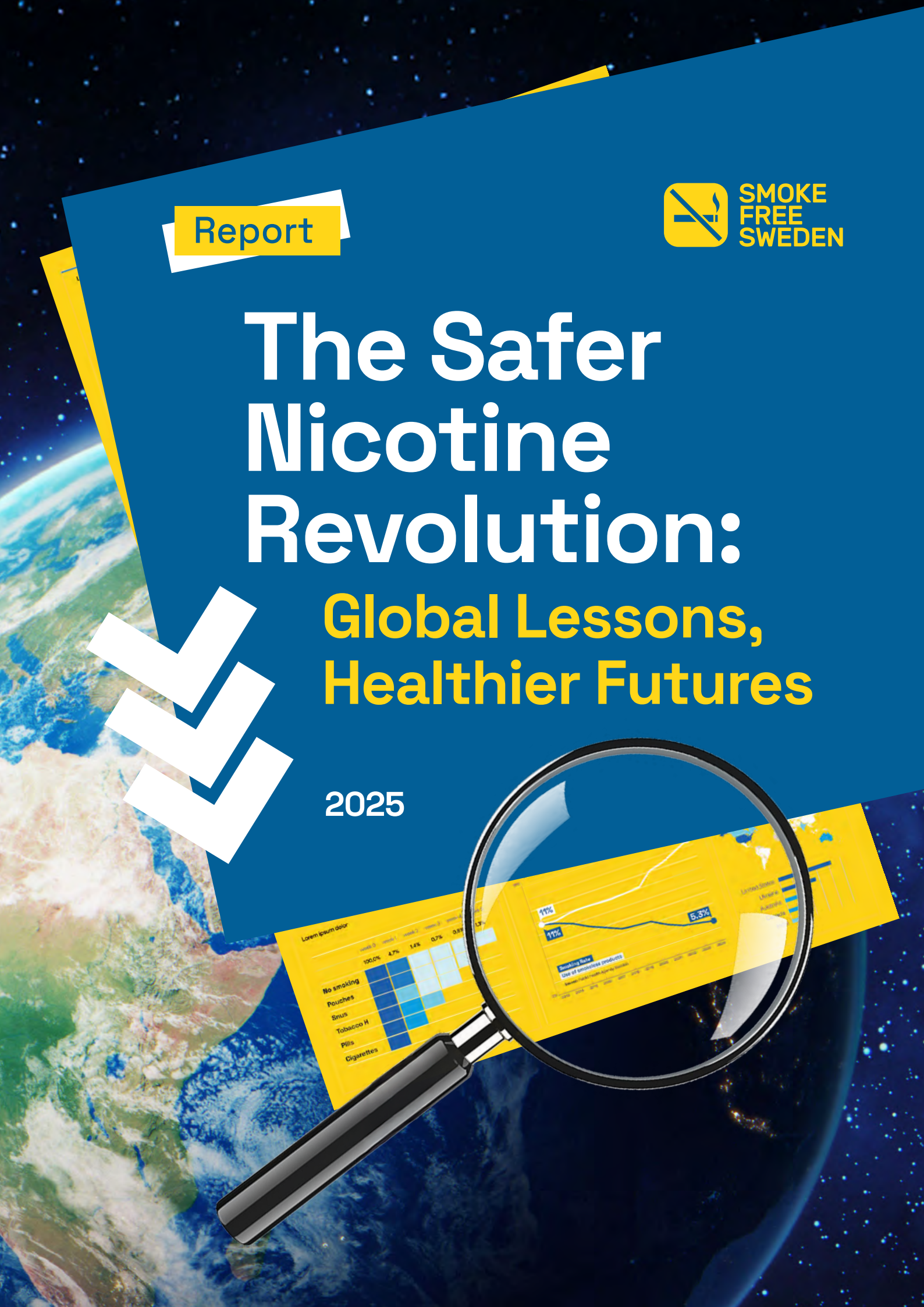
Report

SMOKE FREE SWEDEN

The Safer Nicotine Revolution:

Global Lessons, Healthier Futures

2025



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The Safer Nicotine Revolution:
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Executive Summary

Despite decades of effort and billions invested in tobacco control, smoking remains the world's biggest preventable killer, claiming more than 7 million lives each year. In many countries, progress to stem this epidemic has slowed.

The question is no longer whether the current approach is enough, as it patently is not. The real question is: **what new strategy can finally break the deadlock and deliver a smoke-free future?**

This report provides an answer that is compelling, evidence-based and actionable. When safer nicotine alternatives (SNAs) are embraced, smoking rates plummet, lives are saved and healthcare costs fall.

Examination of the real-world experience of four countries – **Sweden**, **Japan**, **the United Kingdom (UK)** and **New Zealand** – shows that integrating safer nicotine alternatives into national strategies delivers dramatic reductions in smoking and measurable public health gains.

In stark contrast, countries with restrictive or prohibitionist models, such as Australia, have seen slower declines in smoking and the emergence of thriving illicit markets and related criminal activities, undermining public health.

These case studies cut through years of ideological debate about 'harm reduction' products with concrete and beneficial outcomes.

In the face of such evidence, it is alarming that, ahead of the upcoming COP11 meeting in November 2025, harm reduction is being framed not as a public health opportunity, but as a potential threat.

This report acts as a call to action for global public health, to further study and validate improved health outcomes in countries where harm reduction methods and products have been employed to complement tobacco control, e.g.:

United Kingdom — Where vapes or electronic nicotine delivery systems (ENDS) have been available since 2010, with strong endorsement by the government from 2015

Sweden — Where regulated smokeless oral tobacco pouches have been available from 1990 and oral nicotine pouches from 2016

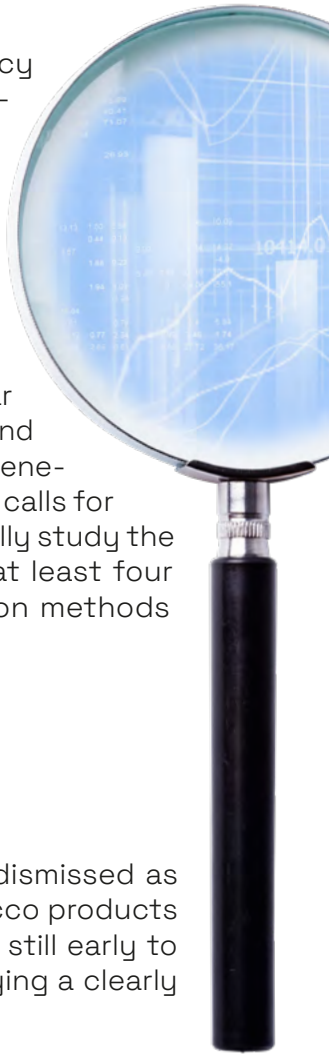
New Zealand — Where vapes have been available from 2017, when regulations were clarified, and heated tobacco products from 2018

Japan — Where heated tobacco products have been available from 2014

The success metrics that public health typically relies on to demonstrate improved outcomes — and which are evident in harm reduction — include:

- **Decline in usage (e.g. of tobacco, drugs) and lower uptake of the habit**
- **Reduced biomarkers of harm (lower exposure to toxicants in SNA consumption)**
- **Lower incidence of smoking-related disease, disability and premature death**
- **Lower societal and healthcare cost**

WHO has historically accelerated its acceptance of reduced-harm interventions — such as vaccines, diagnostics or therapeutics — when three conditions converge: robust scientific evidence, global health urgency and political will. In the case of tobacco harm reduction, however, WHO continues to question the long-term benefits of smokeless safer nicotine alternatives, largely due to perceived ties to industry.

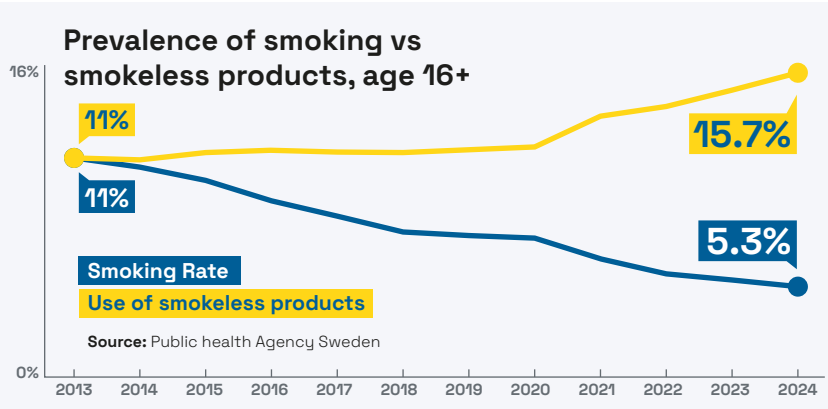


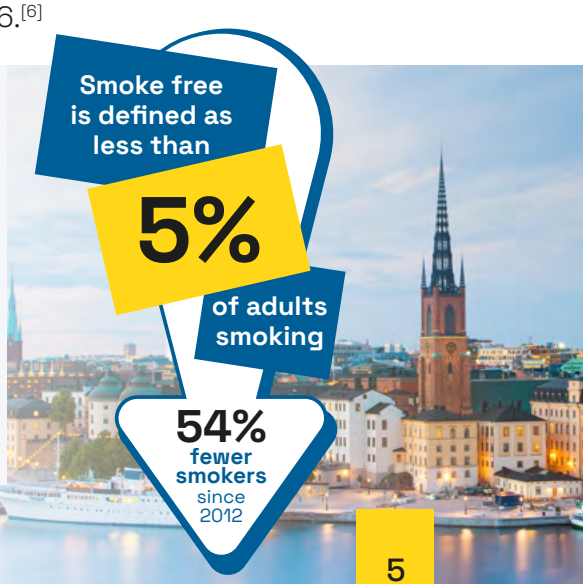
Against the background of 7 million needless deaths per year due to smoking-related disease and the increasing evidence of the benefits of safer nicotine, this report calls for global public health to specifically study the improved health outcomes in at least four countries where harm reduction methods have been employed.

Real-world results: Four countries leading the way

The four countries studied show that harm reduction should no longer be dismissed as theory. In each country, oral nicotine pouches, vaping devices or heated tobacco products (HTPs) have helped millions of adults move away from smoking. Although it is still early to measure the full extent of this public health dividend, each country is displaying a clearly identifiable trend towards less disease, less disability and less death.

