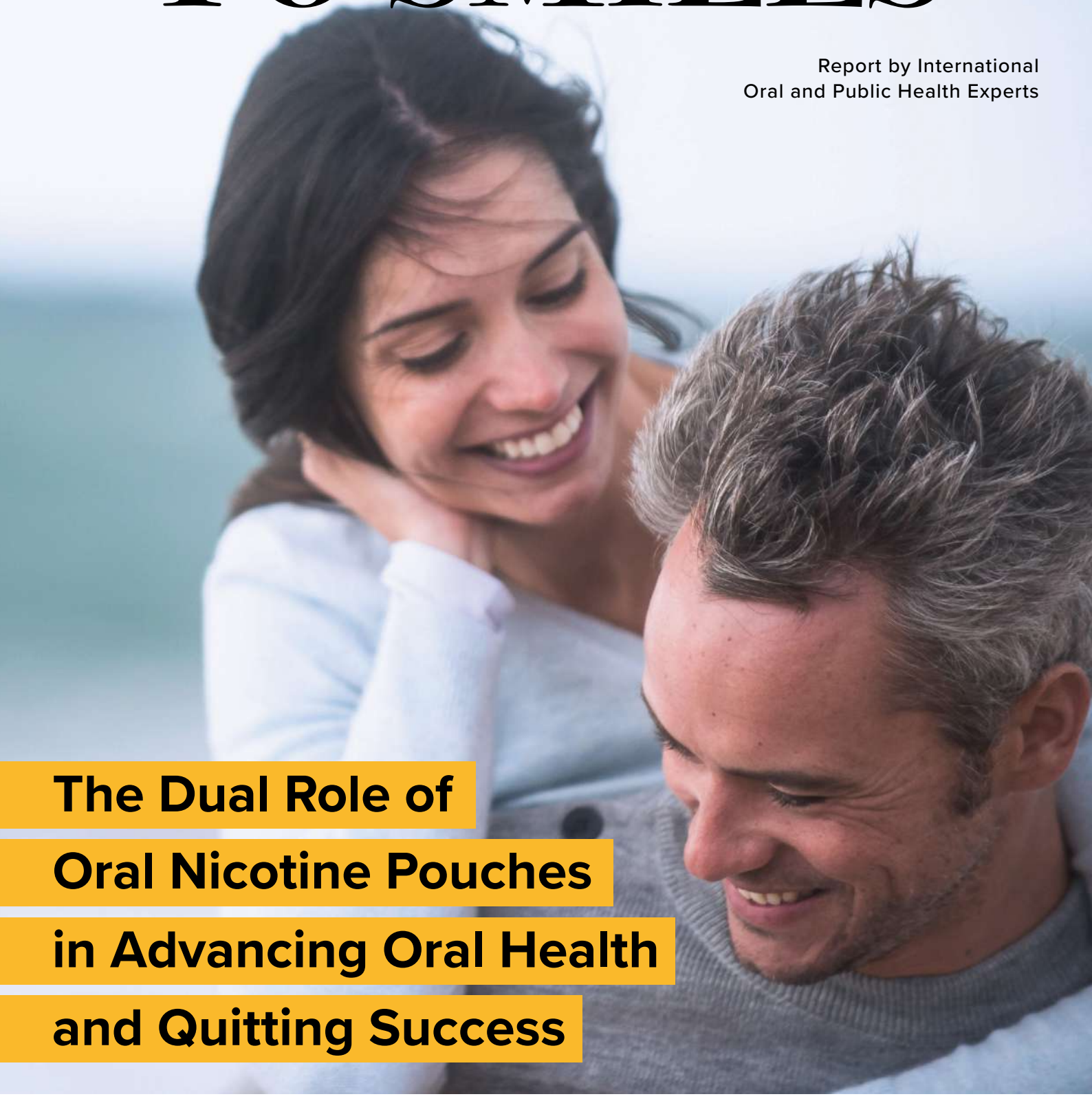
# CIGARETTES TO SMILES

Report by International
Oral and Public Health Experts



## The Dual Role of Oral Nicotine Pouches in Advancing Oral Health and Quitting Success

ORAL NICOTINE COMMISSION

In collaboration with SMOKE FREE SWEDEN AsHRA AHRA PAHRA Pan America Harm Reduction Alliance

# CONTENTS



# ABBREVIATIONS

| | |
|---|---|
| DALYs | disability adjusted life-years |
| EU | European Union |
| FCTC | Framework Convention on Tobacco Control |
| FDA | Food and Drug Administration |
| GBD | Global Burden of Disease |
| IARC | International Agency for Research on Cancer |
| LMICs | low- and middle-income countries |
| NRT | nicotine replacement therapy |
| ONC | Oral Nicotine Commission |
| ONP | oral nicotine pouch |
| SLT | smokeless tobacco |
| THR | tobacco harm reduction |
| US | United States of America |
| WHO | World Health Organization |

# EXECUTIVE SUMMARY

**THE GLOBAL HEALTH COMMUNITY KNOWS EXACTLY HOW SMOKING DESTROYS ORAL HEALTH – PERIODONTAL DISEASE, ORAL CANCER, TOOTH LOSS AND DISABILITY – YET CONTINUES TO RELY ON CESSATION METHODS THAT FAIL MORE THAN 90% OF THOSE WHO TRY TO QUIT.**

With 1.27 billion smokers worldwide and oral diseases affecting 3.7 billion people, this persistent failure represents one of public health's most devastating and preventable tragedies.

Yet within this crisis lies an unexpected breakthrough. Oral nicotine pouches (ONPs) represent a transformative dual intervention, serving as highly effective cessation tools while directly improving oral health outcomes.

Unlike combustible cigarettes that release thousands of toxic chemicals or traditional smokeless tobacco laden with carcinogens, ONPs deliver nicotine without combustion, without tobacco leaf and with dramatically reduced harm.

More significantly, evidence now demonstrates ONPs may be one of the most effective smoking cessation tool available today, offering smokers a familiar oral experience and satisfying nicotine delivery, as well as being a measurable pathway to better health.

This report – the third in the Oral Nicotine Commission's five-year series – examines this unique dual role through clinical evidence, population-level success stories and emerging science that validates why the oral health community should embrace ONPs as essential tools to combat tobacco-related disease and to achieve the World Health Organization (WHO)'s Global Strategy on Oral Health (2023–2030).

## THE CHALLENGE

The scale of this oral health crisis demands urgent innovation. There were 3.7 billion incidences of oral disorders and 430,000 new incidences of oral cancer in 2023.

Low- and middle-income countries (LMICs) bear a disproportionate 84% of this burden, largely driven by smoking and high-risk smokeless tobacco use. In South-Central Asia, products such as gutka, khaini and betel quid account for 88% of smokeless tobacco-related oral cancers; that is 105,500 cases annually.

Despite decades of tobacco control efforts, current approaches have plateaued in their effectiveness, particularly where smoking rates remain stubbornly high and access to cessation support is severely limited.

## THE OPPORTUNITY

Building on the foundational work of Prevent Disease, Save Lives (2020) and Transforming Oral Health for All (2024), this 2025 report presents measurable health gains from switching to ONPs and positions them as essential tools that address the smoking epidemic while promoting better outcomes for the very part of the body most affected by tobacco use: the mouth itself.

## WHAT MAKES ONPs DIFFERENT

Unlike combustible cigarettes or traditional smokeless tobacco products laden with carcinogens, ONPs are:

**Tobacco-free:** Eliminating tobacco-specific nitrosamines that cause oral lesions and cancer.

**Combustion-free:** Avoiding tar, carbon monoxide and thousands of toxic chemicals produced by burning.

**No inhalation:** ONPs deliver nicotine without inhalation, so minimal impact on the lungs and respiratory system compared to traditional smoking.

**More than 95% less harmful** than cigarettes, representing one of the lowest-risk oral nicotine options available.

**Socially considerate and environmentally friendly:** Addressing stigma barriers, particularly for women.

## THE EVIDENCE BASE

### Cochrane Review (2025) validation

The 2025 Cochrane systematic review provides the most authoritative evidence to date that ONPs offer smokers a safe transition from combustible tobacco.

Critically, the Cochrane Review found no evidence of serious health harms associated with switching to ONPs – a significant finding given Cochrane's rigorous, globally respected methodology and reputation as the gold standard for healthcare evidence synthesis. They do highlight that this finding is based on limited evidence and that more research is needed to compare oral nicotine pouches to other active treatments, e.g. nicotine replacement therapy (NRT).

This absence of demonstrable harm, combined with cessation efficacy, establishes ONPs as a credible, evidence-based intervention that should inform clinical practice and regulatory policy worldwide.

### Toxicological validation

Multiple biomarker studies confirm 60–90% reductions in carcinogen exposure when smokers transition to non-combustible nicotine products. Health Canada's 2023 approval of Zonnic® as a licensed NRT – the first ONP globally to achieve medicinal status – validates that ONPs can meet pharmaceutical safety standards while retaining consumer appeal.

### Population-level success

**Sweden:** Approaching smoke-free status with 5.3% smoking prevalence, with 61% lower male lung cancer death rates than the European Union (EU) average and a 34% lower rate of total cancer deaths. The introduction of ONPs in 2016 accelerated women's quit rates by nearly 200%.

**Canada:** Zonnic's pharmaceutical approval demonstrates regulatory pathways to recognise ONPs as legitimate cessation aids.

### Clinical outcomes

The ongoing SMILE Study, conducted across Italy, Poland, Moldova and Indonesia, demonstrates that smokers switching to smokeless nicotine products (referred to as combustion-free nicotine alternatives or C-F NAs in the article) display visible reductions in plaque and tooth staining. Full results of the prospective, randomised arms of the trial are not yet published.

## THE LMIC IMPERATIVE

Lower and middle-income countries (LMICs) account for 83% of tobacco-related oral cancer deaths and 96.4% of all oral cancer cases caused by smokeless tobacco and areca nut. India alone represents 83,400 of the 120,000 annual oral cancer cases attributed to these products. In terms of access, affordability and consumer acceptance, ONPs offer a uniquely suited intervention for LMIC contexts:

- Minimal infrastructure requirements
- Shelf-stability and low-cost potential
- Cultural compatibility with oral product use patterns
- Elimination of the spitting associated with traditional smokeless tobacco

The magnitude of benefits from switching to ONPs is greatest where high-risk smokeless tobacco prevalence is highest and where oral disease burdens are largest.

