



Nicotine Pouches Literature Review

A review of evidence on consumer behaviours, cessation efficacy, composition, and clinical impacts of nicotine pouches



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Acronyms and abbreviations

Acronym	Full name
ARTG	Australian Register of Therapeutic Goods
CDC	Centres for Disease Control and Prevention
EDRS	Ecstasy and Related Drugs Reporting System
FDA	Food and Drug Administration
NAB	N-nitrosoanabasine
NAT	N-nitrosoanatabine
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone
NNN	N-nitrosonornicotine
NRT	Nicotine replacement therapy
pH	Potential of hydrogen
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
TGA	Therapeutic Goods Administration
TSNAs	Tobacco-specific nitrosamines
UQ	The University of Queensland



Glossary

Term	Definition as used in this report
Abuse Liability	Determining the ability of nicotine pouches to cause dependence
Cigarette	A combustible tobacco product consisting of finely cut tobacco wrapped in paper intended to be ignited and smoked, delivering nicotine and other chemicals through inhaled smoke
E-cigarette	Electronic nicotine delivery device that heats a liquid solution to generate an inhalable aerosol
Nicotine pouches	Small tobacco free pouches containing nicotine that are placed between the lip and gum to allow nicotine absorption through the lining of the mouth
Snus	Smokeless oral tobacco product originating from Sweden
TikTok	Social media platform that allows users to create, share and view short-form videos
Zyn	Brand of nicotine pouches

Executive summary

Background

Nicotine pouches are small tobacco free sachets containing nicotine that are placed between the lip and gum to allow nicotine absorption through the oral mucosa. First introduced to the United States (US) market in 2016, global sales have increased significantly from 292 million units in 2018 to 20.2 billion in 2023, with the majority (85%) occurring in the US. Nicotine pouches have been described by manufacturers as a novel smoking cessation aid for individuals transitioning away from tobacco smoking or other tobacco products and have been promoted as a reduced-risk alternative to smoking.

Nicotine pouches are unapproved therapeutic goods in Australia, have not been evaluated by the Therapeutic Goods Administration (TGA), and are not included in the Australian Register of Therapeutic Goods (ARTG). Nicotine pouches are in Schedule 4 (Prescription Only) of the Poisons Standard. Despite their status as unapproved therapeutic goods and the national ban of their sale and advertisement, a 2024 survey of 1,598 Australians aged 16 to 39 found that over a quarter of respondents (27%) had used nicotine pouches on one or more occasions.

Nicotine pouches have been identified as a product category requiring scrutiny due to their unknown long-term health effects, capacity to cause dependence or addiction, and growing popularity among adolescents and young adults, who are the population least likely to smoke cigarettes.

Report aims and methods

This document presents findings from a review of reviews of global evidence on nicotine pouches, examining consumer behaviours, cessation efficacy, product composition, health impacts, and clinical outcomes.

A rapid review of reviews was conducted as an accelerated, highly focused synthesis of higher-level research, providing a pragmatic approach to evidence synthesis that is cognisant of the short timeframe. This was undertaken in November 2025 across 10 academic databases, yielding 2,198 records. An additional search of the grey literature identified 61 records. Following screening, 23 academic studies and 40 grey literature reports were included for data extraction and synthesis.

Findings

Due to their recent market introduction and relatively low usage prevalence globally, limited evidence exists on the long-term health harms of nicotine pouches, necessitating future monitoring and surveillance.

Questions have been raised about the safety profile of nicotine pouch products. Concerns exist regarding the significant variability in product composition between manufacturers, with nicotine content ranging from 1 to over 40 mg per pouch and pH levels between 5.5 and 10.5. Some nicotine pouches have been found to contain harmful substances including tobacco-specific nitrosamines (TSNAs) and heavy metals.

Despite a limited evidence base, the literature indicates that use of nicotine pouches among adolescents and young people in Australia is rising, even with limited legal availability. Uptake is motivated by multiple factors, including flavours, ease of concealment, rapid nicotine delivery, weight-loss claims, and perceptions that the products are “safer” and “cleaner” than cigarettes and vapes. However, these claims are not substantiated within the literature, and the health implications of nicotine pouch use warrant careful consideration.

Prolonged nicotine exposure has demonstrated detrimental effects on brain development and potential long-term cardiovascular risks. In addition to this, short-term adverse effects reported in the literature include headaches, nausea, oral irritation, and increased heart rate. Evidence indicates that nicotine pouches pose reduced toxicological risk and may decrease disease risk relative to tobacco smoking; however, these comparisons are made against cigarettes, a product with substantial disease and toxicological risks. In

addition, there are limited in vitro studies assessing whether reduced exposure translates into reduced biological response.

Nicotine pouches have been promoted by manufacturers as offering potential benefits when used as a cessation aid; however, their effectiveness and health implications remain uncertain. They also pose additional risks—particularly if adopted by people who do not smoke—along with potentially unknown long-term health impacts. Nicotine pouches have been described by manufacturers as a reduced-risk alternative for people who smoke who completely switch from combustible tobacco, owing to lower exposure to harmful chemical toxicants compared with tobacco smoking. Some evidence supports short-term effectiveness in reducing smoking; however, nicotine pouches may be less effective than nicotine replacement therapies (NRT), which are a safe and effective strategy to support long-term smoking cessation. When considered solely for cessation purposes, no short-term serious health harms from nicotine pouch use were identified. Overall, there is no direct evidence assessing long-term health impacts due to the product’s recent market introduction.

Contributing to current consumer perceptions is a substantial social media presence, particularly for Zyn brands on TikTok, where “Zynfluencers” normalise use among younger audiences. Young people report seeing products promoted as “tobacco-free” and “smoke-free” alternatives without accompanying public health counter-messaging, potentially reinforcing misconceptions about product safety.

Policy implications

The current evidence does not support nicotine pouches as a smoking cessation aid when compared with approved NRT. Combined with the risk of adverse health impacts and the notable absence of evidence on longer-term health risks, there is an urgent need for independent studies examining sustained health impacts and the comprehensive risk profile of these products. This evidence gap is particularly concerning given the risk of creating nicotine dependence among young people and non-tobacco users if nicotine pouches become widely available, a pattern already observed in countries with legal availability of pouches such as the US.

The current marketing landscape presents additional policy challenges. Marketing of nicotine pouches by manufacturers and social media influencers as “safer” and “reduced risk” nicotine products, without balanced public health counter-messaging, may create misleading narratives that promote use, particularly among young people. This risk necessitates ongoing monitoring of product use—especially among young people that have not previously used tobacco products—alongside urgent monitoring of, and action to address promotion of nicotine pouches on social media. Several reviews recommended ensuring counterarguments and fact-checking materials are made available to younger audiences to combat potentially unsafe messaging. Further independent research is needed on the long-term health outcomes when using nicotine pouches recreationally, and for cessation purposes, to build a robust evidence base that can inform future policy decisions.

Limitations

Many included articles were narrative reviews with poorly documented methods, often lacking search strategies, databases searched, inclusion and exclusion criteria, and final study counts. The existing literature typically compares the safety, risks, and benefits of nicotine pouches with cigarettes or other tobacco products, with limited research examining nicotine pouches independently. Several reviews noted that some of the research they cited received industry funding, and many publications did not declare conflicts of interest.

This report reviews the available literature published between 2016 and November 2025 (the period covered by the searches). New evidence within this scope will continue to emerge after this date.

1. Introduction

Nicotine pouches are small tobacco-free pouches containing nicotine that are placed between the lip and gum to allow nicotine to be absorbed through the oral mucosa.¹ The product is distinct from other products consumed this way, such as Swedish snus, as it contains extracted or synthetic nicotine rather than leaf tobacco.^{2,3} Nicotine pouches come in a variety of flavours and can be used discreetly, without the need for “spitting”, refrigeration, or exhaling vapour or smoke.⁴ Nicotine pouches have been marketed as “smoke-free”, “tobacco-free”, and even “reduced risk” alternatives to smoking, e-cigarettes, and vaping.⁵

A small Swedish pharmaceutical company, Nicovum, developed nicotine pouches and registered them as a smoking cessation medicine in the late 2000s.¹ Nicovum was acquired by a United States (US) tobacco company (Reynolds American Inc) in 2009.² Despite their origin as a medicinal product, most nicotine pouch products now on the market are not registered/licensed as medicines and are instead marketed as non-therapeutic products. Nicotine pouches were first reported to have entered the retail market in the US in 2016, and estimated global sales have increased from 292 million units in 2018 to 20.2 billion units in 2023; the majority of sales are within the US (85%),³ over 70% by one brand (Zyn). The introduction of the product, variety of flavours, rapid increase in global availability, and ability to be used discreetly has caused concern due to the potential for rapid uptake by youth and young adults.⁴

Nicotine pouches are unapproved as therapeutic goods in Australia, have not been evaluated by the Therapeutic Goods Administration (TGA) and are not included in the Australian Register of Therapeutic Goods (ARTG). Nicotine pouches are in Schedule 4 (Prescription Only) of the Poisons Standard.⁵ Under Australian law, nicotine pouches cannot be sold by retail outlets or tobacconists and cannot be advertised to the public. Despite these restrictions, a 2024 survey of 1,598 Australians aged 16 to 39 reported that over three-quarters (77%) were aware of nicotine pouches and around a quarter (27%) had used them on one or more occasions.⁹ Nicotine pouches are advertised globally; for example, brands have featured on Formula 1 and IndyCar teams,¹⁰ reaching a wide audience despite advertising bans in some jurisdictions. Reports have also highlighted nicotine pouches being promoted by Australian social media influencers as a “safe” and “effective” way to quit vaping.¹¹ It was reported that 1.3 million nicotine pouches were seized by Australian Border Force during 2024,¹² highlighting the potential size of the illegal sales market.