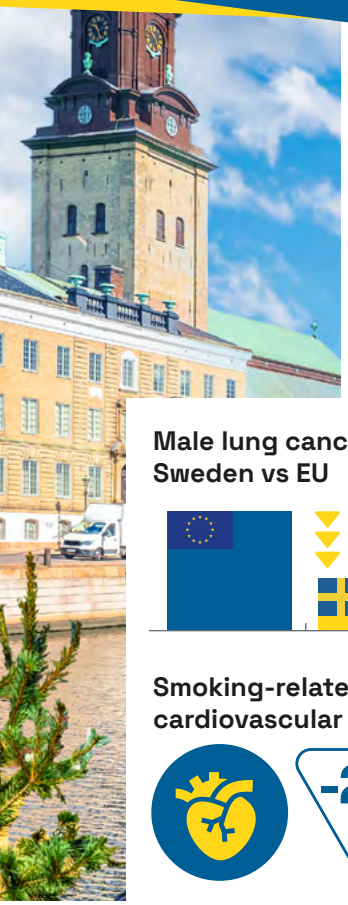
Sweden is poised to become the first country in the world to achieve official "smoke-free" status, with just **5.3% adult smoking prevalence, including 4.9% among men** – the lowest in Europe. This is driven by the widespread use of smokeless products (15.7% overall, 21.6% among men) including growing adoption of nicotine pouches (5% overall, 5.4% among women). Smoking dropped by 54% over 12 years, with women's smoking declining by 49% after the introduction of nicotine pouches in 2016.[6]





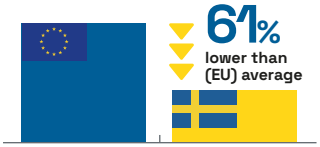
The Safer Nicotine Revolution

Global Lessons, Healthier Futures



- **Improved smoking cessation**: 76.3% of men and 71.6% of women who use snus have **quit smoking completely.**[7]
- **Reduced cardiovascular health risk**: Studies show that smokers who switch to snus have a relative risk of 0.55 for ischemic heart disease (IHD) or acute myocardial infarction compared with current smokers — a 45% lower risk.[75] Analysis shows that snus use in Sweden has **saved around 3,000 lives per year**. Without snus, smoking-related male mortality in 2021 would have been 70% higher.[76]

Male lung cancer deaths Sweden vs EU



Smoking-related cardiovascular deaths

- **Lower cancer death and disability rates**: Sweden has **61% lower lung cancer deaths among men** than the European Union (EU) average.[8] Overall, Sweden has **34% fewer cancer deaths** than the EU average.[8] Between 2015 and 2021, Sweden saw a 22% reduction in smoking-related cardiovascular deaths and DALYs, and a 14% reduction in all smoking-related deaths and disease. [8]
- **Biomarker reduction:** Although there is limited data, there is strong epidemiological evidence of tobacco harm reduction and the lowest tobacco-related mortality in the EU.[81]
- **No smoke, less harm:** Nicotine use per capita in Sweden is similar to the EU average, yet health outcomes are dramatically better, proving that it is the mode of delivery, not nicotine itself, that drives harm.[24]

Japan's introduction of HTPs in 2014-15 marked the beginning of the fastest decline in smoking in the country's history. Smoking prevalence dropped from **21% (2015)**[1] to **16% (2023)**[2].

- **Switch to HTPs:** 12.4% of adults now use HTPs,[3] reflecting a substantial consumer shift away from cigarettes. HTP stick sales have risen to 72 billion units between 2015 and 2023.[1]
- **Historic drop in cigarette sales:** The introduction of HTP marked the most rapid and significant decline in cigarette sales ever recorded in Japan, dropping 52% from 182 billion sticks (2015) to 88 billion (2023).[4]
- **Decrease in smoking-related disease:** Modelling suggests that if half of smokers switched to HTPs, 12 million cases of smoking-related disease (COPD, stroke, myocardial infarction and lung cancer) could be prevented.[83]
- **Biomarker reduction:** There is a significant reduction in biomarkers of harm at population level, with a significant reduction in NNAI, cotinine and inflammatory markers and modeled health gains.[79]
- **Potential lives saved through harm reduction:** A 2024 modelled impact analysis estimates thousands of premature deaths already avoided.[5]

12 MLN

cases of smoking-related disease

PREVENTED

(if half smokers switched to HTPs)

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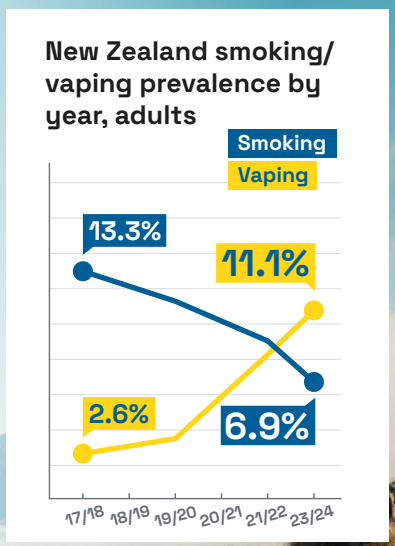
By formally integrating vaping into its quit-smoking services, the **United Kingdom** has seen smoking rates fall from **20.2% (2011)** to **11.9% (2023)** – a **41% reduction**.[9]

- **Quitting by switching**: as of 2025, **approximately 5.5 million adults in Great Britain use e-cigarettes**, with more than half (55%) have quit smoking entirely. [84] Researchers project 166,000 fewer smoking-attributable deaths from 2012-2052 due to vaping.[77]
- **Cardiovascular health benefits**: A University of Dundee study found a **'significant improvement within one month of switching'** from cigarettes to vaping, particularly among women. The study reported a **-2 mm Hg drop in systolic blood pressure** following the switch.[78] Since 2013, smoking-related deaths and DALYs have fallen sharply: cardiovascular deaths down 19%, COPD deaths down 15%, all-cause deaths down 15% and cancer deaths down 13%.[8]
- **Smoking-related hospital admissions have decreased**: Hospitalisations for smoking-related illnesses such as chronic obstructive pulmonary disease (COPD), stroke and heart disease have fallen – from 446,400 admissions in 2019–20 to 408,700 in 2022–23.[11]
- **Evidence of biomarker reduction:** There is a lower exposure biomarkers in people who vape and a significant decline among youth smoking.[82]

New Zealand halved its smoking rate between 2018 and 2024 alone, directly coinciding with the legal recognition and government promotion of vaping as a less harmful alternative.



- **Quitting by switching**: In the same period, vaping prevalence increased more than fourfold (from 2.6% to 11.1%, 2018–2024).[13] Almost four in five (78%) daily vapers are ex-smokers, demonstrating vaping's strong role as a quitting aid.[14]
- **Reduced smoking-related hospitalisations**: Between 2017 and 2022, COPD-related hospitalisations for adults aged 45 years and over **decreased from 645 per 100,000 to 455 per 100,000, a fall of 29.4%**. [74] Between 2009 and 2021, New Zealand reduced its smoking-related cardiovascular disease death and DALY rate by 20%. New Zealand also saw a 9% reduction in all smoking-related deaths and a 10% reduction in all smoking-related DALYs.[8]
- **Biomarker-based modelling shows:** At population level, there is a projected gain of 195,000 Quality adjusted life years (QALYs).[81]

New Zealand Ministry of Health

Report

The Safer Nicotine Revolution

Global Lessons, Healthier Futures

Executive Summary

Why this matters globally

Low- and middle-income countries (LMICs) bear the brunt of the global tobacco burden, accounting for 80% of all smoking-related deaths.

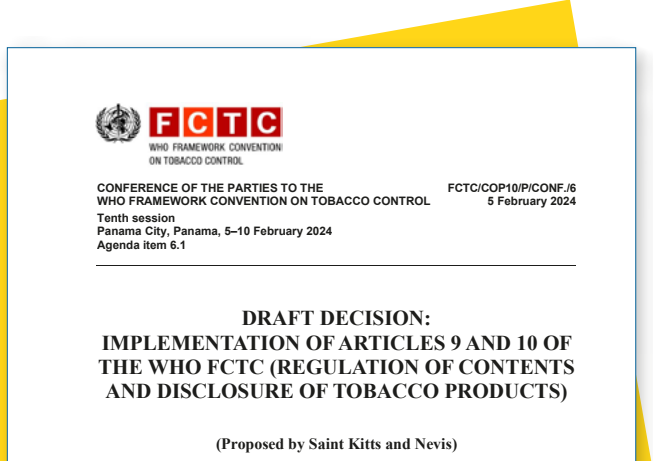
In many of these countries, conventional quitting tools are scarce or unaffordable, leaving millions with few options beyond harmful tobacco. SNAs, if regulated and accessible, can offer a culturally relevant, cost-effective path away from the most dangerous products.

For example, in India and Bangladesh, oral tobacco products such as gutka are widely used — especially among low-income and rural populations — and are a major driver of oral cancer, particularly among women. Substituting these products with regulated, non-combustible alternatives such as oral nicotine pouches could provide a crucial path to reduce harm and healthcare costs in these settings

The policy gap

The Framework Convention on Tobacco Control (FCTC) explicitly includes harm reduction as one of its pillars under Article 1(d), yet this provision is routinely overlooked in global policy discussions. While countries that embrace harm reduction strategies are seeing faster declines in smoking and related disease, World Health Organisation (WHO) and FCTC guidance has not kept pace with the growing scientific and public health evidence.

The result is a widening disconnect between what works on the ground and what is promoted at the global level.



FCTC
WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

CONFERENCE OF THE PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL
Tenth session
Panama City, Panama, 5–10 February 2024
Agenda item 6.1

FCTC/COP10/P/CONF./6
5 February 2024

DRAFT DECISION:
IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC (REGULATION OF CONTENTS AND DISCLOSURE OF TOBACCO PRODUCTS)

(Proposed by Saint Kitts and Nevis)

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A turning point for global health

The world stands at a crossroads. Meetings such as the United Nations High-Level Meeting on the Prevention of Noncommunicable Diseases and Mental Health (UN NCD High-Level Meeting) and the FCTC Eleventh session of the Conference of the Parties (COP11) offer a rare opportunity to align policy with progress. Countries that have integrated SNAs are proving that a smoke-free future is achievable, and that it can be reached faster with the right tools.

This report offers a roadmap for action:

1. **Activate Article 1(d) of the FCTC** by formally including harm reduction in tobacco control plans.
2. **Adopt risk-proportionate regulation** that reflects the major differences in risk between combustible and non-combustible products.
3. **Expand access and affordability** of safer alternatives, especially in LMICs, while protecting against underage access.
4. **Support nicotine pouches** as a particularly promising option for widespread implementation due to their portability, cost-effectiveness and cultural acceptability.
5. **Build global evidence platforms** to track outcomes and support data-driven policymaking.

The choice ahead

The case for SNAs should no longer be a subject for theoretical debate. Countries that integrate SNAs into their policymaking are seeing fewer deaths, healthier populations and real progress toward smoke-free goals.

The challenge now has moved from science to politics. Will global institutions and national governments be willing to rethink outdated approaches and embrace what works?

The success of Sweden, Japan, the UK and New Zealand shows that SNAs are not a niche solution. They are a global opportunity that the world cannot afford to ignore.

