SUBMISSION TO ANVISA

Targeted Consultation No. 6/2026 on Nicotine Products

Call for Contribution Notice No. 3/2026

Submitted by: Smoke Free Sweden (SFS)

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About Smoke Free Sweden

Smoke Free Sweden (SFS) is a collective of global physicians and public health experts with a focus on harm reduction science and policy across diverse areas, including tobacco, alcohol, food, drugs, HIV, and COVID-19. Our mission is to prevent and control diseases and premature deaths associated with lifestyle habits and substance use, with a particular emphasis on tobacco and nicotine.

SFS strongly endorses evidence-based tobacco control, in alignment with the WHO Framework Convention on Tobacco Control (FCTC), and places specific emphasis on tobacco harm reduction (THR) as a paramount public health strategy, consistent with Article 1(d) of the FCTC. We champion harm reduction as a vital and complementary tool within comprehensive tobacco control - not as a substitute for prevention, but as an essential pathway for the millions of adults globally who continue to smoke. [1,2]

Our work is grounded in Sweden's public health experience. Sweden has achieved one of the lowest daily smoking rates in Europe - around 5.4% in 2024, according to the Public Health Agency of Sweden. According to the latest figures from the Swedish Council for Information on Alcohol and Other Drugs, this percentage has further decreased to just 3.7% in 2025, gaining Sweden a smoke-free status. This result is strongly associated with the long-term substitution of cigarettes with smoke-free oral nicotine products, particularly snus, and more recently with nicotine pouches and vaping. The Swedish experience demonstrates that tobacco control and harm reduction are not opposing strategies: they are complementary. [2,3,4,12]

SFS welcomes ANVISA's Targeted Consultation No. 6/2026 on Nicotine Products as an important opportunity to contribute evidence-based perspectives to the regulatory framework for nicotine products in Brazil. We commend ANVISA for undertaking this consultation and for its commitment to transparent, participatory policy development.

Introduction

The central public health challenge in tobacco control remains combustible smoking. The overwhelming burden of tobacco-related disease - cancer, cardiovascular disease, chronic obstructive pulmonary disease, and many others - is caused by the

inhalation of toxic chemicals produced by the combustion of tobacco. Nicotine is addictive and must be regulated responsibly, but it is not the primary driver of smoking-related disease and death. [2,8]

Effective tobacco regulation should therefore distinguish clearly between combustible tobacco products and non-combustible alternatives. A risk-proportionate regulatory framework - one that most heavily restricts the most harmful products while providing clear, consistent rules for lower-risk alternatives - offers the best prospect of reducing smoking prevalence and the harms it causes. [2,9]

Brazil faces a significant public health burden from tobacco. SFS encourages ANVISA to consider the evidence on smoke-free nicotine products as part of a comprehensive and evidence-based approach to tobacco control. The following responses address the questions set out in the Consultation. [8]

Question 1: Respondent Group

Smoke Free Sweden is responding to this consultation as a non-governmental organisation (NGO) with expertise in public health, tobacco harm reduction, and evidence-based tobacco policy. Our collective includes researchers, physicians, and public health professionals.

Question 2: What Would Constitute Nicotine Products?

Nicotine products are any products that deliver nicotine to users through means other than the combustion of tobacco. This broad category encompasses a wide range of delivery mechanisms and formulations, and should be distinguished from combustible tobacco products - such as cigarettes, cigars, and roll-your-own tobacco - which deliver nicotine primarily through the burning of tobacco leaf. [2]

In our view, nicotine products include:

- Oral nicotine products, including nicotine pouches (tobacco-free) and traditional snus (tobacco-containing) [2,4]
- Electronic nicotine delivery systems (ENDS), including e-cigarettes and vaping products [2,5]
- Heated tobacco products (HTPs), which heat rather than burn tobacco [2]
- Nicotine replacement therapies (NRT), including patches, gums, lozenges, and inhalers [2]
- Other emerging products containing synthetic nicotine or tobacco-derived nicotine used in non-combusted form [2]

Critically, not all nicotine products carry equivalent risk. Their risk profiles differ substantially depending on delivery mechanism, the presence or absence of combustion, and the source and purity of nicotine. A sound regulatory framework must reflect these differences. [2,9]

Question 3: Which Nicotine Products Is Smoke Free Sweden Familiar With?

Smoke Free Sweden has extensive familiarity with the full range of nicotine products currently available globally, including:

- Nicotine pouches (tobacco-free oral nicotine sachets)
- Snus (moist tobacco oral products, long-established in Scandinavia and now available in tobacco-free variants)
- E-cigarettes and vaping products (open and closed systems, disposable and rechargeable)
- Heated tobacco products (devices that heat rather than burn tobacco)
- Nicotine replacement therapies (patches, gums, lozenges, nasal sprays, inhalers)

Our submissions, publications, and policy work draw on the scientific and regulatory literature concerning all of these product categories, with particular depth of knowledge in oral nicotine products and nicotine pouches given their centrality to Sweden's public health experience. [2,4]

Question 4: Do Nicotine Products Cause Any Health Impact?

