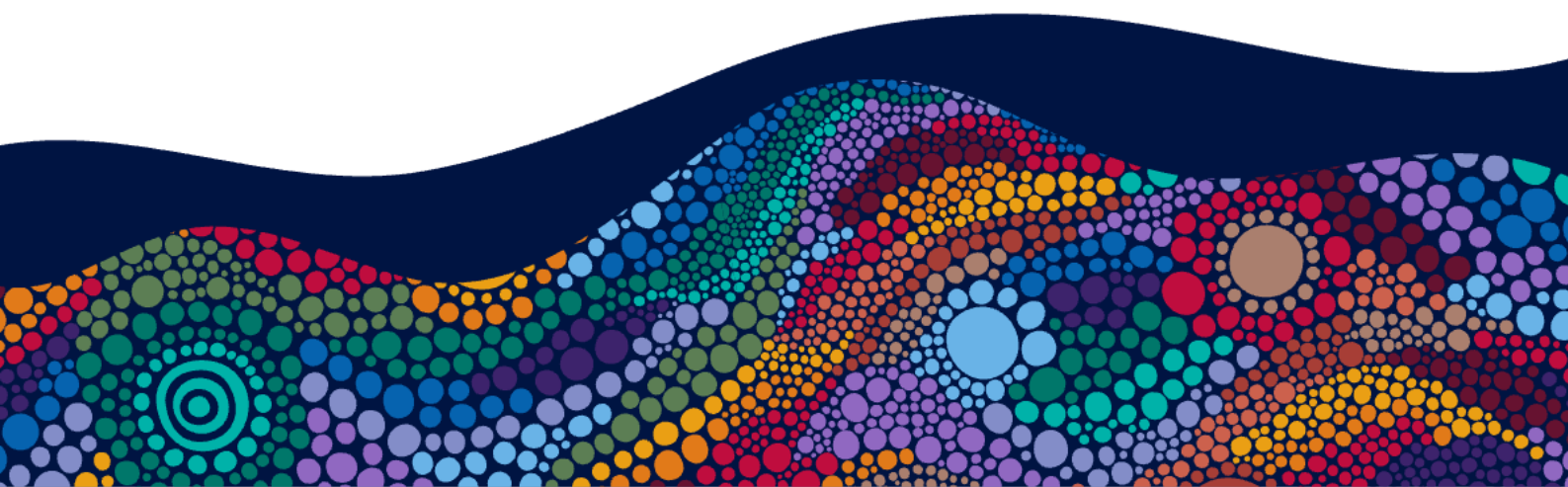


Regulation of nicotine pouches

Submission to Therapeutic Goods
Administration

April 2026



About NACCHO

NACCHO is the national peak body representing 148 Aboriginal Community Controlled Health Organisations (ACCHOs). We also assist a number of other community-controlled organisations.

The first Aboriginal medical service was established at Redfern in 1971 as a response to the urgent need to provide decent, accessible health services for the largely medically uninsured Aboriginal population of Redfern. The mainstream was not working. So it was, that over fifty years ago, Aboriginal people took control and designed and delivered their own model of health care. Similar Aboriginal medical services quickly sprung up around the country. In 1974, a national representative body was formed to represent these Aboriginal medical services at the national level. This has grown into what NACCHO is today. All this predated Medibank in 1975.

NACCHO liaises with its membership, and the eight state/territory affiliates, governments, and other organisations on Aboriginal and Torres Strait Islander health and wellbeing policy and planning issues and advocacy relating to health service delivery, health information, research, public health, health financing and health programs.

ACCHOs range from large multi-functional services employing several medical practitioners and providing a wide range of services, to small services which rely on Aboriginal health practitioners and/or nurses to provide the bulk of primary health care services. Our 148 members provide services from about 550 clinics. Our sector provides over 3.1 million episodes of care per year for over 410,000 people across Australia, which includes about one million episodes of care in very remote regions.