Report Terminology and Abbreviations

Abbreviation	Definition
COP11	FCTC Eleventh session of the Conference of the Parties
COPD	chronic obstructive pulmonary disease
DALYs	disability-adjusted life year
EU	European Union
FCTC	Framework Convention on Tobacco Control
HTPs	heated tobacco products
LMICs	low- and middle-income countries
NCDs	non-communicable diseases
NHS	National Health Service
ONPs	Oral nicotine pouches
PHE	Public Health England
SDGs	Sustainable Development Goals
SNAs	safer nicotine alternatives
THR	tobacco harm reduction
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UN NCD High-Level Meeting	United Nations High-Level Meeting on the Prevention of Noncommunicable Diseases and Mental Health
UK	United Kingdom
US	United States
WHO	World Health Organisation

Chapter 1: Tobacco Harm Reduction — A Missing Pillar in Global Tobacco Control

Tobacco harm reduction (THR) refers to strategies and policies that aim to reduce the health risks associated with tobacco use, particularly for individuals who are unable to or who do not want to quit nicotine altogether. Instead of insisting on abstinence as the only acceptable outcome, THR embraces safer nicotine alternatives (SNAs) that pose substantially fewer risks than combustible tobacco. These include vaping products (e-cigarettes), heated tobacco products (HTPs), oral nicotine pouches (ONPs), and snus, all of which deliver nicotine without the vast majority of harmful by-products generated by burning tobacco.

While WHO FCTC tobacco control methods such as smoking bans, taxation, advertising restrictions and health warnings, have led to important reductions in smoking prevalence in many countries, they are no longer enough. Global tobacco control, as currently framed by the World Health Organisation (WHO) and Framework Convention on Tobacco Control (FCTC), is falling short of its own stated goals. It is time to fully activate and integrate the third pillar of tobacco control – harm reduction.

The WHO's FCTC global treaty,[17] which came into force in 2005, remains the world's foundational public health treaty for addressing tobacco-related death and disease. Its primary aim is to reduce the health, social and economic burden caused by tobacco use. Meanwhile, the United Nations Sustainable Development Goals (SDGs) include Target 3.4, which aspires to reduce premature mortality from non-communicable diseases (NCDs), including those caused by smoking, by one-third by 2030.[18]

But despite two decades of efforts, these goals are not on track. Globally, more than 1.1 billion people still smoke, and tobacco remains responsible for more than 7 million deaths annually,[19] the vast majority of which occur in low- and middle-income countries (LMICs). WHO FCTC tobacco control tools are important but insufficient on their own. In many high-smoking-prevalence countries, smoking rates are plateauing or declining far too slowly.

Although often overlooked, the FCTC clearly defines harm reduction as one of its core pillars in Article 1(d) of the treaty's preamble.

> **"Tobacco control means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."**

Yet the implementation of this third pillar has been inconsistent and, at times, outright rejected by global health authorities. The WHO and many national health agencies continue to frame tobacco control largely through the binary lens of "quit or die", sidelining harm reduction as either unproven or a threat to youth. This framing fails to reflect the growing body of independent scientific evidence showing that SNAs can dramatically reduce exposure to toxicants and reduce health risks compared to smoking. Therefore, although harm reduction is embedded in the FCTC's principles, current guidance often interprets tobacco control through a prohibitionist lens, effectively ignoring this crucial third pillar and creating a direct conflict with the treaty's own text.

A defining feature of modern public health is the recognition that risk exists on a continuum. While nicotine is dependence forming, it is not the primary cause of smoking-related diseases; combustion is. Burning tobacco releases thousands of harmful chemicals, including dozens of carcinogens. By eliminating combustion, products such as e-cigarettes, HTPs, snus and nicotine pouches can cut individual health risks by up to 95%, according to multiple independent reviews, including those commissioned by The Office for Health Improvement and Disparities[20] and the Royal College of Physicians.[21]

As a result, relative risk compared to the use of combustible cigarettes – not absolute risk – must be the basis of responsible, ethical communication. Misrepresenting the risks of SNAs or equating them with smoking not only distorts public understanding but actively discourages smokers from switching to significantly safer options. For public health to be credible, its policies and messaging must be scientifically accurate, evidence-based and proportional to the actual risks involved.

Beyond Article 1(d), the FCTC provides other practical mechanisms for incorporating THR into policy.

Articles 9 and 10 deal with product regulation and disclosure of product contents. These provisions can and should be used to develop science-based standards for SNAs, ensuring product quality, toxicant limits, and safety features that protect consumers while encouraging safer substitution.

Article 14 emphasises cessation support. THR strategies can expand cessation options for people who cannot or do not want to quit using nicotine. Offering SNAs through healthcare systems can make quitting smoking more achievable, especially in hard-to-reach populations. The UK is conducting just such a trial with its "Swap to Stop" campaign whereby people who smoke are offered vaping products instead.[22]

Article 4 of the FCTC also commits to gender-responsive policies, and THR products, especially socially considerate options like nicotine pouches, can be crucial for women in contexts where smoking is culturally taboo but harm remains high.

Real-world examples underscore the promise of THR. In Japan, HTPs have rapidly accelerated the decline of cigarette smoking since 2015. [4] Sweden has the lowest smoking-related mortality in Europe, thanks in large part to widespread use of snus and nicotine pouches, both proven to be far less harmful than cigarettes. Sweden is about to become the first "smoke-free" country in Europe, with a smoking rate among its native population already less than 5%.[23]

According to the No Smoke, Less Harm report,[24] Sweden's overall nicotine consumption is on par with the EU average, yet the fundamentally different way that Swedes consume nicotine leads to more positive health outcomes. The Swedes' use of smokeless alternatives such as snus and nicotine pouches avoids the combustion process that produces most tobacco-related toxins. The report concludes that it is not nicotine itself, but the method of delivery, that determines the scale of harm – making Sweden a compelling example of how shifting consumption patterns can improve public health.

In the United Kingdom (UK), government agencies actively support vaping as a smoking cessation tool. More than half of ex-smokers who quit in the past five years (2.7 million) used vape as a "last quit attempt".[25] New Zealand has used a bold regulatory framework to promote vaping as a cessation tool while tightly regulating youth access. This dual-track approach has contributed to a significant decline in smoking prevalence, from 16.4% in 2011/12 to 6.9% in 2023/4.[26] The drop in the numbers of smokers has been particularly successful among Māori populations historically underserved by conventional cessation strategies.

The burden of smoking-related disease is heaviest in LMICs, where health systems are stretched and access to cessation support is often limited. THR offers a cost-effective, scalable and humane solution for these settings. Products such as nicotine pouches and low-cost vaping devices can be deployed with minimal infrastructure and tailored to local contexts.

Yet global bodies such as the WHO continue to discourage or outright condemn these approaches, denying millions of smokers in LMICs the chance to access life-saving alternatives. This represents not only a public health failure but a breach of basic health equity and human rights principles.

Harm reduction is an approach aligned with human rights, rooted in dignity, autonomy and evidence. Just as harm reduction in HIV and drug policy has saved lives, THR offers an ethical pathway to reduce suffering and death. Denying access to safer alternatives, or misinforming the public about their benefits, is not a precautionary measure, it is negligence.

The global community has an obligation to rethink and complete the tobacco control framework envisioned by those who originally created the FCTC. Integrating THR and SNAs into the heart of global policy would unlock enormous public health benefits, especially in populations left behind by current strategies.

Success must be redefined not as abstinence at any cost, but as the reduction of disease, disability and death from tobacco use by any effective, evidence-based means available. In this way, THR should not be regarded as an enemy of tobacco control, but as a vital missing pillar.

Chapter 2: Harm Reduction Potential of Smoke-Free Categories

This report examines the efficacy of smoke-free nicotine products in achieving the harm reduction formally stipulated in Article 1(d) of the FCTC.

The current smoke-free product landscape encompasses three primary categories, each offering distinct pathways to reduce the devastating health impacts of combustible tobacco use.

Electronic cigarettes (vapes), HTPs and ONPs represent three well known and complementary approaches that can collectively address the diverse needs and preferences of the world's one billion smokers.

While each category demonstrates significant harm reduction potential, ONPs emerge as the most promising solution for widespread implementation, particularly in LMICs where the burden of tobacco-related disease is most acute.

Electronic cigarettes

Electronic cigarettes, otherwise known as vapes or electronic nicotine delivery systems (ENDS) have demonstrated substantial harm reduction potential by delivering nicotine without combustion, eliminating the tar and most carcinogens associated with traditional cigarettes.

Public Health England's (PHE's) landmark assessment concluded that vaping is at least 95% less harmful than smoking,[27] while population-level studies from the UK show accelerated quit rates among smokers who switch to vaping.[28]

The behavioural mimicry of smoking provides psychological comfort during transition, making e-cigarettes particularly effective for heavily dependent smokers.

However, regulatory complexity, variable product quality and public perception challenges have limited their global adoption.

Heated tobacco products

HTPs represent a technological bridge between conventional cigarettes and complete nicotine replacement.

By heating rather than burning tobacco, HTPs eliminate combustion while maintaining tobacco's familiar taste and ritual.

Japan's experience with HTPs, which is analysed in Chapter 3, demonstrates their potential impact: cigarette sales in Japan declined by 52%.

HTPs offer particular advantages for adult smokers who have struggled with complete cessation through conventional methods. The lower risk profile provides a meaningful harm reduction pathway.

However, regulatory uncertainty and higher cost compared to cigarettes limit their accessibility, particularly in LMICs where price sensitivity is paramount.

Oral nicotine pouches

ONPs represent the most transformative category within the THR landscape, offering a tobacco-free, socially considerate and accessible solution that addresses multiple barriers to cessation.

Sweden's remarkable public health achievement – putting it on the cusp of becoming the first country to reach official 'smoke-free' status – demonstrates the profound potential of ONPs.

This success story, built on decades of snus use and now enhanced by modern nicotine pouches, provides compelling evidence for their integration into global tobacco control strategies.

Unlike other THR products, pouches require no heating or vapour generation, making them suitable for use in all environments.

This characteristic is particularly crucial for women, who often face greater social stigma around visible tobacco use.

The groundbreaking **Power in a Pouch**[29] report reveals that, since their introduction in Sweden in 2016, nicotine pouches have helped to accelerate the decline in smoking rates for both genders, with an almost 200% rise in the quit rate among women.[30]

Furthermore, in comprehensive nationwide surveys of ex-smokers, they outperformed all other quit aids, with both men and women ranking nicotine pouches as the most effective method.[29]

The report's comprehensive analysis of Swedish women's experiences demonstrates how gender-sensitive policies recognising the socially considerate nature of pouches can enhance cessation outcomes among wom-

en, who represent a critical yet underserved population in tobacco control efforts.

The simplicity of pouches commend them as a strong option for those seeking to quit smoking. This simplicity translates to lower costs and easier distribution networks, particularly relevant for LMICs where infrastructure limitations and economic constraints impede access to more complex cessation aids.

