Closing the Off-Ramp:

The TPD Review's Threat to Harm Reduction

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Summary

- The European Commission's review of the Tobacco Products Directive (TPD) proposes tighter regulations for novel nicotine products, including e-cigarettes, nicotine pouches, and heated tobacco products, which are among the most effective tools available to help smokers switch away from combustible tobacco. Measures such as flavour bans and design restrictions could reduce incentives to switch without meaningfully reducing tobacco uptake by youth.

- Extending pictorial health warnings and plain-packaging requirements to novel products compounds the problem: applying equivalent warnings to products with fundamentally different risk profiles may mislead consumers rather than inform them.

- Product design restrictions intended to reduce 'appeal' impose costs on a possible harm-reduction pathway that far outweigh any plausible benefits; age verification and marketing restrictions are the appropriate tools for youth protection.

- The one area where the European Commission's proposals have merit is supply-chain traceability and anti-smuggling enforcement, which address genuine public health and fiscal problems without restricting consumer choice.

- The revised directive should be based on a simple principle: regulate in proportion to harm. Novel nicotine products carry a fraction of the risk of cigarettes and should face a proportionate regulatory burden.

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Introduction

The Tobacco Products Directive (TPD) 2014/40/EU sets out harmonised rules for the manufacture, presentation, and sale of tobacco and nicotine products across the EU. Since 2014, the product landscape has changed considerably. E-cigarettes, nicotine pouches, and heated tobacco products have evolved from niche categories into widely available alternatives. The European Commission's current review must grapple with a tobacco control framework that was developed before this shift. There is a reasonable case for updating a twelve-year-old directive, although the very framework it requires to be revised has never been satisfactorily evaluated. The Commission's own advisory body, the Regulatory Scrutiny Board (RSB), which examined the evidence base for the review, found it insufficient to answer the central questions of effectiveness and impact (Regulatory Scrutiny Board 2026). It is against this background that the specific proposals must be assessed.

This briefing examines the Commission's consultation proposals from a market-liberal, evidence-led perspective. It draws on the wider analysis of EPICENTER member think tanks and EPICENTER's recent assessment of the parallel revision of the Tobacco Taxation Directive (Snowdon and Saravakos 2026).

An uncertain evidence base

The RSB, which reviews the quality of the Commission's impact assessments, examined the evaluation underpinning the TPD review and published its opinion on 8 April 2026. The opinion does not endorse the evidence base. The RSB's principal conclusions are that 'the evidence base is insufficient to draw informed conclusions on evaluation criteria' and that 'the analysis of effectiveness is not robust' (Regulatory Scrutiny Board 2026). More specifically, the board found that the Commission's evaluation does not adequately distinguish among product categories when measuring the effects of existing measures, does not account for divergent national policies that complicate attribution, and does not model alternative regulatory scenarios to assess the current framework against plausible counterfactuals. These are not minor technical shortcomings. This means that the Commission cannot reliably determine what its existing directives have achieved across member states, let alone predict the effects of extending them.

The importance of this finding for the proposals under consideration should not be underestimated. Analysts who accept that some targeted revision is warranted argue that new measures should be confined to areas where the evidence meets a minimum threshold for robustness; others have concluded that the revision process should be paused until a credible evaluation is complete. Both positions follow from the same premise: expanding a directive whose effects cannot be measured is difficult to justify. The Commission has not responded to this challenge in its consultation materials.

Harm reduction: The central principle

Quitting cigarettes is difficult, and existing cessation tools have historically had modest success rates. Evidence on e-cigarettes and novel nicotine products indicates that they provide a viable alternative. Cochrane's most recent systematic review on e-cigarettes synthesised data from 90 completed studies (Lindson et al. 2025). It found high-certainty evidence that nicotine e-cigarettes help more people achieve sustained abstinence from smoking than nicotine replacement therapy, with a risk ratio of 1.59 across seven randomised trials. This is not a minor effect. An evidence base of this size and quality supports the conclusion that nicotine e-cigarettes are among the most effective smoking-cessation interventions available without a prescription in most EU member states.

The price side of the equation is also well documented. Pesko, Courtemanche, and Maclean (2020), in their analysis of variations in US state e-cigarette and cigarette tax rates, found that higher e-cigarette taxes reduce e-cigarette consumption while increasing cigarette use among adults, with enough consumers moving back to cigarettes to represent a meaningful public health cost. Similar effects have been inferred from European consumption data (Snowdon and Saravakos 2026). Restrictions on product availability, presentation, and appeal are likely to operate through comparable mechanisms. By reducing the attractiveness of novel products relative to cigarettes, these restrictions may redirect consumers who would otherwise have switched from combustible tobacco. The Commission's consultation documents contain no analysis of this substitution effect.