In the US, tobacco-free nicotine products are classified as tobacco products if they are not licensed as smoking cessation medicines. Currently, the US Centers for Disease Control and Prevention (CDC) states that there are no safe tobacco products, and nicotine pouches are included within this definition.¹³ Nicotine pouches are part of a regulatory blurring of lines between medicinal nicotine products and non-therapeutic nicotine products.^{7,14} Nicotine pouches have been promoted by manufacturers as offering potential benefits when used as a cessation aid; however, their effectiveness and health implications remain largely uncertain because most nicotine pouch products are not regulated as medicines and, hence, are of unknown quality and subject to unknown quality control.² Marketing them as recreational products may encourage non-beneficial patterns of use that pose additional risks—particularly if adopted by people who do not smoke—along with potentially unknown long-term health impacts.¹⁵ Evidence from Eastern Europe found that nicotine pouches were sold in higher strengths than required for craving relief and withdrawal management from other tobacco products, if the products were to be used directly for smoking cessation.² It is important to understand the short and long-term risks associated with nicotine pouches, given their growing popularity without regulatory oversight as therapeutic goods, including among non-smoking youth and young adults.¹⁵

Priority Area 9 of the Australian National Tobacco Strategy 2023–2030⁵ highlights the need to strengthen regulations on e-cigarettes and emerging products, including nicotine pouches. Nicotine pouches have been identified as a product category requiring scrutiny because of their unknown long-term health effects, abuse liability (ability to cause dependence/addiction), and growing popularity among young adults.^{4,6} Although some research suggests these pouches may present a lower-risk alternative to combustible tobacco,⁷ their novelty necessitates robust independent evidence reviews to assess potential harms that may be contrary to

manufacturer claims. Furthermore, any population health benefit is contingent on the products resulting in less smoking.

1.1 Purpose and scope

This document reports the findings of a review of the global evidence on nicotine pouches regarding composition and safety; prevalence and use; supply and access; consumer trends; nicotine dependency and dual/poly use; health and public health impacts; use as a cessation aid; marketing and advertising; and public health policy. The research was funded by the Australian Government Department of Health, Disability and Ageing and was undertaken independently by researchers from the Institute for Social Science Research (ISSR) and School of Public Health, The University of Queensland (UQ).

2. Methods

2.1 Aims and objectives of the review

The overarching objective of the review was to identify and review existing national and international public health evidence on nicotine pouches. Seven key literature review questions were developed around 3 main research areas:

- consumer behaviours, access and prevalence of use
- efficacy for smoking cessation and public health impacts
- composition and clinical evidence

To address these broad objectives, the review was guided by the following literature review questions:

1. What is the current evidence on prevalence and/or patterns of nicotine pouch use in Australia?
2. What is the current evidence on consumer behaviour and attitudes towards nicotine pouches, consumer exposure to marketing and advertising, and consumer use of nicotine pouches?
3. What is the current evidence of nicotine pouches contributing to nicotine dependence and/or influencing dual/poly use of other nicotine products?
4. What is the current evidence on the effectiveness of nicotine pouches as a smoking cessation tool?
5. What does the current evidence show about the health effects, composition, and safety of nicotine pouches and what are the potential public health risks or benefits?
6. What are key existing data and knowledge gaps recommended for further monitoring and research regarding the health impacts, consumer behaviours, safety and market trends of novel oral nicotine products, including nicotine pouches?
7. What are the implications for public health policy regarding the public health impacts of nicotine pouches?

2.2 Literature review methods

The overarching review aim was to identify and review existing national and international public health evidence on nicotine pouches to inform strategic decision-making, policy development, and stakeholder engagement.

2.2.1 Search strategy

The methodological approach of the review was primarily a **rapid review of reviews** across multiple domains in the nicotine pouches academic literature, supplemented by a broader but targeted search of the grey literature. A UQ expert librarian conducted academic searches across 10 databases (Table 1) on 17 November 2025, yielding 2,198 academic records. Additional searches across targeted websites and databases yielding 61 grey literature records (Table 2). An example of the academic search strategy is included in **Appendix A**.



Table 1 Academic database search record

Database	Results
PubMed	578
Embase	336
PsycINFO	115
Scopus	358
Web of Science	455
CINAHL	192
ABI/INFORM	35
ProQuest Dissertations & Theses Global	86
ProQuest Research Library	39
Informit Health Collection (Informit)	4
TOTAL	2,198*

Note: *includes duplicate records.

Table 2 Grey literature search record

Organisation/database	Website	Results
ACOSH - The Australian Council of Smoking and Health	https://acosh.org/	0
AIHW - Australian Institute of Health and Welfare	https://www.aihw.gov.au/	0
Australian Policy Online	https://apo.org.au/	1
Cancer Council (including Generation Vape data)	https://www.cancer.org.au/	3
Centre of Research Excellence on Achieving the Tobacco Endgame	https://tobacco-endgame.centre.uq.edu.au/	1
Department of Health, Disability and Ageing	https://www.health.gov.au/	1
Google Advanced search	site:.gov.au "nicotine pouch" site:.edu.au "nicotine pouch"	22
National E-cigarette Monitoring and Evidence Consortium (NEMEC)	https://nceph.anu.edu.au/research	0
NDARC National Drug & Alcohol Research Centre (including Illicit Drug Reporting System)	https://www.unsw.edu.au/research/ndarc	12
News sites ABC & (Factiva Database)	site: https://www.abc.net.au/ "nicotine pouch"	4
NHMRC National Health and Medical Research Council	https://www.nhmrc.gov.au/	2
MEdRxiv (Preprints)	https://www.medrxiv.org/	1
SSRN (Preprints)	https://www.ssrn.com/index.cfm/en/	1
TGA (Therapeutic Goods Administration)	https://www.tga.gov.au/	1
The Alcohol and Drug Foundation (ADF)	https://adf.org.au/	0
Tobacco in Australia (Cancer Council Victoria)	https://www.tobaccoinaustralia.org.au/	10
TROVE – National Library of Australia	https://trove.nla.gov.au/	2
TOTAL		61

Further searches using the Google Advanced Search tool and other ad hoc searches were conducted by the project team yielding another 14 grey literature records for screening.

2.2.2 Inclusion and exclusion criteria

Academic studies and grey literature records were considered eligible for inclusion if they reported on outcomes relating to nicotine pouches and were published from 2016 onwards, when nicotine pouches first entered in the US market.⁸ The full inclusion and exclusion criteria are provided in **Appendix B**.

2.2.3 Data screening and extraction

Once the academic and grey literature searches were complete, records were uploaded into Covidence, an online screening and data extraction tool. Records were sorted into 2 project folders ('academic literature' and 'grey literature') for title and abstract screening, followed by full text screening. After removing duplicates, screening of titles, abstracts, and then full texts were done to identify studies fulfilling the

inclusion and exclusion criteria by 3 review authors. Discrepancies as to whether a record met the eligibility criteria or not were resolved through consensus. Information and data from review articles were extracted using a pre-specified and piloted data extraction template within Covidence. Where information was not reported this was noted in the extraction template by the review authors.

2.2.4 Quality appraisal

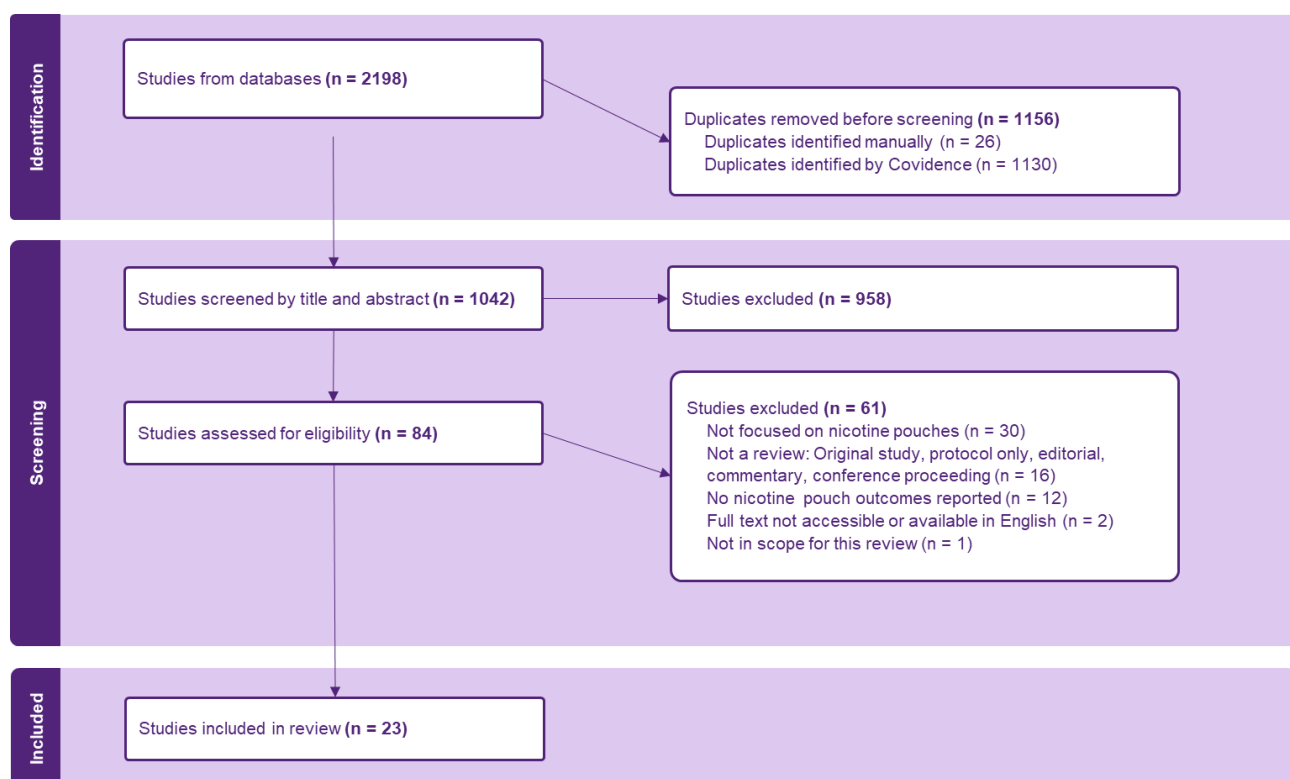
Throughout the review process, quality appraisal occurred to ensure rigour and consistency in the approach and to identify and address any issues. Before commencing title and abstract screening, a 10% cross-check occurred between the 3 reviewers ensuring consensus was reached on eligibility of academic studies. When developing the data extraction templates, all reviewers conducted test extractions of records to ensure the extraction fields were appropriate and made refinements before embarking on the extraction process.