Furthermore, ONPs hold particular promise for LMICs with established cultural traditions of oral stimulant use.

Throughout Asia and Africa, populations have long histories of consuming substances such as betel nut, khat and various traditional tobacco preparations through oral routes. This cultural familiarity with oral delivery methods creates a salient pathway for introducing modern nicotine pouches as safer alternatives. Additionally, ONP's require no electricity for charging, have a long shelf-life and do not depend on complex supply chains for liquids or devices. Their simplicity and low cost-per-use make them uniquely suited for adoption in remote or resource-poor settings in LMICs.

The tactful, spit-free nature of contemporary pouches addresses hygiene and social acceptability concerns while building on existing behavioral patterns, making them more readily adoptable than completely novel delivery systems.

From a regulatory perspective, pouches offer the clearest path forward. Their tobacco-free composition eliminates many regulatory complexities associated with tobacco-containing products, while their socially considerate nature addresses public use concerns.

Moreover, the absence of secondhand exposure removes a significant policy barrier, enabling broader implementation in public spaces and workplaces.

...since their introduction in Sweden in 2016, nicotine pouches have helped to accelerate the decline in smoking rates for both genders, with an almost 200% rise in the quit rate among women.

Chapter 3: Evidence of Impact – Country Case Studies in Tobacco Harm Reduction

Japan's Transformation with Heated Tobacco Products

Over the past decade, Japan has undergone a remarkable transformation in its tobacco market, driven largely by the introduction and widespread adoption of HTPs. Since their initial launch in 2014-2015, HTPs have gained substantial market share, coinciding with a significant decline in cigarette sales and a reduction in smoking prevalence. This chapter highlights the positive public health signals associated with this shift, considers current health outcome data, and recommends ongoing surveillance to assess the long-term benefits of THR.

Background and market transition

Japan is considered a unique case study in THR due to its rapid consumer shift from combustible cigarettes to alternative nicotine delivery systems, particularly HTPs. Unlike nicotine-containing e-cigarettes (or vapes), which are heavily restricted in Japan, HTPs have been embraced by both consumers and the market. Since the introduction of HTPs, cigarette sales in Japan declined by an estimated 52%.[4][31] This dramatic reduction in combustible tobacco use has occurred alongside a consistent rise in HTP prevalence.

Independent, nationally representative data from the 2023 JASTIS survey[3] show that **12.4% of Japanese adults currently use HTPs**. Cigarette smoking prevalence stood at **18.9%** in the same survey, reflecting a substantial consumer shift away from combustibles. These figures demonstrate that millions of Japanese adults have transitioned entirely away from cigarettes to HTPs – a shift that aligns with broader declines in cigarette sales and prevalence.

Split smoking vs HTP use [32][33]

	2019		2022	
	Male	Female	Male	Female
Smoking	19.5%	5.5%	15.5%↓	3.9%↓
HTP use	5.5%	1.6%	7.5%↑	2.4%↑
Other tobacco	0.3%	0.2%	0.3%↓	0.1%↓

Indicators of positive change

- **Cigarette sales decline:** Annual sales of cigarette sticks fell approximately by 94.2 billion units from 2015 to 2023, representing a 52% reduction.[4][31]
- **Behavioral substitution:** Surveys and modeling suggest that many smokers have completely or partially replaced cigarette use with HTPs.[34]
- **Potential lives saved**: A 2024 modelling study by Yach et al estimated that the adoption of HTPs may have already contributed to significant premature deaths being avoided in Japan through reduced smoking-related morbidity and mortality. The authors estimated that 2.04 million lives could be saved by 2060, if tobacco harm reduction methods and early diagnosis of smoking-related disease were to be added to conventional tobacco control. While causality has not been definitively proven, these findings underscore the potential of HTPs to deliver measurable public health benefits over time.

Why health outcomes will take time

These data points are likely only to improve as the impact of HTP adoption unfurls. For example, it can take years for smoking-related illnesses to develop and thus there can be a lag in behavioural change manifesting in better health outcomes. Age is also a factor, with uptake being more common among younger adults so that the disease burden will only become more apparent as the years go by.[36]

Japan's tobacco landscape has shifted dramatically over the past decade, with HTPs playing a central role in the decline of cigarette consumption. While it is too early to observe definitive health benefits at the population level, the trends are promising. With careful monitoring and evidence-based policy, Japan could serve as a leader for THR strategies worldwide.

Sweden's Experience with Snus and Nicotine Pouches

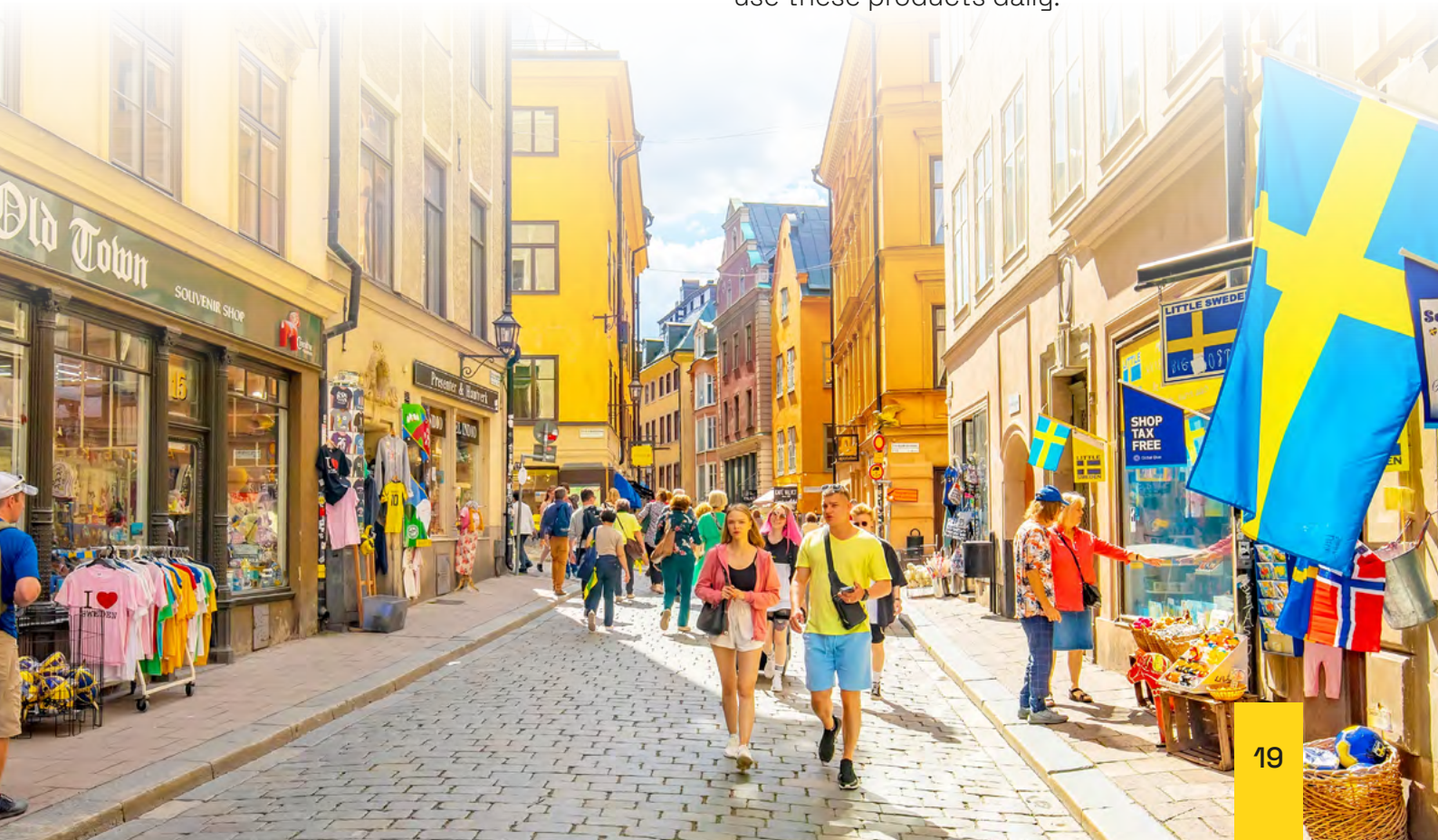
Sweden is a leading example of an effective and integrated THR strategy. In parallel with the WHO FCTC recommendations, Sweden has endorsed the use of lower-risk alternatives such as snus and tobacco pouches. As a result, the country reports the lowest smoking prevalence in the European Union (EU) – 5.3% overall, with male smoking at just 4.9%.[6] It is therefore on the brink of achieving the global benchmark for official "smoke-free" status – defined as a smoking rate of 5% or lower – well before the 2040 EU target.

In a landmark development, the Swedish Parliament formally adopted THR into national policy in late 2024. Consequently, the primary objective of the national tobacco strategy shifted from simply reducing tobacco *use* to reducing the medical and societal *harms* associated with tobacco.[37] This makes Sweden the first country to formally enshrine harm reduction into government policy, marking a significant acknowledgment of the evidence base and effectiveness of THR at the state level.

Background and market transition

The transition away from combustible tobacco began in 1973 with the introduction of snus, a smokeless tobacco product that gained significant popularity, particularly among Swedish men. Empirical studies have demonstrated that snus use increases the probability of smoking cessation and lowers the risk of progressing to daily smoking.[38] As of 2024, 15.7% of the general population and 21.6% of men use smokeless products daily. Retrospective, hypothetical calculations have suggested that the smoking-related mortality among males in 2021 would be 1.7 times higher if not for snus. Similarly, snus is calculated to save around 3,000 per year.[76]

Complementing snus, vaping and tobacco-free nicotine pouches were introduced in 2015 and 2016, respectively. Nicotine pouches – entirely free of tobacco – have witnessed rapid uptake, particularly among women. Currently, 5.0% of the general population and 5.4% of women use these products daily.



Indicators of positive change

- **Smoking prevalence:** In just 12 years, Sweden has reduced its smoking prevalence by 54% and now stands at the threshold of smoke-free status (5.3%). The target has already been achieved among men (4.9%) and Swedish-born individuals (4.5%). The smoking rate of Swedish citizens born elsewhere in Europe is 7.8% — less than one third of the EU average, and further evidence of Sweden's effective harm reduction environment.[6]

- **Cessation aid:** Before the introduction of nicotine pouches, research had already confirmed snus as a successful aid to quit smoking: 76.3% of male smokers surveyed who started using snus had completely quit smoking. It was also found that snus "yielded higher success rates than nicotine replacement therapy and other alternatives."[39]

  However, according to Sentio, snus was not as popular among female smokers, who often cited lack of appeal, practicality, or stigma as barriers to switching.[29] Before the arrival of pouches, cigarette consumption among Swedish women declined by just 16% between 2009 and 2015, compared to 27% among men. But from 2016 onward, the trend flipped: the female quit rate actually accelerated, outpacing that of the men.

