

European Commission
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RE: Call for Evidence: Tobacco Products and Tobacco Advertising – Revision of EU Rules

Prohibition Does Not Work (PDNW), an international network of non-government organisations and think tanks working to promote evidence-based policies that reduce smoking, protect consumers, and prevent illicit trade, welcomes the opportunity to respond to the European Commission's call for evidence on the revision of the Tobacco Products Directive and Tobacco Advertising Directive.

We share the Commission's stated objectives: reducing the harms caused by smoking, protecting young people, improving consumer safety, ensuring legal certainty, and preserving the functioning of the internal market. Smoking remains one of the leading preventable causes of death and disease in Europe. Reducing combustible tobacco use should remain the central public-health priority of EU nicotine policy.

This distinction is supported by a substantial body of public-health evidence and by the principle, increasingly recognised by regulators, that nicotine products exist on a continuum of risk. The U.S. Food and Drug Administration has itself recognised this concept, stating that while no tobacco product is safe, different products present different levels of risk, with combustible cigarettes sitting at the most harmful end of that continuum. The Royal College of Physicians has long recognised that the harms from smoking arise overwhelmingly from the toxic products of combustion rather than nicotine itself. The UK Government's Office for Health Improvement and Disparities has concluded that vaping exposes users to only a small fraction of the risks of smoking, while Cochrane reviews have found nicotine e-cigarettes to be more effective for smoking cessation than traditional nicotine replacement therapy. Similar conclusions are reflected in public-health approaches in New Zealand, Japan and Sweden, where regulated access to smoke-free alternatives has been incorporated into broader strategies to reduce smoking.

However, the Commission's call for evidence ironically appears to ignore this scientific evidence, and risks treating all nicotine products as extensions of the cigarette problem, rather than recognising that smoke-free alternatives can be part of the solution. The public-health question is not whether novel nicotine products are entirely risk-free. They are not. The question is whether adult smokers are better served by having access to regulated, lower-risk alternatives, or by being left with cigarettes and illicit products.

In assessing the "evidence" presented, the Commission correctly identifies internal-market fragmentation as a serious problem. Member States have adopted divergent rules on e-cigarette flavours, disposable vapes, nicotine pouches, heated tobacco products, non-nicotine delivery systems, packaging, advertising, and online sales. But the answer to fragmentation is not to harmonise prohibition. A single EU-wide restrictive model that bans or severely limits the products adult smokers use to switch would not solve the problem. It would scale it.

Evidence from EU Member States and comparable jurisdictions shows a consistent pattern. When legal access to reduced-risk products is curtailed, demand does not disappear. It shifts into illicit, informal, cross-border, online, and unregulated channels. This undermines product safety, weakens age verification, increases enforcement burdens, reduces tax revenue, damages legitimate businesses, and in some cases empowers organised crime.

The forthcoming impact assessment should therefore directly assess the consequences of prohibition-style regulation. This includes substitution back to smoking, illicit and cross-border sourcing, youth access through

informal channels, unsafe products and DIY mixing, criminal-market profits, enforcement and inspection costs, lost tax revenue, regulatory burdens on legitimate operators, and consumer confusion about relative risk.

As such, we submit we are fully in agreement that the EU should modernise its framework, but modernisation should mean risk-based regulation, not cigarette-style restrictions applied indiscriminately to every nicotine product. The revised framework should protect young people through age verification, retail licensing, compliance checks, digital enforcement, penalties for illegal sales, and restrictions on youth-targeted marketing. However, should preserve adult access to regulated smoke-free products that can help smokers move away from cigarettes, and as such should accept evidence based policies and not adopt EU-wide flavour bans, de facto nicotine pouch bans, blanket disposable-vape bans, or plain-packaging rules for reduced-risk alternatives.

1. The Commission is right to identify fragmentation, but wrong if it assumes prohibition is harmonisation

The call for evidence correctly identifies divergent national rules on flavours in e-cigarettes, plain packaging, disposable e-cigarettes, tobacco heating devices, nicotine products such as nicotine pouches, and electronic non-nicotine delivery systems as sources of internal-market fragmentation. EU consumers, businesses, and regulators face a patchwork of inconsistent national approaches. Products that are legally available to adults in one Member State may be banned, misclassified, restricted, or practically unavailable in another. This undermines legal certainty, distorts competition, and creates incentives for cross-border and informal purchasing.

