

Australian College of Nurse Practitioners response to:

THERAPEUTIC GOODS ADMINISTRATION (TGA)

**- PROPOSED REFORMS TO THE REGULATION OF VAPES
IN AUSTRALIA**

Australian College of Nurse Practitioners

A: PO Box 33175 Melbourne Vic 3004 | Office: St Kilda Rd Towers, Suite 502, 1 Queens Road Melbourne

E: admin@acnp.org.au **P:** 1300 433 660 **W:** www.acnp.org.au

24 September 2023

Therapeutic Goods Administration (TGA)

By Online survey form nvp@health.gov.au

To Whom it May Concern

Thank you for the invitation to provide a response to the proposed reforms to the regulation of vapes in Australia. We have responded to the recommendations most relevant, or most significant to our organisation and our members.

The Australian College of Nurse Practitioners (ACNP) is the national peak organisation for Nurse Practitioners, advancing nursing practice and consumer access to health care. A key focus for the role and scope of practice development for Nurse Practitioners is on unmet needs within the community and increasing access to health care.

Please find below our feedback:

Consultation questions

Intended to be entered into survey form: <https://consultations.tga.gov.au/medicines-regulation-division/df36e4a0/consultation/subpage.2023-08-25.4062514106/> Email copy sent as above.

1. Have you or your organisation ever received services, assistance or support (whether monetary or non-monetary in nature) from the tobacco industry and/or e-cigarette industry? If this scenario applies to you or your organisation, please provide relevant details in the textbox.

(Required)

Yes

No

If you have selected yes, please provide details here. Otherwise, please state 'Not Applicable':

(Required)

2. Have you or your organisation ever provided services, assistance or support (whether monetary or non-monetary in nature) to the tobacco industry and/or the e-cigarette industry? If this scenario applies to you or your organisation, please provide further information in the textbox.

(Required)

Yes

No

If you have selected 'yes', please provide details here. Otherwise, please state 'Not Applicable'

(Required)

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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

2. How would you anticipate industry and consumers to respond to a ban on the importation, manufacture and supply of non-therapeutic vapes?

* Please provide answer here.

We believe there will be some resistance from industry with a commercial interest, and consumers.

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?

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 would reduce administrative burden on prescribers, and potentially increase the number of prescribers as a result, improving access.

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

* How new pathway will change your approach to prescribing therapeutic 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

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)

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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

Proposal 3 - Improving quality standard for unapproved (unregistered vapes)

16. Are the definitions of nicotine and mint flavours appropriate? If not, please provide reasons.

(Required)

Yes

No (* please provide reason below)

* Please provide reason here.

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.

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)

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

ACNP strongly supports the reduction of potential and actual harms from the use of vapes. Nurse Practitioners play key roles in Australia in smoking cessation and management and treatment of people who misuse substances. Nurse practitioners should be considered as an important part of these changes, and prescribing vapes in future.

Thank you again for the opportunity to participate in this important review.

Yours sincerely



Leanne Boase

Chief Executive Officer

Australian College of Nurse Practitioners

PO BOX 33175 Melbourne VIC 3004

St Kilda Rd Towers, Suite 502, 1 Queens Road Melbourne



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