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AMA Submission to the Therapeutic Goods Administration – interim decision on amendments to the Poisons Standard – nicotine

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Introduction

The AMA thanks the TGA for the opportunity to provide feedback on the interim decision for the proposed amendment to the Poisons Standard regarding nicotine.

The AMA opposes the use of nicotine-containing vaping products, including for therapeutic purposes. There is international evidence from multiple studies that nicotine containing vaping among non-smokers is associated with an increased risk of future tobacco smoking[1], and the AMA is highly concerned that their uptake among non-smokers will detract from hard-won successes in tobacco control in Australia. There is a lack of high-quality evidence that vaping is an effective cessation aid and there is strong high-quality evidence that vaping causes harm.

If this interim decision is incorporated into the Poisons Standard, the AMA will continue to highlight the lack of evidence to support vaping as a means of smoking cessation, both in communications to members as well as in broader public commentary. The TGA must ensure that the use of vaping as a cessation aid is a method of last resort, recognising the lack of evidence for its use for this purpose and the ample evidence showing harm.

While the AMA opposes the use of vaping products, the AMA recognises that the interim decision closes an existing loophole and will prevent access to nicotine-containing vaping products for those previously accessing them for non-therapeutic use. The AMA regards this as an important move to ensure that patients see their doctor for advice on the most reliable and safe smoking cessation methods, creating an additional barrier for people to take up vaping.

Therefore, the AMA accepts the proposal to down-schedule nicotine to Schedule 4 for all human use (except in preparation for oromucosal or transdermal administration as cessation aids and in tobacco prepared and packed for smoking).

As the TGA is aware, there is currently no vaping product approved as a smoking cessation aid on the Australian Register of Therapeutic Goods (ARTG) due to a lack of evidence for their safety or efficacy. Since the AMA made its first submission regarding this decision, a new evidence review from the Australian National University (ANU) has been published, which sets out several

[1] National Health and Medical Research Council (2017) *CEO Statement: Electronic Cigarettes*

concerning findings regarding e-cigarette use[2]. Of primary relevance to this decision is the finding that e-cigarette use was not associated with a significant difference in quit rates, compared to other forms of smoking cessation assistance. Additionally, the reviewers noted that people using nicotine vaping products for smoking cessation purposes were significantly more likely than people using other forms of nicotine-replacement therapies to continue using these products after one year. These findings, along with the existing low level of evidence about e-cigarette safety and efficacy, are likely to prompt uncertainty among medical practitioners about the appropriate circumstances in which vaping products should be prescribed.

Additional guidance for medical practitioners

The AMA anticipates an influx of patients requesting nicotine-containing vaping products from medical practitioners when the changes come into effect. To ensure prescribers are prepared for this, the AMA suggests further, clear communication consisting of guidance around the changes and when it might be appropriate to consider nicotine-based products. The AMA is aware of the existing document on *National guiding principles for e-cigarettes*, as well as the Royal Australian College of General Practitioner's (RACGP's) *Supporting smoking cessation* guide which is promoted on the TGA's website. The recommendation that prescribers use the precautionary principle when considering e-cigarette prescriptions, and the RACGP's guidance that e-cigarettes only be employed as a last-line cessation aid, is welcome. However, when these changes come into effect, clear and well-communicated guidance will be needed on the appropriate dosage of nicotine vaping products, as well as recommended timeframes for use as a cessation aid. It would be useful for the TGA to communicate these materials and additional guidance widely across the medical profession well before the implementation date.

Additional regulation for prescribing nicotine-containing vaping products

The AMA understands that the interim decision amends the S4 entry to include nicotine for all human use, not just therapeutic, with an aim to clarify rules around importing vaping products. However, it must be clear through a tighter TGA Access Pathways process that approval should be based on the TGA and RACGP guidance materials. Further, while the TGA aims with these changes to prevent youth uptake in vaping in Australia and to facilitate access to nicotine-containing vaping products for smoking cessation[3], this is not clear in the Schedule wording. The proposed scheduling does not specify that nicotine-containing products should only be prescribed to current smokers. The AMA understands that this is proposed so all human use is captured in the S4 entry. However, the AMA believes that only prescribing to existing smokers should be specified as a condition to prescribe via the TGA Access Pathways so the TGA's aims will be met.

The AMA recommends a time limit for prescribing nicotine-containing vaping products as a condition under the TGA Access Pathways, to ensure that patients who do not intend on quitting are not supplied with nicotine-containing vaping products on an ongoing basis. A specific time limit would require further consultation with the medical profession.

[2] Banks E, Beckwith K, Joshy G (2020) *Summary report on use of e-cigarettes and impact on tobacco smoking and cessation, relevant to the Australian context.*

[3] Therapeutic Goods Administration (2020) *Update on nicotine scheduling and proposed restriction on importation of nicotine for use in e-cigarettes*

The AMA is concerned that the interim decision does not specify standards for the quality of the nicotine-containing vaping products being imported under prescription. There should be safeguards in place to ensure vaping products being imported come from countries with at least equal standards for quality to Australia.

The AMA supports including additional child safety protection measures in the Schedule for nicotine such as child-safety proof packages and warning labels.

The AMA would also strongly recommend an evaluation process 12 months after the implementation date to assess the impact of the changes on smoking rates. The evaluation should also include feedback from prescribing medical practitioners.

Conclusion

The AMA's priority is to reduce smoking and vaping use in Australia. There is not enough evidence that nicotine-containing vaping products are successful smoking cessation aids and there are serious concerns around their potential to cause harm. However, the AMA accepts the decision to make nicotine Schedule 4 for all human use on the basis that it closes a current loophole and further restricts access to nicotine-containing vaping products. The TGA will need to provide additional guidance to the medical profession well before the implementation date to ensure doctors are prepared for an influx of patients, and the TGA Access Pathway should be tightened to offer better protections for the medical profession.

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