## GENDER-SENSITIVE HARM REDUCTION

Women face unique barriers to cessation including dual stigma – for smoking itself and for cessation failure.

In Sweden, women ranked ONPs almost three times higher than vaping and 56% higher than nicotine gum as quit aids, citing social acceptability, cleanliness and convenience as key factors.

This approach is particularly relevant for the 70 million women in India and millions more across South-Central Asia who use high-risk smokeless tobacco products where smoking is less socially acceptable.

> The growing recognition of ONPs in cessation and tobacco harm reduction (THR) solidifies its role in the pragmatic prevention and control of smoking-related oral disease, disability and premature death

## THE POLICY GAP

Nicotine, in the form of NRTs such as patches and gum, has been on the WHO's list of essential medicines since 2009.

Despite mounting evidence, the WHO Framework Convention on Tobacco Control (FCTC) and the Global Strategy on Oral Health (2023–2030) lack explicit reference to harm reduction.

The WHO's failure to distinguish between combustible and non-combustible products, treating 95% safer alternatives the same as cigarettes, perpetuates preventable disease and death.

On 12 November 2025, WHO published the WHO Position on Tobacco Control and Harm Reduction. In response, Professor Jean-Francois Etter, a former Professor of Public Health from Switzerland, argues that "enough is enough" and that WHO wrongly equates independent harm reduction advocates with tobacco industry front groups, dismisses clear evidence that non-combustible products are significantly less harmful than cigarettes and suggests that all nicotine products are equally toxic and addictive.

Harm reduction strategies are explicitly mentioned in Article 1(d) of the FCTC and should not be delegitimised. Etter warns that the WHO's call for prohibition and restrictions on alternatives such as e-cigarettes risks protecting the cigarette market, fueling illicit trade, and ultimately increasing smoking-related disease and death – an outcome he views as detrimental to the mission of global public health.

Precautionary bans on ONPs in France, Belgium and Germany risk creating unregulated black markets while protecting cigarette sales, as evidenced by events in Australia, where 39.4% of cigarette sales shifted to illicit channels following excessive taxation and restrictions on access to vaping products.

The contrast is stark: while Cochrane, the world's most trusted source of evidence for healthcare decision-making, finds no serious harms from ONPs and confirms their cessation efficacy, regulatory bodies continue to restrict or ban these products, condemning millions to continued smoking and its devastating health consequences.

The growing recognition of ONPs in cessation and THR solidifies its role in the pragmatic prevention and control of smoking-related oral disease, disability and premature death, while reducing the immense costs borne by health systems and societies.

By eliminating combustion and toxic exposures, these products substantially lower risks to oral health compared with continued smoking, supporting healthier gums, teeth and mucosa and thereby improving quality of life across populations.

To realise these benefits, THR must be embedded within global and national policy frameworks: the WHO and governments should adopt risk-proportionate regulation, establish clear product standards, deploy affordability levers to ensure equitable access and integrate THR into cessation services as complementary tools. Policies must also be gender-sensitive, recognising different patterns of tobacco use and barriers to quitting. Such measures will accelerate declines in smoking prevalence, safeguard oral health and deliver sustainable public health gains.

## POLICY RECOMMENDATIONS FOR ORAL HEALTH AND THR INTEGRATION

### Adopt risk-proportionate regulation

- Differentiate non-combustible THR products such as ONPs from smoked tobacco
- Ensure regulatory frameworks reflect relative risk profiles to incentivise substitution away from cigarettes

### Establish clear product standards

- Mandate quality, safety and labelling requirements for oral nicotine pouches
- Guarantee consistency in nicotine delivery and minimise harmful constituents

### Introduce affordability levers

- Apply differential taxation aligned with risk, making less harmful options, such as ONPs, more accessible and affordable than cigarettes
- Support equitable access across socio-economic groups to reduce oral health disparities

### Integrate THR into cessation services

- Position ONPs as complementary tools within national quit-smoking programmes
- Train dental and medical professionals to advise patients on THR options for oral health protection

### Ensure gender-sensitive approaches

- Address distinct patterns of tobacco use among men and women
- Tailor THR interventions to overcome gender-specific barriers to cessation and oral healthcare

### Highlight oral health benefits

- Promote THR as a means to prevent and control smoking-related oral disease, disability and premature death
- Emphasise cost savings for health systems through reduced treatment needs and improved population oral health outcomes

# CONCLUSION

ONPs represent a legitimate, effective harm reduction tool capable of delivering measurable improvements in both cessation rates and oral health outcomes, without causing serious health harms.

The 2025 Cochrane Review's safety findings, combined with Sweden's population-level success, biomarker evidence showing dramatic toxicant reductions, the ongoing SMILE Study's clinical validation and Canada's pharmaceutical approval of Zonnic establish an evidence base that meets the highest standards of scientific rigour.

For 3.7 billion people suffering from oral diseases, the 1.27 billion smokers worldwide, and particularly the millions in LMICs using toxic oral tobacco products, ONPs offer something unprecedented: a pathway to better health that acknowledges the real-world barriers to cessation while delivering tangible harm reduction.

With the oral disease burden rising, cessation rates stagnating and health inequalities widening, risk-proportionate regulation of ONPs represents an essential component of 21st century public health policy. It could save millions of lives and dramatically reduce the global disease burden of oral disease, disability and premature death.

This report provides the evidence base, policy frameworks and strategic roadmap needed to transform oral health through harm reduction. What we need now is for policymakers to follow the science, learn from the real-world experience of countries such as Sweden and prioritise health outcomes over the outdated orthodoxies that have left so many smokers behind.

# 5 YEARS OF PROGRESS: BUILDING THE GLOBAL CASE FOR TOBACCO HARM REDUCTION IN ORAL HEALTH

## THE EVOLUTION OF THE ORAL NICOTINE COMMISSION REPORTS (2020–2025)

### Setting the scene: A global turning point for oral health and harm reduction

Over the past five years, the Oral Nicotine Commission (ONC) has contributed to transforming harm reduction in oral health from a novel idea into an evidence-based global policy agenda. The three cornerstone reports – Prevent Disease, Save Lives: An Introduction to Oral Nicotine Delivery Systems (2020),[1] Transforming Oral Health for All: The Case for Tobacco Harm Reduction (2024)[2] and From Cigarettes to Smiles: The Dual Role of Nicotine Pouches in Advancing Oral Health and Quitting Success (2025) – chart this evolution from awareness to accountability.

The 2020 report laid the foundation by reframing nicotine through a risk-proportionate lens. It established that combustion, not nicotine, drives harm and proposed integrating tobacco harm reduction (THR) into oral health strategies.[1] Acting as a manifesto for change, it called for regulatory innovation and the inclusion of oral health professionals in the harm reduction dialogue.

Building on that foundation, the 2024 report expanded the argument from concept to global context. It quantified the burden of oral disease – oral cancer, periodontal disease and disability – and positioned THR within the World Health Organization (WHO) Global Strategy on Oral Health 2023–2030.[2] By aligning science with governance, it advanced harm reduction as a pragmatic pathway to achieve oral health equity, particularly in low- and middle-income countries (LMICs).[3]

This report closes the loop by demonstrating the measurable health gains of switching to oral nicotine pouches (ONPs). Not only has ONPs' role in smoking cessation been validated, but drawing on biomarker evidence and the SMILE Study,[4] this report documents reductions in gum inflammation, lesions and oral cancer risk. It also confronts poor policy outcomes, contrasting Sweden's and Canada's success with other countries' prohibitions that perpetuate smoking and health inequality.[5]

## EMERGING REGULATORY DEBATES

The regulation of ONPs is becoming a defining public health battleground. The WHO's recent move to create a clinical treatment guideline for tobacco cessation that includes nicotine replacement therapy (NRT) further strengthens the global recognition of nicotine's therapeutic role in smoking cessation, rather than its vilification as a harmful substance in itself.[6]

With the startling similarities between NRTs and ONPs, highlighted further within this report, the WHO's recognition of NRTs should reflect on ONPs as well. The recent Cochrane Review[7] supports these conclusions by confirming that there is no evidence of any serious health harms from ONPs when used as a transition tool.

The case of Zonnic – a nicotine pouch brand initially developed under pharmaceutical frameworks and authorised as an over-the-counter cessation aid – illustrates this evolving understanding in practice. Together, these developments reflect a shifting evidence-based consensus: nicotine, when decoupled from tobacco combustion and regulated appropriately, can serve as an essential component of public health strategies aimed at reducing the global burden of smoking-related disease.

Canada's approval of Zonnic as a licensed NRT[8] signals a shift towards evidence-based, risk-proportionate regulation, recognising ONPs as legitimate cessation aids rather than tobacco products. In contrast, precautionary bans in countries such as France, Belgium and Germany hinder innovation, protect cigarettes and delay progress.[9] The divergence exposes a broader global challenge: whether institutions will follow the Canadian model of science-led regulation or remain locked in outdated frameworks that stall harm reduction and limit public health gains.

These reports form a coherent progression – from concept (2020) to framework (2024) to measurable impact (2025) – redefining oral health policy through the principles of harm reduction, scientific integrity and equitable access.

> Developments reflect a shifting evidence-based consensus: nicotine, when decoupled from tobacco combustion and regulated appropriately, can serve as an essential component of public health strategies aimed at reducing the global burden of smoking-related disease.

## COMPLEMENTARITY AND STRATEGIC EVOLUTION

Across the three publications, the Oral Nicotine Commission's body of work forms a progressive trilogy. Each report builds on its predecessor while responding to emerging data, global trends and policy challenges:

| Year | Purpose | Core contribution | Strategic advancement |
|---|---|---|---|
| 2020 | Conceptual awareness and advocacy | Establish risk hierarchy and introduce THR in oral health | Define the framework and initiate dialogue |
| 2024 | Policy alignment and evidence consolidation | Quantify oral health burden and integrate THR with WHO frameworks | Globalise and legitimise the approach |
| 2025 | Evidence measurement and accountability | Demonstrate measurable oral health gains; confront policy failures | Operationalise THR and embed evaluation |

These reports reflect a scientific and strategic continuum. The 2020 report asked *why change is needed*; the 2024 report demonstrated *how change can occur within systems*; and the 2025 report shows *what measurable impact this change delivers*.

