Submission No 50

E-CIGARETTE REGULATION AND COMPLIANCE IN NEW SOUTH WALES

Organisation: Australian Medical Association (NSW)

Date Received: 6 November 2023

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Legislative Assembly
Committee on Law and Safety
Parliament of New South Wales
Macquarie Street
Sydney, NSW, 2000

Re: E-cigarette regulation and compliance in New South Wales

After a prolonged decline in nicotine use doctors are now seeing more and more people using e-cigarettes – otherwise known as vapes - with a particularly concerning uptick in young people. Members of the Australian Medical Association are seeing more associated conditions like chronic cough and new lung disease in young people. These are people who through their vapes are ingesting the equivalent of three to four packs of cigarettes per day. And with it the ingestion of other harmful chemicals and heavy metals which will impact their bodies over the coming years and decades.

AMA (NSW) believes the implementation of new measures is required to curb the uptake and deeply concerning rate of e-cigarette use and that the NSW Government should work with other states and territories as well as the Federal Government to achieve these goals.

AMA (NSW) calls for similar policies to those taken with tobacco products like rotating health warnings, and the standardising of packaging to make products less visually appealing.

The NSW Government must work collaboratively with the Commonwealth Government to implement consistent, co-ordinated action on the federal e-cigarette reforms.

Advertising restrictions are an urgent and necessary step. AMA (NSW) believes the rules that apply to tobacco should be extended to e-cigarettes, including restrictions on social media marketing that targets individuals based on algorithms.

It took decades for the health harms of tobacco to come to light, with the powerful tobacco industry disputing the evidence and relentlessly promoting their addictive products. We are seeing the same tactics play out today with vapes, hooking new generations onto nicotine by marketing directly to younger people and downplaying the health harms.

AMA (NSW) does not support political parties accepting sponsorship or gifts from e-cigarette companies and calls on all parties to refuse to enter into arrangements that clearly have the potential to compromise policy making on public health matters.

AMA (NSW) believes a retail ban on all vaping products is an overdue change to protect younger people from becoming addicted to nicotine. Without such a ban we are failing to protect younger people from making the same mistakes with tobacco that were made by past generations. A retail ban that is consistent across the country is critical to the smoke free future of NSW.

While the cost of enforcement is prohibitive due to the sheer scale of the problem AMA (NSW) believes the state's police require further resourcing to bolster what has already been allocated. The

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NSW Government must support and encourage the Federal Government in enhancing border controls on importation of all e-cigarette products.

Preventative education is vital to ensure young people understand the damage they are doing to their bodies and the danger of falling prey to lifelong addiction. AMA (NSW) acknowledges the work that NSW Health has done in planning for education on the dangers of e-cigarettes to be incorporated into school curricula and encourages the urgent implementation of these programs. AMA (NSW) believes such education must include both primary and high schools, as children as young as six have been hospitalised after using e-cigarettes.

We encourage a wider range of measures to engage young people, including peer to peer programs, and the inclusion of the voices of young people in shaping these programs.

In addition to engaging young people, AMA (NSW) believes that educating and engaging parents is critical to improving the discourse at home and supporting NSW families.

AMA (NSW) supports rational co-ordination of government agencies to address vaping to avoid duplication and augment the actions of NSW Health.

AMA (NSW) feels that the support services available to young people are limited and calls for the extension and promotion of cessation support for young people. AMA (NSW) calls upon NSW Health to prioritise these actions to align with the Federal Government retail ban which will ultimately drive an increase in the need for vaping cessation services and resources.

There is a window of opportunity to intervene before e-cigarette use becomes a social norm. It is vital that we act now to empower young Australians to make good choices.

Please find attached the submission made by the Federal AMA to proposed reforms to the regulation of vapes consultation paper.

Yours sincerely,

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SUBMISSION

AMA Submission to Proposed reforms to the regulation of vapes consultation paper

September 2023

The AMA strongly supports the reforms to the regulation of vapes as outlined in the consultation paper. We welcome the broader scope of this consultation to include all vaping products, not just nicotine vaping products. This was a recommendation of the AMA and other key public health stakeholders in the January consultation. It is refreshing to see the expert medical, public health and scientific advice seriously guiding reforms. The AMA commends the TGA and the Minister for Health and Aged Care on the scope and ambition of these reforms.

