Submission to the European Commission Call for Evidence

Submission by Smoke Free Sweden (SFS),

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Meet the Authors: We are a collective of global physicians and experts with a focus on harm reduction science and policy across diverse areas, including alcohol, tobacco, food, drugs, HIV, and COVID-19. In collaboration with Smoke Free Sweden (SFS), we champion harm reduction as a vital public health tool. Our mission is to prevent and control diseases and premature deaths associated with various lifestyle habits and substance abuse, encompassing tobacco and drugs. SFS strongly endorses tobacco control, aligning with the Framework Convention on Tobacco Control (FCTC) [3], and places specific emphasis on tobacco harm reduction (THR) as a paramount public health strategy (Article 1d of the FCTC) [3].

Introduction

Smoke Free Sweden welcomes the European Commission's Call for Evidence on the revision of EU rules on tobacco products and tobacco advertising [1]. We support strong, effective and evidence-based tobacco control, and recognise the important role that the Tobacco Products Directive 2014/40/EU and the Tobacco Advertising Directive 2003/33/EC have played in strengthening the EU regulatory framework for tobacco and related products [1].

The Commission's Call for Evidence identifies that these Directives govern the manufacture, presentation and sale of tobacco and related products, as well as advertising and sponsorship. Their objectives are to support the smooth functioning of the internal market, protect human health, and meet the EU's obligations under the WHO Framework Convention on Tobacco Control [1,3]. The Call also recognises that Europe's Beating Cancer Plan and the Safe Hearts Plan underline the importance of tobacco control as a core component of disease prevention, and that the revision should support the objective of a tobacco-free generation by 2040 [1].

Smoke Free Sweden believes that this revision is a critical opportunity to modernise EU tobacco policy in a way that protects young people, strengthens the internal market, addresses digital marketing, improves product standards, and accelerates the decline of combustible tobacco use [1].
The central public health challenge remains combustible smoking. The overwhelming burden of smoking-related disease is caused by inhalation of toxic chemicals produced by the combustion of tobacco. Nicotine is addictive and should be regulated responsibly, but it

is not the primary cause of smoking-related disease [4]. EU tobacco legislation should therefore distinguish clearly between combustible tobacco products and non-combustible alternatives. Sweden's experience demonstrates that strong tobacco control and tobacco harm reduction can work together. By ensuring that adult smokers have access to acceptable, accessible, affordable and regulated smoke-free alternatives, Sweden has achieved exceptionally low smoking prevalence and provides a practical model for the rest of Europe [5,6,21,22].

A tobacco-free generation will be achieved faster if the EU focuses first and foremost on reducing combustible tobacco use, while regulating smoke-free alternatives proportionately.

Key Messages

1. Combustible tobacco should remain the central target of EU tobacco policy

The revised EU framework should be judged primarily by whether it reduces smoking-related disease and death. Cigarettes are uniquely harmful because they deliver nicotine through combustion, exposing users to toxicants including carbon monoxide, oxidising chemicals and fine particulates [4].

Nicotine is not risk-free. It is addictive and should not be used by children, young people or non-smokers. However, public policy should not conflate nicotine use with smoking. Adult smokers need accurate information about the relative risks of different products if they are to make informed decisions and move away from cigarettes [4].

The scientific basis for tobacco harm reduction is straightforward: when adult smokers who are unable or unwilling to quit nicotine completely switch from combustible cigarettes to regulated smoke-free alternatives, their exposure to combustion-related toxicants can be significantly reduced [4,5,6].

This does not mean that smoke-free products are risk-free. It means they should be regulated according to their risk profile, use patterns, and potential contribution to reducing smoking-related harm.

2. Sweden shows how Europe can move faster towards the tobacco-free generation objective

Sweden is the EU's clearest real-world example of tobacco control strengthened by harm reduction. While many Member States remain far from the EU's 2040 tobacco-free

generation objective, Sweden has achieved one of the lowest daily smoking rates in Europe [5,6,21,22].

According to the Public Health Agency of Sweden, daily smoking prevalence in Sweden was 5.4% in 2024 [21]. This achievement 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 [5,6,22].

Sweden's experience shows that tobacco control and harm reduction are not opposing strategies. They are complementary. Traditional tobacco control reduces the appeal, affordability and social acceptability of smoking. Harm reduction gives adult smokers who do not quit outright a realistic pathway away from combustible tobacco [5,6].