  Today, the smoking rate among Swedish women has dropped to 5.7%, down from 11.2% in 2015 – a remarkable 49% decline.[30] The widespread adoption of pouches has helped to reverse long-standing disparities, offering a quit method that better aligns with women's daily routines, preferences and concerns.

  The efficacy of pouches is not restricted solely to women, with both genders now ranking them as their preferred quitting aid.[29]

- **Tobacco-related disease and death:** Studies have found that snus has only 5% of the harm of cigarettes and at least 90-95% less smoking related mortality.[40] It is also considered to cause minimal to no reduction in life expectancy,[40] with no established snus-related premature death.[41] Additionally, smokers who switch to snus have a combined relative risk of 0.55 for ischemic heart disease (IHD) or acute myocardial infraction when compared to current smokers. This means that switchers had a 45% lower risk of IHD or heart attack.[75] Therefore, switching to snus has clear health benefits. Sweden's tobacco-related DALYs and death rates are consistently lower than the EU average, with 44% lower male tobacco-related deaths and 61% lower male lung cancer deaths than the rest of the EU.[8] Sweden has also reduced its smoking-related cardiovascular disease death and DALY rate by 22% since 2015 and its all causes death and DALY rate by 14%.[8]

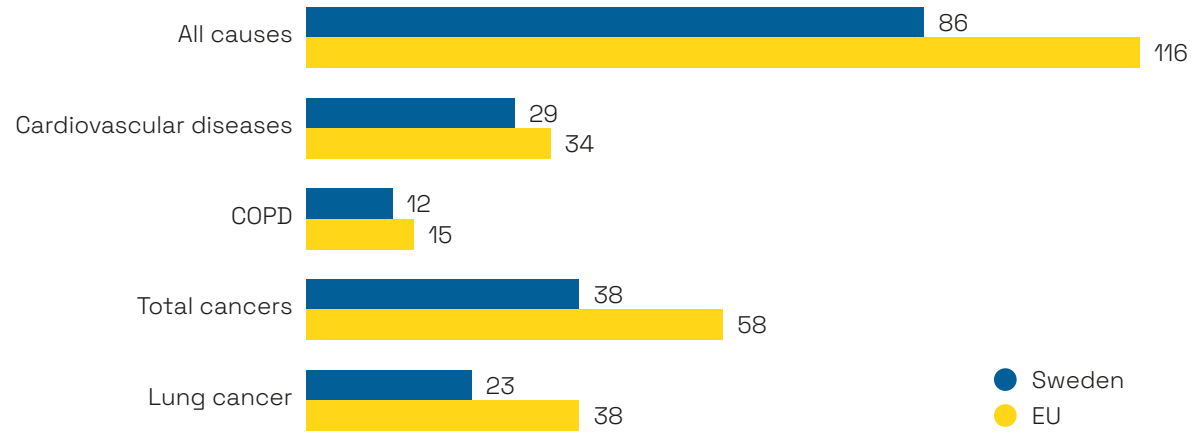
- **Risk-proportionate taxation:** With a parliamentary decision to tax tobacco and nicotine products on the basis of their risk,[42] the excise rates of nicotine pouches were made only 8% that of cigarettes in 2023. This makes SNAs more affordable, adding another benefit to switching.

- **Consumer preference:** A factor in publicly promoting snus as an alternative to smoking has always been its social subtlety and the absence of smoke that might bother others. These factors, alongside others, have also become key benefits for nicotine pouches – especially among women. A recent survey found that nicotine pouches are preferred for their subtlety, sustainability, accessibility and social convenience.[29] One

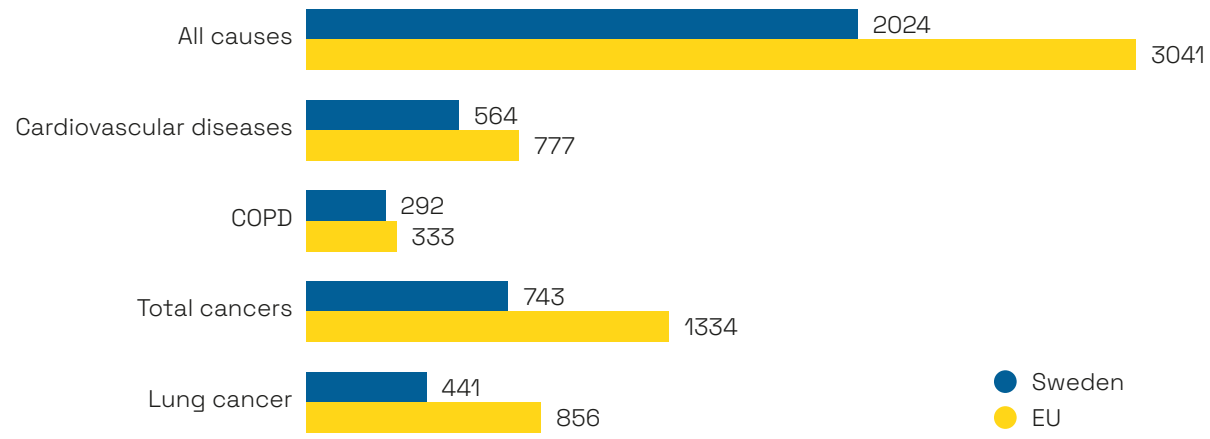
participant says, "It doesn't smell, it doesn't show, and you don't have to go outside or bother anyone."[29]

- **Delivery versus consumption:** The use of alternative products in Sweden also proves an interesting point about total nicotine consumption versus method of delivery. While smoking rates in Sweden have dropped significantly, the nation's total nicotine consumption levels remain largely the same. Despite this, Sweden has experienced all the benefits associated with a lower smoking rate. Sweden is a real-world laboratory demonstration that it is the delivery mechanism, not nicotine itself, that causes the vast majority of harm. For example, with nicotine consumption levels similar to the EU average, Sweden's smoking-related disease rates for men are dramatically lower, proving that when smoke is removed from the equation, harm plummets.[29]

Tobacco-related deaths (2021) (per 100,000)



Tobacco-related DALYs (2021) (per 100,000)



United Kingdom: Vaping Reduces National Health Service Burden

Smoking remains the leading cause of preventable death and disease in the UK. In 2021, tobacco caused an estimated 75,800 deaths, accounting for around 11% of all deaths from all causes, and 37,700 cancer deaths, representing a fifth of all cancer deaths.[43]

Smoking prevalence and product use trends

- **Smoking prevalence**

  Smoking prevalence in the UK has substantially declined over the past decade. In 2023, 11.9% of adults aged 18 years and over were current smokers, the lowest recorded rate since data collection began in 2011. This represents a decrease from approximately 20.2% in 2011, reflecting a sustained drop of 8.3 percentage points. This reduction coincides with the growing popularity of alternatives such as e-cigarettes.[9] The smoking prevalence gap between men and women has narrowed, with men experiencing a more substantial reduction in smoking rates. However, women's smoking rates have also steadily decreased. In 2023, 11.1% of women were current smokers compared to 12.6% of men.[9]

- **E-cigarette / vape adoption and smoking cessation**

  E-cigarettes (or vapes), have become a pivotal tool in the UK's efforts to reduce smoking rates. As of 2025, approximately 5.5 million adults in Great Britain use e-cigarettes, with a significant proportion being former smokers. Notably, about 55% of current vapers have successfully quit smoking.[84] A study calculated that vaping is responsible for an adult smoking prevalence reduction of 20.2% in males and 20.4% in females.[77]

  Smokers who use e-cigarettes to quit, report reduced cravings, lower relapse rates, and improved respiratory function compared to those relying solely on traditional nicotine replacement therapies.[44]

  Furthermore, a 2025 analysis of the Smoking Toolkit Study published in JAMA Network Open[45] found that among participants who used an e-cigarette in their quit attempt and quit successfully, 84.8% continued to use an e-cigarette at follow-up.

Impact of E-Cigarettes on public health

The widespread adoption of e-cigarettes in the UK has been accompanied by measurable public health benefits. E-cigarettes are consistently recognised as a significantly less harmful alternative to smoking. The UK Government and its health agencies continue to support the 2015 PHE conclusion that vaping is at least 95% less harmful than smoking.[20] A 2025 Cochrane review concluded that e-cigarettes are more effective than nicotine replacement therapies in helping smokers quit.[46] Smoking causes more than 75,000 deaths annually, with tobacco responsible for around one in five cancer deaths in the UK. Encouragingly, mortality from tobacco-linked cancers has shown a steady decline in recent years, reflecting the impact of reduced smoking prevalence and improved early detection and treatment.[43]

A study projected 166,000 fewer smoking-attributable deaths from 2012-2052 due to vaping.[77] Research indicates that switching from smoking to vaping can lead to significant

improvements in cardiovascular health, including enhanced vascular function, reduced arterial stiffness, and better exercise tolerance within months.[47] Another study also found 'significant improvement within one month of switching' from tobacco cigarettes to electronic cigarettes, particularly among women. It reported a -2 mm Hg drop in systolic blood pressure following the switch.[78] Although long-term data on health gains are still evolving, early trends are encouraging.

Smoking-attributable admissions peaked at 446,400 in 2019–20 and fell to 408,700 by 2022–23.[11] Since 2013, the United Kingdom has had significant reductions in smoking-related deaths and DALYs: 19% less cardiovascular disease death, 15% less COPD deaths, 15% fewer all-causes deaths and 13% total cancer deaths. Similarly, the United Kingdom has 18% less cardiovascular disease DALY, 17% less lung cancer DAY, 15% less total cancer DALY and 13% less all causes DALY.[8]

Other references

Title / Source	Date	Summary of Key Findings
NHS England – Smoking-related Hospital Admissions Statistics	Dec 2023	Smoking-attributable hospital admissions fell from 446,400 (2019–20) to 408,700 (2022–23). Supports reduced hospital burden aligned with smoking prevalence decline.
Full URL:		https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-public-health/2023/part-1-hospital-admissions
NHS Digital – Smoking-related Mortality (Part 2)	Jun 2025	Estimated 74,600 deaths from smoking in 2019, showing a downward trend from 2009. Supports long-term mortality reduction linked to falling smoking rates.
Full URL:		https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-public-health/2023/part-2-mortality
Wandsworth Director of Public Health Report (ADPHR)	May 2025	Estimated annual NHS smoking cost of £1.9 billion and 300,000 projected cancer deaths. Used as a model for NHS burden reduction through harm reduction.
Full URL:		https://www.wandsworth.gov.uk/media/x10jk3kk/adph_report_wandsworth_2025.pdf
ASH / UCL / Imperial – Fiscal Returns to Smoking Decline	Feb 2025	Each 1 percentage point drop in smoking prevalence yields £690 million in public finance benefits, including healthcare savings.
Full URL:		https://ash.org.uk/media-centre/news/press-releases/new-analysis-shows-spending-to-reduce-smoking-is-a-good-deal-for-the-chancellor
LSE & Allender Research – Direct NHS Smoking Costs	2010 (historical)	Historic NHS costs from smoking estimated between £2.7 billion and £5.2 billion annually. Useful for comparison with current trends and projected savings.
Full URL:		https://eprints.lse.ac.uk/35188/1/Boyle_Estimating_cost_smoking_2010.pdf

New Zealand: A Vaping-Driven Cessation Success

New Zealand is also well on its way to becoming smoke-free with the help of harm reduction. The government-endorsed promotion of vapes as a quitting tool has helped to halve smoking rates in just five years and they now stand at s 6.9%.[13]

Background and market transition

In response to its historically high smoking rates, New Zealand passed the Smokefree Environments and Regulated Products Act as early as 1990.[49] This was followed by a complete ban on indoor smoking in public workplaces in 2004. However, these measures did not achieve the significant reductions in smoking required and more was needed to make a lasting change.

