



The Royal
Australian &
New Zealand
College of
Psychiatrists



Therapeutic Goods Administration (TGA)
Proposed Reform to the Regulation of Vapes
September 2023

Advocacy to improve access and equity

Royal Australian and New Zealand College of Psychiatrists submission

Proposed Reform to the Regulation of Vapes

About the Royal Australian and New Zealand College of Psychiatrists (RANZCP)

The RANZCP is a membership organisation that prepares doctors to be medical specialists in the field of psychiatry, supports and enhances clinical practice, advocates for people affected by mental illness and advises governments on mental health care. The RANZCP is the peak body representing psychiatrists in Australia and New Zealand and as a bi-national college has strong ties with associations in the Asia-Pacific region.

The RANZCP has more than 8000 members including more than 5500 qualified psychiatrists. Psychiatrists are clinical leaders in the provision of mental health care in the community and use a range of evidence-based treatments to support a person in their journey of recovery.

Introduction

The RANZCP welcomes the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) regarding [proposed changes to the regulation of vapes in Australia](#).

The consultation summarises the proposed approach and seeks your specific feedback about proposals to:

- prohibit the importation, manufacture and supply of all vapes unless for therapeutic use in compliance with the Therapeutic Goods Act 1989 (TG Act).
- strengthen the regulation of therapeutic vapes by introducing pre-market notification requirements for unapproved vapes and facilitating legitimate patient access.
- strengthen the minimum quality and safety standards set out in TGO 110, including on e-liquid and device components.
- enhance domestic compliance and enforcement mechanisms to facilitate effective implementation of the vaping reforms.

The TGA stipulates that feedback must be provided by completion of the survey.

Survey answers have been informed by the College's Position Statement: [E-cigarettes and vaporisers](#) and in liaison with the Faculty of Addiction Psychiatry Committee.

The survey responses will be provided via the online portal.

Royal Australian and New Zealand College of Psychiatrists submission

Proposed Reform to the Regulation of Vapes

Page 4

INTRODUCTION

1. What is your name?

Dr Elizabeth Moore

2. What is your email address?

policy@ranzcp.org

3. What is your organisation name?

Royal Australian and New Zealand College of Psychiatrists

4. Please choose a stakeholder group that best describes you or your organisation. (Required)

- Government agency
- Public health organisation
- **Health professionals' peak body**
- University, researchers and experts
- Schools and other educational institutions
- Advocacy groups
- Consumer groups and associations
- Pharmacy retailers,
- Vape stores
- Convenience stores
- Petrol stations
- Other retailers
- Vape manufacturers
- Vape importers.
- Pharmacy wholesalers
- Pharma industry
- Others*

*If other, please specify: n/a

5. Which best describes your response? (Required)

I am responding on behalf of an organisation.

I am responding as an individual.

Royal Australian and New Zealand College of Psychiatrists submission

Proposed Reform to the Regulation of Vapes

6. Are you an authorised prescriber? (Required)

Yes (please go to next question)

No (please go to next page)

PROPOSAL 1 -RESTRICTIONS ON IMPORTATION, MANUFACTURE AND SUPPLY OF ALL VAPES.

1. Do you support the proposed approach to ban disposable single use vapes absolutely and all other vapes, except those for legitimate therapeutic use in compliance with the TG Act? (Required)

Yes

No

3. Do you support removal of the personal importation scheme exception for vapes? If not, what would be the impact on you? (Required)

Yes

No (* if not, what would be the impact on you?)

* What would be the impact on you?

n/a

4. Do you agree with the proposal to retain a traveller's exemption, including the proposed limits? (Required)

Yes

No

5. Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)? (Required)

Yes

No

PROPOSAL 2 -CHANGES TO MARKET ACCESSIBILITY REQUIREMENTS, INCLUDING BETTER REGULATION OF DEVICE COMPONENTS.

7. Do you support the approach to require a pre-market notification of compliance with TGO 110? (Required)

Yes

No

9. Do you support the proposed access to vapes under the SAS C notification system? (Required)

Yes

No

9 (a). What impact would this pathway have on facilitating patient access to therapeutic vapes?