The previous Smoke Free Sweden submission emphasised that tobacco harm reduction products are "here to help, not hinder", and that alternatives such as snus and tobacco-free nicotine products should be viewed as tools to help reduce smoking-related harm rather than risks to prohibit.

The central lesson for the EU is clear: Member States will move faster towards the tobacco-free generation objective when adult smokers have access to regulated, acceptable and affordable alternatives to combustible cigarettes.

3. Smoke-free alternatives can support quitting and switching

Despite decades of cessation interventions, long-term quit rates remain relatively low and millions of adults in Europe continue to smoke [4]. For many smokers, the practical public health choice is not between nicotine use and no nicotine use, but between continued smoking and switching to a less harmful alternative.

The evidence base is strongest for vapour products. A 2025 Cochrane review found high-certainty evidence that nicotine e-cigarettes are more effective for smoking cessation than traditional nicotine replacement therapy [7]. The review found that, for every 100 smokers using nicotine e-cigarettes, approximately 8–11 successfully quit smoking, compared with around six using traditional NRT [7].

This conclusion is reinforced by a 2026 overview of systematic reviews, which found that higher-quality reviews consistently favoured nicotine e-cigarettes over NRT, non-nicotine e-cigarettes and other comparators for smoking cessation [8].

Public health practice is also evolving. The United Kingdom has incorporated vaping into stop-smoking support through its "Swap to Stop" programme, and the NHS provides public

guidance on vaping to quit smoking [9,10]. New Zealand has similarly incorporated vaping into its stop-smoking approach [11]. These examples demonstrate that smoke-free alternatives can be integrated into public health strategies with appropriate safeguards, behavioural support and age restrictions [9,10,11].

The revised EU framework should not undermine adult smokers' access to regulated vapour products. Instead, it should ensure that these products are subject to high product standards, responsible marketing rules, youth protections and accurate consumer information.

4. Heated tobacco products and nicotine pouches require clear, proportionate EU rules

The Call for Evidence rightly identifies the need to address novel products and rapid market developments. It specifically refers to heated tobacco devices, nicotine products other than e-cigarettes and refill containers, such as nicotine pouches, disposable e-cigarettes and electronic non-nicotine delivery systems [1].

Smoke Free Sweden agrees that these categories require clear regulation. However, regulation should be evidence-based, proportionate, and designed to reduce harm rather than simply restrict access to all non-combustible alternatives.

For heated tobacco products, clinical evidence on cessation remains less developed than for vaping. However, real-world evidence from Japan suggests that these products may contribute to population-level declines in cigarette use. Since the introduction and adoption of heated tobacco products in Japan, cigarette sales and smoking prevalence have declined, while heated tobacco product use has increased [15,16,17]. Although causality cannot be conclusively established, Japan provides an important example of how non-combustible products may accelerate movement away from cigarettes [15,16,17].

Nicotine pouches are a newer category, and the evidence base is still developing. However, early evidence suggests that they are increasingly being used by adult smokers in quit attempts. UK data indicate that among smokers who made a quit attempt in the previous year, use of nicotine pouches in the most recent quit attempt rose from 2.6% in October 2020 to 6.5% in March 2025 [18]. US data also suggest nicotine pouch use among tobacco users attempting to quit [19]. Early clinical evidence further indicates that nicotine pouches can reduce cigarette consumption and support complete switching among some adult smokers [20].

Nicotine pouches should therefore be brought into a clear EU regulatory framework. This should include product notification, ingredient standards, nicotine-content rules, health

warnings, child-resistant packaging, age-of-sale rules, market surveillance, and strict restrictions on marketing to young people.
However, regulation should not become prohibition by another name. Adult smokers should retain access to properly regulated smoke-free alternatives.

5. Youth protection must be central, targeted and enforceable

Smoke Free Sweden shares the Commission's concern about youth uptake, flavours, colourful packaging, digital promotion and influencer marketing. Novel products can pose a risk of initiation into nicotine addiction and tobacco use, particularly among young people [1]. The revised framework should directly address youth access and youth appeal.

The EU should adopt robust youth protection measures, including:

1. A binding minimum age of sale for all tobacco and related nicotine products.
2. Strong enforcement against sales to minors, including online sales.
3. Mandatory age verification for online purchases.
4. Restrictions on packaging, imagery, descriptors and branding clearly designed to appeal to children.
5. Clear rules on social media, influencer marketing, affiliate marketing and covert digital advertising.
6. Penalties for manufacturers, retailers, platforms and intermediaries that facilitate youth-targeted promotion.
7. EU-level monitoring of youth uptake, product trends and emerging marketing practices.