However, the EU should not respond to fragmentation by copying the most restrictive national approaches. To the contrary, harmonisation should encourage the most evidence regulatory regimes. If a harmonised EU rule removes legal access to products that adult smokers and nicotine users already demand, it does not eliminate the market. It merely changes who supplies it. The proper internal-market response is to create clear EU-wide legal categories for reduced-risk products, including vaping products, heated tobacco products, nicotine pouches, and other smoke-free alternatives. Those categories should be subject to proportionate rules on product standards, notification, labelling, nicotine content, age-of-sale, digital sales, retail licensing, and enforcement. But they should remain legally available to adults. The Commission should therefore treat internal-market fragmentation as an argument for regulated access, not for EU-wide restrictions that would drive demand outside the regulated system.

2. “Novel products” should not be treated as a single category of risk akin to combustible tobacco

The call for evidence states that increasing evidence indicates health risks associated with novel products, and that several such products, including nicotine pouches and heated herbal products, are not currently covered by the Directives. However this is not grounded in the best available scientific evidence, and would seem to be driven more by ideology than data.

The central public-health problem remains combustion. Cigarettes cause harm primarily because they burn tobacco and produce smoke containing toxic and carcinogenic substances. Smoke-free nicotine products do not pose zero risk, but they do not expose users to the same toxic profile as combustible cigarettes.

The impact assessment should therefore evaluate products based on the continuum of risk. It should assess the risks of each product not only in isolation, but against realistic alternatives. For adult smokers, the relevant comparator is often continued smoking. For regulators, the relevant comparator to a legal regulated product is often an illegal unregulated one, with significant costs to member states in terms of law enforcement and social issues created by black markets, and public health risks being exacerbated through unregulated products.

Furthermore a framework that collapses all nicotine products into a single tobacco-control model risks misleading consumers. If reduced-risk products are regulated, labelled, taxed, packaged, and restricted in the same way as cigarettes, many smokers will reasonably conclude that switching offers little benefit. That would undermine the Commission's own objective of reducing the burden of smoking-related disease.

3. Youth protection is essential, but bans can make youth access worse

The Commission's call for evidence rightly emphasises youth protection. Preventing underage nicotine use is a legitimate and important public-health objective. However, the policy tools chosen matter. Measures that weaken the legal market can make youth access harder to control, not easier. Legal retailers can be licensed, inspected, fined, suspended, or shut down. Online sellers can be required to verify age. Manufacturers and importers can be made accountable for packaging, labelling, ingredients, and product standards. Illicit sellers and informal social-media suppliers do not operate within those safeguards.

This is not theoretical. The Netherlands provides a clear EU warning. In a PDNW report on the Dutch flavour ban,¹ drawing on official data, market evidence, enforcement findings and consumer research, the Netherlands was shown to have failed on the central youth-protection justification for the policy. Current vaping among Dutch 12- to 18-year-olds rose from 3.7% in 2023 to 7.6% in 2024. The policy did not eliminate youth access. It coincided with youth vaping more than doubling.

The same pattern can be seen internationally. A PDNW report on Australia¹¹ found that the country's highly restrictive approach to vaping, including prescription and pharmacy-based controls, did not prevent youth access. Instead, with legal access made impractical for adult consumers and the legal market sharply constrained, illicit sellers filled the gap. The report found that 14.5% of 14- to 17-year-olds in Australia were current vapers in 2023. That outcome is consistent with the core problem of prohibition-style policy: sellers already operating outside the law have little incentive to comply with age-of-sale rules.

Brazil provides another warning. A PDNW and Livres Mercado report on Brazil¹¹¹ found that, despite a nationwide ban on vaping products, 8.7% of Brazilian teens aged 14 to 17 were regular vapers in 2023, amounting to roughly one million underage users. Because all supply is illegal, there are no licensed retailers, no legal age-verification systems, no accountable supply chains, and no regulated product standards. The ban has not shielded young people from access. It has removed the legal tools that would make access easier to police.

Mexico shows the same dynamic in an even more serious form. A PDNW report, *Vapes and Violence: Mexico's Prohibition Problem*^{11V}, found that despite varying levels of prohibition since 2009 and a constitutional ban, youth vaping had increased by more than 400%. The report also documents how criminal organisations have entered the vapour trade. In such an environment, youth protection is weakened twice over: minors remain able to access products, while the supply chain itself becomes more dangerous and less accountable.