2.3 Search Results and Study Characteristics

The screening process resulted in 23 academic studies, and 40 grey literature reports relevant for data extraction and analysis. The academic literature was reviewed and information extracted into Covidence by 3 reviewers.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for the screening stages of the academic literature is presented in Figure 1.

Figure 1 PRISMA flow diagram for academic literature



Of the 23 academic studies that were identified, the majority were a systematic review (n=6), followed by narrative reviews (n=5), academic reviews (n=3), other literature review types (n=3), scoping reviews (n=2) and a comprehensive review (n=1). Three original research studies were also included as they were directly relevant to the Australian context. Several study types were included in the reviews; most were cross-

sectional (n=7), followed by randomised controlled trial (RCT) (n=4), quasi-experimental (with control) (n=2), and cohort (n=2). Nine studies did not report the study types included.

Most studies did not report the search timeframe of the review, although of those that did report a timeframe, the earliest included study was from 1990 (n=1), followed by 2000 (n=2), and 'inception' (n=2).[†]

Research from a broad range of countries was included in the reviews, with most including studies from Europe (n=19), followed by the United States (n=11), and Australia (n=5).

2.3.1 Grey literature

Grey literature also underwent similar title and abstract screening then full text screening in Covidence. However, eligibility criteria differed as records did not need to be a review. The grey literature was extracted manually by 2 reviewers into a spreadsheet with the assistance of the AI tool Notebook LM, an AI-powered research and content organisation tool by Google. Notebook LM extracted data according to the pre-determined fields assigned through prompts. The grey literature AI output data were cross-checked for accuracy and refined by the project team reviewers as they were transferred across to an Excel extraction sheet for analysis.

2.4 Analysis

After data extraction, analysis and synthesis occurred, 3 reviewers were assigned 1 of the 3 review areas (see [section 2.1](#)) to analyse and synthesise information extracted from Covidence. Framework analysis was the analytical approach used, where the review questions guided synthesis, identifying any themes in the literature relevant to the project questions (see [Appendix C](#)).

2.5 Methodological limitations

The following limitations were noted during the extraction and synthesis of the academic and grey literature:

- Overall, there were a limited number of publications extracted during the review due to the relatively recent introduction of the product.
- There is no direct evidence of the long-term efficacy of nicotine pouches as a cessation tool or long-term impacts on population health.
- Where reported, many studies were funded by tobacco companies.
- There are a limited number of studies conducted in Australia. However, the evidence from North America and Europe (except for Scandinavia due to the lower prevalence of cigarette smoking and higher prevalence of snus use, which emerged in the 1970s)^{9,10} will likely be applicable to the Australian population.
- The quality of included reviews varied considerably, and few reviews provided a detailed description of their methodology in terms of search strategy, number of studies included, or their geographical scope.
- Most reviews did not report using formal quality appraisal processes when selecting studies, such as formal quality appraisal tools or risk of bias assessments (e.g. AMSTAR 2: a critical appraisal tool for systematic reviews).
- This was a review of reviews, whereby original research articles were mostly not assessed,[‡] and therefore the information extracted was as reported within the review articles.

[†] The date of inception was not specified in these articles.

[‡] Recent original studies were included if they were not already included in a review and were relevant to this review

3. Results

The following sub-sections present synthesised findings organised under broad thematic categories that align with the review questions. Results are differentiated according to source type: evidence extracted from peer-reviewed scientific literature reviews, and grey literature sources. This distinction enables appropriate assessment of evidence quality and facilitates transparent interpretation of findings based on the rigour and peer-review status of the underlying sources.

3.1 Composition and safety

Composition of nicotine pouches

Evidence on the composition of nicotine pouches reveals considerable variability in ingredients and chemical properties, which may influence both safety and nicotine delivery. Studies have examined the structural components, nicotine sources, and additional additives, highlighting important factors that could affect health outcomes.

Nicotine pouches are made of a permeable pouch that is filled with a tobacco-free substrate to which nicotine and flavours are added.^{11–13} The nicotine within nicotine pouches is either natural, extracted from tobacco plants, or synthetic, made in a lab and should therefore be free from tobacco-specific nitrosamines (TSNAs), known carcinogens.^{14,15} The filler within nicotine pouches is mainly composed of water and microcrystalline cellulose which absorbs the nicotine.^{11–13,16} Other ingredients within pouches include salt (to enhance nicotine absorption through the oral mucosal membrane),¹⁵ sweeteners, and flavour additives.^{11,12,14,16}

Sodium carbonate and bicarbonate are commonly used as pH buffers to regulate the pH of pouches.¹² The higher the alkalinity of pouches (pH > 7), the greater the amount of bioavailable free-base nicotine (the most easily absorbed form of nicotine via oromucosal delivery).⁷ The pH content in pouches varies widely, and one study reported ranges of 5.5–10.5 which in turn had a median proportion of free-base nicotine of 86%.⁷

Nicotine content in pouches also varies widely by brand and strength, with ranges of 1.79 – 47.5mg/pouch reported by one study.⁷ In contrast, another study reported nicotine contents of 1.2 – 10 mg/pouch,¹⁴ and another reported total nicotine content ranges of 5.8 – 17 mg/g.¹²

One study reported TSNAs found in 46 nicotine pouch products, made by 20 different manufacturers.¹⁴ TSNAs found include NNN (N-nitrosornicotine), NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone), NAT (N-nitrosoanatabine), and NAB (N-nitrosoanabasine) – known carcinogens. Twenty-six of the nicotine pouches contained detectable levels of TSNAs, though most only contained trace levels. Notably, TSNA levels were lower in nicotine pouches than in combustible tobacco products and other smokeless tobacco products, defined by the US National Cancer Institute¹⁷ as *types of tobacco that are not smoked or burned*.[§] The study did not specify whether pouches contained natural or synthetic nicotine. One study that screened 48 nicotine pouches, showed 186 different chemical components present besides nicotine with each nicotine pouch containing an average of 17 constituents. Of these 186 chemical components, 8 were classified as hazardous.⁷ These studies did not quantify the amount of harmful or potentially harmful constituents, or provide comparison with combustible tobacco products or smokeless tobacco products.

Safety, risks, and benefits of nicotine pouches

Clinical evidence on the safety, risks, and benefits of nicotine pouches suggests that while these products may present a lower risk profile compared to combustible tobacco, they are not without harm. Research highlights both potential advantages, such as reduced toxicity compared with combustible tobacco, and ongoing concerns related to addictive properties and chemical constituents.

[§] Smokeless tobacco products include items such as chewing tobacco, dry snuff, and snus.

Toxicological analyses indicate that nicotine pouch formulations generally contain fewer harmful constituents than combustible tobacco products and smokeless tobacco products, reflecting differences in chemical composition rather than established clinical safety.²⁶ However, studies have not been able to quantify these differences consistently, and some analyses are limited by methodological weaknesses. Despite being marketed as “tobacco-free”, the chemical composition of nicotine pouches—including variable nicotine concentrations and the presence of impurities—indicates that they cannot be considered inherently low-risk products, unlike oral nicotine products that comply with therapeutic goods manufacturing standards.²⁸

Nicotine pouches are not intended for inhalation, and therefore their potentially harmful constituents may be expected to impact oral gastrointestinal and cardiovascular health, rather than respiratory health.⁷

Nicotine pouches that contain high levels of nicotine may be comparable to traditional tobacco products, such as oral snuff. Some pouches have been found to contain TSNAs, as well as chromium and formaldehyde.²¹ Because nicotine pouches do not involve combustion, they may be a less harmful alternative to smoking in that they do not expose the lungs to combustion products such as carbon monoxide and fine particulate matter.¹⁸ Nicotine release and absorption from nicotine pouches is slower than from combustible tobacco products and therefore takes longer to reach peak blood levels. One implication is that people using nicotine pouches may have less control over overall nicotine exposure than with cigarettes, which can be adjusted on a puff-by-puff basis. However, further research is needed to determine how people adapt to differences in nicotine delivery from pouches compared with cigarettes. Similar to oral nicotine replacement therapies (NRTs) (e.g., gum, lozenge), how the product is used (e.g., time held against the gum, moving the pouch in the mouth, and whether it is used in conjunction with caffeinated drinks) may also influence nicotine uptake, but more research is needed.²⁷

Grey literature on composition and safety

The grey literature review found that nicotine pouches are defined as small, disposable sachets designed to deliver nicotine when placed between the lip and gum, typically containing nicotine (extracted from tobacco or synthetic), fillers like plant fibres, flavourings, and sweeteners, but explicitly excluding tobacco leaf.^{19–21} They may contain tobacco-related contaminants, such as TSNAs. Within the Australian context, nicotine pouches containing nicotine are classified as Schedule 4 prescription-only medicines.²² The existence of a nicotine pouch product that has gained approval as a medicine in Sweden indicates the technical feasibility of manufacturing nicotine pouches to comply with pharmaceutical standards when manufacturers are required to comply with these standards. Crucially, the sources confirm that no nicotine pouches have been evaluated, registered, or regulated by the TGA for quality, safety, or efficacy, meaning no product is included in the ARTG or approved for lawful therapeutic supply in Australia other than through regulatory pathways that allow the supply of unapproved therapeutic goods.^{19,23,24} Despite this status, regulatory actions in Australia, such as seizures in Western Sydney, indicate the illicit supply of pouches.²⁴ The Australian Government has noted nicotine pouches as novel and emerging products necessitating the development of a comprehensive regulatory framework.⁵

Although nicotine pouches are advertised as “tobacco-free”, analysis has shown that some products contain toxic chemicals.²⁵ Specifically, known carcinogens such as TSNAs have been detected in some pouches.^{20,26,27} Furthermore, certain brands have been found to contain impurities, including heavy metals like toxic lead and arsenic, and probable carcinogens such as methyl eugenol.^{28,29} The incorporation of synthetic nicotine and nicotine analogues, like 6-methyl nicotine (sometimes up to 25 mg per pouch), adds complexity to regulation and raises concerns due to evidence of cellular toxicity.^{28–30} Given the product’s relatively recent entry into the market, there remains a critical lack of independent research regarding the long-term health effects of nicotine pouch use.^{25,31,32}

3.2 Prevalence and use of nicotine pouches

There were limited academic studies reporting on nicotine pouch prevalence or consumer use patterns specifically in Australia;^{33–35} three recent studies, however, were in the Australian context. Two of these

studies drew from the same larger cross-sectional quantitative survey exploring nicotine pouches in Australia.^{33,34} The other study was a qualitative study with adolescents (aged 14-17 years) and young adults (aged 18-24 years) who had vaped or were currently vaping.³⁵