In combination, they offer a comprehensive roadmap for risk-proportionate, equitable and evidence-led global oral health policy that aligns scientific innovation with public health imperatives and positions ONPs as a transformative tool for a smoke-free future.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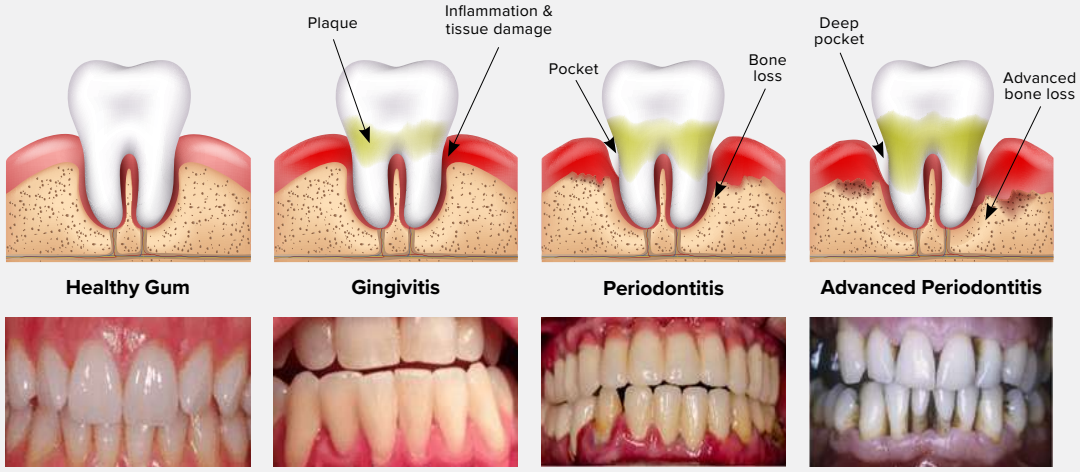
# THE ORAL DISEASE BURDEN REVISITED

## THE FACTS AND FIGURES

Despite efforts to the contrary, the incidence of oral disease and disability has only been on the rise. The Global Burden of Disease's (GBD) latest figures show 3.7 billion incidences of oral disorders and 430,000 new incidences of oral cancer in 2023.[1] Oral conditions accounted for almost 24 million disability adjusted life-years (DALYs) in 2023. This number has increased since 2020, when the figure sat at an already-high 22.89 million. These oral conditions or disorders include caries, periodontal diseases, edentulism and other oral disorders.[1]

Though categorised separately, the figures for oral cancer, including cancer of the lip and oral cavity, show a similar story. While 2020 already saw 201,000 deaths and 5.76 million DALYs due to oral cancer, the situation in 2023 had increased to 226,000 deaths and 6.45 million DALYs. Of these, more than one-third of deaths (80,000) and DALYs (2.27 million) can be attributed to tobacco use.[1]




*The progression of disease from healthy gums to advanced periodontitis; smoking is the biggest risk factor for periodontitis*

## TOBACCO HARM REDUCTION: LIFELINE

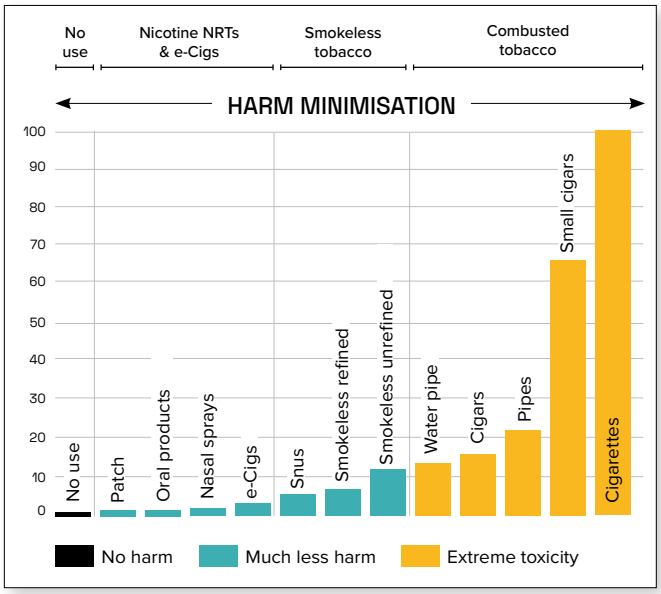
In this increasingly dire situation, harm-reduced products can present a much-needed alternative that complements traditional tobacco control. Moving away from an all-or-nothing approach, THR presents a paradigm shift that accounts for a variety of preferences and circumstances while prioritising reduced harm.

Among the THR innovations, ONPs present a unique and almost tailor-made opportunity to fight the oral disease burden. Unlike traditional smokeless tobacco products, ONPs are tobacco-free, smoke-free and combustion-free.

With the absence of tobacco, both the tobacco leaf and its associated carcinogens that cause oral lesions and oral cancer, through nitrosamines, are eliminated. The absence of combustion eliminates exposure to tar, carbon monoxide and a host of other combustion-related toxins that contribute to inflammation and staining.

Instead, when legalised and regulated in a risk-proportionate manner, ONPs deliver pharmaceutical-grade nicotine via an oral pouch placed between the lip and gum, providing a socially considerate, environmentally friendly and satisfactory transition away from smoking.

## ORAL NICOTINE POUCHES AND THE RISK CONTINUUM




*The continuum of harm resulting from different forms of use (or no use) of combustible tobacco vs non combustibles*

A critical step towards this paradigm shift lies in understanding the risk continuum across tobacco and nicotine products. Originally developed by Nutt et al.[2] and modified by Abrams et al.,[3] this graph helps convey the goal of THR.

The risk continuum[4] showcases the harm of various alternatives relative to cigarettes and, by doing so, aims to encourage smokers to move down the continuum to minimise harm. While acknowledging that no tobacco or nicotine product is risk-free, this visual depiction helps us understand the profound difference between, for example, cigarettes (100% harm) and e-cigarettes (less than 5% harm).

ONPs stand almost at the bottom of the graph, minimising harm by even more than 95% and representing the lowest-risk oral nicotine option currently available. This makes ONPs a low-risk, tobacco-free nicotine alternative to smoking or toxic oral tobacco, for those who are unable or unwilling to quit tobacco products entirely.

> While working towards cessation, switching from high-risk to lower-risk products can dramatically reduce the rate of disease and the public health burden and provide switchers with tangible health gains.

## ORAL NICOTINE POUCHES AND IMPROVED HEALTH OUTCOMES

When focusing on oral health considerations, the theoretical principles of harm minimisation can be seen in practice through their effect on the oral disease burden. While cigarettes come with a high risk of oral cancer and disease, removing both the tobacco and smoke by using oral nicotine products such as pouches has resulted in significant improvements in oral health outcomes and a significant reduction in risk of smoking-related diseases.

A 24-week study among smokers switching to a particular ONP found significant reductions in gingival inflammation (28%) and gingival bleeding (23%) compared to those who continued smoking.[5] The absence of combustion in nicotine products significantly reduces exposure to the toxic chemicals that contribute to periodontal disease. A 2022 study on a test oral tobacco-derived nicotine product found reductions in exposure to harmful and potentially harmful constituents to be “comparable to complete abstinence from tobacco products”.[6]

Other, smaller studies are being generated more frequently,[7] including a study among Swedish dentists who used snus or ONPs. They reported a reduction in mucosal lesions (from 95.7% to 69.9%) and gingival irritation (by 90%) following the exclusive use of a novel ONP technology for five weeks.[8] Improvement and innovation in the ONP space is constant and, as evidenced by this study, constantly aims to minimise harm.

These studies underscore a key THR principle: while working towards cessation, switching from high-risk to lower-risk products can dramatically reduce the rate of disease and the public health burden and provide switchers with tangible health gains. With these studies, we move beyond potential impact and see the measurable impacts of ONPs.

While emerging evidence clearly proves reduced risk in health outcomes with a switch to ONPs, the relatively recent categorisation of this product necessitates the generation of larger, longer-term studies to further support current findings.

## MYTH VS FACT

**Myth:** ONPs are a form of smokeless tobacco.

**Fact:** ONPs are tobacco-free nicotine alternatives, lowering the risk to users significantly through the absence of carcinogens found in tobacco-specific nitrosamines.

**Myth:** Nicotine cannot be part of the solution.

**Fact:** While traditional tobacco control denies risk-proportionate regulation, THR prioritises risk differentiation between combustibles and smokeless nicotine alternatives. Nicotine used in smokeless delivery systems helps reduce the harm from smoking, as acknowledged by the WHO including nicotine replacement therapies on the WHO Model List of Essential Medicines.

**Myth:** There is no evidence regarding the health benefits of ONPs.

**Fact:** As tobacco-free oral nicotine pouches were first launched in Sweden in 2016, evidence regarding the health benefits of ONPs is comparatively limited but promising and constantly emerging. In addition, the United States Food and Drug Administration (FDA) issued its first ever marketing authorisation for oral nicotine pouches in January 2025,[9] after an exhaustive scientific and regulatory review. Hereby the FDA signalled that, based on current evidence, these products may benefit public health by offering adults who smoke a less harmful alternative to cigarettes – but it does not mean they are risk-free. Health benefits within existing studies are shared throughout this report.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# BAD POLICY: HOW BANS UNDERMINE HARM REDUCTION

The prohibition of ONPs in **Germany**, **Belgium** and **France** (effective March 2026) represent a significant retreat from evidence-based harm reduction policy. These measures sharply curtail access to safer nicotine alternatives for the millions of people who smoke and either cannot or do not want to quit nicotine use. The bans thereby undermine public health objectives and replicate policy failures already observed in other jurisdictions.

**France** alone counted 685,000 people who smoke in 2023 using nicotine replacement products such as lozenges, gum and tablets to support cessation attempts.[1] Removing ONPs from the market will leave people who smoke with a stark choice: quit abruptly – something most are unable to achieve – or continue smoking combustible tobacco, which remains exponentially more harmful.

France's classification of ONPs as "venomous substances" has resulted in an unusually punitive regulatory approach. There are hefty penalties for possession, including a possible one-year imprisonment, that are more severe than those for narcotics.[2] The disparity in penalties reflects a regulatory disproportionality that is difficult to justify and risks criminalising people who smoke attempting to transition away from combustible tobacco.

International experience shows that banning harm-reduced nicotine products does not eliminate demand. Rather, it pushes consumers towards unregulated, criminal supply chains.