ACCHOs contribute to improving Aboriginal and Torres Strait Islander health and wellbeing through the provision of comprehensive primary health care, and by integrating and coordinating care and services. Many provide home and site visits; medical, public health and health promotion services; allied health; nursing services; assistance with making appointments and transport; help accessing childcare or dealing with the justice system; drug and alcohol services; and help with income support. Our services build ongoing relationships to give continuity of care so that chronic conditions are managed, and preventative health care is targeted. Through local engagement and a proven service delivery model, our clients 'stick'. Clearly, the cultural safety in which we provide our services is a key factor of our success.

ACCHOs are also closing the employment gap. Collectively, we employ about 7,000 staff – 54 per cent of whom are Aboriginal or Torres Strait Islanders – which makes us the third largest employer of Aboriginal or Torres Strait people in the country.

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Recommendations

- 1 **NACCHO recommends** any interventions to address regulation of nicotine pouches align with the National Agreement and its four Priority Reform Areas.
- 2 **NACCHO recommends** reinstating affordable access to short-acting nicotine replacement therapy (NRT) through the PBS.

Acknowledgements

NACCHO welcomes the opportunity to provide a submission on the regulation of nicotine pouches.

National Agreement on Closing the Gap

Advocating for and securing the National Agreement on Closing the Gap was an historically significant act of Aboriginal and Torres Strait Islander self-determination. The National Agreement is evidence of a new era of engagement by and with Aboriginal and Torres Strait Islander people. It commits Australia to a new direction and is a pledge from all governments to fundamentally change the way they work with Aboriginal and Torres Strait Islander communities and organisations – to support self-determination and build the capacity of the community-control sector.

This Government's first Closing the Gap Implementation Plan commits to achieving Closing the Gap targets *through implementation of the Priority Reforms*. This represents a shift away from focussing on the Targets, towards the structural changes that the Priority Reforms require, and which are more likely to achieve meaningful outcomes for our people in the long term.

The reforms and targets outlined in the National Agreement seek to overcome the inequality experienced by Aboriginal and Torres Strait Islander people, and achieve life outcomes equal to all Australians. Governments at all levels have committed to the implementation of the National Agreement's four Priority Reform Areas, which offer a roadmap to meaningfully impact structural drivers of poor health and social outcomes for Aboriginal and Torres Strait Islander people:

Priority Reform Area 1 – Formal partnerships and shared decision-making

This Priority Reform commits to building and strengthening structures that empower Aboriginal and Torres Strait Islander people to share decision-making authority with governments, and to accelerate policy making that centres Aboriginal and Torres Strait Islander voices.

Priority Reform Area 2 – Building the community-controlled sector

Recognising that community-controlled services achieve better outcomes, employ more Aboriginal and Torres Strait Islander people and are often preferred over mainstream services, this Priority Reform commits to building Aboriginal and Torres Strait Islander community-controlled sectors to deliver services to support Closing the Gap.

Priority Reform Area 3 – Transformation of mainstream institutions

This Priority Reform commits to systemic and structural transformation of government organisations to identify and eliminate racism, embed and practice cultural safety, deliver services in partnership with Aboriginal and Torres Strait Islander people, support truth telling about agencies' history with Aboriginal and Torres Strait Islander people, and engage fully and transparently with Aboriginal and Torres Strait Islander people when programs are being changed.

Priority Reform Area 4 – Sharing data and information to support decision making

This Priority Reform commits to shared access to regional data and information to inform local-decision making and support achievement of the first three Priority Reforms. This Priority Reform supports principles of Indigenous Data Sovereignty.

Despite some progress, the need for fundamental systemic reform remains evident. In its first review of the National Agreement on Closing the Gap, the Productivity Commission found that governments are not adequately delivering on their commitments. Despite support for the Priority Reforms and some good practice, progress has been slow, uncoordinated, and piecemeal.

The Commission noted that to enable better outcomes, governments needs to relinquish some control, share

decision making and acknowledge that Aboriginal and Torres Strait Islander people know what is best for their communities. Aboriginal Community Controlled Organisations, must be treated as critical partners rather than passive funding recipients, and trusted to design, deliver and measure government services in ways that are culturally safe and meaningful for their communities.

‘Too many government agencies are implementing versions of shared decision-making that involve consulting with Aboriginal and Torres Strait Islander people on a pre-determined solution, rather than collaborating on the problem and co-designing a solution’¹

NACCHO recommends any interventions to address regulation of nicotine pouches align with the National Agreement and its four Priority Reform Areas.