Although e-cigarettes (or vapes) were introduced to the New Zealand market in 2009 it took several years of peer-to-peer communications before vaping attracted public health attention. Responding to the increased influence of vapes and utilising an evidence-based approach, the government passed the Smoke-free Environments and Regulated Products (Vaping) Amendment Act in 2020, which recognised vaping. Significantly, the act stated an intention , "to support smokers to switch to regulated products that are significantly less harmful than smoking".[50] This open and legal recognition of vaping as a harm reduction tool was accompanied by a government-led campaign known as **Vape To Quit Strong**.[16] During the same initiative, the government also released a 2019 website to provide accurate information about vaping.[51]

Indicators of positive change

- **Smoking prevalence:** The introduction of vapes in New Zealand has been accompanied by a strong drop in smoking rates among adults (15+) – from 16.4% in 2011/12 to 6.9% in 2023/24.[14] With vaping becoming more socially acceptable as a switch and cessation method through laws and campaigns, daily and current smoking rates dropped by almost 50% between 2018 and 2024.[52] At the same time, vaping increased from 2.6% to 11.1%. Within the Māori population, smoking prevalence has dropped from 37.7% in 2011/12 to 14.7% in 2023/24, while the Pacific peoples saw a drop from 22.6% to 12.3% in the same timeframe.[13]

- **Cessation aid:** In 2021/22, 78% of daily vapers were ex-smokers or dual users – proving its effectiveness as a quitting aid.[14] Notably, the New Zealand Public Health Communication Centre states that "the most plausible explanations for the observed changes in smoking prevalence… [include] growing use of [vapour products] resulting in increased quitting smoking among people who smoke and/ or reduced uptake if young people substitute vaping for smoking".[52]

- **Tobacco-related death:** A reduced smoking rate also has a strong impact on New Zealand's smoking-related deaths. In 2019, New Zealand had 40% fewer smoking-related deaths than the EU – as well as 43% lower smoking-related lung cancer deaths and 40% lower smoking-related cardiovascular deaths.[15] These figures only go up when looking at male smoking-related deaths. When compared to the US, New Zealand has 36% lower total smoking-related deaths, 33% lower smoking-related lung cancer deaths and 35% lower smoking-related cardiovascular deaths.[15]

Between 2017 and 2022, COPD-related hospitalisations for adults aged 45 years and over decreased from 645 per 100,000 to 455 per 100,000, a fall of 29.4%.[74] Between 2009 and 2021, New Zealand reduced its smoking-related cardiovascular disease death and DALY rate by 20%. The country saw a 9% reduction in all smoking-related deaths and a 10% reduction in all smoking-related DALYs.[8]

Based on biomarker modelling, New Zealand also gained 195,000 quality adjusted life years at a population level.[81]

- **Accessibility, acceptability, affordability:** Through its evidence-based policy approach and the mass media campaign that followed, New Zealand understands that vaping improves health outcomes for those seeking to quit smoking and to continue to use nicotine.

  By only applying a general sales tax (GST) to the sale of vapes, New Zealand understands the importance of communicating reduced harm through its fiscal treatment — something which is vitally important if safer alternatives are to be seen as affordable. New Zealand also permits a variety of strengths and flavours which enhances their acceptability as alternatives to smoking for consumers.

- **In contrast with Australia:** Unlike New Zealand, Australia made e-cigarettes available only by prescription in 2021.[53] This decision has worried experts as it does not take a risk-proportionate approach, removes access to options for many smokers and opens avenues for the black market to thrive – creating more problems than solutions.[54] Estimates share that 90% of vapers in Australia access their products through the unregulated black market.[55] While Australia used to have a lower smoking rate than New Zealand, this changed in the past few years. In 2022-23, Australia had an adult smoking rate of 8.3%.[56] Changing their stance on harm reduction could prove to be an important step towards a lower smoking rate in Australia.

Chapter 4: Tobacco Harm Reduction in Low- and Middle-Income Countries – A Missed Opportunity for Equitable Impact

The global tobacco epidemic claims more than 7 million lives each year,[19] and 80% of these deaths occur in LMICs,[57] where health systems are often overstretched and prevention infrastructure is limited. In these settings, the WHO FCTC provides an essential roadmap for action. Article 4 of the FCTC affirms the guiding principles of tobacco control, including the right to protect all people from tobacco-related harm and the importance of evidence-based, participatory and inclusive strategies that respect national circumstances.[58]

THR offers a pragmatic and life-saving approach that is especially appropriate for LMICs. To be effective in these contexts, however, THR must reflect three essential criteria: affordability, access and acceptance. Furthermore, to align with the equity principles outlined in Article 4 of the FCTC, THR must be implemented through gender-sensitive policies that address the distinct patterns and drivers of tobacco use among women and girls.[58][59]

Culturally and economically relevant harm reduction

In many LMICs, conventional cessation tools are either unavailable or unaffordable to large portions of the population. In these contexts, SNAs, if appropriately regulated and accessible, can provide people who use tobacco with a safer pathway to reduced harm or cessation. But for THR to gain traction in LMICs, it must not only be cost-effective but also culturally familiar. This means offering alternatives that reflect local norms and consumption patterns.

Take India and Bangladesh as illustrative examples. In both countries, the dominant form of tobacco use is smokeless oral tobacco, often produced and sold informally and used disproportionately by low-income and rural populations. Critically, these products are linked to extremely high rates of oral cancer, which contributes significantly to disability and early mortality, especially among women who are often hidden from tobacco control narratives.[60][61][62]

Substituting these harmful products with regulated, non-combustible nicotine pouches or low-nitrosamine products (decreasing the likelihood of exposure to carcinogens) such as Swedish snus provides a realistic and evidence-based opportunity to:

- Reduce the oral cancer burden by eliminating exposure to the carcinogens found in traditional smokeless tobacco.[63]
- Lower healthcare costs associated with late-stage cancer treatment, surgery and palliative care, especially important for public health systems with constrained budgets.[61]
- Improve product safety and consumer protection through regulation consistent with FCTC Articles 9 and 10, which call for oversight of product contents and disclosure of ingredients.[64]

Why gender-sensitive THR policies matter

The FCTC, through Article 4.2(d), recognises the need for comprehensive multisectoral measures that take into account gender-specific risks and responses.[58] This is especially urgent in LMICs, where women and girls often use tobacco in ways that are under-recognised, such as through smokeless products, and face greater stigma in accessing support.[59] Existing efforts on this topic are often limited in scope and rare in practice.[65] THR provides a socially considerate and acceptable option for these populations, but only if policies are designed to reach them.

Gender-sensitive THR approaches should include:

- Tailored education and messaging that reflect women's lived experiences with tobacco.
- Ensuring safe, stigma-free access points to safer nicotine alternatives, including through community health networks.
- Addressing gendered marketing, price barriers and structural inequalities in product availability.

THR, anchored in affordability, access, acceptance and gender equity, represents a vital but underused strategy for LMICs. Aligning THR with Article 4 of the FCTC ensures it complements rather than contradicts global tobacco control efforts. By recognising the social, economic and gendered dimensions of tobacco use in LMICs, policymakers can craft context-appropriate, inclusive harm reduction policies that protect the most vulnerable, particularly women, and help drive down the global burden of tobacco-related disease.

In a world where the vast majority of tobacco deaths occur in LMICs, THR is not a luxury, it is a necessity and it is time for global policy to reflect this reality.

Chapter 5: Implications for the UN, WHO and COP

Tobacco harm reduction: A missing link in global non-communicable disease strategy

The global fight against NCDs took centre stage at the United Nations General Assembly High-Level Meeting on Universal Health Coverage (UHC) on 25 September 2024.[66] The WHO describes an NCD as a chronic disease that is not passed from person to person such as "cardiovascular diseases (such as heart attacks and stroke), cancers, chronic respiratory diseases and diabetes".[67] Governments from around the world recommitted to reducing premature mortality from NCDs by one-third by 2030 under Sustainable Development Goal (SDG) 3.4.[18] Among the central risk factors targeted was tobacco use, which remains a leading cause of preventable death globally.

But while the declaration highlighted the importance of equitable access to cessation services, particularly for LMICs, it stopped short of acknowledging one of the most promising and scalable solutions available today: THR. As the global public health community moves toward COP11 and a reassessment of frameworks like the WHO FCTC, this omission must be addressed.

In resource-constrained settings where health systems cannot manage behavioural cessation support or pharmaceutical treatments, THR products offer a low-cost, easily accessible solution. Ignoring these tools not only undermines UHC ambitions but risks perpetuating health inequalities the UN declaration sought to address.

The September declaration rightly called for the integration of NCD services into UHC packages and emphasised primary health care as a platform to deliver cessation support equitably. This is precisely where THR can play a transformative role.

The WHO has long promoted its "best buys", which are described as cost-effective interventions for NCD control.[68] Yet, notably absent from this list are safer nicotine products that are supported by a growing body of evidence and endorsed by regulatory agencies such as the United States Food and Drug Administration through premarket tobacco product applications[69] and modified risk tobacco product[70] authorisations.

It is time for the WHO to expand its best buys to reflect the full spectrum of cessation and harm reduction tools.

The WHO can save lives by studying the evidence

The WHO FCTC was built on a bold promise: to reduce the global burden of tobacco-related death and disease. Yet nearly two decades later and despite other novel measures such as the MPOWER model, over a billion people still smoke – and millions will die preventable deaths unless we expand the toolbox. Harm reduction, though often dismissed as an "industry construct", is already saving lives in countries such as Sweden, the UK, Japan and New Zealand. The FCTC itself contains the mandate to explore these strategies, if only the WHO were to embrace its leadership role as the premier technical global health agency. It does not explicitly have to deny or formally endorse harm reduction in tobacco control (although it does so in HIV, Covid, alcohol and drug-related disease, road traffic accidents) – it merely has to lead the way in studying whether harm reduction can improve health outcomes.