These examples should be central to the Commission's impact assessment. If young people are obtaining products from informal sellers, social-media channels, friends, older peers, or shops already willing to break the law, a

¹ <https://www.prohibitiondoesnotwork.com/news/dutch-vape-flavour-ban-backfires-newreport-shows-rise-in-youth-use-illicit-trade-and-smoking>

¹¹ <https://www.prohibitiondoesnotwork.com/resources/australias-war-on-tobacco-is-leading-to-violence>

¹¹¹ <https://www.prohibitiondoesnotwork.com/resources/consequences-of-the-ban-on-e-cigarettes-in-brazil-english>

^{11V} <https://www.prohibitiondoesnotwork.com/resources/mexicos-vape-ban-fuels-crime-and-undermines-public-health>

product ban may weaken rather than strengthen control. A seller who is already selling an illegal flavoured vape is unlikely to be scrupulous about age verification.

The right approach is not to remove products from the legal market for adults. It is to prevent minors from buying them. That requires strict age-of-sale rules, licensing of retailers and distributors, mandatory age verification online and in physical stores, regular compliance checks, meaningful penalties for sales to minors, enforcement against illicit online sellers, and education campaigns aimed at parents, schools, and young people. Youth protection should be targeted, enforceable, and evidence-based. It should not be used as a justification for measures that push the market into channels where youth access is harder to police.

Greece now provides an EU example of a better youth-protection model. Rather than relying on product bans that push supply into informal channels, Greece has moved toward digital age verification and retailer accountability for alcohol, tobacco and related products. Its model uses point-of-sale digital verification, a business registry, penalties for non-compliance, and potential licence consequences for retailers that sell to minors. This is the type of approach the EU should examine in its impact assessment: enforce the age-of-sale rule directly, make retailers accountable, and use digital tools to close enforcement gaps, rather than removing products from the legal adult market.

4. Flavours should be regulated by presentation and channel, not prohibited outright

The Commission identifies flavours as a major concern, particularly in relation to youth appeal. It is appropriate to examine how flavours are described, packaged, advertised, and sold. But the evidence does not support treating adult flavours as inherently illegitimate.

Flavours are not incidental to harm reduction. For many adult smokers, non-tobacco flavours help break the sensory connection with cigarettes. They make vaping or other smoke-free products more acceptable, and help former smokers avoid returning to combustible tobacco. Consumer polling across several jurisdictions consistently shows that flavours are important to adult users.

The Netherlands is again instructive. The PDNW report on the Dutch flavour ban cites consumer polling conducted by Dynata among current adult vapers in the Netherlands in December 2025 and January 2026. Dynata is a global market research firm regularly used for consumer and public-opinion research. That polling found that 85% of adult vapers considered flavours important or very important in their decision to vape. Despite the ban, 69% continued using nominally banned flavours. Many obtained them from abroad, illicit online sellers, or local shops disregarding the law. Fruit flavours remained dominant despite being illegal.

A study by the Tholos Foundation, a PDNW partner, on Estonia, based on Ipsos consumer survey research, shows the same pattern. Ipsos is one of the world's most established public-opinion and market research firms. After Estonia banned all vape flavours except tobacco and menthol, almost 60% of vapers continued to use banned flavours, supplied through DIY mixing, local sellers, online sources, or cross-border channels. Only 10% of Estonian vapers supported the flavour ban, while 86% supported alternative measures such as stricter enforcement, education, and adult-only channels. The lesson is not that flavours should be unregulated. The lesson is that flavour prohibition does not remove demand. It moves supply.

The EU should therefore begin with less restrictive and more directly targeted measures: better enforcement of existing age-of-sale laws, retailer and distributor licensing, meaningful penalties for sales to minors, improved online age verification, enforcement against illicit sellers, education campaigns aimed at young people and parents, and action against marketing that is demonstrably targeted at minors. These measures address the actual problem of underage access without reducing the attractiveness of legal products for adult smokers.

A similar principle should apply to flavours. The EU should not treat flavour regulation as a binary choice between unrestricted marketing and prohibition. The Czech Republic's recent amendments to its e-cigarette rules offer a more proportionate model. They restrict youth-oriented presentation, prohibit packaging that resembles food, cosmetics or toys, limit how flavour information can be displayed, and target inappropriate or child-appealing branding. That is closer to the right regulatory question: not whether adults may access non-tobacco flavours at all, but whether those products are labelled, packaged, sold and marketed in a way that is appropriate for an adult-only category.

Recent FDA analysis points in the same direction. In authorising the Glas G2 products, the FDA found that the products produced significant rates of complete switching and cigarette reduction, that they could effectively substitute for combustible cigarettes for adult smokers, and that their benefits outweighed their risks when considered for the population as a whole. Crucially, FDA placed weight on device-level age verification and access restrictions as safeguards against youth use. The lesson for the EU is not that all flavours should be permitted without conditions. It is that flavours can be regulated through adult-only access, responsible presentation, product standards and effective age-gating, without resorting to blanket prohibition.