**Australia** introduced a de facto prohibition on consumer access to vaping products by making them prescription-only. While intended to reduce youth access, the policy has been ineffective across age groups. Only 8% of the country's 1.7 million adult vapers obtain products legally; around 88% rely on the black market. This vast illicit channel is completely unregulated, creating clear public-health risks and strengthening criminal distribution networks.[3]

During **South Africa**'s COVID-19 lockdown, the government banned the sale of tobacco and nicotine products from March to August 2020,[4] intending to reduce the transmission of the virus but instead fuelling a massive surge in illicit trade. With legal sales prohibited, people who smoke turned to unregulated channels, allowing criminal networks to dominate the market. By 2025, illicit cigarettes accounted for as much as 75% of sales.[5] The state has lost billions in excise revenue, legitimate businesses were crippled and public health goals backfired as tobacco and nicotine users continued smoking cheaper, unregulated products. The prohibition entrenched illicit trade long after the ban was lifted, leaving lasting economic and health consequences.

Removing ONPs from the regulated marketplace contradicts core harm reduction principles endorsed by leading public health bodies, including the WHO's own guidance on risk-proportionate regulation. Rather than protecting public health, prohibitions are likely to undermine cessation efforts, entrench smoking and stimulate illicit markets.

> Experience shows that banning harm-reduced nicotine products does not eliminate demand. Rather, it pushes consumers towards unregulated, criminal supply chains.


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# LMICs: THE BURDEN AND THE OPPORTUNITY

## UNDERSTANDING THE DIFFERENCE BETWEEN SMOKELESS ORAL TOBACCO PRODUCTS AND ONPs

The crucial difference is that tobacco-free oral nicotine pouches contain no tobacco leaf material, unlike traditional smokeless oral tobacco products such as snus, chewing tobacco, moist snuff or snuff.

Tobacco-free nicotine pouches are made from plant-based fibres infused with nicotine, flavourings and stabilisers, delivering nicotine without the carcinogenic nitrosamines and other harmful compounds naturally present in tobacco.[1,2] In contrast, snus in Sweden is a moist, ground tobacco product placed under the lip, which – while less harmful than smoking – still exposes users to tobacco-specific nitrosamines and other constituents.[1]

The WHO recognises several major forms of smokeless oral tobacco: snus, chewing tobacco, moist snuff, dry snuff and tobacco bits, all of which involve direct consumption of processed tobacco. These products vary in preparation and use (chewed, sucked, or placed under the lip), but they share the defining feature of containing tobacco leaf.

ONPs break from this tradition by offering nicotine delivery without tobacco, positioning them as a distinct category in harm reduction discussions.

Tobacco-free oral nicotine pouch

Swedish snus

Areca nuts

## THE DISPROPORTIONATE BURDEN OF ORAL DISEASE

LMICs face a disproportionate burden of oral disease. This is largely because, alongside smoking, LMICs experience a widespread use of high-risk smokeless tobacco, areca nut – or a mixture of the two (gutka or khaini) – and other unregulated oral products. While smokeless tobacco (SLT) is used by an estimated 300 million people, the use of areca nut is even higher, with 600 million users.[3]

Consumed without burning, smokeless products can be taken in a variety of ways, including chewing, sucking, ingesting, inhaling or applying topically.

Statistics from the GBD help showcase the excessively disproportionate rates of oral disease in LMICs. While incidences of oral disorders in 2023 were at 3.7 billion, 84% of those (3.1 billion) were from LMICs.[4] Similarly, out of the 430,000 incidents of oral cancer in 2023, 71% (305,000) were from LMICs and out of the 80,000 tobacco-related oral cancer deaths in the same year, 83% (66,000) of deaths occurred in LMICs.[4]

For SLT and areca nut use, a 2022 study by the International Agency for Research on Cancer (IARC) found more than 120,000 cases of oral cancer – a third of oral cancers worldwide. The study also shared that 96.4% of all oral cancer incidences caused by SLT and areca nut use occurred in LMICs, with 88% attributed to South-Central Asia.[5]

Alongside current statistics, a Lancet study[6] examining the prevalence of chewing tobacco use between 1990 and 2019 found "little change", sharing that chewing tobacco "remains a substantial public health problem in several regions of the world, and predominantly in south Asia". The study specifically shared how "control efforts have had much larger effects on the prevalence of smoking tobacco use than on chewing tobacco use in some countries".[6]

## MICRO STUDIES

### South Asia

South Asia carries the world's highest rates of SLT and areca nut use[3,7] as well as the highest burden of oral cancer from these products.[8]

Out of the 120,000 cases of oral cancer attributed to these smokeless products in 2022, 105,500 cases (88%), were from South-Central Asia.[5]

### India

While oral cancer accounts for 5% of cancers worldwide, it accounts for 40% of cancers in India.[9] The country had 126,000 new cases in 2023 and 78,000 oral cancer deaths in the same year.[4] Alongside being the most common cancer among men in India, an Indian hospital shares that "the use of tobacco is directly associated with approximately 80% of oral cancers, especially in older men over 40 years of age".[10]

India accounts for 83,400 of the 120,000 cases of oral cancer caused by SLT and areca nut use. The IARC study further breaks this down by gender. Among men, khaini (47%), gutka (43%), betel quid with tobacco (33%) and areca nut (32%) were the most common causes of oral cancer while women could attribute it to areca nut (30%) and betel quid with tobacco (28%).[5,11]

### Bangladesh

With the next highest proportion of smokeless product-related oral cancer deaths at 9,700, the IARC study shared how 67% of cases among women and 54% of cases among men were caused by the use of betel quid with tobacco.[5]

### Other countries

Other countries with high rates of oral cancer include Pakistan,[12] Sri Lanka and China. In Papua New Guinea, 84% of oral cancer cases are caused by areca nut consumption, which is used by more than 77% of the population.[5]

At a time when public trust in health authorities is fragile, tobacco control must more precisely distinguish the harms associated with chewing tobacco alone from those arising when it is combined with other substances such as areca nut. It is equally important to account for additional risk factors, including exposure to indoor cooking smoke and bacterial contamination in chewing products. Progress depends on clear, transparent and evidence-based health communication that enables people to make informed choices.

## INFRASTRUCTURE CHALLENGES AND THE REALITIES OF ACCESS

Users in LMICs already face multiple barriers, including awareness, accessibility and affordability, to effective healthcare in general and lack of effective oral care in particular. Similar challenges are found and compounded when it comes to effective cessation programmes, knowledge of harm and meaningful access to alternatives.

While other THR products may not be able to cross the accessibility and affordability threshold, ONPs mimic the experience of many smokeless alternatives while also being potentially low-cost – due to their shelf-stability and minimal need for infrastructure. In addition to the lower harm, ONPs are socially hygienic and considerate, eliminating the spitting that often accompanies traditional smokeless oral products.

These features make ONPs particularly suitable for LMIC environments featuring thinly stretched health systems, minimal cessation programmes and potential social stigma associated both with quitting and with continuing. Pushing towards equity, ONPs can help close the gap in oral health outcomes between higher- and lower-income countries and regions. Emerging biomarker studies that show tangible health benefits to ONPs (detailed in Chapter 5) for switchers are also particularly relevant and promising for LMICs, with their high burden of oral conditions and oral cancer.

## GLOBAL AND REGIONAL OPPORTUNITIES FOR LMICs

The situation is dire and needs immediate action, especially as the magnitude of benefits from switching to ONPs is greatest where high-risk SLT prevalence is highest and oral disease burdens are largest.

Meaningful change requires policy and on-the-ground changes tailored to these regions, which have been under-represented in current global frameworks. As observed by various studies, “mitigating the health effects of chewing tobacco requires stronger regulations and policies that specifically target use of chewing tobacco, especially in countries with high prevalence”.[6,13] At an international minimum, this requires more data-gathering on SLT and areca nut use and health impacts as well as discussions and studies on the potential of THR in these contexts.

On a regional and local level, providing ONPs as a viable alternative necessitates affordability levers such as risk-proportionate taxation and pricing that incentivises regulated ONPs over unregulated smokeless products. Additionally, incorporating ONP substitution into community health initiatives and, therefore, moving away from a traditional tobacco control framework must be supported. This should allow harm-reduced alternatives to not only reach relevant nations but also those under-represented within (for example, gender-sensitive interventions discussed in Chapter7).

In this manner, LMICs represent high-leverage settings for oral health gains via THR and can spark significant change in the landscape of smokeless toxic product use and the oral health complications that accompany them.


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# EMERGING SCIENCE: NEW INSIGHTS

The evidence base on ONPs and other combustion-free nicotine alternatives has evolved rapidly, allowing for more precise evaluation of their clinical, toxicological and behavioural outcomes. This chapter integrates recent findings from Power in a Pouch (Sweden), the SMILE Study, Zonnic (Canada) and the Cochrane Review (2025), alongside biomarker and epidemiological evidence from the Global Oral Health Report (2024). Together, these data confirm the growing scientific consensus that ONPs can deliver substantial harm reduction benefits, particularly in improving oral health outcomes and reducing toxicant exposure.[1]

## Power in a Pouch

**Evidence of a successful gender-differentiated approach for a smoke-free Sweden**


Sweden remains the most compelling real-world demonstration of THR. Decades of snus use and the more recent adoption of ONPs have driven smoking prevalence to 5.3%, the lowest in the EU.[2] Epidemiological data show that Swedish men have the lowest oral cancer mortality rates in the EU.[3]

The national survey detailed in the Power in a Pouch report[2] explored the role of nicotine pouches in helping Swedish people who smoke – particularly women – quit cigarettes and remain smoke-free. Conducted by Sentio in April–May 2025, the survey included 892 ex-smokers, nicotine pouch users and snus users, with 60% female participants, complemented by focus groups of female pouch users.

Findings showed that nicotine pouches were rated as the most effective quitting aid, ranking nearly three times higher than vapes and 56% higher than nicotine gum among women. The variety of flavours was identified as a key factor, cited by 60% of women as the top reason for choosing pouches, alongside their tobacco-free composition, reduced harm and social acceptability.

Focus group participants consistently described pouches as clean, socially considerate and stigma-free, aligning with modern lifestyles and female preferences. Emotional investment in the product was also high: one in three women said they would seek out their preferred pouches abroad if banned, underscoring user loyalty and public resistance to restrictive policies. Overall, the survey illustrates how nicotine pouches have empowered Swedish women to quit smoking, contributing to a 49% reduction in female smoking rates since 2016 and positioning Sweden as a global model for THR.