Vaping is a significant public health issue for Australia. Younger people and children are increasingly becoming addicted to vaping because vapes are so easily accessible. While proponents push vaping as a smoking cessation tool, the evidence demonstrates that people who vape are three times more likely to smoke than people who have never vaped, and that former smokers who vape are more likely to relapse.[1] We now have a situation where smoking rates for 14-17 year olds in Australia is trending upwards.[2]

Vaping is also presented as safe, however the research led by Professor Emily Banks and the National Health and Medical Research Council has demonstrated clearly that for non-smokers, there are multiple health risks associated with vaping.[3]

While the AMA recognises that vaping may assist some people to quit smoking, this should be a last resort, prescribed by a patient's doctor who has a strong understanding of their patient's health and history. Indeed, there is no strong evidence that vaping is an effective smoking cessation tool.[4]

[1] Baenziger et al., March 2021, E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis, *BMJ Open.*
[2] Wakefield et al. May 2023, Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.
[3] Banks et al., February 2022, Electronic cigarettes and health outcomes: systematic review of global evidence. *Report for the Australian Department of Health.*
[4] Lung Foundation Australia, Can nicotine e-cigarettes be used for smoking cessation.; Centers for Disease Control and Prevention, About Electronic Cigarettes (E-Cigarettes).

These reforms acknowledge the risks to the public, the risks to individuals, and the need to act now. As such, the AMA agrees with the proposals outlined in the consultation paper. More details and suggestions for improvement are provided in response to questions which are relevant to the AMA as the peak body representing Australia's doctors.

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?*

Yes. Single use vapes are both a public health and environmental problem, as demonstrated in the UK where five million single use vapes are thrown away each week.[5] The AMA also strongly supports banning all vapes outside of legitimate therapeutic use. As noted in our submission to the Potential reforms to the regulation of nicotine vaping products consultation earlier this year, the distinction between nicotine vaping products (NVPs) and non-nicotine vapes underplays the risks with non-nicotine vapes and makes regulation more challenging. This approach addresses this issue by only allowing vapes for therapeutic purposes, which is what they were originally presented as.

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

While there is some disagreement on the role of vapes, the general consensus is that the individual and community harm warrants the strong regulation outlined in this paper. We also expect that there will be an increase in consumers seeking consultations with their GPs about vaping. There will need to be a strong communications campaign that explains the change, that GPs may not want to prescribe vapes and the legitimate reasons why. The AMA would like to be involved ahead of the campaign.

It is also essential that this campaign anticipates the industry response to change and pre-empts the talking points that will be and are already are being used. Specifically, it must highlight that there are better smoking cessation tools with more evidence of efficacy and the safety risks of vaping.

While there are telehealth providers who currently prescribe vapes, the AMA would prefer that a patient discusses this with their usual GP. The AMA is supportive of the Medical Board of Australia's telehealth guidelines which detail best practice telehealth consultations. We expect all providers to meet these standards.

3. *Do you support the proposal to remove the personal importation scheme exception for vapes? If not, what would be the impact on you?*

Yes. The AMA has been calling for an end to the personal importation scheme (PIS) since NVPs became prescription only in 2021. The PIS bypasses many of the product standards outlined in TGO 110, such as labelling, packaging, and record-keeping requirements. The PIS has proven challenging to enforce and keeping it in place while pursuing other reforms outlined in the consultation paper would undermine the ability to ensure the safety of vapes

[5] Sarah Marsh, 8 September 2023, Call for UK ban on single-use vapes as more than 5m discarded each week, *The Guardian*.

used in Australia, the dispensing of these vapes, and the stricter requirements of the updated TGO 110. This is an essential reform.

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

Yes. This will also be useful from a clinical perspective should a traveller need to see a doctor regarding a further script in Australia, as it provides an understanding of what they are currently using.

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

The AMA strongly supports this proposal. In addition to the prohibition of advertising vapes, the TGA should give thought to how the advertising of the prescribing of vapes should be regulated. Given the proposal to allow all GPs to prescribe under the SAS C notification system, access to prescribing doctors will be greatly expanded. The AMA has previously raised concerns with "pop-up" services which masquerade as smoking cessation services when they exist solely to provide easy access to vapes.

Proposal 2 - changes to market accessibility requirements for therapeutic vapes

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

The AMA supports this approach. While the AMA maintains the position from the January consultation that establishing a regulated source of quality vaping products by requiring registration on the Australian Register of Therapeutic Goods (ARTG) is preferable, we acknowledge the practical challenges this position presents.

Noting there are currently no registered vaping products on the ARTG, pre-market notification compliance where the product has to demonstrate compliance with an enhanced TGO 110 and is assessed by these standards is a reasonable approach. However, the AMA suggests that this could be an interim measure while vaping products are gradually added to the ARTG and be reviewed after a set period of time.

The AMA remains concerned that this new approach has challenges. The TGA will need to be very clear in messaging that these products are not on the ARTG, and will need to communicate with international regulators to ensure this level of compliance is not used by suppliers to push their products as safe, therapeutic goods in overseas jurisdictions.

The AMA also notes that there are many doctors who do not feel it is appropriate to prescribe goods that are not on the ARTG. The AMA strongly supports a doctor's right to not prescribe vaping products that have only met the pre-market compliance level.

