group (EAG) responsible for producing the Smoking cessation guidelines. The EAG is a multi-disciplinary group consisting of health professionals from the fields of general practice, respiratory medicine, addiction psychiatry, nursing and pharmacy, therefore ensuring that the guideline has broad applicability to all health professionals supporting smoking cessation.

The following feedback is provided from a clinical perspective with a focus on the improvements required to bolster confidence of health professionals and patients in the legal use of NVPs for the purpose of achieving better outcomes for smoking cessation. The challenges of addressing broader public health policy issues including border control, importation requirements, and the uptake of illegal vaping by young people are critical but the RACGP's expertise does not lie in these areas so our comments are limited.

As outlined in the TGA Consultation Paper, the stated objectives of the potential reforms are two-fold:

1) to refine existing requirements for NVPs to better support the intent of the 2021 reforms (TGO 110), namely preventing children and adolescents from accessing NVPs, and

2) to support access to products of known composition and quality for smoking cessation with a doctor's prescription.

The RACGP recommends these two objectives be viewed separately as the proposed legislation, at times, conflates these two issues. The reforms required to achieve the public health objective may be quite different to those required to improve the quality and safety of legally prescribed NVPs for smoking cessation.

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The RACGP notes that the scope of topics to be considered does not include clinical guidelines and recommended dosage regimes for NVPs. We agree these topics should be out of scope but also note that some of the proposed options under 'minimum quality and safety standards' for NVPs presented in the TGA Consultation Paper have implications for dosage regimes.

1. Border controls

1.1 Option 1 – no legislative changes but increase enforcement action at the border

The RACGP considers Option 1 as unlikely to be effective given the fact that a large proportion of imported NVPs are not being labelled correctly (i.e. nicotine is not listed but is present). As discussed in the TGA Consultation Paper, unlike tobacco, liquid nicotine cannot be identified by sight and smell, and the fact that non-nicotine containing vaping products can be sold legally in many jurisdictions makes it difficult for enforcement authorities to detect illegal or incorrectly labelled imported products.

1.2 Option 2 – remove personal importation scheme (PIS) exemption for NVPs

The RACGP has previously expressed its support for the removal of the PIS exemption for NVPs to increase the likelihood of NVPs prescribed by medical practitioners meeting the TGO 110 standard. The RACGP publication *Supporting smoking cessation: A guide for health professionals* [2] encourages doctors prescribing NVPs to use the Authorised Prescriber pathway and to encourage patients to have the prescription filled locally rather than importing NVPs from overseas through the PIS.

It is acknowledged that removal of the PIS exemption will require an adequate timeframe to allow adjustment to this change and allow continuity of supply for the purpose of supporting smoking cessation. Currently the product range of NVPs available within Australia is limited, so reasonable notice would be required to allow the community and health professionals to make the adjustment and for the industry to adjust by improving the range of appropriate products available via prescription.

However, as noted in the TGA Consultation Paper, the PIS is not the major source of NVPs that are being used by younger people.

1.3 Option 3 – impose tighter controls on the importation of NVPs by requiring an import permit

Options 2 and 3 together may be feasible however, it is unclear as to whether this legislation could reasonably be expected to address nicotine-free vapes being imported. As previously mentioned, it is understood that a high proportion of these vapes do in fact contain nicotine.

1.4 Option 4 – introduce controls on the importation of all vaping products through the Customs Regulations to assist with the enforcement of the controls on NVPs

Whilst Option 4 might be a feasible suggestion, the introduction of blanket controls on all vaping products may have some unintended consequences. For instance, would there be a requirement for a prescription for non-nicotine vaping products?

A requirement for the provision of an ingredient list for non-nicotine products, may enable the products to be tested. Fines and importation sanctions can then be imposed for non-compliance if nicotine was found to be present.

2. Pre-market assessment

2.1 Option 1 – make no changes

The current lack of data on both quality and safety of NVPs is of considerable concern and therefore the position of making no changes is not supported by the RACGP. For the purposes of smoking cessation, the RACGP supports the establishment of robust safety standards but acknowledges the difficulty in achieving such a standard for an unapproved product.