Only if these measures are properly implemented, evaluated, and shown to be insufficient should policymakers consider further restrictions on presentation or retail channels. Even then, any additional measures should be targeted and proportionate, such as addressing clearly child-oriented branding, rather than imposing broad flavour prohibitions. A blanket flavour ban would make legal products less attractive to adults while leaving illicit products to supply the flavours consumers continue to demand.

5. The Debunked Gateway Theory Should Not Be Used As The Basis for EU Regulation

The call for evidence refers to the risk of initiation into nicotine addiction and tobacco use. But the claim that vaping or other reduced-risk nicotine products cause young people to progress to smoking, often described as the "gateway" theory, should not be treated as a sound basis for EU regulation, as not only has it been completely debunked by all credible academic studies, if anything the reverse is true – restrictions on e-cigarettes lead to increases in youth smoking

The gateway theory has been repeatedly challenged by population-level evidence. In jurisdictions where vaping or other smoke-free alternatives have become widely available, smoking rates have generally continued to fall rather than rise. If vaping were a major causal gateway into smoking, one would expect youth and adult smoking trends to move upward as vaping became more common. In practice, the opposite has often occurred. The more plausible explanation is common liability: young people who experiment with one risk-taking behaviour may be more likely to experiment with another, without one product necessarily causing the other.

The better documented risk in several jurisdictions is not a gateway from vaping to smoking, but a reverse substitution effect from reduced-risk products back to cigarettes when legal access is restricted. The PDNW report on the Netherlands notes that RIVM's own post-implementation survey found that 27% of those who quit vaping because of the flavour ban either smoked more or started smoking. Total cigarette consumption in the Netherlands also increased by 1% in 2024, roughly 60 million additional cigarettes, the same year flavour restrictions took effect.

Spain, Poland, and Denmark point in the same direction. Dynata^{VI} and Ipsos^{VII} polling of nicotine pouch users shows that many use these products to reduce or stop smoking. If the products are banned or severely restricted, many expect to seek products through informal channels, while others say they would return to smoking.

This is also supported by U.S. evidence from Abigail Friedman, published in JAMA Pediatrics,^{VIII} examining San Francisco's ban on flavoured tobacco product sales. Using Youth Risk Behavior Surveillance System data and a difference-in-differences design comparing San Francisco with seven other districts, Friedman found that San Francisco's flavour ban was associated with increased smoking among high school students under 18 relative to comparison districts. The study is important not because San Francisco should be treated as identical to the EU, but because it demonstrates the precise risk the Commission must assess: restrictions intended to reduce youth nicotine use may unintentionally increase youth cigarette smoking if they reduce access to lower-risk substitutes or shift behaviour in unintended ways.

The impact assessment should therefore focus on real-world substitution, not speculative gateway claims. A policy that reduces the visibility of vaping or nicotine pouch use but increases cigarette consumption would be a public-health failure.

6. Digital marketing should be controlled without suppressing adult risk communication

The Commission identifies digital marketing, social media, and influencer promotion as issues that were not adequately anticipated by the existing Directives. PDNW agrees that specific youth-targeted digital promotion should be prohibited and enforced against.

However, the EU should distinguish between youth-targeted promotion and adult risk communication. Adult smokers need accurate information about the relative risks of smoking and smoke-free alternatives. If truthful communication is suppressed, the information environment will be shaped by fear, misinformation, and illicit sellers. Public health depends not only on restricting misleading claims but also on allowing accurate claims. Smokers who wrongly believe vaping, nicotine pouches, or heated tobacco products are as harmful as cigarettes are less likely to switch. A heavy handed regulatory framework that prevents adults from receiving truthful relative-risk information may unintentionally preserve smoking.

The EU should therefore prohibit digital marketing that targets minors or promotes unlawful products. But it should permit factual, evidence-based communication to adult smokers about product standards, relative risk, legal access, and switching. A regulated market can be required to communicate responsibly. An illicit market cannot.

7. Plain packaging for reduced-risk products risks misleading consumers

The call for evidence identifies plain packaging as an area for possible further action. Whatever the arguments for plain packaging of combustible cigarettes, the case is very different for smoke-free alternatives.

Packaging rules for reduced-risk products should prevent youth appeal and misleading claims. But plain packaging risks collapsing the distinction between cigarettes and products that do not involve combustion. This may mislead consumers into believing that all nicotine products carry equivalent risk.

