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SUBMISSION

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# TGA: Targeted consultation on the regulation of nicotine pouches

## Australian Medical Association

The Australian Medical Association (AMA) thanks the Therapeutic Goods Administration (TGA) for this important consultation to strengthen regulation of nicotine pouches. The AMA urges the TGA, and relevant government and enforcement agencies, to act rapidly to prevent a further public health crisis, similar to that experienced with vaping. The tobacco industry is actively seeking to establish a new generation of people addicted to nicotine, supported by marketing and sponsorship that normalises use, including visible branding on Formula One race cars. At present, nicotine pouches are being promoted and supplied in the absence of adequate safety and health data, standardised health warnings, and child-resistant packaging. They are also too easily obtained without a prescription, including through online sellers who advertise the ease of postage and convenience. Australia's regulatory settings must be future-proofed so that policy and enforcement stay ahead of industry tactics and product innovation.

### Qu. 1 Do you support the proposed amendments to prevent access to unapproved nicotine pouches through the following pathways:

- Special Access Scheme (SAS)
- Authorised Prescriber (AP) scheme
- Personal Importation Scheme
- Extemporaneous compounding by pharmacists

Please explain the reasons for your position, including any relevant evidence or experience.

The AMA supports the TGA's proposed amendments to prevent access to *unapproved* nicotine pouches through all existing access pathways, including the Special Access Scheme (SAS), the Authorised Prescriber (AP) scheme, the Personal Importation Scheme, and extemporaneous compounding.

Nicotine for human use is scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) as a Schedule 4 'prescription only medicine'. As there are currently no nicotine pouches included on the Australian Register of Therapeutic Goods (ARTG), there is no approved product that can be supplied through routine channels. In practice, the only potential legal routes of access are via these schemes or through compounding, and only with a valid prescription.

The AMA's understanding is that legitimate prescribing for nicotine pouches is low to non-existent in Australia, yet the commercial market is expanding, and products remain readily available online and through some retail outlets, including tobacconists. The increasing use of synthetic nicotine in these products further highlights a regulatory gap, as many existing controls and enforcement mechanisms are

framed around 'tobacco products'. This has contributed to inconsistent coverage across jurisdictions, including the absence in many states and territories of appropriate health warnings, age-based controls, and retailer licensing and enforcement powers for nicotine pouches. We note that South Australia and Queensland have acted to address this gap by declaring nicotine pouches to be prohibited/illicit products under their respective tobacco legislation; the proposed Commonwealth amendments are necessary to close access loopholes nationally and support consistent, enforceable regulation.

## Qu. 2 What impacts do you anticipate if the proposed amendments are implemented or not implemented? Consider impacts on:

a) Public health outcomes (including youth uptake and nicotine dependence)
b) Clinical practice and patient care
c) Regulatory integrity and compliance
d) State and territory regulatory activities

If implemented, the proposed amendments will strengthen the integrity of Australia's therapeutic goods and poisons regulatory framework by closing practical access pathways that are not appropriate for a product category that is unapproved, widely marketed, and increasingly available through illicit supply chains. If not implemented, current loopholes will continue to be exploited, undermining public health objectives and creating inconsistent and difficult-to-enforce regulation across jurisdictions.

a) Public health outcomes (including youth uptake and nicotine dependence)
If implemented, the amendments will reduce the risk of nicotine pouches becoming normalised and more widely accessible — particularly to young people — by limiting avenues for supply and reinforcing that these are not approved therapeutic products. This is important in the context of aggressive promotion of nicotine products (including through youth-attractive branding and sponsorship/marketing strategies) and the risk of establishing a new cohort of nicotine-dependent consumers, including adolescents who are otherwise nicotine-naïve. If not implemented, the continuing availability of nicotine pouches through online supply and illicit retail channels is likely to accelerate uptake, increase nicotine dependence, and create downstream harms from long-term nicotine exposure, including dual use with other nicotine and tobacco products.

b) Clinical practice and patient care
If implemented, the amendments will support clearer clinical messaging: nicotine pouches are not approved on the ARTG, are not established as smoking cessation therapies, and should not be positioned as a 'healthier alternative' to smoking. This will help clinicians steer patients toward evidence-based, approved cessation options, including registered nicotine replacement therapies and other established pharmacotherapies and supports. If not implemented, clinicians will continue to face confusion and patient misconceptions fuelled by marketing and widespread availability of unapproved products, increasing the burden on clinical consultations and complicating cessation care.