2.2 Option 2 – establish a regulated source of quality NVPs by requiring pre-market assessment of NVPs by the TGA against a quality and safety standard. A safety evaluation would relate only to the safety of ingredients and not a full safety analysis of the product. No evaluation of efficacy for smoking cessation.

As the approval and listing of NVP remains to be confirmed, we are concerned whether Option 2 will bring enough confidence to clinicians to increase prescribing. The RACGP recommends specifying the quality and safety standard being used for the pre-market assessment to allow clinicians to make a fully informed decision on whether they wish to prescribe the product.

From a practical prescribing perspective, it is understood that dosage of nicotine received through a NVP can vary greatly depending on the how the person inhales. For example, if the clinician is prescribing a lower dose of nicotine in the NVP, and the patient inhales more in order to receive a stronger dose, will this practice increase their exposure to the toxicants? This is an important question for prescribers and there is concern that the safety standards may not adequately address these types of clinical questions.

2.3 Option 3 - establish a regulated source of quality NVPs by requiring registration in the ARTG, following successful evaluation of quality, safety, and efficacy for smoking cessation.

The RACGP supports progressing toward an Australian Register of Therapeutic Goods (ARTG) registered NVP. This would give clinicians greater confidence about efficacy, quality and safety and bring NVPs into line with most medicines prescribed by doctors. Given the importance of the issue to public health the RACGP encourages the TGA and other relevant organisations to work collaboratively with suitable sponsors (those not connected with the tobacco industry) to progress NVPs to achieve registration.

The cost of an ARTG registered NVP and whether it may be subsidised for smoking cessation will need to be addressed. It would be necessary to educate consumers and health professionals as to the benefits of using a registered product particularly as cost may be a barrier to its uptake.

2.4 Options 2 and 3 together – which would enable supplies of both unapproved NVPs that meet quality and safety standard and of TGA-approved NVPs that have been assessed for quality, safety and efficacy.

The purpose of having both unapproved NVPs that meet quality and safety standards in addition to TGA-approved NVPs is unclear. Will this create greater competition among unapproved NVPs that may meet minimal safety and quality requirements vying for a share of the marketplace?

In addition to the quality, safety and efficacy of nicotine liquids, there remain challenges around the type of vaping device used. Devices are not covered by any TGA standard. The RACGP recommends the use of closed systems to reduce the risks of inappropriate or incorrect dilution of liquid nicotine, ingestion or exposure through skin or eyes and the addition of potentially toxic or illegal substances, or contamination.

3. Minimum quality and safety standards for NVPs

3.1 Option 1 – make no changes to minimum safety and quality requirements

It is questionable whether greater regulation will be effective or whether such regulation, in particular limits on nicotine concentration, will impair the ability of practitioners to prescribe effectively to support smoking cessation. Advice around quality and safety issues is provided within the RACGP Smoking cessation guidelines.

3.2 Option 2 – prohibit all flavours (except tobacco) and additional ingredients

The *RACGP Smoking cessation guidelines* recommends the restriction of flavours where possible to tobacco flavour. There is limited evidence about the long-term safety of inhaled flavourings. It is also acknowledged that flavourings increase the appeal of vaping, and fruit and sweet flavours are popular with young people and may encourage uptake among non-smokers. However, within the framework of medically prescribed NVPs the issue of flavours can be managed, and the greatest problem is with illegal use.

3.3 Option 3 – Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements

The RACGP supports pharmaceutical-like packaging with additional warning statements outlining the short- and longer-term risks of vaping, including poisoning and burns. It should be noted that nicotine in salt form in pods has a reduced poisoning risk. However, the relevance of packaging of medically prescribed NVPs to addressing the issue of youth uptake is extremely limited as overwhelmingly that is not how young people are getting access to vaping products.

3.4 Option 4 – Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent)

The RACGP's view is that decisions about nicotine concentration are best made by clinicians who have access to evidence-based guidance.

The dose of nicotine received by the person can vary by the type of vaping device, concentration of nicotine and inhalation technique. Therefore, the *RACGP Smoking cessation guidelines* provide advice on initial dosing but note that dose titration may be needed with regular follow-up and should be discussed with the patient.