Quantitative survey data from young Australians (aged 16–39 years, n = 1,598) found 77% were aware of nicotine pouches, and 27% reported having used them on one or more occasions.⁴¹ A second Australian study, drawing on a subset of the same dataset (aged 16–39 years, n = 817) who were aware of nicotine pouches but had never tried them, found 70% were classified as susceptible to nicotine pouch use, 55% willing to try nicotine pouches if offered, and 46% intending to try nicotine pouches in the next 6 months.⁴² The study defined susceptibility as the absence of a firm decision not to use a product.⁴² Susceptibility was assessed by measuring curiosity about the product, willingness to use the product, and intentions to use the product; responses of “probably not”, “probably yes”, or “definitely yes” to any of these items were classified as indicating susceptibility to future nicotine pouch use.⁴²

Grey literature on prevalence and use

The grey literature review also identified prevalence and use of nicotine pouches in Australia and internationally. In Aotearoa New Zealand (NZ) between 2023 and 2024, awareness among youth aged 16–19 years was 36%, and ever-use among young adults increased from 6% to 10% between 2023 and 2024.³⁶ Finland saw daily use among young adults triple in 2 years between 2022 and 2024 to 10% following regulatory changes whereby nicotine pouches were deregulated from Finland’s Medicines Act and permitted to be sold with conditions such as requiring a licence to sell, nicotine limits, and only adult flavours allowed.²⁹ US sales surged by 183.7% between 2022 and 2024, and by 207% between 2023 to 2025.³⁰ While there were no reasons reported for increased sales in Finland and the US, it was stated that in the US there are strong marketing campaigns for certain nicotine pouch products such as Zyn, On!, and Velo.³⁰

Nicotine pouches are unapproved therapeutic goods in Australia and have not been evaluated by the TGA, and are not included in the ARTG, yet recent grey literature described growing interest among certain subgroups.³⁷ For instance, 19% of young (median age = 23 years, Interquartile Range (IQR) =20-32) people who use illicit stimulant drugs reported recent use of nicotine pouches in the 2024 Ecstasy and Related Drugs Reporting System (EDRS) survey (N=740), with a median frequency of 3 days over 6 months.³⁸ Regional harm reduction studies in Australia also found highest prevalence rates of nicotine pouch use of 27% in Canberra (n = 100)³⁹ and 22% in Perth (n =100)⁴⁰ among people who regularly consume ecstasy and/or related drugs.²³ While overall ever use among young Australians remains low—1.9% among 14–17-year-olds in 2025,⁴¹ these early figures indicate a concerning trend given Australia’s strict regulation.²² Furthermore, the EDRS survey only commenced reporting nicotine pouch use in 2024.^{**37}

3.3 Supply and access

A qualitative study of Australian adolescents (aged 14-17 years) (n=98) and young adults (18-24 years) (n=112) who vaped or who had tried vaping, found a perceived increase in use and popularity of nicotine pouches (especially the Zyn brand) amongst study participants.³⁵ The study found that although nicotine pouches are not legally available for sale in Australia without a prescription, young people were able to access the product.³⁵ Participants were quoted stating that there was an increased use in their peer groups, especially where people were trying to quit vaping.³⁵ Some participants in this study stated the growth in use was a direct consequence of Australia’s vaping reforms and that the novelty of vaping was wearing off.³⁵ No information on where nicotine pouches were sourced from was reported in the studies.

Grey literature on supply and access

The grey literature also states that nicotine pouch access in Australia is legally restricted to personal importation with a valid prescription under the TGA’s Personal Importation Scheme.¹⁹ However, reports also document widespread unlawful supply through physical retailers and online platforms, with enforcement

^{**} Unpublished data from the 2025 EDRS shows a similar prevalence of use as seen in the 2024 EDRS.

actions such as the seizure of 284 containers across 60 Sydney retailers in early 2024 highlighting the illicit trade of nicotine pouches.⁴²

3.4 Consumer trends

Consumers, often young adults or adolescents, were reported to generally perceive nicotine pouches to be less harmful and addictive than cigarettes and e-cigarettes.^{7,14–16,33,35} However, in one recent Australian study of participants aged 16-39 years, of those who were aware of nicotine pouches, only a minority (23-33%) had favourable attitudes to nicotine pouches, and less than half (29-40%) believed nicotine pouches to be less harmful than tobacco products.³³ While most of those in the study aware of nicotine pouches had unfavourable attitudes (42-53%), those who used nicotine pouches were more likely to have low harm perceptions than high harm perceptions.³³ Additionally, participants who used nicotine pouches and had a high number of close friends and immediate family members who also used them had lower risk perceptions.³³ The study found individual-level characteristics associated with attitudes towards nicotine pouch use included gender, age, nicotine pouch use among friends and family, current nicotine pouch use, and tobacco product and e-cigarette use.³³ Those more likely to have favourable attitudes to nicotine pouches than others were men and adults aged 25+ years, those with a greater number of immediate family members and close friends who use nicotine pouches, and those who use nicotine pouches.³³ There was also a positive relationship between use of tobacco products and e-cigarettes, and attitudes to nicotine pouches.³³ One narrative review of English-language articles providing information on safety, consumer behaviour, regulatory frameworks, and market trends of nicotine pouches found varied awareness of nicotine pouches among different populations ranging from 7% with Dutch adolescents and adults to 47% in the US among former adult tobacco users.¹⁵ However, the review found from surveys conducted in Poland, the United Kingdom (UK) and the US, that awareness was more likely in men, younger adults, and people with a history of smoking or vaping.¹⁵ The review reported 5 studies^{43–47} in which consumers, ranging from adolescents to adults, perceived nicotine pouches to be equally or more harmful than cigarettes.¹⁵

In other reviews, younger consumers (ranging in ages from 13 to 40 years) were reported to be attracted to nicotine pouches' appealing flavours.^{14,18,48,49} Other consumer appealing characteristics include the possibility that they may facilitate cessation from cigarettes, e-cigarettes or other tobacco products,^{14,18,35} use was convenient and easy to conceal,^{48,50} use aided in weight loss,⁵⁰ sports performance enhancement, and was part of a partying and clubbing culture.³⁵

Furthermore, consumers who currently use tobacco or other nicotine products such as cigarettes and/or e-cigarettes were generally reported to have favourable attitudes to the use of oral nicotine products, including nicotine pouches to assist with cessation.^{7,14–16,18,35} It was also reported that many consumers use nicotine pouches to control nicotine cravings or as an alternative to other tobacco or nicotine products.³⁵

However, some consumers reported negative experiences of using nicotine pouches such as feeling sick, gums burning and disliking the taste.³⁵ Some also did not consider the experience of using nicotine pouches to be as enjoyable as vaping.³⁵ Recent national research with Australian adolescents, young adults, and adults aware of nicotine pouches (N=1230) found 68% agree that using nicotine pouches is harmful to health.³³

Grey literature on consumer behaviours and attitudes

The grey literature review found that in Australia, motivations for nicotine pouch use among young Australians include curiosity, socialising, stress coping, and perceived performance enhancement.^{31,51} The Alcohol and Drug Foundation reports that young people also use nicotine pouches to manage cravings when quitting vapes, when they are not able to use vapes, and because vapes are less available.³¹

3.5 Nicotine dependency and dual/poly usage

Evidence on dual usage of nicotine pouches with other tobacco and nicotine products remains limited. A commonly reported reason for nicotine pouch use was as an aid to quit smoking or vaping, driven by marketing that emphasises their tobacco-free formulation,¹⁵ which could be a key behavioural influence for the dual use of nicotine pouches with other tobacco and nicotine products.

One study examined two independent surveys of people who used Zyn nicotine pouches in the US. Among those who currently use Zyn, 26% concurrently used smokeless tobacco and 8% currently smoked. Only 4% of people who used Zyn were classified as 'never tobacco users'—defined as individuals who had not smoked at least 100 cigarettes or regularly used other tobacco products (other products not defined in this study). Among 'never' and 'former tobacco users', 9 in 10 indicated nicotine pouches were not appealing, with only 3% and 2% respectively expressing interest in purchasing the product. However, this research was funded by unrestricted grants from tobacco manufacturers, raising questions of conflicts of interest and bias.⁵²

Grey literature on nicotine dependency and dual/poly usage

A Norwegian Government agency report highlighted the discrepancy in regulation of different tobacco and nicotine products whereby the most harmful products (combustible tobacco products) are the least regulated. The report positions nicotine pouches as significantly less harmful than high-risk tobacco products because they avoid combustion.⁵³ The independent 'Khan review: Making Smoking Obsolete', commissioned by the UK Government, recommended that the government should not reverse the current UK sales ban on tobacco-based snus but instead facilitate access to nicotine pouches to use for quitting in a way that does not create new risks for young people.⁵⁴

3.6 Health and public health impacts

Clinical evidence examining the health impacts of nicotine pouches reinforces that while these products may demonstrate a lower risk profile compared with combustible tobacco, they are not without health risk. Some studies have reported that nicotine pouches exhibit greatly reduced toxicity compared with cigarettes and Swedish snus, and agencies such as the US Food and Drug Administration (FDA) have noted that nicotine pouches pose less risk of cancer and other serious health conditions than combustible tobacco.^{15,18} Despite nicotine pouches containing fewer and lower levels of toxicants than combustible tobacco, evidence exploring how this translates to biological responses are limited to a few in vitro studies. Of these studies, the toxicant exposure of nicotine may be similar to that of NRT use.¹⁸ Nicotine pouches remain addictive, are not risk-free, and present ongoing concerns regarding their chemical constituents and potential impact on health.

Relative to tobacco smoking and snus, nicotine pouches demonstrated reduced toxicological risk and potential to reduce disease risk when used as an alternative to cigarette smoking. This evidence relates only to current smokers rather than people who have never smoked, people who had quit smoking, or youth.¹⁸ A clinical trial funded by the tobacco industry (Altria Group Inc.) of 42 smokers aged 21 to 65 years that measured several biomarkers associated with tobacco-related harm. The study found all biomarkers, except those related directly to nicotine exposure, significantly decreased over 7 days for individuals who switched from tobacco smoking completely to nicotine pouches compared to those who continued tobacco smoking, with mixed evidence suggesting these reductions were comparable between participants who switched to nicotine pouches and those who were abstinent from all tobacco and nicotine products.¹⁴ Participants were single-blinded and knew whether the product was a nicotine pouch or cigarette and were provided with unbranded nicotine pouches; blinding was the flavour.