Selected Response: Both Positive and Negative Impacts

Nicotine products have both positive and negative health impacts. The nature and magnitude of these impacts depend critically on the specific product type, the population using it, and the context of use. A blanket characterisation of all nicotine products as equivalent in risk is not supported by the scientific evidence and would undermine effective tobacco control. [2,9]

Negative Impacts

Nicotine is an addictive substance. Regular use can establish and sustain dependence, which carries its own health burden and makes cessation more difficult. Nicotine is not appropriate for use by children, young people, pregnant women, or those with certain cardiovascular conditions. [2]

Clarifying the Role of Nicotine

This distinction is particularly important for regulatory purposes. Combustible cigarettes cause disease primarily because smoke contains carbon monoxide, fine particulates and thousands of combustion-related toxicants, including carcinogens. Nicotine sustains dependence and can have acute cardiovascular effects, such as increases in heart rate and blood pressure, but it is not classified as a carcinogen and is not the principal cause of smoking-related cancers. Misattributing cancer risk to nicotine itself can mislead adult smokers about the relative risks of non-combustible alternatives and reduce their willingness to switch away from cigarettes. [2,10]

Combustible tobacco products - cigarettes in particular - carry severe and well-documented health harms, caused principally by the thousands of toxic chemicals generated through combustion, not by nicotine per se. These harms include lung cancer, oral and oesophageal cancer, cardiovascular disease, stroke, chronic obstructive pulmonary disease, and many others. Combustible tobacco remains the single leading cause of preventable death globally. [2,8]

Non-combustible nicotine products also carry some risk - they are not risk-free. However, the scientific consensus is that their risk profile is substantially lower than that of combustible cigarettes, because the primary drivers of smoking-related disease (combustion toxicants, carbon monoxide, fine particulates) are absent or present at far lower levels. [2,9]

Positive Impacts

For adult smokers who are unable or unwilling to quit nicotine entirely, switching completely from combustible cigarettes to regulated non-combustible nicotine products represents a meaningful harm reduction opportunity. The substitution of a uniquely harmful product with a substantially less harmful alternative can reduce individual risk and, at population level, reduce smoking-related morbidity and mortality. [2,9]

Evidence for the harm reduction potential of smoke-free nicotine products is growing:

- A 2025 Cochrane systematic review found high-certainty evidence that nicotine e-cigarettes are more effective for smoking cessation than traditional nicotine replacement therapy. [5]
- UK data show that nicotine pouch use among smokers making quit attempts has grown substantially, from 2.6% in 2020 to 6.5% in 2025. [6]
- Early clinical evidence suggests nicotine pouches can reduce cigarette consumption and support complete switching among adult smokers. [7]
- Sweden's public health experience - the lowest smoking rate in Europe achieved alongside widespread use of oral nicotine alternatives - provides a compelling real-world demonstration of harm reduction at population scale. [2,3,4]

SFS therefore urges ANVISA to adopt a risk-proportionate approach: one that regulates all nicotine products responsibly, most heavily restricts combustible tobacco, and provides a clear and proportionate framework for smoke-free alternatives that reflects their lower risk profile and potential role in reducing smoking prevalence. [2,9]

Question 5: Additional Information

Smoke Free Sweden wishes to draw ANVISA's attention to three further considerations that we believe are relevant to this consultation.

1. The Importance of Risk-Proportionate Regulation

Tobacco regulation that treats all nicotine products as equivalent - regardless of their risk profile, delivery mechanism, or role in reducing smoking - risks undermining

public health goals. If adult smokers believe that smoke-free alternatives are as harmful as cigarettes, they are less likely to switch. Misinformation about relative risk effectively protects the cigarette market. [2,9]

ANVISA's regulatory framework should communicate clearly and accurately that: combustible tobacco is uniquely harmful; smoke-free alternatives are not risk-free but are substantially less harmful than cigarettes; and adult smokers who switch completely from cigarettes to regulated non-combustible products can meaningfully reduce their health risk. [2,9]

2. Youth Protection Must Be Targeted and Effective

SFS shares concerns about youth uptake of nicotine products. No nicotine product is appropriate for children or young people, and regulation must include robust age-of-sale requirements, restrictions on youth-oriented marketing and packaging, and effective enforcement. However, youth protection measures should be targeted and evidence-based. Blanket prohibitions that remove adult smokers' access to regulated smoke-free alternatives may generate unintended consequences - including discouraging switching, encouraging illicit trade, or increasing misinformation - without effectively protecting young people. [6,9]

3. The Current Evidence Regarding "Gateway" Effects

Concerns about a possible gateway from smoke-free nicotine products to cigarette smoking should be taken seriously, particularly for young people and never-smokers. However, the current evidence should be interpreted carefully. Some longitudinal studies show an association between youth e-cigarette use and later experimentation with cigarettes, but observational associations do not by themselves prove that vaping causes subsequent smoking. Shared risk factors - including risk-taking behaviour, peer influence, family smoking, mental health factors and broader susceptibility to substance use - may explain part of the observed relationship. [11]