The Swedish experience illustrates how product innovation, social acceptability and risk communication can converge to achieve measurable population-level health gains. Importantly, the shift has been consumer-driven, with women and younger adults adopting ONPs as a hygienic, socially considerate alternative to smoking.

## The SMILE Study

### Clinical evidence

The SMILE Study (by CoEHAR, ongoing)[4] is an international, open-label, randomised controlled clinical trial investigating whether smokers who switch from combustible cigarettes to combustion-free nicotine delivery systems show measurable improvements in oral health and dental appearance over an 18-month period.

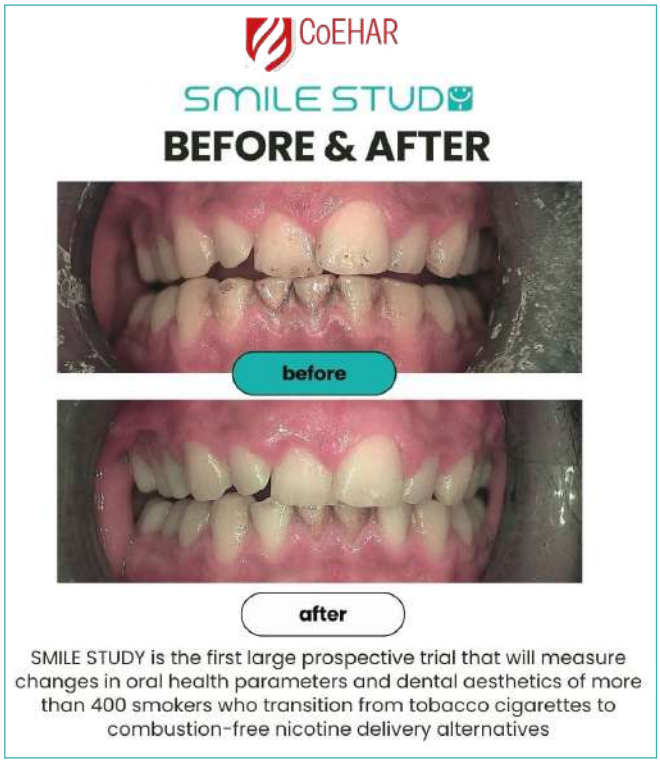
The study assesses outcomes such as tooth colour and appearance, gum health, dental plaque and caries, and supragingival tartar in groups of current smokers, switchers and never-smokers. It is being conducted across multiple centres (including in Italy, Poland, Indonesia and Moldova), and more than 500 participants have taken part, including more than 340 from LMICs. The trial aims to generate rigorous evidence on the impact of switching to reduced-risk nicotine products on periodontal health and aesthetics, thereby contributing to the field of THR.

The study included 136 subjects (30 smokers, 24 ex-smokers, 29 never-smokers, and 53 users of electronic nicotine delivery systems): participants were asked to keep their oral hygiene habits unchanged to assess whether there could be a correlation between these and plaque accumulation.

Both daily tooth brushing and the use of mouthwash were found to be significant covariables. They were also asked to abstain from smoking or using other products in the two hours preceding the study for correct measurement detection. Smoking status was verified through carbon monoxide level tests, which provide an objective picture of the patients' smoking habits.

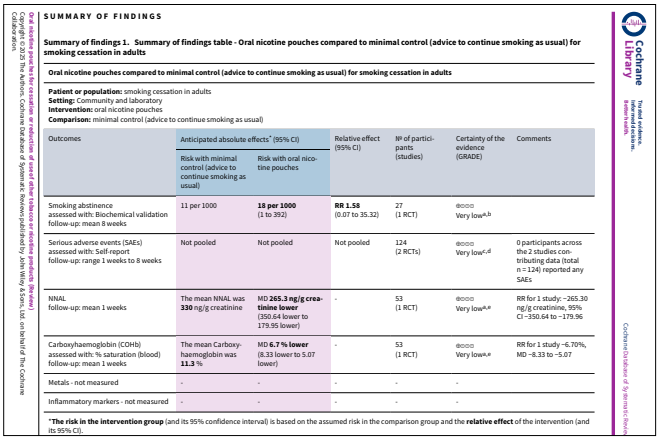
During the visits, plaque accumulation was monitored through images captured by a high-definition camera using light-induced fluorescence technology, then transmitted to software that processed the photographs at the pixel level to identify plaque accumulated on the vestibular surfaces of the front teeth.

> The results from the SMILE project shed new light on the possibilities in the field of oral health by modified-risk devices, which represent an additional tool in the hands of doctors, healthcare providers and policymakers to reduce the impact of cigarette smoking globally.


The study is in its infancy; however, preliminary analysis indicates that exclusive use of combustion-free nicotine products is associated with significantly lower dental plaque accumulation and improved tooth colour compared to current smoking. The full results of the prospective, randomised arms of the trial (18-month follow-up) are not yet published, with major findings expected at the end of 2025.

Professor Riccardo Polosa, founder of CoEHAR, explained: "The innovative results obtained from the SMILE project validate our previous research and shed new light on the possibilities presented in the field of oral health by modified-risk devices, which represent an additional tool in the hands of doctors, healthcare providers and policymakers to reduce the impact of cigarette smoking globally. A narrative focused on the well-being and aesthetics of the smile, our first calling card in daily life, can be an additional incentive for all those smokers who, today, need new weapons to fight the deadly scourge of smoking."

SUMMARY OF FINDINGS

**Summary of findings 1. Summary of findings table - Oral nicotine pouches compared to minimal control (advice to continue smoking as usual) for smoking cessation in adults**

**Oral nicotine pouches compared to minimal control (advice to continue smoking as usual) for smoking cessation in adults**

**Patient or population:** smoking cessation in adults
**Setting:** Community and laboratory
**Intervention:** oral nicotine pouches
**Comparison:** minimal control (advice to continue smoking as usual)

| Outcomes | Anticipated absolute effects* (95% CI) | | Relative effect (95% CI) | № of participants (studies) | Certainty of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Risk with minimal control (advice to continue smoking as usual) | Risk with oral nicotine pouches | | | | |
| Smoking abstinence assessed with: Biochemical validation follow-up: mean 8 weeks | 11 per 1000 | **18 per 1000** (1 to 392) | **RR 1.58** (0.07 to 35.32) | 27 (1 RCT) | ⊕○○○ Very low[a,b] | |
| Serious adverse events (SAEs) assessed with: Self-report follow-up: range 1 weeks to 8 weeks | Not pooled | Not pooled | Not pooled | 124 (2 RCTs) | ⊕○○○ Very low[c,d] | 0 participants across the 2 studies contributing data (total n = 124) reported any SAEs |
| NNAL follow-up: mean 1 weeks | The mean NNAL was **330** ng/g creatinine | MD **265.3 ng/g creatinine lower** (350.64 lower to 179.95 lower) | - | 53 (1 RCT) | ⊕○○○ Very low[a,e] | RR for 1 study: −265.30 ng/g creatinine, 95% CI −350.64 to −179.96 |
| Carboxyhaemoglobin (COHb) assessed with: % saturation (blood) follow-up: mean 1 weeks | The mean Carboxyhaemoglobin was **11.3** % | MD **6.7 % lower** (8.33 lower to 5.07 lower) | - | 53 (1 RCT) | ⊕○○○ Very low[a,e] | RR for 1 study −6.70%, MD −8.33 to −5.07 |
| Metals - not measured | - | - | - | - | - | |
| Inflammatory markers - not measured | - | - | - | - | - | |

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

## Zonnic Canada

### Comparative insights: Zonnic vs nicotine replacement therapy in Canada

In 2023, Health Canada authorised Zonnic as a licensed nicotine replacement therapy (NRT) for smoking cessation – the first ONP globally to achieve medicinal status.[5] Toxicological analyses confirmed negligible tobacco-specific nitrosamines and no detectable carbonyls or polycyclic aromatic hydrocarbons, with overall toxicant levels over 95% lower than cigarettes or oral tobaccos.[6]

According to manufacturer-submitted data described in industry reports, Zonnic contains pharmaceutical-grade nicotine, has a neutral pH (7.5–8.0), and shows no cytotoxic activity in in-vitro testing. Pharmacokinetic evaluations submitted to regulators were reported to deliver nicotine comparably to Nicorette® gum, with controlled absorption and bioavailability estimated at 20–25%.

Health Canada concluded overall that Zonnic meets the safety, quality and efficacy requirements for licensed NRTs and authorised it as an approved smoking cessation aid (NPN 80125630).[7]

This decision contrasts with precautionary bans in parts of Europe and underscores how science-based, risk-proportionate regulation can both protect consumers and accelerate innovation. Zonnic bridges consumer harm reduction and medical cessation, demonstrating that ONPs can meet pharmaceutical safety benchmarks while retaining behavioural appeal – a critical development for future policy frameworks.


## Cochrane Review

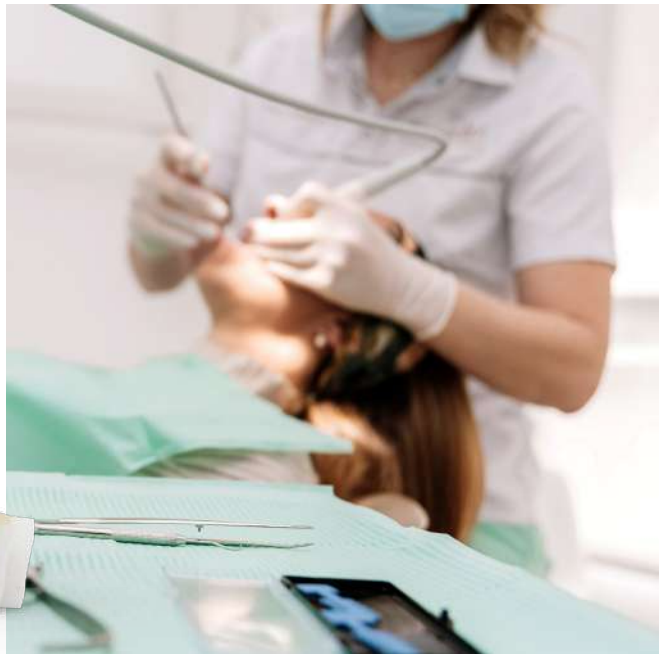
### Scientific gaps and future research priorities

Despite growing evidence, several research needs persist. After conducting a scoping review of current research on ONPs, Travis et al.[8] recommend more studies comparing ONPs and SLTs in terms of harm.