A broad range of adverse events associated with nicotine pouch use have been reported in the literature. These include headaches, acute upset stomach, sore mouth/throat, dry mouth, nausea, throat irritation, dizziness, gingival blisters, increased heart rate, and elevated blood pressure.^{14,15} If the pH of a pouch is too alkaline (pH > 7), this can further contribute to irritation of the oral mucosa.¹² The following oral health

impacts have been described: redness, stinging, itching, or a burning sensation in the oral mucosa can be manifested by repeated placement of a nicotine pouch under the upper lip.⁵⁵ These changes can extend to the entire oral cavity and throat. Some people who use nicotine pouches affirm that visible mucosal alterations were observed at the sites of snus or nicotine pouch placement. Studies have also demonstrated that nicotine pouches can lead to gum recession due to the pouch being held against the gumline. Their use is associated with plaque buildup, which may contribute to additional oral health issues such as cavities, gingivitis and tooth decay.^{11,50} In-vitro toxicity studies have identified increased cytotoxicity and inflammatory responses for some nicotine pouch products. They have also been shown to induce an oxidative stress response in human gingival fibroblasts after 24 hours of exposure—distinct from the effect observed from snus, which induced both oxidative stress and inflammatory responses.⁷

There are concerns about long-term nicotine use. While nicotine is not classed as carcinogenic there is evidence that it can promote the growth and spread of tumours.⁵⁶ The nicotine within nicotine pouches also appear to play a role in augmenting bone loss.¹¹ Clinical evidence also points to systemic and developmental risks associated with nicotine exposure. Prolonged nicotine use has shown detrimental effects on brain development, and early exposure has been linked to increased risk of developing future addictions to other drugs.¹⁵ Cardiovascular risks remain a concern, with nicotine contributing to elevations in heart rate and blood pressure. Although nicotine pouches release nicotine slower and in a more controlled manner than combustible tobacco products, the time it takes for the body to eliminate nicotine remains relatively similar, with notable variability in absorption due to differences in pouch formulations.⁵⁷

Nicotine content within pouches varies by brand and remains unregulated, resulting in significant variation in nicotine levels and other chemical constituents across product types. A systematic review of 54 studies across the US, Europe, and Australia analysing the chemical composition of nicotine pouches, found that their use as a cessation tool appears to expose consumers to lower levels of toxic compounds than Swedish snus.¹⁸ The commercial importation of snus was banned in Australia in 1991 and it is not considered a therapeutic product.⁵⁸ In Australia, as retail sales of nicotine pouches are illegal, people who obtain them must use illegal supply routes or personal importation, meaning the type of products used in Australia and their nicotine levels are unknown. Dry powder nicotine pouches likely pose substantially reduced exposure risk to metals (arsenic, beryllium, cadmium, selenium) compared to smokeless tobacco products, while plant-based nicotine pouches contain quantifiable but low levels of these materials.¹⁸

Some nicotine pouch products have been found to contain TSNAs, chromium, and formaldehyde, demonstrating that chemical risks remain present in certain formulations.¹¹ Pouches with high nicotine levels may deliver effects comparable to traditional tobacco products.⁷ Due to the oral route of administration, potentially harmful constituents in nicotine pouches may be expected to affect oral, gastrointestinal and cardiovascular systems rather than respiratory function.⁷

A modelled microsimulation analysis funded by Swedish snus manufacturer Swedish Match, which is based on a US population from the year 2000, suggested that nicotine pouches could reduce excess mortality by 20% over a 50-year period when compared to smoking.⁵⁹ This US focused and modelled analysis may have a series of limitations when generalised to an Australian context due to varying regulations, other emerging nicotine products since 2000, differing trends in smoking by population groups, and other factors that might affect who uses nicotine pouches and for what purpose (e.g., whether use is primarily among young people who don't smoke or among older people who use them to quit smoking).

Grey literature on health and public health impacts

A primary health concern centres on the high potency and variability of nicotine content found in nicotine pouches, especially in unregulated products, which can range widely up to 47.5 mg per pouch.^{31,60,61} The potency is often unpredictable, with labelling sometimes using misleading descriptors rather than specific mass amounts, creating an increased risk of overdose.^{28,62} Users have reported severe acute side effects, frequently called "nic-sick" due to cardiovascular effects causing symptoms like feeling dizzy, faint, and

sick.⁶³ Other common short-term effects reported by users include irritation of the oral mucosa, mouth lesions, a sore mouth or throat, and nausea.^{51,64}

3.7 Nicotine pouches as a cessation aid

Compared to tobacco smoking, evidence shows that nicotine pouches can suppress the "urge to smoke" and related nicotine withdrawal effects (e.g., "craving") in a dose-dependent manner, although reductions in craving relief were often lower than those achieved when participants used their 'usual' brand of cigarettes, highlighting that nicotine pouches do not fully address cravings.¹⁴ In this respect, nicotine pouches may have similarity to approved NRTs, which reduce nicotine withdrawal symptoms but do not fully suppress them.

A Cochrane review identified 4 randomised controlled trials—three conducted in the US and one in NZ—evaluating the benefits and harms of nicotine pouches for transitioning away from combustible tobacco use.⁶⁵ All studies included an 8-week follow-up to assess cessation efficacy. Nicotine pouches were used in a variety of flavours and strengths, and comparator products were e-cigarettes, snus, and pharmaceutical nicotine gum. Two studies asked participants to use the products when they had the urge to smoke, but were not asked to quit smoking, and one study explicitly told participants to stop smoking their usual brand of cigarettes. One study included a weekly phone check-in for safety monitoring, and no studies included comprehensive behavioural support. The review found low-certainty evidence that smoking abstinence may be slightly higher among people randomized to nicotine pouches compared to no intervention at 8-weeks. When compared to e-cigarettes, low-certainty evidence suggests those using nicotine pouches may be slightly less likely to quit smoking. One study included a comparison for NRTs (pharmaceutical gum) and found that nicotine pouch use was associated with fewer reports of bad taste and gastrointestinal side effects, although one participant stopped using nicotine pouches due to gastrointestinal symptoms (compared to two who stopped using the gum due to the same issue). No serious health harms from nicotine pouches were identified during the 8-week follow-up periods of the trials. No evidence on health impacts beyond an 8-week period were reported.

A tobacco industry-funded systematic review (funded by Imperial brands) concluded that nicotine pouches were a reduced-risk alternative to smoking (note this definition does not relate to the product being defined as a cessation tool) when people completely switch from combustible tobacco to nicotine pouches, due to reduced exposure to harmful chemical toxicants compared with tobacco smoking.⁷ Studies have demonstrated that nicotine pouches produce stronger craving reductions than both NRT gum and zero-nicotine pouches, yield favourable changes in disease risk indicators, result in significant reductions in oral mucosal lesions, and elicit reduced inflammatory responses compared with tobacco-containing products.¹⁸ The review did not provide the scientific basis for these outcomes or relationships, and the authors reported funding from the tobacco industry.

Nicotine and chemical content vary significantly by nicotine pouch product and brand, therefore reported outcomes from studies assessing the cessation efficacy of nicotine pouches may not be applicable to all products. Moreover, many studies compare differences with tobacco smoking, which itself carries significant harmful health outcomes¹⁴ and therefore the reported benefits of nicotine pouch use could be misinterpreted without this note.

In terms of perceptions of nicotine pouches as a cessation tool, people who currently use tobacco believe these products may facilitate cessation from e-cigarettes and other tobacco products.^{15,16,35} Young adults who used e-cigarettes and were motivated to quit expressed greater interest in trying nicotine pouches compared to conventional NRTs, due to a perception that they are a 'healthier alternative to vaping and/or smoking'.^{14,16} In another study of young Australians, participants also believed nicotine pouches were a healthier and safer alternative to vaping or smoking and could aid in cessation.³⁵ Multiple participants noted anecdotally that young people were using nicotine pouches to quit vaping, either to control nicotine cravings, as noted earlier due to its perceptions as 'being healthier' than other products, or as an alternative nicotine product due to it being undetectable and providing a 'quick' nicotine boost.³⁵

At present, it remains unclear whether nicotine pouches will have a net positive or negative effect on population health when considered for tobacco smoking cessation, due to the limited evidence-base and lack of longitudinal studies.¹⁴ Evidence from 8-week follow-up studies (reported earlier in this section) examining nicotine pouches as smoking cessation aids identified no short-term serious health harms.⁶⁵ Similarly, when compared to cigarettes, nicotine pouches were well tolerated in the short term, with no serious adverse events reported.¹⁸

A key limitation in understanding the effectiveness of nicotine pouches as a cessation tool is the lack of robust evidence and clinical studies. Further independent, non-industry-sponsored controlled trials and rigorous observational studies incorporating biochemical verification are necessary to determine whether nicotine pouches promote long-term, sustained product switching and reduce tobacco-related harm.¹⁴ While these products are likely to work in a similar way as oral NRTs, the products that are currently being supplied illegally in Australia do not meet the same standards of quality control in their manufacturing that approved medicinal nicotine products do.

Grey literature on nicotine pouches as a cessation aid

The majority of nicotine pouches on the global market have not gained medicines licensing or approval as a smoking cessation aid. The TGA state there is “no strong evidence to support the use of nicotine pouches for smoking or vaping cessation”¹⁹ and the Canadian Ministry of Health advised against a legalisation proposal, citing a lack of evidence that oral tobacco and nicotine products help people stop smoking.³⁶ Additionally, the Ministry expressed concern that novel nicotine products are being marketed to youth rather than people who smoke as a cessation tool. Additionally, a number of public health risks associated with use of nicotine pouches have been highlighted, including irritation of the gums, nausea, hiccups, and nicotine addiction, which can harm brain development in adolescents.^{22,31} Despite the suggestion these products could be a feasible cessation tool and therefore lead to the approval of nicotine pouches by government bodies under strict regulation, the long-term health risks are unknown, particularly in the context of unknown manufacturing quality. The European Centre for International Political Economy (an independent and non-profit policy research think tank) recommended governments consider a population level threshold when considering approving nicotine pouches for therapeutic use based on tobacco-related mortality.⁵³ For example, the case for approving the use of nicotine pouches for smoking cessation may be more suitable in low-income countries that are experiencing high, or rising, smoking related mortality compared to high-income countries with lower and/or decreasing smoking related mortality, such as Australia.