^V <https://tholosfoundation.org/2025/04/spains-proposed-nicotine-pouch-ban-faces-overwhelming-consumer-backlash/>

^{VI} <https://tholosfoundation.org/2025/03/poll-poles-protest-pouch-prohibition/>

^{VII} <https://tholosfoundation.org/2024/12/exclusive-danish-nicotine-limits-in-pouches-will-lead-to-black-market-explosion-return-to-smoking-strongly-opposed-by-consumers/>

^{VIII} <https://pubmed.ncbi.nlm.nih.gov/34028507/>

For reduced-risk products, packaging also serves important regulatory functions. It helps consumers identify legal products, distinguish product types, understand nicotine content, verify manufacturer accountability, and avoid illicit goods. If legal products become less distinguishable, less informative, and less trusted, illicit suppliers may benefit.

Plain packaging would also raise serious intellectual-property concerns. Trademarks, brand names, trade dress, logos and other distinctive packaging elements are not merely marketing tools; they are legal assets that help consumers identify the origin, quality and legitimacy of a product. Removing or severely restricting their use interferes with those rights and should only be considered where there is strong evidence of necessity, proportionality and effectiveness. This is especially important for reduced-risk products, where brand identity can help consumers distinguish lawful, regulated products from illicit or counterfeit goods. Weakening legitimate brands while illegal sellers remain able to use attractive packaging, counterfeit marks or informal online promotion may perversely damage compliant businesses and make illicit products harder to identify.

8. Nicotine pouches should be brought into a legal risk-based framework, not banned by design

The call for evidence notes that nicotine products other than e-cigarettes and refill containers, including nicotine pouches, are not currently covered by the Directives. This is a legitimate regulatory gap. But filling the gap should mean creating legal certainty, not creating de facto prohibition.

Nicotine pouches are tobacco-free and smoke-free. They do not involve combustion. Their pharmacological and toxicological makeup is practically identical to nicotine gums prescribed by doctors and listed by the World Health Organisation as essential medicines. They are not risk-free, and should not be sold to minors or marketed to non-users. But for adult smokers, they can provide an alternative to cigarettes.

A PDNW report on nicotine pouches in Germany^{ix} shows what happens when nicotine pouches are effectively removed from legal sale through inappropriate classification. By treating nicotine pouches as food products, Germany has effectively banned legal sale since 2021. This has not eliminated demand. It has pushed users toward unregulated sources while depriving adult smokers of a legal alternative.

Spain, Poland, and Denmark show that similar restrictions would likely generate substitution into illicit channels or back to cigarettes. In Spain, Dynata conducted a March 2025 survey of 515 current nicotine pouch users. The results, published by the Tholos Foundation, found that 84% of pouch users opposed a proposed de facto ban and 90% said flavours were important. In Poland, a March 2025 Dynata survey of 510 current nicotine pouch users found that 93% opposed a pouch ban and 88% opposed a pouch flavour ban. In Denmark, the Tholos Foundation published Ipsos polling of 503 current nicotine pouch users on a proposed 9 mg nicotine limit. That survey found that half of users would seek alternative channels if the limit were imposed, and nearly one in five said they might return to smoking.

Sweden provides the positive counterexample. The Tholos Foundation white paper Safer Nicotine Works^x shows that Sweden's success in reducing smoking has been driven in large part by the availability of oral nicotine products, first snus and more recently tobacco-free nicotine pouches. The report showed Sweden's daily smoking rate falling from 11.4% in 2012 to 5.6% in 2022, with more recent data now indicating that Sweden has effectively crossed the internationally recognised smoke-free threshold of below 5% daily smoking. This was not achieved by eliminating nicotine use, but by shifting consumption away from cigarettes. The report also notes that nicotine pouches have been particularly important for women. Historically, Swedish men were more likely to switch from

^{ix} <https://www.prohibitiondoesnotwork.com/resources/consequences-of-the-de-facto-ban-on-nicotine-pouches-in-germany>

^x <https://tholosfoundation.org/wp-content/uploads/2023/10/Tholos-Safer-Nicotine-Works.pdf>

cigarettes to snus, while women's smoking patterns were closer to those seen elsewhere in Europe. Since nicotine pouches entered the market, they have provided a more acceptable smoke-free alternative for many female smokers. Over the last decade, women's smoking rates declined by 6.1 percentage points, while women's use of snus and nicotine pouches rose by 3.5 percentage points. This is exactly the type of public-health outcome the EU should seek to preserve: adult smokers, including groups less likely to switch to older products, moving away from combustible tobacco through regulated lower-risk alternatives.