The same authors also suggest future studies to assess the “awareness of, susceptibility to, and initiation of” ONPs amongst those with no history of tobacco or nicotine use as well as studies to understand use and transition patterns better amongst those who use other tobacco or nicotine products. Additionally, more research is needed on the toxicology and health effects compared to non-use, combustible use and non-combustible use.

The latest Cochrane Review[9] also recommends comparative studies, particularly focusing on ONPs and other active interventions, such as NRTs or nicotine e-cigarettes. They emphasise the need for longer-term studies (six months or longer) of abstinence as well as serious adverse events.

Further articles, such as Wouden et al.,[10] share specific and patient and practitioner-led oral health research agendas from the perspective of health and well-being, such as affordability, accessibility and organisation.



## THE POTENTIAL ROLE OF INDUSTRY IN ACCELERATING HARM REDUCTION

The nicotine and tobacco industries can play a meaningful role in conducting transparent, independent science and supporting responsible innovation. Priorities include:

- Supporting biomarker and epidemiological research
- Expanding oral health cohorts in LMICs
- Publishing open toxicology data
- Collaborating with regulators to define ONP product safety standards

**In the United States (US), nicotine manufacturers are legally required to engage directly with regulators through rigorous scientific submissions, while in many other countries bound by the WHO FCTC, Article 5.3 prohibits such contact altogether.**

The recent FDA authorisation of 20 ZYN oral nicotine pouch products in January 2025 illustrates this contrast: the FDA conducted an extensive scientific review under the premarket tobacco product application pathway, determining that the products met the public health standard by containing substantially fewer harmful constituents than cigarettes.[11]

Notably, the FDA accelerated its decision-making process, completing the review in months rather than years, reflecting a regulatory model where industry must provide detailed data on health risks, population impact and compliance measures.

By contrast, countries adhering strictly to Article 5.3 of the FCTC maintain a 'firewall' between regulators and industry, preventing manufacturers from submitting scientific dossiers or engaging in dialogue. This divergence highlights a fundamental tension: the US system treats industry as a regulated scientific partner whose evidence is scrutinised, while the FCTC views industry as an adversarial actor whose influence must be excluded to safeguard public health policy.

Industry engagement aligned with public health goals can accelerate the transition to a nicotine market defined by innovation, integrity and measurable health outcomes.


## CONCLUSION

The convergence of clinical, biomarker and toxicological evidence confirms that ONPs represent a legitimate and effective harm reduction tool. From SMILE's oral health improvements to Zonnic's pharmaceutical approval and Sweden's population-level results, the science now clearly supports ONPs' contribution to reducing harm and improving oral health globally. To realise this potential, policy must evolve as fast as the evidence to embed ONPs within oral health frameworks, cessation strategies and international harm reduction discourse.

### Building the future: A global research and education agenda

The next phase of scientific progress in oral nicotine research demands a coordinated, interdisciplinary research agenda, capable of connecting clinical, toxicological, behavioural and educational dimensions. The ONC is ideally placed to lead this agenda, acting as a bridge between laboratory science, clinical research, regulatory evidence and health education systems.

### A new collaborative research framework

Future research should prioritise three interconnected domains:

1. **Clinical and biomarker research:** Expanding multicentre trials like SMILE to assess the long-term oral and systemic outcomes of switching to oral nicotine products. This includes harmonising biomarker endpoints, validating lesion regression data and quantifying oral cancer risk reduction in diverse populations.
2. **Behavioural and epidemiological studies:** Investigating product use patterns, gender differences and social determinants of substitution, especially in LMICs where unregulated oral tobaccos remain widespread.
3. **Policy and regulatory science:** Generating comparative evidence to support risk-proportionate regulation, informed by toxicology and pharmacology data such as those underpinning Zonnic's medicinal classification.

By integrating these strands, the ONC can establish a unified evidence base that supports global oral health policy transformation, aligning with the WHO Global Oral Health Strategy 2023–2030.

## The Hungarian model: Integrating harm reduction into dental education

Hungary's leadership in integrating THR into dental curricula offers a transformative model for global replication.[12] Researchers such as Dr Barbara Kispélyi and Dr Orsolya Vámos at Semmelweis University have pioneered clinical and translational research on the oral effects of traditional and alternative nicotine products. Their work explores the biological and prosthodontic implications of e-cigarettes, heated tobacco and ONPs, while emphasising evidence- based prevention and cessation.

Crucially, the Semmelweis dental curriculum has been restructured to include modules on THR, equipping new generations of dentists to discuss nicotine use scientifically and compassionately with patients. This curriculum innovation bridges science and practice to position oral health professionals as agents of behavioural change and public health advocacy.

As a global model, the Hungarian experience demonstrates how integrating harm reduction principles into professional education can accelerate knowledge translation and improve clinical outcomes. The ONC can leverage this example to encourage dental faculties worldwide to adopt similar frameworks, fostering a new generation of clinicians equipped to deliver risk-proportionate, patient-centred oral care.

## Towards global impact

To achieve global impact, the ONC should convene a Global Oral Nicotine Research Network, bringing together universities, dental schools, clinicians and policymakers to:

- Develop shared research protocols and open biomarker data platforms
- Support curriculum innovation through international partnerships
- Ensure equitable access to harm reduction knowledge in emerging markets

Through this collaborative model, the ONC can evolve from a research initiative into a global knowledge hub, championing oral health as a key pillar of THR and sustainable public health policy.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# CASE STUDY: ORAL HEALTH AND THR IN SWEDEN

## SWEDISH SUCCESS

With a smoking rate of 5.3% in 2024,[1] Sweden is on track to become a smoke-free country (marked by a smoking rate below 5%) well before the EU goal of 2040. This historic success has been built on a policy of making safer nicotine alternatives accessible, acceptable and affordable to adults who smoke.

The 2024 Public Health Agency survey found that 10.9% of the population uses snus daily (a traditional oral tobacco product) and 5% uses nicotine pouches (locally known as "white snus") daily,[1] with these products progressively substituting smoking.

In contrast to unregulated and SLT use seen in many LMICs, Swedish snus is strictly regulated for quality and quantity, making it more than 90% less harmful than cigarettes.[2] While many SLTs, such as chewing tobacco, are fermented, snus is pasteurised - which results in much lower levels of harmful nitrosamines. The benefits of this switch can clearly be seen in Sweden's public and oral health outcomes.


Source: WHO International Agency for Research on Cancer[10]

> With a smoking rate of 5.3% in 2024, Sweden is on track to become a smoke-free country well before the EU goal of 2040. This historic success has been built on a policy of making safer nicotine alternatives accessible, acceptable and affordable to adults who smoke.

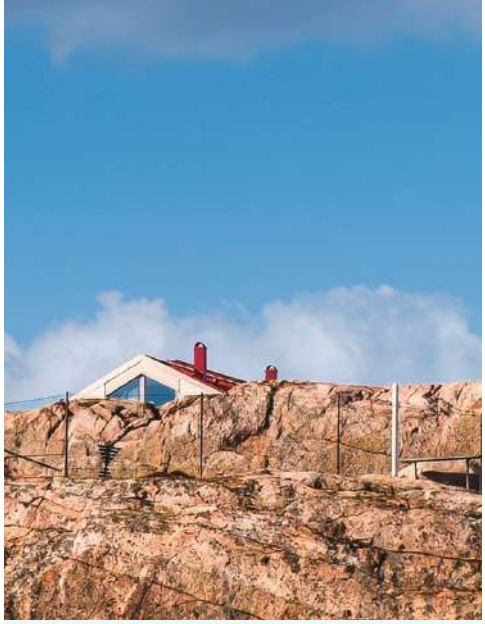
## PROVEN HEALTH OUTCOMES

With the presence of snus in Sweden over the years, studies have been able to conclude that "health risks associated with snus use, where nicotine is decoupled from harmful tobacco smoke, are considerably lower than those associated with smoking cigarettes".[3]

Among men, Sweden is already under the smoke-free threshold with a 4.9% smoking rate.[1] This is also reflected in public health outcomes, with Sweden having a 61% lower male lung cancer death rate than the EU average.[4]

Another study on the association between snus and oral cancer in Swedish men found that "compared to never-snus use, ever-snus use was not associated with oral cancer". This also applied to snus use in general when compared to never-smokers. The study concluded that "Swedish snus use does not appear to be implicated in the development of cancer among men".[5] It is clear to see that "the increase of snus use has been the major factor behind Sweden's low smoking-attributable mortality".[6]

Consumer voices also echo the benefits of snus as an alternative. During a seven-year follow-up study of former smokers, more than 80% cited snus as "of great importance to succeed with smoking cessation".[7] Alongside health benefits, it is important to consider that "snus appears to be a viable alternative to smoking tobacco, is acceptable to consumers and does not act as a gateway product to smoking cigarettes".[3]



> More than 80% of former smokers cited snus as "of great importance to succeed with smoking cessation".

## THE SUCCESS OF RISK-PROPORTIONATE POLICY

The popularity of safer nicotine alternatives did not happen overnight. The Swedish government pursued harm reduction through policy implementation, switch incentivisation, clear regulation and risk-proportionate taxes.

The Swedish example shows how a well-established, regulated, oral product ecosystem can underpin a strong oral health benefit via substitution away from smoking. Effective regulation includes risk-proportionate taxation, quality assurance, data collection and adult-only marketing.

Sweden's experience proves that "in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking".[8] This applies beyond Sweden to nations, including LMICs,[9] across the globe.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# GENDER, EQUITY AND STIGMA

## GENDER-SENSITIVE TOBACCO HARM REDUCTION

The needs of women and the unique obstacles they face in tobacco control and cessation are often overlooked. These include, but are not limited to, social stigma around smoking, caretaking roles, informal employment and restricted social settings. Historically, tobacco control efforts have been male-centred and much THR discourse has emphasised male smokers. However, ONPs – and their already-growing acceptance amongs women – present a significant and often overlooked oral health opportunity.

