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RACP Submission on the TGA's consultation on the proposed reforms to the nicotine vaping product regulation

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About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 18,863 physicians and 8,830 trainee physicians, across Australia and New Zealand. The RACP represents a broad range of medical specialties including general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, infectious diseases medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients.

Forward

The RACP welcomes the Therapeutic Goods Administration (TGA)'s consultation on the proposed reforms to the regulation of nicotine vaping products (NVPs).

The burgeoning black market in vaping products and the sharp increase in NVP uptake among young Australians are critical concerns for the RACP in light of the risk of potential health impacts, nicotine addiction and subsequent smoking uptake associated with NVP use. Action on NPVs is urgently needed to curtail illegal access to NVPs, tackle the increase in youth users and close the regulatory loopholes that are being exploited by producers and vendors.

The RACP supports the TGA's proposed reforms to the existing regulation of NVPs to limit access by children and adolescents and to restrict vape use to smoking cessation with a doctor's prescription. As a strong advocate for tobacco control, the RACP produced a Policy on E-cigarettes in 2018 with an emphasis on youth protection and the need for effective regulation and enforcement to strengthen Australian tobacco controls.

Recent reports such as the updated NHMRC CEO Statement on E-cigarettes, the ANU Report on Health Impacts of E-cigarettes, and the Generation Vape Study highlighted in the TGA's consultation paper underline the need for an ongoing precautionary approach to NVPs. We are pleased to see that the Australian Government and the TGA are committed to maintaining such an approach and are now looking to strengthening the NVP regulatory environment.

Besides enhancing the current NVP regulation in Australia, a great emphasis must be placed on stronger enforcement action across all levels of government in executing existing and planned policy and regulation. Regular reviews and re-orientation of the NVP policy and regulation by the Australian Government and the TGA are needed in response to the evolving tobacco and NVP market.

Comments

Area 1: Reform Options for Border Control

Widespread illegal imports and supply of NVPs have contributed to the expansion of the NVP black market and the growth in purchases from illegal sources. Current importation controls need to be tightened to curb illegal NVPs entering Australia. **The RACP recommends the implementation of Option 5 which is the combination of Option 2: Prevent NVPs being imported under the Personal Importation Scheme exemption under the Therapeutic Goods Regulations 1990 and Option 3: Impose tighter controls on the importation of NVPs by requiring an import permit**. Option 5 is most likely to allow the border force to intercept and block illegal NVP imports and to prevent the circumvention of the border control laws.

The implementation of Option 5 is expected to take some time to design and come into effect (e.g., there will be the need to implement a new import permit system). As such, 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) could be introduced in the meantime to help limit NVP access by youth. It would temporarily address the issue of vaping products with undeclared nicotine, which has important implications for nicotine addiction and health impacts[1], especially for the youth. 70 percent of e-liquid samples collected by NSW Health were found to contain nicotine without labelling nicotine as an ingredient in 2013[2]. Anecdotal evidence from our members shows that all NVPs purchased by youth in Sydney did not declare nicotine as an

[1] Chivers E, Janka M, Franklin P, Mullins B, Larcombe A. Nicotine and other potentially harmful compounds in "nicotine-free" e-cigarette liquids in Australia. Med J Aust. 2019 Jan 14;210(3):127-8.
[2] NSW Health alert – warming on e-liquid https://www.health.nsw.gov.au/news/Pages/20131023_00.aspx

ingredient, yet when tested 95% of the products contained nicotine[3]. The implementation of Option 4 would reduce the need for testing of vaping products and the number of seizures made by enforcement teams under the Poisons & Therapeutics Goods Act.

The implementation of Option 5 would reduce patient access to NVPs but increase the workload of the compliance teams of state public health units, which need to be adequately funded to perform their enforcement functions.

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Area 2: Reform Options for Pre-market assessment of NVPs

There are currently no TGA-approved NVPs for therapeutic use which means no NVPs have been assessed by the TGA on their quality, safety and efficacy for smoking cessation. In the interest of public health, it is essential to ensure the safety and quality of products marketed for therapeutic use in Australia.