As indicated in the *RACGP Smoking cessation guidelines*, blood concentrations of nicotine similar to or greater than combustible cigarettes are attainable with free-base liquid nicotine concentrations of up to 20 mg/mL which is thought to be an adequate concentration for more dependent smokers. Also, concentrations over 20mg/ml of freebase nicotine will typically result in throat irritation. Therefore, exceeding 20 mg/mL of freebase nicotine should not be necessary.

Nicotine e-liquid concentrations of 100 mg/mL are not necessary and should not be prescribed. The risks of poisoning through skin contact and accidental ingestion are far greater for patients who choose to dilute their own e-liquids.

At the time of writing the *RACGP Smoking cessation guidelines* in 2021, there were no trials of the efficacy of nicotine in salt form to assist smoking cessation, however, trial evidence is beginning to accumulate. This new

information will assist with answering questions around adequate dosing for nicotine salt pods. The *RACGP Smoking cessation guidelines* note the potential advantages of higher-concentration nicotine salt NVPs in that their pharmacokinetics more closely replicate nicotine from smoking, which may facilitate people transitioning away from combustible tobacco. Also, the consumption of e-liquid is reduced, which may result in reduced exposure to toxic compounds (including volatile aldehydes) and flavouring molecules with unknown toxicity. The guidelines note the lack of evidence of efficacy in smoking cessation (though as pointed out earlier trials are now emerging and are included in the recent Cochrane review update[3]) and the concerning level of uptake of high concentration nicotine salt products in non-smokers including young people. This has been a particular feature in countries with consumer availability such as the United States and Canada. Therefore, risk of diversion needs to be considered and minimised. As far as the RACGP is aware, diversion has not been an issue of concern with medically prescribed nicotine salt pods.

Importantly, if any restriction of concentration is to be applied, clarification is required about how the equivalence of freebase versus salts concentration is determined and to be clear about distinguishing the concentration of the nicotine salt compound versus the concentration of nicotine. Any limits set on the concentration of nicotine salts should not be too low, to ensure that the product is useful for smoking cessation. Higher concentrations nicotine salt NVPs should not be an issue if under prescription by a doctor under a medical model.

3.5 Option 5 – Limit the maximum volume of liquid NVPs

The *RACGP Smoking cessation guidelines* recommends limiting the supply of NVPs to a maximum of 3 months' supply.

3.6 Option 6 – Remove access to disposable NVPs

The RACGP recommends against the supply of disposable NVPs due to their poor manufacture and environmental footprint.

3.7 Option 7 – Options 2, 3, 4, 5 and 6 together. (Except for the option to require additional warning statements)

In terms of legislating these options together, it is uncertain as to what extent regulation should be increased (which may have unintended effects) or whether it would be preferable for health professionals to manage most of the issues with reference to the *RACGP Smoking cessation guidelines*. For instance, legislating limits on dosage and a lack of clarity around equivalent concentrations of nicotine salts versus free base may result in reducing practitioners' ability to prescribe effectively.

4. Clarifying the status of NVPs as 'therapeutic goods'

4.1 Do you support regulating NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework?

It is unclear exactly what this question is asking. Our interpretation is – if NVPs fall under the status of a therapeutic good, then if the product is not labelled correctly as containing nicotine but in actual fact it does contain it, appropriate sanctions could then be taken by the relevant authorities.

To fully understand the implication of this question, the TGA needs to clarify if an illegal import will be classified as a 'therapeutic good' and if this legislation would also cover NVPs manufactured locally as well as any illegal imports.

The RACGP thanks the TGA for the opportunity to provide input on this very important consultation. If you have any queries regarding this submission, please contact Mr Stephan Groombridge, National Manager, Practice Management, Standards and Quality Care on (03) 8699 0544 or at Stephan.groombridge@racgp.org.au.

Yours sincerely

Dr Nicole Higgins
RACGP President

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[1] The Royal Australian College of General Practitioners. General Practice: Health of the Nation 2022. East Melbourne, Vic: RACGP, 2022.

[2] The Royal Australian College of General Practitioners. Supporting smoking cessation: A guide for health professionals. 2nd ed. East Melbourne, Vic: RACGP, 2019 Available from: https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation

[3] Hartmann-Boyce J., Lindson N., Butler AR., McRobbie H., et al. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022, Issue 11 Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7