Stigma plays a major, often under-recognised role in tobacco use and cessation. Women, in particular, frequently experience dual stigma: for smoking itself and for cessation failure. In many settings, smoking is gender-normatively male; women may feel judged or marginalised. Offering a stigma-sensitive and socially considerate pathway to nicotine substitution with harm reduction, the benefits of ONPs among women can already be observed in the Swedish context.

Detailed in Smoke Free Sweden's Power in a Pouch report,[1] the introduction of ONPs in 2016 has seen an acceleration in the quit rate among women by nearly 200%.

A survey discussed within this report also shares how women ranked pouches almost three times higher than vaping and 56% higher than gum as a quit aid.

> The introduction of ONPs in 2016 has seen an acceleration in the quit rate among women by nearly 200%.

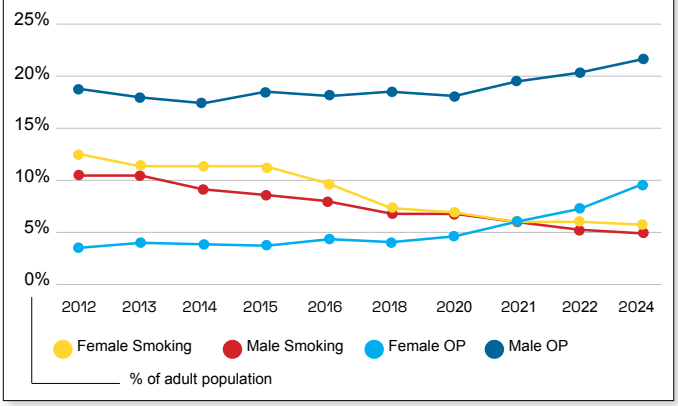
Tellingly, complete social acceptability, discretion, cleanliness and convenience were key factors in their preference for ONPs. In 2024, the smoking rate among women in Sweden dropped to 5.7%, significantly closing the gender gap and heading to a smoke-free status of under 5%. The Swedish government also helps support a risk-proportionate approach by taxing nicotine in smoke-free nicotine alternatives at a much lower rate than tobacco.[2]

The lessons from Sweden also apply to cultures where the switch might be from high-risk SLTs to ONPs rather than cigarettes to ONPs. A gender-sensitive THR strategy, including a female-focused ONP substitution scenario targeting adult female SLT users, can offer an alternative that mitigates both systematic and oral disease harms. For example, stigma sensitivity means recognising that women may prefer alternatives that align with social acceptability and may transition more readily when the product meets this criteria. In this manner, ONPs serve as not only quit aids but also socially considerate nicotine alternatives.

In India, where it is less socially acceptable for women to smoke, the use of high-risk SLT products among women is common, with 70 million women in India over the age of 15 using SLT regularly.[3] In such cases, safer oral alternatives made accessible in gender- conscious ways can make a big difference.

Rumgay et al. also share that Southern Africa and South-East Asia see a higher prevalence of SLT or areca nut use among women. They recommend implementing "gender-sensitive policies" in order to reduce high-risk SLT use across a variety of cultural contexts.[4]

**Rates of smoking and use of oral products (OP) (including snus and nicotine pouches)**




Source: Public Health Agency Sweden

## EQUITY ACROSS POPULATIONS

Beyond gender, many populations face layered disadvantages on the path to harm reduction and cessation, such as social expectations or stigmatisation and limited access to healthcare. Responding to challenges that are often similar to the infrastructural limitations in LMICs (see Chapter 4), ONPs can become an equitable alternative for under-represented groups across the world, such as informal workers, refugees or incarcerated individuals.

The scope for accessibility, affordability and discretion with ONPs both reduces health risks and poses less of a barrier to social acceptability and integration, unlike the stigmas and negative connotations often attached to smoking or high-risk SLT use. In this manner, ONPs offer a realistic harm reduction intervention that aligns with everyday constraints and social realities.

In prison and refugee settings, where visibility and reputation matters, ONPs may reduce the social penalties of traditional smoking. In informal work settings, where breaks and smoking areas may be restricted, ONPs may offer nicotine maintenance, while reducing risk, in a less disruptive manner.

Although specific studies for these population groups are almost non-existent, a 2024 study among adults with low socioeconomic status who smoke found that, after eight weeks of access to ONPs, participants had reduced their intake of cigarettes per day from 15 to 8.3.[5]


1. Smoke Free Sweden. Power in a pouch. 2025 Jun 17. [cited 2025 Nov 16].
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4. Rumgay H, Nethan ST, Shah R, et al. Global burden of oral cancer in 2022 attributable to smokeless tobacco and areca nut consumption: A population attributable fraction analysis. Lancet. [serial online]. 2024 Nov. [cited 2025 Nov 16]; 25(11):1413–1423.
5. Avila JC, Maglalang DD, Nollen NL, et al. Using pod based e-cigarettes and nicotine pouches to reduce harm for adults with low socioeconomic status who smoke: A pilot randomized controlled trial. Nicotine Tob Res. [serial online]. 2024 Aug 22. [cited 2025 Nov 16]; 26(9):1150–1158.

# WHO AND THE GLOBAL POLICY GAP

> The absence of proportionate legislation enabling access to lower-risk nicotine products for people who smoke and wish to quit, or who do not want to do so without support, stands at odds with any reasonable or evidence-based public health framework.

In 2003, the WHO released the FCTC, which advises all of the 194 WHO member states on tobacco control policy. It states, at the start, that the WHO is deeply concerned with the increase in smoking among "children and adolescents ... women ... and indigenous peoples".

It goes on to list a series of policies to help counteract the growing demand for cigarettes.[1]

Many of these policies are recognised and proven to work, such as legislation that includes but is not limited to "price and tax measures".[1] This is effective in reducing the number of children and adolescents smoking as they simply cannot afford it, but for the older generations in employment who are more likely to be heavy smokers, it is not as effective. It suggests other means such as carefully controlled advertising on packaging, ensuring that the purchaser is aware of the negative "health effects, hazards or emissions". It also suggests that terms such as "low tar, light, ultra-light" be banned to dispel the idea that some cigarettes are less harmful than others.[1]

The gaping hole at the centre of the FCTC (as well as the 2024 WHO Global strategy and action plan on oral health 2023–2030) for those unwilling or unable to quit is the lack of legislation or even mention of THR. Products such as ONPs are not risk-free, but the harm is greatly reduced.[2] The absence of proportionate legislation enabling access to lower-risk nicotine products for people who smoke and wish to quit, or who do not want to do so without support, stands at odds with any reasonable or evidence-based public health framework.

Sweden provides the clearest demonstration of what effective harm reduction policy can achieve. As the only EU Member State that has not prohibited snus, Sweden has driven smoking prevalence to 5.3% and is on track to become the world's first smoke-free nation.

To disregard such a compelling, real-world example when shaping global tobacco control policy represents a profound policy failure. Ignoring Sweden's outcomes risks denying millions of smokers access to proven, safer alternatives, with predictable and avoidable consequences for cessation, disease burden and mortality.

On 12 November 2025, the WHO published the WHO Position on Tobacco Control and Harm Reduction.[3] In response, Professor Jean-Francois Etter, a former Professor of Public Health from Switzerland, argues that "enough is enough" and that this statement could undermine public health. He contends that the WHO wrongly equates independent harm reduction advocates with tobacco industry front groups, dismisses clear evidence that non-combustible products are significantly less harmful than cigarettes, and wrongly asserts that all tobacco and nicotine products are equally toxic and addictive.

Etter also questions the WHO's use of quotation marks when referring to "harm reduction", which might be seen as an attempt to delegitimise a principle explicitly recognised in the FCTC. Finally, he warns that the WHO's call for prohibition and restrictions on alternatives such as e-cigarettes risks protecting the cigarette market, fuelling illicit trade and ultimately increasing smoking-related disease and death – an outcome he views as detrimental to the mission of global public health.

Although the US is not a member of the WHO, it has shown that rigorous scientific and regulatory evaluation of new harm reduction products is both feasible and essential.

Through agencies such as the FDA, the US has established structured pathways to assess the safety, efficacy and public health impact of alternatives such as e-cigarettes and heated tobacco products. More recently, it has chosen to accelerate this review process, signalling a proactive commitment to exploring the potential benefits these innovations may offer in reducing smoking-related disease.

This approach demonstrates leadership by prioritising evidence-based regulation and acknowledging that harm reduction strategies can play a meaningful role in advancing public health.


1. World Health Organisation. WHO framework convention on tobacco control [Internet]. Geneva; 2003 [cited 2025 Aug 3].
2. Nutt DJ, Phillips LD, Balfour D, et al. Estimating the harms of nicotine-containing products using the MCDA approach. Eur Addict Res [serial online]. 2014 Apr 16 [cited 2025 Nov 16]; 20(5):218–25.
3. World Health Organisation. WHO Position on Tobacco Control and Harm Reduction [Internet]. Geneva; 2025 [cited 2025 Nov 16].

# POLICY RECOMMENDATIONS FOR ORAL HEALTH AND TOBACCO HARM REDUCTION

### Adopt risk-proportionate regulation

- Differentiate non-combustible THR products such as oral nicotine pouches from smoked tobacco
- Ensure regulatory frameworks reflect relative risk profiles to incentivise substitution away from cigarettes

### Establish clear product standards

- Mandate quality, safety and labelling requirements for ONPs
- Guarantee consistency in nicotine delivery and minimise harmful constituents

### Introduce affordability levers

- Apply differential taxation aligned with risk, making pouches more accessible than cigarettes
- Support equitable access across socioeconomic groups to reduce oral health disparities

### Integrate THR into cessation services

- Position ONPs as complementary tools within national quit-smoking programmes
- Train dental and medical professionals to advise patients on THR options for oral health protection

### Ensure gender-sensitive approaches

- Address distinct patterns of tobacco use among men and women
- Tailor THR interventions to overcome gender-specific barriers to cessation and oral healthcare

### Highlight oral health benefits

- Promote THR as a means to prevent and control smoking-related oral disease, disability and premature death
- Emphasise cost savings for health systems through reduced treatment needs and improved population oral health outcomes

# CONCLUSION

ORAL NICOTINE COMMISSION

**Oral nicotine pouches represent a legitimate, effective harm reduction tool capable of delivering measurable improvements in both cessation rates and oral health outcomes, without causing serious health harms.**

**The 2025 Cochrane Review's safety findings, combined with Sweden's population-level success, biomarker evidence showing dramatic toxicant reductions, the SMILE Study's ongoing clinical validation and Canada's pharmaceutical approval of Zonnic establish an evidence base that meets the highest standards of scientific rigour.**