Please provide details here: (or mark Not applicable).

This potentially improve appropriate access to the use of therapeutic vaporisers including those that face barriers to accessing psychiatric care.

10. [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How? (Required)

Yes (* please tell us how)

No

Not a prescriber of vapes

11. [If applicable] For prescribers, which access pathway (SAS B, SAS C, or AP) would you envisage using to prescribe therapeutic vapes? Why? (Required)

Authorised Prescriber scheme (AP)

Special Access Scheme -B (SAS-B)

Special Access Scheme C (SAS-C)

Not a prescriber of vapes

Please tell us why

Royal Australian and New Zealand College of Psychiatrists submission

Proposed Reform to the Regulation of Vapes

12. [If applicable] For prescribers, would integration of SAS or AP applications or notifications into existing clinical software systems ease the administrative burden and/or encourage you to use the new pathway? (Required)

Yes

No

Not a prescriber of vapes

13. Do you agree with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity? (Required)

Yes

No

14. Will these changes have direct or indirect impact on you? Please provide details. (Required)

Yes (please provide details below)

No

Please provide details here:

15. Do you require time to adjust to these requirements? If yes, how long? (Required)

Yes

No

15 (a). How long do you require to adjust to these requirements? **(N.B. answer required)**

Less than 3 months

3 to 6 months

6 to 9 months

6 to 12 months

More than 12 months

PROPOSAL 3 - IMPROVING QUALITY STANDARD FOR UNAPPROVED (UNREGISTERED) VAPES)

16. Are the definitions of tobacco and mint flavours appropriate? If not, please provide reasons. (Required)

Yes

No (* please provide reason below)

* Please provide reason here.

The RANZCP supports changes to legislation that limits access to commercial flavours outside of therapeutic use.

17. Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons. (Required)

Yes

No (* please provide reason below)

* Please provide reason here

19. Do you agree with the proposal to require pharmaceutical-like packaging and presentation for vapes, e.g., vapes manufactured in black, white or grey coloured materials, predominantly white background on packaging, clear warning statements and other restrictions on labels in addition to other selective TGO 91 requirements for vapes? (Required)

Yes

No (* please provide reason below)

20. [If applicable] What impact will the labelling and packaging changes have on you?

* Please provide detail here.

n/a

20 a). How long would you need to transition your product to comply with the proposed requirements? **(N.B. answer required)**

Less than 3 months

3 to 6 months

6 to 9 months

6 to 12 months

More than 12 months

21. Do you agree with our approach to allow only permitted ingredients in vapes, instead of trying to prohibit individual chemical entities from use in e-liquids? (Required)

Royal Australian and New Zealand College of Psychiatrists submission

Proposed Reform to the Regulation of Vapes

Yes

No

23. Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?

(Required)

Yes

No

25. Do you agree with the proposed requirements under TGO 110 that will apply to unapproved device components of vapes? (Required)

Yes

No

PROPOSAL 4 - STRENGTHENING DOMESTIC COMPLIANCE AND ENFORCEMENT MECHANISMS

29. Do you have any other comments in relation to this proposal? (Required)

Yes (* provide your comments below)

No

Comments

The RANZCP continues to support the legalisation and regulation of nicotine vaporising products (NVPs) for the purpose of facilitating their use as a harm reduction tool. NVPs are not first-line treatments for smoking cessation. The strongest evidence base for efficacy and safety is for currently TGA approved pharmacological therapies combined with behavioural support. The RANCP highlights the importance of short-term use of vapes in conjunction with behavioural support.

The RANZCP also recognises the potential harms associated with these products, but that it is invariably lower when compared with smoking. It should be noted that there are no long-term studies on the nature and magnitude of the effects of long-term vapour inhalation on people's health.

The RANZCP supports proposed reforms to the regulation of vapes that would require stronger reporting for approved vaporiser products to assure their safety and quality and reduce the variability of design and decrease uncertainties associated with their use.

Please see the following RANZCP documents addressing vaping products ([Position Statement: E-cigarettes and vaporisers](#)) ([Clinician's Guidance Mental Health Clinician Guidance for Managing People's Smoking Cessation](#))