The RACP recommends the implementation of Option 4 (which is a combination of the Option 2 and the Option 3) to enable supplies of both unapproved NVPs that meet a quality and safety standard and of TGA-approved NVPs that have been assessed for quality, safety and efficacy. This option would ensure adequate quality and safety standards are met across the board. Further, being a prescription medicine for smoking cessation, NVPs should be subjected to the regulations and standards applied to other smoking cessation medicines.

The implementation of Option 4 would reduce patient access and associated health impacts. The RACP maintains that not smoking tobacco or using NVPs remain the safest options for the community. The proven and registered smoking cessation technologies, including pharmacotherapies, are advised to be used ahead of vaping.

Area 3: Strengthening Minimum Quality and Safety Standards for NVPs

The RACP agrees that there is scope to tighten the minimum quality and safety standards for NVPs either through amending TGO110 or refining the exemptions under which unapproved NVPs are presently imported. More specifically**, we support the following requirements be introduced by the TGA**:

- **Restricting or prohibiting the inclusion of flavours in NVPs** – The vaping industry designs e-cigarettes with a variety of flavours to appeal to young people. Evidence shows that flavours are a key contributor to e-cigarette use and appeal among youth[4]. Further, the safety of these flavours has not been well studied and the risks they pose remain unclear[5]. In light of this, all flavours should be banned as this would be the simplest approach to implement and monitor. Alternatively, all but the tobacco flavour should be banned, but this flavouring should be used for smoking cessation purposes only. This would render NVPs less of a recreational device and more of use as a smoking cessation treatment.

- **Restricting additional ingredients such as cooling and colouring agents –** the use of cooling (e.g., menthol) and colouring agents should be banned. This would not only reduce the appeal of NVPs to young people and ensure NVPs are used exclusively for treatment rather than for recreation, but also minimise the unknown health impacts of inhaling these ingredients. The restrictions on additional ingredients should be informed by the pre-market TGA assessment of NVPs against an adequate quality and safety standard. Additionally, NVPs can contain undeclared ingredients; it is vital that the TGA monitors and arrives at a good understanding of all listed and unlisted ingredients and mandates the disclosure of all ingredients and their concentrations.

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[3] Written feedback provided by AFPHM member. More details are available on request

4 Davis DR, Morean ME, Bold KW, Camenga D, Kong G, Jackson A, Simon P, Krishnan-Sarin S. Cooling e-cigarette flavors and the association with e-cigarette use among a sample of high school students. PLoS One. 2021 Sep 1;16(9): e0256844.

5 Barrington-Trimis JL, Samet JM, McConnell R. Flavorings in electronic cigarettes: an unrecognized respiratory health hazard? JAMA. 2014 Dec 17;312(23):2493-4

- **Introducing plain packaging requirements for NVPs –** being a prescription medicine, NVPs should be subjected to plan packaging requirements similar to prescription only medicines. The introduction of this measure is consistent with its intended therapeutic use.

- **Introducing additional warning statements for NVPs –** No additional warning statements are required for TGA approved NVPs, as is in the case of other prescription medicines such as opioids. However, if NVPs fall short of inclusion on the Australian Register of Therapeutic Goods, additional warming statements should include cautions in relation to risk of nicotine addiction, use in pregnancy and potential unknown health impacts. A warning statement to reinforce that '*NVPs should only be used as prescribed by a doctor. Not for other use'* might also be considered for inclusion.

- **Restricting nicotine concentrations in NVPs to 20mg/mL –** as indicated in the TGA consultation, many national regulators have moved to limit the maximum nicotine concentration in NVPs to 20 mg/mL, albeit this is not in a prescription-only scheme context which operates in Australia.

- **Limiting the maximum volume of liquid NVPs –** the maximum volume should be set similar to other prescription medicines and be limited to a 30-day supply for a single user.

- **Preventing access to disposable NVPs –** access to disposable NVPs should be limited to reduce young people's access and minimise their negative impact on the environment and climate through litter, plastic pollution and resource consumption.

Area 4: Clarifying the status of NVPs as 'therapeutic goods

The RACP supports regulating NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework. Vaping products with undeclared nicotine can easily escape through the loophole, creating significant public health implications. It is critical that the TGA is able to take regulatory actions in relation to such products.

The RACP looks forward to the effective and practical reforms to the current NVP regulation in Australia and to further engagement in this clinical and regulatory space.