Youth protection should be targeted at youth access and youth appeal. It should not remove adult smokers' access to products that may help them move away from combustible cigarettes.

A blanket approach, such as treating all nicotine products as equivalent to cigarettes or prohibiting entire categories without considering their role in smoking reduction, could create unintended consequences. It may discourage switching, increase misinformation, encourage cross-border purchasing or illicit markets, and slow progress towards the tobacco-free generation objective.

6. Flavours should be regulated carefully, not simplistically

The Call for Evidence identifies divergent national rules on flavours in e-cigarettes and possible future rules on flavours in e-cigarettes, disposable e-cigarettes, tobacco heating devices, nicotine pouches and electronic non-nicotine delivery systems [1]. Smoke Free Sweden agrees that flavours require careful regulation.

Flavours are a legitimate area of concern where they are combined with child-appealing descriptors, colourful packaging, cartoon imagery, confectionery-style branding or youth-oriented marketing [1]. These practices should be restricted.

However, flavours can also play a role in helping adult smokers switch away from cigarettes. Many adult smokers do not want products that taste like tobacco, particularly when they are trying to distance themselves from smoking. A blanket flavour ban could reduce the acceptability of smoke-free alternatives and push some adult users back towards cigarettes.

The revised framework should therefore adopt a balanced approach:

- prohibit flavour descriptors, imagery and packaging clearly targeted at children;
- restrict youth-oriented branding and promotional tactics;
- allow flavours that support adult smokers in switching under strict age-gated conditions;
- monitor flavour use among adults and young people;
- evaluate the impact of any flavour restrictions on smoking prevalence, switching, relapse and illicit trade

The public health objective should be to prevent youth uptake while preserving adult smokers' ability to switch away from combustible tobacco.

7. Disposable products should be addressed through youth, product safety and environmental policy

The Call for Evidence identifies disposable e-cigarettes as one area where divergent national rules are creating internal market fragmentation [1]. Disposable products also raise concerns around youth appeal, low-cost access, product standards and post-consumption waste.

Smoke-Free Sweden supports proportionate measures to address these concerns. Disposable products should be subject to strict age-of-sale enforcement, product notification, labelling, packaging, ingredient standards and rules preventing youth-oriented branding or promotion.

Environmental concerns should also be considered. The Call for Evidence notes that the Directives do not currently explicitly regulate environmental aspects, but that environmental benefits may arise as reduced consumption reduces litter from post-consumption waste [1].

Any measures on disposable products should therefore consider both youth uptake and environmental waste. However, restrictions should be evidence-based and should avoid unintentionally pushing adult smokers back towards combustible tobacco. The objective

should be to reduce youth uptake and environmental harm while preserving access to regulated alternatives for adults who smoke.

8. Electronic non-nicotine delivery systems should be included where they raise comparable risks

The Call for Evidence identifies electronic non-nicotine delivery systems as a category contributing to divergent national rules and internal market fragmentation [1]. While these products do not deliver nicotine, they may raise comparable issues around youth appeal, flavours, packaging, device design, digital promotion and enforcement.

The revised framework should therefore address electronic non-nicotine delivery systems where they create similar risks of youth uptake, product confusion or market fragmentation. Rules should be proportionate to actual risk, but the EU should not leave regulatory gaps that allow youth-oriented products or marketing practices to migrate into adjacent categories.

9. Digital marketing rules must be modernised

The Tobacco Advertising Directive was not designed for today's digital marketing environment. Novel products are increasingly promoted through social media, influencers, affiliate marketing, algorithmic advertising, user-generated promotional content and cross-border online retail [1].

The revised framework should strengthen rules on digital marketing and advertising by:

- prohibiting paid or sponsored promotion aimed at minors;
- regulating influencer and affiliate marketing;
- requiring transparency for sponsored content;
- strengthening cross-border enforcement;
- creating obligations for online retailers to verify age;
- requiring platforms to act against illegal youth-targeted promotion;
- enabling coordinated EU-level monitoring of digital marketing practices.

The goal should not be to prevent adult smokers from receiving accurate, factual information. It should be to prevent youth-targeted promotion and misleading commercial practices.