Background

NACCHO recently wrote a submission to the Parliamentary inquiry into the illegal tobacco crisis in Australia. In it, we noted that the growing availability of illegal tobacco products presents a significant public health concern. By providing cheaper alternatives to regulated tobacco products, the illicit market undermines one of the most effective tobacco control measures currently in place (that is, price). When tobacco becomes more affordable through illegal supply, the price signal that encourages quitting is weakened, potentially slowing or reversing the progress that has been made in reducing smoking prevalence.

Nicotine addiction – especially in young people, is of increasing concern for clinicians.

Question responses

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

- *Special Access Scheme*
- *Authorised Prescriber scheme*
- *Personal Importation Scheme*
- *Extemporaneous compounding by pharmacists*

☒ *Yes, support* ☐ *No, do not support*

NACCHO supports the prevention of access to unapproved nicotine pouches in all their forms. Nicotine pouches do not have a place in evidence based smoking cessation, therefore access should be restricted.

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*

¹ Productivity Commission, Review of the National Agreement on Closing the Gap, Study Report, Canberra, 7 Feb 2024 <https://www.pc.gov.au/inquiries/completed/closing-the-gap-review/report>.

— d) State and territory regulatory activities

Nicotine can be fatal, and children are at particular risk. Low dose exposure may result in gastrointestinal symptoms, but larger doses – possible through liquid nicotine solutions or products such as nicotine pouches – can cause severe toxicity resulting in seizures, cardiovascular collapse, coma² and have even resulted in child death.³

Nicotine pouches do not come in child safe packaging, further emphasising the need for restricted access.

3. Overall, what do you consider the likely impact to be: ☐ Predominantly positive ☐ Predominantly negative ☐ Mixed (both positive and negative) ☐ No material impact ☒ Unsure

Given limited timeframes for feedback, NACCHO has not had capacity to consult members about their specific concerns relating to nicotine pouches, however the suggested amendments appear to be sensible.

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)?

No.

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

Not to our knowledge.

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?

Short-acting NRTs, including oral sprays, lozenges and gum, are widely regarded as an important component of best-practice smoking cessation treatment.⁴ When used alongside nicotine patches, these products help manage cravings and withdrawal symptoms that can arise throughout the day. This combination therapy approach allows individuals to maintain a steady baseline level of nicotine through patches while using short-acting products to respond to sudden cravings, which can significantly improve the likelihood of successfully quitting smoking.

Recent changes to the Pharmaceutical Benefits Scheme (PBS), including the withdrawal of some short-acting NRT products, have created additional barriers for both health services and patients seeking support to quit smoking. Participants indicated that reduced access to these therapies can undermine the

² The Royal Children's Hospital Melbourne, Nicotine Poisoning, January 2019, https://www.rch.org.au/clinicalguide/guideline_index/Nicotine_Poisoning/.

³ Australian Associated Press, Toddler died after consuming liquid nicotine while mothers' head was turned, coroner says, The Guardian, July 2019, <https://www.theguardian.com/australia-news/2019/jul/08/toddler-died-after-consuming-liquid-nicotine-while-mums-head-was-turned-coroner-says>.

⁴ Kennedy et al. *Smoking cessation support strategies for Aboriginal and Torres Strait Islander women of reproductive age: findings from the Which Way? study*. Med J Aust. 2022 Jul 18;217 Suppl 2(Suppl 2):S19-S26. doi: 10.5694/mja2.51631. PMID: 35842910; PMCID: PMC9544708.



effectiveness of cessation support programs delivered through community health services. This can be particularly challenging in regional and remote communities where access to alternative cessation supports may already be limited. For many ACCHOs and other frontline services, these changes have increased the cost to services of providing comprehensive cessation support, particularly impacting communities where financial barriers already limit access to treatment.

Where affordable cessation supports are not readily available, some individuals may turn to cheaper sources of tobacco, including illicit tobacco products circulating through informal markets. This can undermine broader public health efforts to reduce smoking rates and may increase exposure to unregulated products that do not comply with Australia's tobacco control standards.

NACCHO recommends reinstating affordable access to short-acting nicotine replacement therapy (NRT) through the PBS.