Against this backdrop, the cross-country smoking data clarify what is at stake. In 2023, approximately 24% of EU residents aged 15 and over were daily or occasional smokers. The figure ranged from 8% in Sweden to 37% in Bulgaria, with twelve member states recording rates above 25% (Eurostat 2026)[1]. Sweden's smoking rate is an outlier compared with the EU average, and this divergence predates any convergence in legislative frameworks that might otherwise help explain it. The widespread availability of snus as a smokeless alternative to cigarettes throughout Sweden's post-war history is a significant part of the explanation. The mechanism is not new: Ramstrom and Foulds (2006), analysing Swedish health data over several decades, find that the availability of low-risk nicotine alternatives was closely associated with Sweden's divergence from EU smoking trends from the 1970s onwards. As recently as the 1980s, Swedish smoking rates were broadly comparable to the EU average; the divergence widened as snus consumption expanded, with daily cigarette smoking among Swedish men falling by 26 percentage points between 1986 and 2022, while snus use rose by 7 percentage points over the same period. A comparable inverse pattern was observed among women (Sjödin et al. 2024). A parallel transition has taken place in Japan since the rapid commercial expansion of heated tobacco products from around 2016. Watase, Ydstedt, and Bäck (2023), in a Tholos Foundation white paper analysing Japanese health data, report that cigarette sales fell by roughly 40% over the following six years, a pace of decline with few equivalents among comparable economies.

Neither country's experience can be transposed directly to EU member states with different product histories and regulatory baselines, but both suggest that, when lower-risk alternatives achieve genuine market penetration, combustible tobacco consumption falls at a rate that conventional cessation tools have not matched.

[1] 'SDG 3 – Good health and well-being', Eurostat, 2026 (https://ec.europa.eu/eurostat/statistics-explained/index.php?title=SDG_3_-_Good_health_and_well-being).

Assessing specific proposals

Flavour restrictions

Article 7 of the TPD 2014/40/EU already prohibits characterising flavours in cigarettes and roll-your-own tobacco. The Commission's consultation asks whether this restriction should be extended to e-cigarettes and nicotine pouches. Its concern centres on youth uptake, although the evidence linking flavour availability to youth initiation in novel product categories is thinner than the consultation framing suggests. In surveys conducted across multiple member states, adult smokers who switch to e-cigarettes consistently report that flavour variety is a significant factor both in their decision to switch and in sustaining that switch. A 2022 study by Gravely et al. across seventeen countries, including several EU member states, found that 56% of e-cigarette users aged 25 and over identified flavour as important to their continued use, compared with 29% who identified nicotine level as important.

The Commission has legitimate concerns about youth use, and it is right to address them. The question is whether flavour restriction is the appropriate instrument. Age verification at the point of sale, restrictions on online retail, and prohibitions on advertising in media accessible to minors are sufficient to address the specific channels through which young people typically access novel nicotine products. A flavour ban, by contrast, applies indiscriminately to all users, regardless of age. Its primary effect is to reduce the utility of novel nicotine products for adult switchers, who make up the majority of users, without closing off the informal supply channels through which young people primarily access them. No analysis in the Commission's consultation materials quantifies the trade-off between the youth-protection benefit of a flavour ban and its cost to the harm-reduction pathway.

Packaging and presentation

The Commission has proposed strengthening health warnings on novel products, potentially extending to these products the mandate to include large pictorial health warnings and standardised ('plain') packaging already applicable to cigarettes and roll-your-own tobacco under Articles 9–14 of the current directive. Requiring accurate labelling of novel products, including disclosure of nicotine content and contraindications for specific populations, is uncontroversially proportionate. Applying the same pictorial warnings and plain-packaging requirements to products with materially different risk profiles is a different matter.

Public understanding of the relative risks associated with different tobacco and nicotine products is consistently poor across European markets. A 2021 survey by Yong et al. across five European countries found that fewer than 20% of respondents believed that e-cigarettes were substantially less harmful than cigarettes, while the majority of respondents in most countries believed that they were equally or more harmful. This misperception is a public health problem: smokers who incorrectly believe that novel products are as dangerous as cigarettes have less reason to switch. Requiring novel products to use the same pictorial warning regime as cigarettes would deepen this misperception rather than address it. The Commission's impact assessment does not examine this effect. Prohibiting claims such as 'natural' or 'organic' on nicotine products is a proportionate intervention; requiring public information campaigns to explain relative risks across product categories would be more effective in closing the information gap than applying warnings equivalent to those on cigarettes.

There is a further consideration that the Commission's consultation does not address. Unlike cigarettes, novel nicotine products produce little or no second-hand emissions. In enclosed public spaces, this distinction has little practical effect given the indoor smoking bans now in place across all member states. However, in settings where smoking prohibitions are partial or absent, including private homes, outdoor hospitality areas, and semi-enclosed spaces, the distinction between an aerosol-emitting device and combustible smoke matters to both users' companions and broader

public acceptance of switching. A warning framework that presents novel products as posing risks equivalent to those of cigarettes obscures this difference and reduces the social licence for harm-reduction alternatives precisely where that licence matters most.

Product design and appeal restrictions

The Commission has also consulted on restricting the design, appearance, and 'appeal' of novel products. Device design and usability are not incidental features of a harm-reduction product; they are directly related to its effectiveness. Research on long-term switching behaviour, including the work of Coleman et al. (2023), which tracked a cohort of UK smokers over two years, found that product satisfaction was among the strongest predictors of sustained abstinence from cigarettes among e-cigarette users and was a stronger predictor in their data than nicotine concentration or price. A regulatory framework that reduces the usability or satisfaction of novel products in the name of reducing 'appeal' simultaneously reduces their effectiveness as cessation tools for the large population of adults who use these products.