10. The internal market requires harmonised, risk-proportionate rules

The Commission rightly identifies divergent national rules as a barrier to the smooth functioning of the internal market [1]. Divergence around e-cigarette flavours, plain packaging, disposable e-cigarettes, tobacco heating devices, nicotine pouches and electronic non-nicotine delivery systems creates uncertainty for consumers, regulators and legitimate operators [1].

A harmonised EU framework is therefore needed. However, harmonisation should be risk-proportionate and should not treat all products as equivalent to combustible cigarettes.

Smoke Free Sweden recommends EU-wide rules on:

1. Product definitions for cigarettes, e-cigarettes, heated tobacco products, nicotine pouches, electronic non-nicotine delivery systems and other smoke-free products.
2. Ingredient disclosure and product notification.
3. Product quality and safety standards.
4. Nicotine limits appropriate to product category and use patterns.
5. Labelling and health warnings.
6. Child-resistant and tamper-evident packaging.
7. Age-of-sale rules.
8. Online sales and age verification.
9. Digital marketing and influencer promotion.
10. Market surveillance and enforcement.
11. Illicit trade monitoring.
12. Disposable product standards and post-consumption waste considerations.

Combustible cigarettes should remain the most heavily restricted and discouraged product category. Smoke-free alternatives should be regulated firmly, but differently, to reflect their lower exposure to combustion-related toxicants and their potential role in helping adult smokers switch [4,5,6].

11. Simplification should improve enforcement and reduce unnecessary burden

The Call for Evidence states that the revision may simplify certain provisions of the Directives to reduce complexity and resource intensity, and that revised legislation is expected to alleviate regulatory burden by simplifying reporting requirements [1].

Smoke Free Sweden supports simplification where it improves compliance, enforcement and regulatory clarity. Simplification should support, not weaken, effective regulation.

Reporting and notification requirements should be clear, proportionate and consistent across Member States so that regulators can enforce rules efficiently and legitimate operators can comply without unnecessary duplication.

Clear product definitions, consistent reporting systems and proportionate notification requirements would support both public authorities and responsible economic operators. Simplification should not create loopholes or reduce public health protections. It should make the regulatory system easier to understand, easier to comply with and easier to enforce.

12. Public communication must be scientifically accurate

Public misunderstanding of nicotine and relative risk remains a major barrier to smoking reduction [4]. If adult smokers believe that vaping, nicotine pouches or other smoke-free alternatives are as harmful as cigarettes, they are less likely to switch and more likely to continue smoking.

EU communication should be clear, cautious and evidence-based. It should communicate that:

- young people and non-smokers should not use nicotine products;
- nicotine is addictive and requires regulation;
- smoke-free alternatives are not risk-free;
- smoking is uniquely harmful because of combustion;
- complete switching from cigarettes to regulated smoke-free alternatives can reduce exposure to harmful toxicants;
- the greatest public health gains will come from reducing combustible tobacco use.

This is not a call for promotional claims. It is a call for accurate public health communication. Misinformation about relative risk protects the cigarette market by discouraging smokers from switching.

Recommendations for the revised EU framework

1. Make reduction of combustible tobacco use the central public health objective

The revised framework should be assessed primarily by whether it accelerates the decline of combustible tobacco use and reduces smoking-related disease and death. Youth prevention is essential, but the largest and most immediate health gains will come from reducing cigarette smoking among adults [1,4].

2. Adopt risk-proportionate regulation

The EU should regulate tobacco and related products according to their risk profile, use patterns and public health impact. Cigarettes should remain the most heavily restricted product. Smoke-

free alternatives should be regulated to ensure safety, quality, age restrictions and responsible marketing, while preserving adult access [4,5,6].

3. Integrate harm reduction into tobacco control

Tobacco harm reduction should be recognised as a complement to prevention and cessation. This is consistent with the WHO Framework Convention on Tobacco Control's definition of tobacco control, which includes harm reduction strategies [3].

4. Create an EU framework for nicotine pouches

Nicotine pouches should be regulated at EU level through product notification, ingredient standards, nicotine limits, warning labels, age restrictions, child-resistant packaging and marketing controls. Fragmented national bans or inconsistent rules should be avoided [1,18,19,20].

5. Preserve adult access to regulated vapour products

Given the evidence supporting nicotine e-cigarettes for smoking cessation, the EU should avoid measures that make regulated vapour products less accessible or acceptable to adult smokers than cigarettes. Regulation should focus on product standards, youth protection, responsible marketing and accurate information [7,8,9,10,11].