Article 1(d) of the FCTC defines tobacco control as a range of strategies including harm reduction. Articles 9 and 10 empower regulators to scrutinise and shape the contents of tobacco products – tools that could be used to encourage innovation toward safer alternatives. Article 12 calls for public education, and Article 14 urges Parties to offer cessation support. These provisions do not endorse any specific product, but they do create space to ask the right questions: What if some nicotine products carry dramatically lower risks? What if they help smokers quit when nothing else works?

Studying harm reduction is not capitulation to industry. It is a commitment to science, equity and pragmatism. During COP10, St Kitts and Nevis showed great leadership in suggesting the establishment of a "THR working group" (see Annex). A WHO working group on harm reduction would not be a policy shift, but a fact-finding mission grounded in the FCTC's own principles. It would allow Parties to examine the evidence, assess risks and benefits, and consider how regulated alternatives might fit into national strategies. Ignoring this opportunity does not protect public health. It delays progress and costs lives.

The FCTC was never meant to be static. It was designed to evolve with the evidence. If we truly believe in saving lives, then we must be willing to study every tool that might help, including harm reduction.

We believe that this type of bold leadership by the WHO will help to:

1. Elevate independent science

- For example, the Cochrane Living Systematic Review, which shows that nicotine e-cigarettes are more effective than traditional nicotine replacement therapies for smoking cessation.[71]
- Existing studies, driven by member states embracing and applying harm reduction as a public health tool, have strengthened tobacco control (e.g. the UK's NHS, PHE, and the New Zealand Ministry of Health).

2. Separate products from producers

- The origin of a product does not determine its public health value. For example, condoms were commercialised by private companies but are universally accepted as harm reduction. Covid vaccines developed by the private sector have helped to reduce disease impact and save lives.
- Strong regulation of harm reduction products would prevent industry interference while still allowing access to safer alternatives.

3. Centre the consumer

- Shift focus from industry motives to public health and consumer outcomes. There are already 130 million smokers who have successfully transitioned to less harmful products
- Respect the circumstances of LMICs, where access to cessation services is limited and harm reduction offers a pragmatic solution

4. Avoid policy contradictions

- The WHO's refusal to engage with harm reduction may unintentionally perpetuate smoking-related deaths, especially in places where quitting is not feasible.
- Precautionary bans ignore the principle of proportionality and risk-benefit analysis in public health.
- WHO has been a global champion for harm reduction in areas such as HIV / AIDS (e.g. needle exchange programmes) and drug use. Its reticence to apply the same life-saving principles to tobacco control — the world's leading cause of preventable death — is a profound and damaging inconsistency. The current selective application of harm reduction undermines the organisation's credibility in tobacco control and costs lives.

5. Facilitate balanced dialogue

- Establishing an "expert group" of cherry-picked experts will not adequately facilitate a balanced dialogue that a neutral, science-based working group would offer. This could include independent researchers, civil society and regulators – and crucially, no industry representatives.
- Ultimately, this is a fact-finding mission, not a policy endorsement of harm reduction. If the evidence shows that harm reduction complements tobacco control, it should be embraced. If not, then at least there are clear non-ideological grounds to reject the improved health outcomes in member states such as the UK, Japan, Sweden, New Zealand and the USA.

The key is to reclaim harm reduction as a public health strategy, not a corporate one. Regulation and innovation can coexist. Ignoring safer alternatives risks leaving millions behind.

COP11 and the FCTC: Bringing THR into the treaty framework

As the FCTC Conference of the Parties (COP11) approaches, there is an opportunity, and indeed a responsibility, for participating nations to realign the treaty with its original purpose, which was reducing the global burden of tobacco-related disease and death.

The FCTC must evolve. Its current posture towards innovation is outdated, risk-averse and, arguably, unscientific. Instead, COP11 should focus on provisions of the treaty that need updating to incorporate THR. For example, Article 1(d) of the FCTC preamble promotes harm reduction strategies as part of tobacco control. This must be more than symbolic, it should guide actual policy. Sadly, it is largely ignored.

Article 4 (gender equity) requires policymakers to consider gender-differentiated impacts. THR offers particular benefits for women in LMICs,[29] where smoking stigma may prevent access to cessation support.

Articles 9 and 10 (product regulation) should guide the standardisation and quality control of safer nicotine alternatives, not ban or marginalise them, as has been the general direction in recent meetings.

Lastly, Article 14 calls for support for smoking cessation, which should explicitly include lower-risk alternatives that have demonstrated effectiveness in helping smokers quit.

Countries like Japan and Sweden offer compelling evidence for THR strategies. Japan's cigarette sales have dropped by half since 2016 due to the uptake of HTPs, with no corresponding increase in youth smoking.[72] Sweden can claim to have become the first smoke-free EU country, driven by widespread snus and pouch use.[23]

These are not coincidences. They are the result of regulatory environments that allow safer products to replace more harmful ones. Instead of sidelining these examples, COP11 and the WHO should elevate them as models for replication, particularly in LMICs.

The tools to accelerate smoking decline are in our hands. If the global community is serious about saving lives, it must overcome political inertia, reject ideological purity and put science first.

**Tobacco harm reduction is not a trick, or a fad.
It is a lifeline.**

Chapter 6: Policy Recommendations

To reduce the global burden of tobacco-related disease and accelerate progress towards the SDGs, particularly SDG 3.4 (reducing premature mortality from NCDs), policymakers must integrate harm reduction strategies into national and international frameworks.

The evidence presented throughout this report demonstrates that SNAs (SNAs) represent a transformative opportunity to achieve the WHO's tobacco control objectives while respecting individual choice and addressing the diverse needs of the world's one billion smokers.

Below are evidence-based, actionable policy recommendations for consideration by the UN, the WHO, COP11 negotiators and national health ministries.

1. Integrate harm reduction into global and national tobacco control strategies

The FCTC already contains the foundation for harm reduction through Article 1(d), which defines tobacco control as including "a range of supply, demand and harm reduction strategies". This provision should be activated and operationalised at both international and national levels. National governments should amend their tobacco control laws to explicitly include SNAs as part of evidence-based cessation pathways, moving beyond the current narrow focus on abstinence-only approaches.

The WHO and Parties to the FCTC must urgently activate Article 1(d) by incorporating SNAs into national cessation strategies as outlined in Article 14. This integration should be accompanied by support for developing appropriate regulation and standards for non-combustible nicotine products under Articles 9 and 10.

The continued marginalisation of harm reduction within FCTC implementation represents a missed opportunity to accelerate progress toward tobacco control objectives, particularly in LMICs where traditional cessation methods have proven insufficient.

Countries such as Sweden, which is on the brink of reaching smoke-free status through harm reduction approaches, demonstrate that FCTC objectives can be met more effectively when the full spectrum of tobacco control strategies is employed.

The international community must learn from these successes rather than dismissing them due to ideological opposition to harm reduction.

2. Ensure regulatory proportionality based on risk

The principle of risk-proportionate regulation must form the cornerstone of modern tobacco control policy. This approach recognises that not all nicotine products pose equivalent risks and that regulatory frameworks should reflect these differences.

Combustible products, which cause virtually all tobacco-related disease and death, should be regulated more restrictively than non-combustibles, which eliminate the primary source of harm through the absence of combustion.

Regulatory authorities should develop separate regulatory tracks for vaping products, HTPs and ONPs, recognising their distinct risk profiles and user needs.

This differentiated approach enables appropriate oversight while avoiding the regulatory capture that occurs when all products are treated identically. The current tendency toward blanket bans or excessive restrictions on low-risk products undermines public health by blocking effective off-ramps from smoking or pushing consumers back to smoking and stifling innovation in safer alternatives.

Japan's experience with HTPs and pragmatic approach to vaping regulation in the UK and New Zealand demonstrate that proportionate regulation can achieve population-level health improvements while maintaining appropriate safeguards.

Policymakers must resist the temptation to apply precautionary principles that effectively preserve the status quo of combustible tobacco use, ironically supporting the continued trade in cigarettes.

3. Build access and affordability, especially in LMICs

The global tobacco epidemic disproportionately affects LMICs, where 80% of smokers reside and where conventional cessation services are often inadequate or inaccessible. Addressing this disparity requires deliberate policy interventions to ensure that SNAs are accessible and affordable to those who need them most.

Governments should implement tax incentives for low-risk nicotine products, creating price differentials that encourage substitution away from combustible tobacco. Perversely, current taxation policies often make safer alternatives more expensive than cigarettes, undermining their adoption. Unnecessary barriers to importation, distribution and prescription-free access to SNAs must be removed to ensure availability across diverse settings.

Integration of SNAs into public cessation programmes represents a cost-effective intervention for resource-constrained health systems. Rather than maintaining expensive abstinence-only programmes with limited effectiveness, governments should subsidise safer alternatives and incorporate them into existing health services. This approach requires comprehensive community education initiatives to counter myths and misinformation about vaping and nicotine that often impede adoption.

The oral nicotine pouch model offers particular promise for LMICs due to its simplicity, affordability and cultural acceptability. Policymakers should prioritise this category while building infrastructure for comprehensive THR implementation.

4. Monitor underage use without sacrificing adult access

Concerns about underage uptake of SNAs must be addressed through targeted interventions that preserve adult access while preventing underage use. This balance requires evidence-based policies that focus on the actual drivers of underage adoption rather than implementing broad restrictions that undermine adult cessation efforts.

Enforcement of age restrictions, marketing guidelines and flavour regulation should be based on robust data on underage appeal rather than speculation or moral panic.

Adult access must be preserved through evidence-based guardrails that focus on retail restrictions and underage-specific deterrents. Prohibitionist approaches unsupported by population health data risk increasing overall harm by maintaining higher smoking rates among adults.

The experience of countries with mature markets for SNAs demonstrates that underage use can be effectively managed without sacrificing adult access. Policymakers should learn from these examples rather than implementing restrictive policies that may inadvertently increase harm.

5. Protect and promote country-level success stories at COP11

The upcoming COP11 negotiations represent a critical opportunity to showcase and defend real-world success stories in tobacco harm reduction. The achievements of Japan with HTPs, Sweden with ONPs and the UK and New Zealand with vapes must be presented as best-practice models aligned with public health objectives, not as aberrations to be discouraged.

These success stories demonstrate reduced hospitalisations, lower cancer rates and cardiovascular disease burden and accelerated progress toward smoke-free objectives.

The international community must promote data-sharing and replication of these approaches across LMICs rather than dismissing them due to ideological opposition to harm reduction.

COP11 negotiators should push for establishment of a new THR Working Group under the FCTC to review emerging science and draft guidance for implementation. This working group would provide a formal mechanism for incorporating harm reduction into FCTC implementation while ensuring that policies remain evidence-based and responsive to evolving scientific understanding.