There is concern that promoting use of nicotine pouches as a cessation tool for other nicotine and tobacco products may further grow the dependency on tobacco and nicotine for young people, particularly in countries where smoking rates are decreasing.²³ Cancer Council NSW highlighted that prevalence of use among youth is low (1.9%), and de-prohibiting access to the product may increase its use amongst this population group, as seen in the US.⁶⁶ Cancer Council Victoria highlighted examples of nicotine pouch use leading to dependence, with one study showing US adults who use nicotine pouches exhibiting preliminary evidence of significant dependence.⁶⁴ Despite one manufacturer in Canada gaining authorisation to market their product as a cessation tool, in most countries where nicotine pouches are permitted to be marketed it is as a non-therapeutic nicotine product, distinct from NRT used for smoking cessation.

3.8 Marketing and advertising

Marketing approaches were seen to be fostering positive attitudes to nicotine pouches with the use of terms such as “cleaner”, “tobacco-free” and “smoke-free”.^{13,14,33,35,48} Some brands have a strong social media presence, such as Zyn (manufactured by Swedish Match, which is owned by Philip Morris), including endorsement by influencers named “Zynfluencers”.^{14,50} Additionally, brands post incentives for consumers to win free products by tagging friends.⁵⁰ Marketing strategies of nicotine pouch brands across platforms such as TikTok were noted as effective in reaching younger consumers.^{14,50}

Grey literature on marketing and advertising

The grey literature review found that the nicotine pouch is a rapidly emerging category of oral nicotine product globally, marketed as discreet, convenient, and “tobacco-free”.⁴² Despite advertising bans, marketing persists via social media influencers, emphasising flavours, convenience, and performance benefits.^{42,67} These tactics mirror global trends, where marketing highlights “tobacco-free” claims and colourful packaging resembling confectionery, raising concerns about the appeal to adolescents and accidental exposure risks.²⁸

3.9 Public health policy

The implications for public health policy regarding nicotine pouches are significant and warrant a precautionary approach. Strong regulatory frameworks are needed to ensure product composition, where permitted for sale, aligns with safety standards, including accurate nicotine content labelling and the exclusion of toxic or harmful substances.^{12,18} Given the evidence of potential oral health risks, variability in nicotine delivery, and the presence of ingredients that may contribute to oxidative stress or bone loss, regulatory oversight should extend beyond nicotine concentration to encompass broader toxicological assessments. Furthermore, policy development must be informed by independent, non-industry-funded research to avoid conflicts of interest and ensure that guidelines reflect unbiased evidence.¹⁴ This is particularly critical in light of existing knowledge gaps concerning long-term health impacts, dual/poly use patterns, and pharmacological properties of nicotine enantiomers. Public health strategies should also consider the potential for nicotine pouches to support smoking cessation or the management of nicotine dependence while balancing and managing the potential adverse risks of dependence, particularly among non-smoking populations. Balancing these considerations will be essential for developing evidence-based regulations that protect consumers and minimise population-level harms.

At present, there is limited evidence to support nicotine pouches as a therapeutic product, although the extensive evidence base on oral NRT (particularly gum and lozenge formulations) is relevant.⁶⁸ Nicotine pouches that are manufactured in compliance with regulatory requirements for medicines (nicotine limits, confirmation of absence of contaminants, consistent nicotine delivery etc) would be expected to be similar to therapeutic products such as approved nicotine gum formulations. More independent, non-industry-funded clinical research is needed on nicotine pouch products in the current market to understand whether they are suitable products to support cessation from other tobacco products and reduce tobacco-related harm. This would provide evidence to understand abuse liability (determining the ability of nicotine pouches to cause dependence), levels of harmful and potentially harmful constituents, and use behaviours among different populations (e.g., current users of nicotine pouches, or dual users of e-cigarettes and nicotine pouches), among other outcomes that are critical for understanding the public health impact of nicotine pouches and informing their regulation.

4. Key findings

Nicotine pouches are a relatively new product category, with a limited evidence base. This is reflected in the literature, where the majority of studies reviewed emphasise the need for further research into their effectiveness as a cessation tool and their broader public health impacts.

Despite the limited research, a series of observations and recommendations relating to the following areas of concern and relevant to the Australian context were highlighted in the literature:

- **Nicotine content in nicotine pouches:** The levels of nicotine within pouches varies by brand and is unregulated, meaning significant variation in the levels of nicotine consumed as well as other chemicals by product type. This could limit the generalisability of studies assessing their cessation efficacy or health impacts to specific products only.
- **Use and perceptions of nicotine pouches with younger cohorts:** Even though it is illegal to sell nicotine pouches in Australia as a consumer good, recent studies in the Australian context reveal product availability particularly for adolescents and younger adults. Authors of the Australian studies reviewed recommend further research to explore nicotine pouch perceptions with younger consumers given the unexpected appeals and uses by this cohort such as use for sport performance enhancement, weight loss, and uses akin to a party drug.
- **Dual use of nicotine pouches with other nicotine products:** Dual use of nicotine pouches described in the academic literature was mainly related to its use as a cessation tool. Industry-funded surveys for one specific product (Zyn) report that only 4% of users had never smoked or used tobacco products. That industry research also reported a quarter of participants who currently use nicotine pouches also used smokeless tobacco and 8% currently smoked. These findings are supported by independent research that found nicotine pouch current and ever use increased between 2022 and 2024 among US adults with established nicotine product use.⁶⁹
- **Short-term health harms:** No generalisable short-term health harms were identified when nicotine pouches were used as a smoking cessation aid and little evidence focused on harms from non-therapeutic use. Adverse health harms were reported with use, including for oral health, within single studies.
- **Long-term health harms:** Due to the new introduction to market and relatively low use prevalence, there is limited evidence of the long-term health harms of nicotine pouches and future monitoring and surveillance is required.
- **Health harms in relation to tobacco smoking:** When compared with tobacco smoking, nicotine pouches convey a reduced toxicological risk and can reduce disease risk. However, it is important to note that this is in relation to a high disease and toxicological risk product and in relation to complete switching from cigarette smoking compared to dual use.
- **Nicotine pouches as a cessation tool:** Low-certainty evidence suggests that nicotine pouches may be an effective cessation tool for tobacco smoking compared to no intervention. However, the limited evidence suggests that e-cigarettes and NRTs may be more effective.
- **Perceptions of nicotine pouches as a 'safer' option to tobacco products:** Several reviewed studies found consumers perceived nicotine pouches to be a "safe" or "healthier" option to cigarettes or vapes, possibly prompted by marketing strategies promoting them as "tobacco-free" and/or "clean" etc. Furthermore, nicotine pouch brands use social media to market products, reaching younger audiences. The literature recommends further research to better understand how the products are promoted, sold and used by all population groups. Consumers should be encouraged to use approved NRTs for quitting as these have strict quality control in their manufacturing. All public health communications about nicotine pouches should be designed to avoid inadvertently encouraging consumers to return or switch to smoking.

- ***Policy and enforcement approaches to nicotine pouches:*** Australian context literature points out that the current policy and approach to enforcement of nicotine pouches needs greater investment in monitoring and enforcement because of the reported illegal access of the product.

4.1 Future research recommendations

Based on the key findings of the review, the following future research recommendations are highlighted for consideration.

- In vitro studies should examine nicotine pouch toxicity compared to other nicotine/tobacco products, including NRTs and non-tobacco products with similar constituents (e.g., gums/candies with comparable flavourings and additives) to contextualise associated harms.
- Research should document any new health harms associated with nicotine pouches.³⁵ Some Australian participants may be using nicotine pouches rather than cigarettes because they are perceived to have a lower health risk than vaping or cigarette smoking.³⁵ Research is needed on how to discourage nicotine pouch use among people who don't smoke without inadvertently generating inaccurate risk perceptions that cigarettes are of equal or lower risk than pouches.
- Australian research should strengthen evidence on use patterns, marketing and sales practices, potential toxicity, and prevalence across all population groups to inform comprehensive public health response.³⁵
- Given that young people show high susceptibility and awareness of nicotine pouches, longitudinal research should examine perceptions among younger adolescents (under 16 years), a cohort not yet studied over time.³³ This research should also consider how Australia's social media age-restrictions for under-16s may affect exposure to product advertising on these and other platforms.
- Longitudinal research with Australian cohorts is needed to track consumer risk perceptions and behaviours over time, as existing Australian research on consumer perceptions has been predominantly cross-sectional in design.³³
- More research is required to examine the impact of increased use of nicotine pouches contributing to the development of new social norms for its use, building on findings that people with more family members and friends who use pouches have lower risk perceptions.³³ This work should contextualise findings within existing norms around tobacco cigarettes and e-cigarettes and should also consider how consumers could be encouraged to use regulated nicotine products for quitting smoking and vaping.
- Large-scale nationally representative longitudinal surveillance surveys should track nicotine pouch use trajectories among different populations to understand the public health impact of these products. Existing population surveys exist such as the International Tobacco Control Policy Evaluation Project that has been measuring nicotine pouch use in Australia since 2022 among adults (includes a longitudinal component) and among youth since 2024, with ability to compare to other countries.
- Research is needed on nicotine pouch advertising and its relationship to consumer susceptibility, particularly among adolescents.^{14,34} Australian research found that despite advertising bans, young consumers encounter pouch promotion through social media influencers and may not recognise it as advertising, warranting investigation into how this exposure influences susceptibility to use.³⁴
- Human exposure studies are needed to clarify harms associated with nicotine pouches, including toxicant exposure.

5. Policy implications

The following policy implications were drawn from the review.