Disposable e-cigarettes illustrate the tension. They are typically the first product a smoker tries when switching: they are simple to use, low-cost, and available in formats that closely approximate the experience of smoking. Several member states have sought to restrict them, combining health policy arguments with environmental concerns about single-use products. Waste-management concerns are legitimate and are addressed through product regulations applicable to single-use goods across many consumer categories. Addressing these concerns through a tobacco health policy instrument creates a secondary restriction on a cessation pathway. Any proposal to restrict disposable products as part of the TPD revision ought to quantify the effect on switching rates before proceeding.

Traceability and illicit trade

Among the proposals considered, strengthened supply chain traceability and anti-smuggling enforcement are more justified. Illegal tobacco products accounted for approximately 9.2% of total EU27 tobacco consumption in 2024, representing around €14.9 billion in foregone excise and value-added tax revenues (KPMG 2025). Traceability requirements for tobacco supply chains address a genuine fiscal and public health problem and, unlike the restrictions discussed earlier, do not impede access to the legal products on which harm-reduction approaches depend.

The primary driver of illicit trade is high excise duty, which creates price gaps between formal and informal supply channels that are large enough to sustain significant criminal infrastructure (Snowdon 2025). Traceability measures address the consequence of the price gap between formal and informal supply rather than its cause. At the same time, meaningful reform of the taxation framework is a separate and more fundamental requirement (Snowdon and Saravakos 2026). Within the scope of what the TPD can accomplish, however, measures to strengthen supply-chain integrity are proportional to their expected benefits, and they are among the relatively few elements of the consultation whose benefits are likely to outweigh the costs.

The scope of the directive

An issue that the Commission has not directly addressed in its consultation is whether novel nicotine products, particularly those containing no tobacco, such as e-cigarettes and nicotine pouches, should remain within a regulatory framework designed for combustible cigarettes. The TPD's core architecture, including its additive restrictions, presentation requirements, manufacturing standards, and packaging mandates, was developed primarily to address the risks associated with tobacco products, particularly those caused by combustion. Applying this framework to products that operate

through different mechanisms and carry materially different risk profiles requires a justification that the Commission's consultation documents do not provide. The RSB opinion noted that the evaluation does not adequately distinguish between product categories when assessing the effectiveness of existing measures, raising questions about extending those measures without differentiation.

The Commission bases the revision on Article 114 TFEU, arguing that differences between national rules are fragmenting the internal market. That may justify EU action, but regulatory differences are not sufficient on their own: they must create, or be likely to create, obstacles to the functioning of the internal market. The Commission should therefore explain more clearly which specific barriers the proposed measures are intended to address and why the response is proportionate. This is particularly relevant because many of the measures under discussion are driven primarily by public health concerns. At the same time, the Commission itself states that EU action should respect member states' competences in health policy.

If novel products remain within the directive's scope for practical harmonisation reasons, the framework must be sufficiently differentiated to reflect the differences in risk across product categories. Applying a single regulatory regime identically to cigarettes and nicotine pouches imposes the same regulatory treatment on products with materially different risk profiles. This is inconsistent with a harm-proportionality approach endorsed by the Commission in other contexts and with the available evidence.

Conclusion and policy recommendations

Several proposals in the Commission's TPD consultation would, if adopted, reduce the utility of novel nicotine products as substitutes for combustible tobacco and thereby slow the transition away from the products associated with the greatest health risks. Although they operate through different mechanisms, flavour restrictions, equivalent pictorial warnings, and design restrictions intended to reduce product appeal could slow the substitution effect. They should not be adopted. The appropriate tools for protecting young people from accessing nicotine products are age-verification requirements and restrictions on marketing in accessible media. These measures will target the mechanisms by which youth access these products, without reducing consumer choice or diminishing the product experience that makes novel products effective for adult switchers.

There is also a process concern that deserves to be stated plainly. The Commission established the RSB as an independent check on the quality of its own impact assessments, and the board found the evidence base for this review insufficient on the central questions of effectiveness and impact. The Commission has proceeded regardless, which sets a damaging precedent for the better regulation agenda. The right course of action is to withdraw the proposal and rewrite it on stronger evidential foundations. Failing that, the Commission should at minimum strip out the measures that the evidence does not support: flavour restrictions, equivalent pictorial warnings, and design restrictions on product appeal have no robust justification and should be removed before the directive advances.

The proposals that do warrant support are those that address supply-chain traceability and illicit trade, as they address genuine problems without restricting product availability, an essential component of a harm-reduction approach. The revised directive should maintain and deepen the regulatory differentiation between combustible tobacco and lower-risk alternatives introduced by the 2014 directive, rather than erode it. The principle on which the revision should be based is not complicated: the regulatory burden on each product category should bear a reasonable relationship to the harm it causes.

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