6. Embed THR in broader NCD and human rights agendas

THR should be recognised as both a public health and human rights strategy, firmly grounded in the Right to Health as outlined in Article 12 of the International Covenant on Economic, Social and Cultural Rights.[73]

The UN Declaration on NCDs mandates equitable access to preventive and therapeutic technologies, creating an obligation to ensure that SNAs are available to those who need them.

This human rights framework provides additional justification for THR integration, particularly in LMICs where traditional cessation methods have proven inadequate.

UN agencies should provide technical support to help LMICs develop THR-inclusive national NCD strategies that align with their broader development objectives.

The intersection of tobacco control with broader NCD prevention creates opportunities for policy integration that can amplify impact while optimising resource allocation.

Policymakers should exploit these synergies rather than maintaining unnecessary barriers between tobacco control and other health interventions.

7. Launch a global evidence and innovation platform

The rapid evolution of SNAs requires new mechanisms for evidence generation, sharing and translation into policy.

A multi-stakeholder observatory under the WHO or the Joint United Nations Programme on HIV/AIDS (UNAIDS) / United Nations Development Programme (UNDP) should be established to track THR implementation, share country-level health outcomes, and guide investment and research in next-generation nicotine technologies.

This platform would serve as a central repository for real-world evidence, enabling policymakers to make informed decisions based on population-level outcomes rather than theoretical concerns.

Investment in next-generation nicotine technologies should be prioritised, with particular attention to products suitable for LMIC contexts. The platform should coordinate international research efforts and ensure that innovation benefits are shared equitably across all income levels.

Chapter 7: Conclusion: A Call for Evidence-Based Leadership

The policy recommendations in Chapter 6 represent a comprehensive roadmap for integrating THR into global and national tobacco control strategies.

Their implementation requires leadership from policymakers who prioritise evidence over ideology and population health outcomes over political convenience – or even political cowardice and conformity.

The stakes could not be higher. With tobacco use projected to kill one billion people this century, the international community cannot afford to maintain policies that inadvertently preserve the status quo of combustible tobacco use.

The evidence for harm reduction provided in this report is clear, the products are available and the success stories are documented.

What remains is the political will and bravery to act decisively in the face of entrenched opposition.

The global case for safer alternatives in the fight to reducing smoking has been made.

The UN NCD High-Level Meeting and COP11 negotiations represent historic opportunities to pivot toward evidence-based tobacco control that can achieve the ambitious objectives set forth in the FCTC and SDGs.

Policymakers must seize these opportunities to unlock the full potential of safer alternatives and accelerate progress toward a world free from tobacco-related death and disease.

To support the statistics and science presented in this report, the authors also call for a collaborative and multi-stakeholder approach in data and evidence gathering. To build accountability in leadership together, we ask that readers from the countries mentioned, as well as other countries across the globe, share any science or data-based information they may have access to on local THR efforts and a corresponding reduction in smoking rates, disease, disability or death. Working collaboratively worldwide can help push for a harm-reduced future today.

Annex

WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

CONFERENCE OF THE PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

FCTC/COP10/P/CONF./6
5 February 2024

Tenth session
Panama City, Panama, 5–10 February 2024
Agenda item 6.1

DRAFT DECISION: IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC (REGULATION OF CONTENTS AND DISCLOSURE OF TOBACCO PRODUCTS)

(Proposed by Saint Kitts and Nevis)

The Conference of the Parties (COP),

Recalling that tobacco control aims to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;

Reaffirming the Parties' commitments to protect public health by prioritizing supply and demand reduction measures;

Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health;

Determined to promote tobacco control measures based on current and relevant scientific, technical, and economic considerations;

Recognizing further the need to be alert to efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts;

Recalling decisions FCTC/COP6(9) and FCTC/COP7(9) inviting Parties to consider applying regulatory measures to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives;

Further recalling decision FCTC/COP7(14) that invites WHO to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as "heat-not-burn" tobacco products;

Recalling decision FCTC/COP8(22) on novel and emerging tobacco products reminding Parties about their commitments under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products such as heated tobacco products and devices designed for consuming such products;

Recognizing that the properties of certain novel and emerging tobacco products may pose regulatory challenges regarding their definition and classification, and that these

may pose challenges for the comprehensive application of the WHO FCTC;

Noting with concern the rising proliferation of novel and emerging tobacco and nicotine products, particularly heated tobacco products, nicotine pouches, ENDS/ENNDS, including disposable ENDS, and future inventions of tobacco industry including those composed of synthetic nicotine, adding complexity to already existing regulatory challenges;

Noting with regret that these novel and emerging tobacco and nicotine products are being marketed with claims of "reduced risk", "cleaner alternatives to conventional cigarettes", and smoke-free alternatives to smoking, and recalling the past "low tar cigarettes" and "reduced carcinogen cigarettes" promoted by the industry;

Emphasizing that tobacco cessation is the best option to reduce the harm caused by tobacco smoking and nicotine use;

Observing with caution that some Parties while designing and implementing their national tobacco control strategies consider novel and emerging tobacco and nicotine products as a less harmful substitute to conventional cigarettes;

Keeping in mind that Parties might require further guidance on the harm reduction strategies in tobacco control as provided by Article 1(d) of the Convention.

DECIDES:

(f) to establish an intersessional Working Group on harm reduction strategies in tobacco control, as referred to in Article 1(d) of the Convention, in order to distinguish public health-oriented proven measures from ineffective ones that add confusion to tobacco control efforts;

(g) to mandate the Working Group to:

(i) assess existing sources of information, research, experience, best practices, and regulations covering the reliable and most effective evidence-based interventions to reduce tobacco- and nicotine-associated harm and to collect and share them as appropriate;

(ii) study best practices from broad range of other public health policy measures on non- and communicable diseases, such as, but not limited to, STIs, AIDS, drug and alcohol addiction and air pollution, that aim to reduce or eliminate exposure to risk factors, from prevention, particularly among young people, women and persons from vulnerable socioeconomic and minority groups, including LGBTQI, through other various risk-mitigating means, to cessation, taking into account cost-effectiveness of such measures, and evaluate applicability of such measures to tobacco control;

(iii) invite Parties to submit in writing to the Working Group best practices and examples of national experiences in regulations on public health proven strategies on minimizing harm in tobacco control;

(iv) invite UN organizations and other intergovernmental organizations, with relevant expertise in public-health oriented harm reduction strategies, such as UNAIDS, UNODC and UNFCCC secretariat, to share the expertise to the WG and present it at COP11 as proven public health expertise in minimizing harm for consideration of the Parties on the relevance of adapting their approaches to tobacco control;

(v) standardize, for the purposes of the Convention, the terminology, on reliable evidence-based interventions to reduce tobacco- and nicotine-associated harm in order to detach it from the

term "tobacco harm reduction" used by the tobacco industry and its acolytes;

(vi) elaborate, based on the above, and as deemed appropriate by the Working Group, comprehensive package of evidence-based interventions to reduce relative risk and population harm associated with tobacco and nicotine for understanding and implementation of Article 1(d) of the Convention, for consideration by the Conference of the Parties at COP11;

(vii) to invite, in line with Article 5.3 of the Convention, civil society organizations that are officially participating, or have participated, in proceedings of the governing bodies of UN organizations referred to in point (iv). to inform the Working Group about their experiences and best practices in public health-oriented policies aimed at reducing or eliminating exposure to risk factors.

(h) that the WG shall be open to all interested Parties, and ensure regional balance, and that such regional nominations shall be coordinated by Regional Coordinators;

(i) that the Working Group shall work mainly through electronic means; however, the Working Group shall have, subject.

About the Authors

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Dr. Delon Human is a specialist family physician, global health advocate, published author, international speaker and healthcare consultant specialising in global health strategy, harm reduction and health communication. He is the former Secretary-General of the World Medical Association, International Food and Beverage Alliance and Co-founder of the African Harm Reduction Alliance (AHRA). He has acted as an adviser to three WHO Directors-General and to the UN Secretary-General on global public health strategies.

Martin Cullip United Kingdom

Martin Cullip is a South London–based consumer advocate and international fellow at the Taxpayers Protection Alliance's Consumer Center, where he champions free-market principles and tobacco harm reduction. With over 15 years of experience in public commentary and activism, he first emerged as "Dick Puddlecote," an anonymous blogger critiquing nanny-state overreach while protecting his business interests. He later revealed his identity after two decades in transport management.

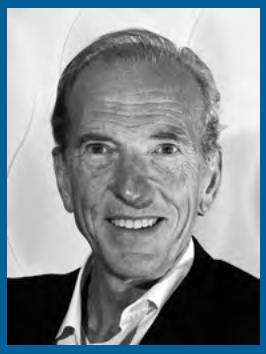
Politically engaged, Cullip stood as a Libertarian Party candidate in the 2010 UK general election. He also served as former Chair of the New Nicotine Alliance (NNA UK), contributing to major harm reduction dialogues and parliamentary inquiries.

Prof. Marewa Glover New Zealand

Professor Marewa Glover is one of New Zealand's leading tobacco control researchers. She has worked on reducing smoking-related harm for 31 years. She is recognised internationally for her advocacy on tobacco harm reduction; and locally was a Finalist in the New Zealander of the Year Supreme Award in 2019 recognising her contribution to reducing smoking in NZ. In 2018, Prof. Glover was appointed Tobacco Section Editor for the Harm Reduction Journal. In that year she also established the Centre of Research Excellence: Indigenous Sovereignty & Smoking, an international programme of research aimed at reducing smoking-related harms among Indigenous peoples globally. The Centre's research was funded with a grant from Global Action to End Smoking (formerly known as Foundation for Smoke-Free World), an independent, U.S. nonprofit 501(c)(3) grant making organisation, accelerating science-based efforts worldwide to end the smoking epidemic.

Dr. Hiroya Kumamaru Japan

Dr. Hiroya Kumamaru is a cardiovascular surgeon and vice director of AOI International Hospital in Kawasaki, Japan, a position he has held since April 2013. A graduate from the School of Medicine at Keio University, Kumamaru studied cardiovascular surgery in Europe and the United States. His professional experience includes time spent as director of the K.I. Akihabara Clinic (July 2008 to March 2013), chief surgeon of the department of cardiovascular surgery at Kawasaki Municipal Hospital, Kanagawa (July 2005 to March 2008) and senior cardiovascular medical directorand group leader of clinical scientific affairs at Pfizer Japan (April 1996 to June 2005). He has been working on preventive medicine for more than 10 years and tobacco harm reduction is one of the biggest issues for that area.



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Prof. Karl Fagerström (Sweden) is a psychologist and founding member of the Society for Research on Nicotine and Tobacco (SRNT) and currently a deputy editor of Nicotine & Tobacco Research. He was awarded the World Health Organization medal in 1999 for his outstanding work in tobacco control. In 2013 he was the recipient of the Award on Clinical Science from the Society for Research on Tobacco and Nicotine.

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