- The current evidence does not support nicotine pouches as effective smoking cessation aids compared to other NRTs that must comply with strict manufacturing quality standards.
- Nicotine pouches are associated with risks of adverse health impacts. The absence of evidence on longer-term health risks highlights an urgent need for studies examining sustained health impacts and the risk profile of these unregulated products.
- Widespread availability of nicotine pouches risks creating nicotine dependence among young people and people who don't use tobacco products, as observed in countries like the US where these products have become more accessible.
- Developing effective and ethical public health counter-advertising to commercial marketing messages must prioritise avoiding potential unintended adverse consequences such as creating a lower risk perception of smoking.
- Evidence based public health messaging regarding use of nicotine pouches should be developed in Australia that encourages people who smoke to use approved smoking cessation aids instead of unregulated nicotine pouches, and that discourages young people from smoking or using other nicotine products.
- Urgent monitoring and regulatory action are needed to address nicotine pouch promotion on social media platforms, including ensuring counterarguments and fact-checking materials reach young audiences who may be exposed to this marketing.
- Ongoing surveillance of nicotine pouch use is required, with particular focus on young people who appear most susceptible to uptake.
- Further independent research is needed to establish long-term cessation outcomes and comprehensive health effects of nicotine pouch use to inform evidence-based policy decisions.
- Manufacturers who wish to market nicotine pouches in Australia are encouraged to seek regulatory approval for inclusion on the ARTG.

6. Conclusions

The current evidence does not support nicotine pouches as a smoking cessation aid when compared to approved NRTs, which are included on the ARTG, after being confirmed as safe and effective for use as an aid in smoking cessation. Due to their recent market introduction and relatively low use prevalence globally, limited evidence exists on the long-term health harms of nicotine pouches, necessitating future monitoring and surveillance. More independent, non-industry-funded clinical research is needed to understand the health harms associated with nicotine pouches.

Despite retail sales and marketing of nicotine pouches being illegal in Australia, awareness and use of the product has increased, particularly among older adolescents (14-17 years) and young adults (18-24 years). Young people report being able to access nicotine pouches, which appear to have entered the Australian retail market in late 2023 despite only being legally available with a prescription via pathways that allow access to unapproved therapeutic goods. Some young people cite recent vaping regulations in Australia as a reason for their increased interest in nicotine pouches. Future public health messaging should highlight that nicotine pouches are unapproved goods in Australia and have not been evaluated or included in the ARTG, and the uncertainty regarding nicotine pouch safety while promoting preferred, legal alternatives to vaping and smoking, such as NRT.

Marketing through social media and influencers presents a significant concern, as young people report forming their perceptions of nicotine pouches from these sources. Strategies should be developed to target illegal advertising on online platforms that promote their use. An additional consideration is whether Australia's social media age-restrictions for under-16s will reduce product awareness among this younger cohort, which warrants investigation.

Australian health agencies should monitor emerging data on nicotine pouch use prevalence relevant to the Australian context to inform ongoing policy responses.

7. References

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Appendices





Appendix A Example Search Strategy

Following is an example academic database search strategy for **PubMed**. The search terms remained consistent across all databases with changes in the prompts based on the database commands and techniques (e.g. syntax) requirements:

("Nicotine"[MeSH Terms] AND "pouch*"[Title/Abstract]) OR (("pouch*"[Title/Abstract] OR "Oral"[Title/Abstract]) AND ("Nicotine"[Title/Abstract] OR "tobacco-free"[Title/Abstract] OR "smoke-free"[Title/Abstract] OR "spit-free"[Title/Abstract] OR "vape-free"[Title/Abstract])) OR "nicotine pouch*" OR ("pouch*"[Title/Abstract] AND "Tobacco Products"[MeSH Terms]) OR "tobacco pouch*"[Title/Abstract] OR ("tobacco"[Title/Abstract] AND "smokeless"[Title/Abstract]) OR "snus"[Title/Abstract] OR ("snuff"[Title/Abstract] OR "snuffs"[Title/Abstract]) AND ("tobacco"[Title/Abstract] OR "Nicotine"[Title/Abstract])) OR "snus-like"[Title/Abstract] OR "oral nicotine product*"[Title/Abstract] OR "tobacco, smokeless"[MeSH Terms] OR ("oral nicotine"[Title/Abstract:~2] AND "product*"[Title/Abstract]) OR "smokeless nicotine"[Title/Abstract] OR "alternative nicotine delivery system*"[Title/Abstract] OR "modern nicotine products"[Title/Abstract:~2] OR "novel nicotine product*"[Title/Abstract] OR "Imitation tobacco products"[Title/Abstract:~3] OR "Tobacco substitute*"[Title/Abstract] OR "New tobacco product*"[Title/Abstract] OR "New nicotine product*"[Title/Abstract] OR "Nicotine containing product*"[Title/Abstract] OR ("non tobacco"[Title/Abstract] AND ("product*"[Title/Abstract] OR "Nicotine"[Title/Abstract]))

OR

("77"[tiab] OR "&chill"[tiab] OR ace[tiab] OR "Airplane mode"[tiab] OR ALP [tiab] OR Apres[tiab] OR Clint[tiab] OR dope[tiab] OR Dryft[tiab] OR DZRT[tiab] OR "Fink pouches"[tiab:~2] OR Fix[tiab] OR FR3SH[tiab] OR FRĒ[tiab] OR Garant[tiab] OR gritt[tiab] OR Helwit[tiab] OR "Juice Head"[tiab:~2] OR "kelly white"[tiab:~2] OR Killa[tiab] OR klint[tiab] OR Knox[tiab] OR loop[tiab] OR Lucy[tiab] OR lundgrens[tiab] OR lyft[tiab] OR lynx[tiab] OR Neovap[tiab] OR NIC-S[tiab] OR Nix[tiab] OR nois[tiab] OR on![tiab] OR Pablo[tiab] OR RELX Airpouch[tiab] OR Rogue[tiab] OR Sesh[tiab] OR skruff[tiab] OR snatch[tiab] OR swave[tiab] OR valo[tiab] OR VELO[tiab] OR volt[tiab] OR "White fox"[tiab] OR "White Label"[tiab] OR XQS[tiab] OR Zone[tiab] OR zonnice[tiab] OR ZYN[tiab]) AND ("nicotine pouch"[tiab:~4] OR "nicotine pouches"[tiab:~4] OR "Nicotine"[Mesh])

AND

(australia[mh] OR australia*[tiab] OR Australian[tiab] OR "northern territory"[tiab] OR Tasmania*[tiab] OR "new south wales"[tiab] OR "South Australia*"[tiab] OR "western australia*"[tiab] OR victoria*[tiab] OR canberra[tiab] OR queensland[tiab] OR Brisbane[tiab] OR Sydney[tiab] OR Melbourne[tiab] OR Adelaide[tiab] OR Darwin[tiab] OR Perth[tiab] OR Hobart[tiab])

OR

"Systematic Review" [Publication Type] OR "Systematic Reviews as Topic"[Majr] OR systematic[sb] OR systematic review*[tiab] OR systematic quantitative review*[tiab] OR systematized review[tiab] OR structured literature review*[tiab] OR systematic qualitative review*[tiab] OR systematic search and review[tiab] OR systematised review[tiab] OR systemic review[tiab] OR systematic literature review*[tiab] OR systematic integrative literature review*[tiab] OR systematically review*[tiab] OR systematic critical review[tiab] OR systematic integrative review*[tiab] OR systematic evidence review[tiab] OR Systematic integrative literature review*[tiab] OR Systematic mixed studies review*[tiab] OR Systematized literature review*[tiab] OR Systematic overview*[tiab] OR Systematic narrative review*[tiab] OR "Cochrane Database Syst Rev"[Journal] OR meta-analysis[pt] OR meta-analysis as topic[mj] OR meta-analysis[mj] OR meta analy*[tiab] OR metanaly*[tiab] OR metaanaly*[tiab] OR met analy*[tiab] OR scoping review*[tiab] OR scoping literature review*[tiab] OR ((systemati*[ti] OR scoping[ti] OR umbrella[ti] OR structured literature[ti]) AND (review*[ti] OR overview*[ti])) OR ((critical[ti] OR rapid[ti]) AND (review*[ti] OR overview*[ti] OR

synthes*[ti])) OR umbrella review*[tiab] OR integrative research[tiab] OR integrative review*[tiab] OR integrative overview*[tiab] OR collaborative review*[tiab] OR collaborative overview*[tiab] OR technology assessment*[tiab] OR technology overview*[tiab] OR "Technology Assessment, Biomedical"[mj] OR "literature review*" [tiab] OR (Literature[tiab] AND review*[tiab]) OR review[pt] OR "Review Literature as Topic"[Mesh]

Appendix B Eligibility Criteria

Eligibility criteria

Following are the inclusion and exclusion criteria used in the literature review for the title and abstract, and full text screening stages. These screening processes were used for both the academic literature and the grey literature reviews.

Academic literature

Title and abstract screening of the academic literature occurred in Covidence to the following criteria:

Table B1 Title and abstract screening inclusion and exclusion criteria

Include	Exclude
Academic reviews	Protocols
Systematic review	Commentary/editorial
Scoping review	Conference proceedings
Umbrella review	
Rapid review	
Meta-analysis	
Structured review	Non-review literature pre-2025
Literature review	
Comprehensive review	
Grey literature review	
Non-review literature in Australian context post 2024	
Non-review literature post 2025 (since latest review)	
Specific to nicotine pouches	Not specific to nicotine pouches
Outcomes for nicotine pouches	No outcomes for nicotine pouches
Completed since 2016	Completed before 2016
Published in English	Not published in English
Full text available	No full text available

Included articles (n=84) then went through full text review. Reasons articles were excluded at this stage were:

- Not a review: Original study, protocol, editorial, commentary, conference proceedings
- Outside time period
- Not focussed on nicotine pouches
- Not available in English
- No nicotine pouches outcomes reported
- No full text available
- Not in scope for this review

Grey literature

Eligibility criteria differed slightly for the grey literature as records did not need to be a review. At the full text screening stage, reasons grey literature were excluded included:

- News article based on review/paper included in Nicotine Pouches Academic Review
- Unpublished / not peer reviewed academic literature (e.g. preprint)
- Not specific to nicotine pouches
- Completed before 2016
- Published academic literature
- Full text not available
- No nicotine pouch outcomes
- Not in scope for this review



Appendix C Review Framework

Table C1 below is a framework matrix for the literature review demonstrating how each review area would address the review questions.