c) Regulatory integrity and compliance
If implemented, the amendments will better align regulatory settings with the Poisons Standard (Schedule 4) and the Therapeutic Goods Act framework by ensuring that unapproved nicotine pouches cannot be supplied via schemes and compounding arrangements in ways that are inconsistent with their intended purpose. This is particularly important given the emergence of synthetic nicotine, which can exploit gaps in legislation framed primarily around 'tobacco products'. If not implemented, a regulatory grey area will persist, enabling ongoing circumvention, weakening compliance, and leaving products available without consistent health warnings, age-based controls, licensing, or effective enforcement mechanisms in many jurisdictions.

d) State and territory regulatory activities
If implemented, the amendments will support more consistent national regulation and reduce the burden on states and territories to use piecemeal mechanisms to address nicotine pouches as an emerging product category. While some jurisdictions have acted — such as South Australia and Queensland prescribing nicotine pouches as prohibited/illicit products under their tobacco legislation — others may not yet have equivalent provisions or enforcement tools. Commonwealth action will help harmonise expectations, improve inter-jurisdictional consistency, and strengthen the overall enforcement environment. If not implemented, regulatory fragmentation will likely increase, with uneven controls and enforcement capacity across Australia and continued opportunities for illicit suppliers to exploit weaker settings.

## Qu. 3 Overall, what do you consider the likely impact to be (choose one):

Predominantly positive

## Qu. 4 Based on your experience or evidence, are there clinical circumstances in which unapproved nicotine pouches provide a therapeutic benefit that is not met by existing smoking and vaping cessation pharmacotherapies (including prescription medicines, NRT and therapeutic vapes)?

The AMA is not aware of robust clinical evidence demonstrating that *unapproved* nicotine pouches provide a therapeutic benefit for smoking or vaping cessation that is not already met by existing, evidence-based cessation treatments (including registered nicotine replacement therapy (NRT), approved prescription pharmacotherapies, and therapeutic vaping goods where clinically appropriate).

In particular, as nicotine pouches are not included on the ARTG, there is no assurance of consistent quality, nicotine content, labelling, or appropriate consumer information that would ordinarily be expected for a therapeutic product. This creates avoidable clinical and patient safety risks (including inadvertent high-dose nicotine exposure and poisoning), and it undermines clear public health messaging when products are marketed as ‘clean’ or ‘safer’ alternatives despite lacking an established cessation indication.

## Qu. 5 Are there any additional issues, risks or considerations relevant to this proposal that the TGA should consider?

Yes. The AMA considers there are additional issues and implementation considerations the TGA should address to ensure the proposed amendments achieve their intended public health purpose.

(1) Stronger online compliance and illegal supply**:** A significant proportion of nicotine pouch promotion and sales occurs via online marketplaces, social media platforms, and cross-border e-commerce. The effectiveness of the proposed amendments will depend on active monitoring, timely takedown processes, and cooperation with relevant regulators and intermediaries (including platform operators, payment providers, and logistics providers), alongside consumer-facing deterrence messaging.

(2) The growth in use of synthetic nicotine increases the risk of regulatory avoidance where controls are framed primarily around “tobacco products”. Clear, technology-neutral definitions are needed to ensure nicotine pouches are captured regardless of nicotine source, formulation, or minor product variations.

(3) There are no market standards for nicotine pouches hence there are no standardised labelling, ingredient disclosure, or health warnings. The packaging also presents a safety risk to children,

elevating the risks of accidental exposure, misunderstanding of dose, and misleading perceptions of safety.

(4) The TGA should support improved monitoring of adverse events and poisoning presentations to inform ongoing regulatory adjustments. The long and short-term health impacts of nicotine pouches are unknown and data collected from general practice and hospital admissions will be important.

(5) Clear public and clinician communication is needed to reinforce that nicotine pouches are unapproved, not established cessation therapies, and should not be marketed as "healthier alternatives".

## Qu. 6 Should the TGA consider additional regulatory measures to address emerging nicotine products that extend beyond the current scope of this proposal? If so, what should these measures be?

Yes. Given the pace of product innovation (including the use of synthetic nicotine and novel delivery formats), the AMA believes the TGA should consider additional, future-focused measures to ensure emerging nicotine products cannot circumvent intended public health protections. The TGA should take measures to establish technology-neutral definitions that capture nicotine products regardless of nicotine source (tobacco-derived or synthetic), format (oral, inhaled, dissolvable, etc.), or minor design changes, to prevent regulatory avoidance and ensure consistent treatment across product classes.