9. *Do you support the proposed access to vapes under the SAS C notification system? What impact would this pathway have on facilitating patient access to therapeutic vapes?*

The AMA supports this proposal. There are some benefits, such as encouraging a patient to discuss vaping or smoking with their usual GP where more efficacious treatments can be discussed, and simplified processes for doctors. This could undermine the "pop-up" business model, but it could also potentially make it easier. This should also be a time-limited arrangement as the registering of vaping products on the ARTG would limit the requirement for a special access scheme entirely.

It is important to note that completing the paperwork for a SAS C will be time consuming and as such will remain a significant hurdle for access in a supported model of care. It is possible doctors would want to charge more for these consultations as there is a counselling element as well as a paperwork requirement. There will need to be communication and clear instructions with examples for doctors.

10. *would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?*

As noted, there are many GPs who are fundamentally opposed to prescribing products not registered on the ARTG, as well as many GPs who are opposed to vapes due to the significant public health problem they have created. While the SAS C will make it easier for GPs who want to prescribe, it will not change the prescribing behaviour of others.

11. *which access pathway (SAS B, SAS C or AP) would you envisage using to prescribe therapeutic vapes? Why?*

We anticipate that SAS C will facilitate prescribing, however there will be many GPs who have never used the SAS C pathway before. GPs will require specific and clear guidance on this process.

12. *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?*

This should make it easier if integrated properly, making it simpler and less time consuming for doctors to use the new pathway. It would therefore ease administrative burden and encourage doctors to prescribe therapeutic vapes who feel that prescription is appropriate for their patient.

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?*

Yes, the AMA strongly supports the simplification of regulation of vapes.

14. *Will these changes have direct or indirect impact of you? Please provide details.*

The AMA anticipates there will be an increase in demand through general practice from the moment the reforms are announced. As such, a strong communications campaign which includes materials for GPs and practices must be ready to go from the announcement, not the start date.

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

There will need to be time for a strong communications campaign for providers and consumers.

Proposal 3 - heightening quality and safety standards for therapeutic vapes

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

The AMA supports the definition of mint flavours, however we have concerns with the lack of definition for tobacco flavour. The lack of a clearly defined composition for tobacco flavour allows for a wide range of chemicals to be included. The AMA recommends that the TGA defines a limited range of low-risk chemicals that can be used in tobacco flavour.

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

Yes.

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?*

The AMA strongly supports this proposal. The AMA would like to make sure that warning statements are specific to the vaping product in the packaging. For example, containers of e-liquids must have a warning statement which specifically warns against ingestion given the research led by Prof Emily Banks found that ingestion was responsible for an estimated 92.5-99.4 per cent of all e-liquid poisonings from over 8,000 cases.[6]

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?*

Yes. This is a sensible approach.

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

Yes. As noted earlier, the AMA strongly supports regulating all vaping products through the same instruments. There is no safe vaping product whether it contains nicotine or not. Products sold as not containing nicotine have regularly been demonstrated to contain nicotine, creating addiction among new, younger, populations. This is an opportunity for Australia to begin undoing the damage caused by vaping and prevent further uptake while retaining some vaping products for legitimate therapeutic use.

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

Yes. The AMA has been advocating for a stronger, stricter TGO 110 since the initial reforms almost two years ago. In particular, the AMA is very pleased to see the maximum nicotine concentration being reduced from 100 mg/ml to 20 mg/mL in base form. The AMA is aware of concerns regarding a potential loophole around the term "base equivalent". To address these concerns, the AMA suggests clarifying that the concentration of the nicotine component of the e-liquid should not exceed 20mg/mL, regardless of whether it is in freebase, salt or other form.

As noted earlier, we would like more specific warnings on the risks of poisoning from ingestion. We strongly support the proposal to include zero-nicotine vapes in TGO 110.

The AMA notes that the maximum amount of e-liquid sold for open system vapes will be 120 mL. The intent is noted as aligning with overseas jurisdictions, however the AMA understands that the current EU and UK volume limit is 10mL for refills for retail sale. The AMA suggests that this be considered further.

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[6] Banks et al., February 2022, Electronic cigarettes and health outcomes: systematic review of global evidence. *Report for the Australian Department of Health.*

The AMA is also concerned about the leaching of certain metals and other chemicals from the devices into the vapour.[7] The TGA should explore this risk and consider further reforms to address it.

Proposal 4 - strengthening domestic compliance and enforcement mechanisms.

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

The AMA is supportive of all aspects of this proposal.

[7] Alcantara et al., March 2023, Occurrence of metals in e-cigarette liquids: Influence of coils on metal leaching and exposure assessment, *Heliyon.*