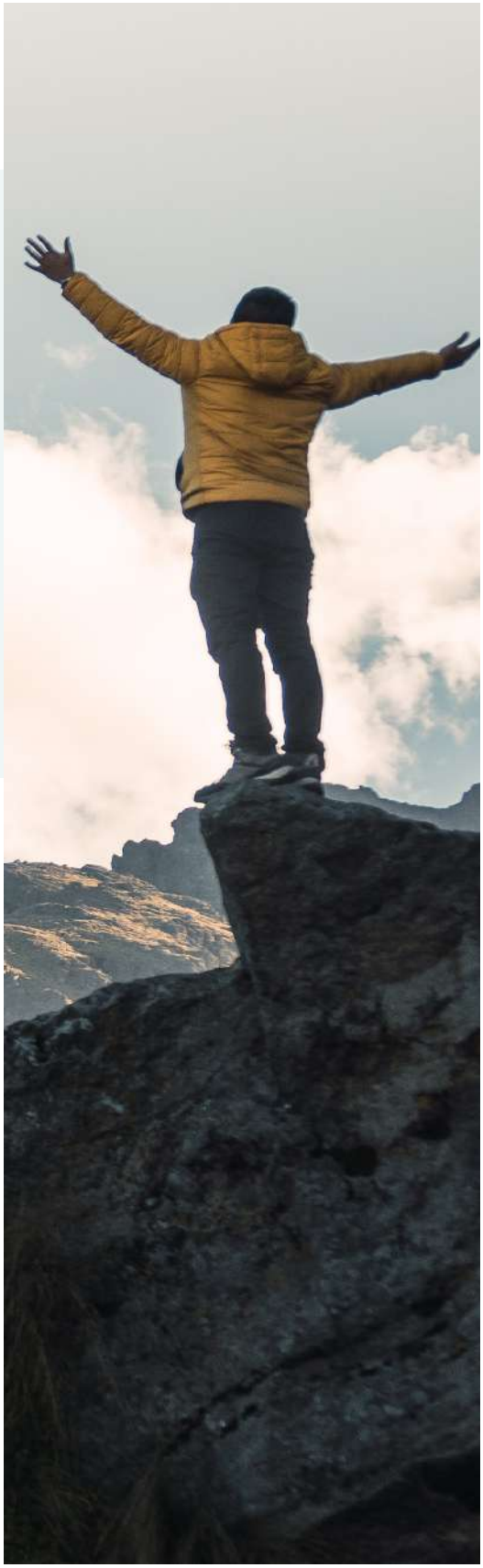
**For 3.7 billion people suffering from oral diseases, the 1.27 billion people who smoke worldwide and particularly the millions in LMICs using toxic oral tobacco products, ONPs offer something unprecedented: a pathway to better health that acknowledges the real-world barriers to cessation while delivering tangible harm reduction.**

**With the oral disease burden rising, cessation rates stagnating and health inequalities widening, risk-proportionate regulation of ONPs represents an essential component of 21st century public health policy. It could save millions of lives and dramatically reduce the global disease burden of oral disease, disability and premature death.**

**This report provides the evidence base, policy frameworks and strategic roadmap needed to transform oral health through harm reduction. What we need now is for policymakers to follow the science, learn from the real-world experience of countries like Sweden and prioritise health outcomes over the outdated orthodoxies that have left so many people who smoke behind.**

# CALL FOR ACTION: ORAL HEALTH AND SMOKING CESSATION FOR ALL

Centred on evidence, consumer protection and equitable access, this report calls on key stakeholders to responsibly integrate tobacco-free oral nicotine pouches into comprehensive tobacco control strategies, while prioritising oral health outcomes.



## GUIDING PRINCIPLES

- **Health-first:** Integrate oral health outcomes alongside smoking cessation metrics in all policy and programme decisions.
- **Risk-proportionate:** Recognise the continuum of risk and prioritise access to lower-risk, non-tobacco nicotine products for adults who smoke while maintaining strong youth protections.
- **Evidence-led:** Commit to transparent standards, independent research and continuous evaluation of benefits and risks.
- **Equity-focused:** Ensure affordability, accessibility and culturally relevant support for high-need populations, especially in LMICs and minority groups.
- **Responsible conduct:** Enforce strict marketing, product safety and age protections aligned with public health goals.

## ACTIONS FOR THE WORLD HEALTH ORGANIZATION (WHO)

- **FCTC:** Elaborate, explain and define harm reduction strategies embedded in Article 1(d) and incorporate tobacco-free oral nicotine pouches into risk-proportionate guidance that distinguishes non-combustible, non-tobacco products from smokeless tobacco containing leaf.
- **Standardised definitions:** Develop clear global terminology (composition, nicotine content, product form) to support consistent regulation and surveillance.
- **Research agenda:** Prioritise independent studies on oral health impacts, cessation effectiveness and long-term safety, including differential effects versus tobacco-containing oral products.
- **Monitoring and reporting:** Add adult harm-reduction metrics (switching, dual use reduction, cessation rates) and youth protection indicators to global tobacco control surveillance.
- **Technical assistance:** Support member states with model regulations that combine product safety standards and strong youth safeguards.

## ACTIONS FOR GOVERNMENTS

- **Risk-based regulation:** Create distinct regulatory pathways for tobacco-free oral nicotine pouches – separate from smokeless tobacco – covering product standards, labelling and verified age protections.
- **Product safety standards:** Mandate limits on impurities, consistent nicotine delivery and disclosure of ingredients; require child-resistant packaging and tamper-evident seals.
- **Consumer information:** Enforce truthful, non-misleading communication with standardised health warnings that reflect relative risk versus smoking and clarify non-tobacco status.
- **Access for adults who smoke:** Enable availability where cessation support is provided (pharmacies, clinics, digital programmes), with pricing and tax policy calibrated to reflect risk reduction and discourage youth uptake.
- **Youth protection:** Apply strict retail controls, digital age verification and flavour policies that balance adult appeal and youth deterrence, with penalties for non-compliance.
- **Integration with services:** Embed pouches into national smoking cessation pathways, dental care initiatives and primary care brief interventions, with referral loops and reimbursement options for eligible populations.
- **Data and evaluation:** Require post-market surveillance and publish annual reports on oral health indicators and cessation outcomes associated with pouch use.

## ACTIONS FOR CONSUMERS (ADULT SMOKERS AND RECENT QUITTERS)

- **Informed choice:** Understand that tobacco-free oral nicotine pouches contain no tobacco leaf and are designed to reduce exposure compared with smoking; prioritise complete cessation when possible.
- **Responsible use:** Follow product instructions, avoid dual use by setting a quit date and seek support from cessation services or healthcare providers.
- **Oral care:** Pair pouch use with improved oral hygiene – regular brushing, flossing, fluoride use – and routine dental check-ups to track benefits.
- **Protection of youth:** Never share or promote products to minors; store securely and dispose responsibly.

## ACTIONS FOR HEALTH PROFESSIONALS

- **Clinical guidance:** Offer risk-proportionate advice that prioritises complete smoking cessation; where appropriate, recommend tobacco-free oral nicotine pouches as a lower-risk alternative or temporary aid for adults who smoke.
- **Oral health integration:** Screen for tobacco use during dental and medical visits; provide brief interventions linking pouch use to improved oral hygiene and reduced exposure to tobacco-specific toxins.
- **Training and tools:** Adopt standardised counselling protocols, dosing education and follow-up schedules that minimise dual use and support full transition away from smoking.
- **Safeguards:** Reinforce age restrictions, monitor adverse oral events and refer patients to cessation services; document outcomes to build practice-level evidence.
- **Community outreach:** Tailor communication for high-risk groups (e.g., heavy smokers, low-income populations) with accessible materials and culturally informed support.

## ACTIONS FOR INDUSTRY

- **Product quality:** Meet rigorous safety and consistency standards; minimise impurities, ensure accurate nicotine labelling and disclose non-tobacco composition.
- **Marketing integrity:** Target adults who smoke only; implement independent age-verification, avoid youth-oriented branding, flavours and claims; prohibit lifestyle appeals that could attract minors.
- **Transparency:** Publish safety data, adverse event reporting and independent study results; collaborate with regulators and researchers on open evidence.
- **Support cessation:** Co-develop tools with health services (step-down plans, usage trackers, educational materials) that discourage dual use and encourage quitting.
- **Compliance culture**: Adopt third-party audits, retailer training and swift corrective actions for violations; contribute to post-market surveillance and continuous improvement.

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## MEASUREMENT AND ACCOUNTABILITY

- **Core indicators:** Track smoking quit rates, reduction in dual use, oral health outcomes (e.g., periodontal status, mucosal health), youth access violations and adverse events.
- **Public reporting:** Publish annual dashboards at national and regional levels with disaggregated data for equity monitoring.
- **Continuous review:** Update policies and clinical guidance as new evidence emerges, maintaining a precautionary stance without obstructing adult harm reduction.

## IMMEDIATE PRIORITIES (NEXT 12 MONTHS)

- **Define standards:** Establish national product and labelling standards for tobacco-free oral nicotine pouches.
- **Integrate services:** Add pouches to smoking cessation pathways and dental screening programmes with clear guidance and training.
- **Protect youth:** Implement robust age protections and retailer controls; audit compliance quarterly.
- **Health communication:** Enforce truthful, non-misleading communication with standardised health warnings that reflect relative risk versus smoking and clarify non-tobacco status.
- **Launch evaluation:** Initiate independent studies on oral health outcomes and cessation efficacy, with early interim reports to inform policy updates.

**This call for action aims to align public health, clinical practice and responsible industry conduct to advance oral health for all, while accelerating progress towards a smoke-free future.**

# AUTHORS

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Prof. Karl Fagerström is a psychologist and founding member of the Society for Research on Nicotine and Tobacco (SRNT). He received the WHO medal in 1999 and the 2013 Award on Clinical Science. He contributed to early development of nicotine replacement products and created the first non-tobacco nicotine pouch.

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Alice Alberta Cittore is an Italian dental hygienist, public health advocate and innovator in oral health care. She has built a multifaceted career that bridges clinical practice, health education, digital health innovation and policy advocacy. Cittore is particularly known for her efforts to promote oral health as a key component of public health, through both community initiatives and involvement in national health policy.

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AsHRA

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