6. Address heated tobacco products proportionately

Heated tobacco products should be subject to appropriate product standards, labelling, packaging, notification and marketing controls. However, they should be assessed according to evidence on exposure, use patterns, switching and public health impact, not treated automatically as equivalent to cigarettes [15,16,17].

7. Regulate flavours according to youth appeal and adult switching

The EU should restrict child-appealing flavour descriptors, branding, packaging and promotional practices. However, any flavour restrictions should be assessed for their impact on adult switching, relapse to smoking, illicit trade and consumer behaviour [1,7,8].

8. Address disposable products through targeted rules

Disposable products should be addressed through strict age enforcement, product standards, packaging rules, market surveillance and environmental considerations. Measures should be designed to reduce youth uptake and waste without unintentionally increasing combustible tobacco use [1].

9. Include electronic non-nicotine delivery systems where appropriate

Electronic non-nicotine delivery systems should be included in the revised framework where they create comparable concerns around youth appeal, flavours, packaging, digital promotion and market fragmentation [1].

10. Modernise digital marketing and advertising rules

The Tobacco Advertising Directive should be updated to address social media, influencers, affiliate marketing, user-generated promotional content, algorithmic advertising and cross-border online retail. Enforcement should be practical, coordinated and capable of addressing actors outside traditional advertising channels [1].

11. Harmonise rules while preserving proportionality

EU-level harmonisation is needed to address internal market fragmentation. However, harmonisation should be risk-proportionate and should avoid imposing cigarette-equivalent restrictions on smoke-free alternatives [1,4,5,6].

12. Simplify reporting and notification requirements

Simplification should reduce unnecessary complexity and duplication while improving enforcement. Clear product definitions, consistent reporting requirements and proportionate notification systems would support both public authorities and legitimate operators [1].

13. Require a full impact assessment of unintended consequences

The impact assessment should evaluate not only the risks of novel products, particularly for young people, but also the potential benefits of complete switching from cigarettes to regulated smoke-free alternatives [1,4,7,8].

It should assess the effect of proposed measures on:

- adult smoking prevalence;
- youth uptake;
- switching from cigarettes to smoke-free alternatives;
- relapse from smoke-free products back to cigarettes;
- illicit trade;
- cross-border purchasing;
- consumer risk perceptions;
- health inequalities;
- environmental waste;
- innovation;
- regulatory burden;
- internal market coherence.

Policies should not be assessed only by whether they reduce the availability of tobacco and related products. They should be assessed by whether they reduce smoking-related disease and death.

14. Use Sweden as a case study for the EU

The Commission should examine Sweden's experience in detail. Sweden shows that the tobacco-free generation objective can be achieved faster when adult smokers have access to acceptable, affordable and regulated alternatives to cigarettes [5,6,21,22]. This lesson should inform the future EU framework.

The revision of the EU tobacco products and tobacco advertising framework is a critical opportunity to accelerate progress towards the tobacco-free generation objective by 2040 [1]. Smoke Free Sweden supports strong tobacco control, robust youth protection, responsible marketing restrictions, high product standards, effective enforcement and a coherent internal market.

However, Europe will not achieve its tobacco-free generation objective by treating all nicotine products as if they are cigarettes. The greatest burden of harm comes from combustible tobacco [4]. The revised framework should therefore focus on reducing smoking as quickly as possible, while preventing youth uptake and ensuring that all smoke-free products are properly regulated.

Sweden has shown that this is possible. By combining tobacco control with harm reduction, Sweden has achieved exceptionally low smoking prevalence and provides a model for other Member States [5,6,21,22]. Vapour products, heated tobacco products, snus and nicotine pouches are not risk-free, but they may offer adult smokers an important pathway away from combustible cigarettes [7,8,15,16,17,18,19,20].

A modern EU framework should be evidence-based, risk-proportionate and focused on outcomes. It should protect young people, inform consumers, harmonise the internal market, address digital promotion, consider environmental impacts, simplify compliance, and enable adult smokers to move away from the most harmful form of nicotine use: combustible tobacco.

A tobacco-free generation will be achieved faster by combining prevention, cessation and harm reduction. Sweden has shown the way. The revised EU framework should help the rest of Europe follow.

Thank you.

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- 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 leading several advocacy platforms (including THR.net) communicating harm reduction science. She is also completing an MBA alongside her work.

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