Table C1 How the review activities contributed to answering the review questions

Research Questions	Consumer behaviours, Access & Prevalence of Usage Review	Efficacy for smoking cessation & Public Health Impacts Review	Composition & Clinical Evidence Review
1. What is the current evidence on prevalence and/or usage patterns of nicotine pouch use in Australia?	✓		
2. What is the current evidence on consumer behaviour and attitudes towards nicotine pouches, consumer exposure to marketing and advertising, and consumer use of nicotine pouches?	✓		
3. What is the current evidence of nicotine pouches contributing to nicotine dependence and/or influencing dual/poly use of other nicotine products?		✓	✓
4. What is the current evidence on the effectiveness of nicotine pouches as a smoking cessation tool?	✓	✓	✓
5. What does the current evidence show about the health effects, composition, and safety of nicotine pouches and what are the potential public health risks or benefits?		✓	✓
6. What are key existing data and knowledge gaps recommended for further monitoring and research regarding the health impacts, consumer behaviours, safety and market trends of novel oral nicotine products, including nicotine pouches?	✓	✓	✓
7. What are the implications for public health policy regarding the public health impacts of nicotine pouches?	✓	✓	✓

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Organisation	Contact name	Email address	Notes	Consultation
ACT Health and Community Services Directorate	s47F		s47G(1)(b)	
Department of Foreign Affairs and Trade (DFAT)				
Department of Home Affairs - Australian Border Force (ABF)				
Department of Prime Minister and Cabinet (PMC)				
National Illicit Tobacco and E-cigarette Coordination Forum (NITECCF) and Illicit Tobacco Enforcement and Compliance Working Group (ITECWG)				
National E-cigarette Working Group				
NSW Health				
Preventive Health SA				
Preventive Strategy Branch, Population Health Division, Queensland Health				
South Australia Police				
Tasmanian Department of Health				
Western Australian Department of Health				

Organisation	Contact name	Email address	Notes	Consultation responses received
DHL Express	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Individual clinician				

Organisation	Contact name	Email address	Notes	Consultation
Advanced Pharmacy Australia	s47F		s47G(1)(b)	
Alcohol and Drug Foundation				
Alcohol Tobacco and Other Drugs Association				
Australasian Professional Society on Alcohol and other				
Australian College of Nurse Practitioners				
Australian College of Nursing				
Australian College of Rural and Remote Medicine				
Australian Commission on Quality and Safety in Health Care				
Australian Council on Smoking and Health (ACOSH)				
Australian Dental Association				
Australian Health Promotion Association				
Australian Medical Association				
Cancer Australia				
Cancer Council Australia				
Cancer Council Victoria				
Cancer Institute NSW				
Consumers Health Forum				
Drug and Alcohol Nurses of Australasia				
Drug Education Network				
Lung Foundation Australia				
Medicines Australia				
National Aboriginal Community Controlled Health Organisation				
National Heart Foundation Australia				
National Rural Health Alliance				
Pharmaceutical Society of Australia				
Pharmacy Guild of Australia				
Professional Compounding Chemists of Australia				
Public Health Association of Australia				
Royal Australasian College of Physicians (RACP)				
Royal Australian and New Zealand College of Psychiatrists (RANZCP)				
Royal Australian College of General Practitioners (RACGP)				
Rural Doctors Association Australia				
Thoracic Society of Australia and New Zealand				
Tobacco in Australia (Cancer Council Victoria)				

Organisation	Contact name	Email address	Notes	Consultation responses received
Centre of Research Excellence on Achieving the Tobacco Endgame	s47F	s47G(1)(b)		
Curtin University, Faculty of Health Policy				
Monash University				
National Centre for Epidemiology and Population Health, Australian National University				
University of Melbourne				
University of Queensland				
University of Sydney, School of Public Health				
South Australian Health and Medical Research Institute				
The Centre for Behavioural Research in Cancer				
The Matilda Centre for Research in Mental Health and Substance Use				

Consultation Analysis

Regulation of Nicotine Pouches

On 10 February 2026, the Minister for Health, Disability and Ageing agreed that the Therapeutic Goods Administration (TGA) undertake targeted consultation on proposed amendments to strengthen the regulation of nicotine pouches.

Consultation was conducted from 27 March to 15 April 2026 with health peak bodies, government agencies, and tobacco control and vaping experts. The TGA identified medical and pharmacy stakeholders who have a primary interest in the proposal – noting nicotine pouches can only be supplied through the existing pathways by prescribers.

The TGA received 24 submissions, the majority of which supported the proposal. This paper summarises the principal issues raised in response to the consultation questions.

Do you support the proposed amendments to prevent access to unapproved nicotine pouches? What impacts do you anticipate if the proposed amendments are implemented or not implemented?

Summary of responses: 24 responses, 23 supportive and 1 not supportive

There was near-unanimous support for strengthening the regulation of nicotine pouches. Stakeholders consider the current evidence base insufficient to demonstrate that nicotine pouches are safe or effective for smoking or vaping cessation. On this basis, there is significant support for the proposal to remove access to nicotine pouches through established TGA pathways for unapproved therapeutic goods. Submissions noted that ongoing access could be interpreted as conferring therapeutic legitimacy.

Protecting young people was a major theme. Nicotine pouches were identified as discreet, flavoured and promoted through social media. Several responses drew parallels with the rapid uptake of vaping among young people. Emerging Australian data was also cited as indicating growing awareness and experimentation among adolescents and young adults, with concerns about nicotine dependence and brain development.

Regulatory clarity and enforcement were also important themes. Current TGA pathways were identified as vulnerable to misuse, creating compliance challenges and potentially weakening state tobacco and nicotine controls. Removing access to nicotine pouches through these pathways is seen as a way to reduce perceived 'loopholes' and enable clearer compliance, seizure and enforcement action. [s47G\(1\)\(b\)](#)

[REDACTED]

[REDACTED] raised concerns that removing access could disadvantage highly nicotine-dependent smokers who have not responded to existing therapies and could increase illicit market activity. This highlighted the tension between population-level prevention and targeted harm reduction.

Overall, what do you consider the likely impact to be: predominantly positive or negative?

Summary of responses: 20 positive, 3 mixed and 1 unsure.

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?

There was broad agreement that no clinical circumstances were identified in which nicotine pouches provide a therapeutic benefit beyond existing evidence-based cessation therapies.

The 2025 Cochrane Review (Hartmann-Boyce et al., 2025) was frequently cited as indicating that the evidence base for these products remains limited and uncertain. Concerns centred on the small number of trials, high risk of bias, and lack of evidence that nicotine pouches support smoking cessation. Some responses also indicated that nicotine pouches may be less effective than e-cigarettes and do not offer a distinct therapeutic benefit.

Product quality, safety and dosing were also identified as concerns. These included variation in nicotine content, inconsistent labelling and consumer information, and the absence of regulation through inclusion in the Australian Register of Therapeutic Goods (ARTG). Collectively, these issues present avoidable patient safety and poisoning risks, particularly for young children who may be inadvertently exposed.

Allowing unapproved nicotine pouches through therapeutic pathways was generally viewed as likely to weaken public health messaging. This could confuse consumers and clinicians, blur the distinction between approved therapies and quasi-regulated products, and normalise ongoing nicotine use, particularly among young people.

Some stakeholders raised that current clinical guidelines prioritise approved pharmacotherapies supported by behavioural interventions. As such, endorsing nicotine pouches would not align with evidence-based cessation practice.

s47G(1)(b) raised equity concerns, arguing that reduced access could disproportionately affect disadvantaged groups if access to approved cessation supports is not improved concurrently. However, it also acknowledged that the therapeutic benefit of nicotine pouches has not been established and called for further evidence rather than clinical endorsement.

Overall, the consultation supported a regulatory approach that reinforces clear public health messaging and prioritises ARTG-approved, evidence-based cessation therapies.

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

The proposed amendments were viewed as an important public health signal that nicotine pouches are unapproved, addictive and not established cessation therapies. Regulation amendments alone however, was generally considered insufficient without strong and sustained enforcement, particularly online.

A consistent concern was that tighter controls could shift supply to illicit markets, including through organised crime. Enforcement resources were described as already stretched by illicit tobacco and vaping activity, with supply likely to move further underground through online platforms, social media and encrypted messaging services.

Misuse of current access pathways was also raised, including online prescribing and commercial practices that may undermine regulatory intent. There was strong support for online compliance measures, platform takedowns and penalties that outweigh commercial incentives.

Several stakeholders mentioned a future-proofed framework. A narrow focus on nicotine pouches was seen as likely to shift demand to other products, including nicotine toothpicks, pearls, nicotine analogues such as 6-methylnicotine, and products marketed as nicotine-free.

Product quality, safety and youth appeal were also identified as key concerns. These included the absence of standards for labelling, ingredients, packaging and child safety, as well as flavours, colours and marketing practices not consistent with therapeutic goods regulation.

Suggested complementary measures included controls on online sales, stronger supply-chain oversight, and coordinated action with states and territories. Public education and affordable, evidence-based cessation support were also identified as important to reduce reliance on unapproved products.

Several responses also emphasised the need to prevent tobacco industry interference and uphold Australia's obligations under the World Health Organization Framework Convention on Tobacco Control.

Overall, the proposal was seen as a necessary first step, to be supported by broader enforcement, supply-side and public health measures.

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?

There was strong support for a product-agnostic approach to emerging nicotine products. Regulating products individually was considered a risk to delayed or fragmented controls, allowing market establishment and youth uptake before enforcement could respond effectively. A broad framework was therefore supported to capture all unapproved nicotine products, including other emerging oral formats, as well as nicotine analogues and substitutes such as 6-methylnicotine.

Online and social media marketing was also identified as contributing to youth appeal and misinformation. Active monitoring, stronger enforcement of advertising restrictions and public health communication were advocated for to counter claims that these products are safe, therapeutic or performance-enhancing.

Protecting the integrity of the therapeutic goods framework was also emphasised. Unapproved access pathways were seen as capable of becoming de facto markets and reducing incentives for evidence generation and ARTG registration. If unapproved products remain available, quality standards, child-resistant packaging and warning requirements were identified as important safeguards.

There was also strong support for coordinated national enforcement and close collaboration with states and territories.

Ongoing surveillance was also emphasised to identify emerging products early. Some responses pointed to evidence that young people are already accessing unapproved nicotine gum and other emerging products.

Consultation Submissions

All stakeholder submissions are in Content Manager: [E26-248563](#)

Submissions were received from the following groups:

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