At population level, countries that have allowed regulated access to smoke-free alternatives for adults have not necessarily seen a reversal of long-term declines in youth smoking. In Sweden, for example, smoking among the youth in 2024 was at 2.3% - lower than any other age group and maintaining a constant and significant decline over the years. [3]

This suggests that ANVISA should distinguish between youth-protection measures, which are essential, and blanket prohibitions that may remove regulated alternatives from adult smokers while leaving demand to be met through illicit or informal channels. A proportionate approach would combine strict age-of-sale enforcement, marketing restrictions, packaging controls and monitoring of youth uptake, while preserving adult access to regulated smoke-free products. [10,11]

4. Brazil's Opportunity

Brazil has an opportunity to develop a forward-looking regulatory framework for nicotine products that draws on the best available international evidence, including Sweden's experience. A framework that focuses primarily on eliminating combustible tobacco use - while providing proportionate, clear, and consistent regulation for

smoke-free alternatives - offers the greatest prospect of reducing tobacco-related disease and death in Brazil. [2,4]

Smoke Free Sweden would welcome the opportunity to provide further evidence, expert input, or engagement with ANVISA as this regulatory process develops. We are committed to supporting evidence-based tobacco policy globally.

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About the authors

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- **Prof. Mihaela Răescu (Romania)** holds a Ph.D. in Medical Sciences - Dentistry (2002) and has taught Oral and Dental Prevention at the Titu Maiorescu University School of Dentistry in Bucharest, Romania, since 2003. She has been a tenured university professor since 2015, in addition to being an active practitioner and primarius doctor. Her professional activities include roles as President of the Ethics Committee, member of the Editorial Board of scientific journals, and Counsellor of the Romanian College of Dentists.
- **Jessica Perkins (UK)** completed her degree in Chemistry at the University of Southampton and worked as a scientist in the R&D of a multinational company. The focus of her work was the novel implementation, development and testing of analytical devices to characterise the aerosols from reduced-risk products in the tobacco and nicotine industry. She then became an innovation product developer, where she focussed on materials science and device development within the heated tobacco products category. Jessica is now a harm reduction advocate and leads several advocacy platforms, including THR.net, communicating harm reduction science. She is also completing an MBA alongside her work.
- **Dr. Hazel Lincy Ebenezer (India)** is a Human Rights Consultant based in India. She holds a Ph.D. in Women's Rights Law from Kent Law School, University of Kent, where her research focused on the intersection of law, cultural norms, patriarchy and private forms of violence against women in India. She has also served as an adjunct professor and guest lecturer for bachelor's and master's students. Hazel has dedicated her career to raising awareness and advocating for policies and opportunities that empower individuals and communities across the world.
- **Carissa During (Sweden)** is a director of Considerate Pouchers Sweden, a global consumer advocacy group set up to represent pouchers around the world. She studies clinical psychology at Uppsala University in Sweden. She uses nicotine pouches as an alternative to smoking and is keen that the world should know how successful pouches have been in helping Sweden get smoking rates to the lowest in Europe.
- **Alice Alberta Cittone (Italy)** is a dental hygienist who graduated with honours from the University of Rome "Tor Vergata" and has worked as a highly experienced

professional and freelancer since 2002. She has held roles in leadership, academic teaching, corporate consultancy and the organisation of nationally and internationally significant events. In her professional career, she holds a degree in Dental Hygiene (University of Piemonte Orientale and University of Rome "Tor Vergata" - with honours) and is a University Lecturer on Dental Hygiene at the Faculty of Medicine in Novara, providing training programmes for dental hygienists. She was the Regional President of UNID (National Union of Dental Hygienists): Piemonte (2002-2008) and has been Vice President of the Board of Directors of TSRM-PSTRP in Torino, Asti, Aosta and Alessandria since 2020.

- **Karl Fagerström (Sweden)** studied at the University of Uppsala and graduated as a licensed clinical psychologist 1975. At that time, he started a smoking cessation clinic and invented the Fagerstrom Test for Cigarette Dependence. In 1981 he got his Ph.D. on a dissertation about nicotine dependence and smoking cessation. In the end of the seventies and early eighties he served as the editor-in-chief for the Scandinavian Journal for Behaviour Therapy. From 1983 through 1997 he worked for Pharmacia & Upjohn as Director of Scientific Information for Nicotine Replacement Products. He has worked with the nicotine gum Nicorette since 1975 and has been contributing to NRT developments such as patch, spray, pouch and inhaler. Ever since 1975 to 2010 he has been working clinically part-time. From 1997 to 2008 he worked with his private research clinic where he studied various drugs intended for treating nicotine dependence.Currently he works with his own private consultancy (Fagerstrom Consulting). He is a founding member of the Society for Research on Nicotine and Tobacco and currently a Deputy Editor of the Nicotine & Tobacco Research. He started the European SRNT affiliate in 1999 of which he was been the president up to 2003.