The EU should also avoid arbitrary nicotine limits that make products ineffective for adult smokers. Nicotine limits should prevent extreme or unsafe products, but should not be set so low that legal products cannot compete with illicit alternatives or cigarettes.

A sensible EU framework for nicotine pouches would include age-of-sale restrictions, product notification, ingredient standards, retailer licensing, enforcement, and adult access through legal channels.

9. Disposable-vape policy should target youth access, waste, and illicit imports, not simply ban the category

The Commission identifies disposable e-cigarettes as an area of concern. However, a blanket disposable-vape ban should not be treated as self-evidently effective. If demand remains, a ban can move supply into illicit channels. Australia's experience with import restrictions and pharmacy-only access shows how quickly illicit vape markets can grow when legal access is made impractical.

The PDNW and Tholos Foundation report on vapour product regulation in Australia describes the country's experience as a case study in failure. Australia adopted a highly restrictive model that has made ordinary legal access to vaping products extremely difficult. The report found that this did not curb demand, but instead helped fuel a large illicit market, widespread non-compliance, youth access, and criminal activity.

This concern is reinforced by comments from Michael Ellis, former Assistant Director of INTERPOL and former head of INTERPOL's Illicit Trade Crime Unit, submitted in connection with PDNW's Australia work. Ellis notes that after Australia banned disposable vape imports in January 2024, Australian authorities reported the seizure of more than 10 million illicit vapes within a year, which he describes as likely only a fraction of the total smuggled volume.

A better approach would be to regulate the specific problems associated with disposables rather than prohibit the category outright. On the environmental side, this should include producer responsibility, battery and waste standards, clear recycling obligations, and incentives for better product design. Policymakers should also encourage industry-led solutions, including take-back schemes, recycling partnerships, and voluntary container-deposit-style programmes that make it easier for consumers and retailers to return used devices. Regulation should reward innovation toward reusable, rechargeable, recyclable, or lower-waste technologies rather than freezing the market through prohibition. Alongside these environmental measures, the EU should focus on product notification, nicotine and volume limits where justified, restrictions on youth-appealing packaging, age-gated retail, enforcement against illegal imports, penalties for sales to minors, and targeted action against non-compliant products.

If the concern is youth access, regulate youth access. If the concern is waste, regulate waste. If the concern is illegal imports, strengthen import enforcement. A categorical ban may turn all three problems into an illicit-market problem.

10. The Commission must assess black-market effects as a central economic, fiscal and enforcement impact

The call for evidence says the Commission will assess likely economic, social, health, environmental and administrative impacts. It is essential that this assessment include the full economic cost of black-market displacement. Too often, the fiscal consequences of prohibition-style nicotine policy are discussed narrowly, as if the main cost is simply lost excise revenue. That understates the problem.

When lawful supply is suppressed but demand remains, the economic activity does not disappear. It moves. The state loses excise, customs duties, VAT, licensing revenue, business-tax revenue, company-tax revenue, employment income, payroll-related revenue, and ordinary taxable commercial activity. At the same time, police, customs, market surveillance authorities, health regulators and local enforcement bodies inherit a larger and more expensive task: inspections, seizures, prosecutions, online monitoring, border interdiction, specialist taskforces, and repeated action against retailers who continue to sell products consumers still demand.

The largest cost may be neither lost excise nor enforcement spending. It is the transfer of market value from lawful businesses to criminal and informal suppliers. When legal retailers are removed or made uncompetitive, illicit sellers gain the market. They do not pay tax, meet product standards, verify age, comply with packaging rules, fund recycling obligations, or maintain transparent supply chains. Those avoided obligations become profit margins. In economic terms, prohibition creates criminal-market rents: large, recurring, untaxed profits generated by the restrictions themselves.

This point is developed in a report by Professor Sinclair Davidson from RMIT university for PDNW, *When Regulation Becomes Prohibition: Black Markets, Enforcement Failure, and Vape Restrictions*^{x1}. The report examines Australia, Brazil, Belgium, the Netherlands and Denmark and finds a consistent pattern. Restrictive nicotine policy reduces the visibility of the market more reliably than it reduces the size of the market. Legal markets generate records, taxable transactions, observable supply chains, age-verification systems, product standards and identifiable retailers. Illegal markets generate none of those things. Once supply shifts outside lawful commercial channels, governments lose visibility over what consumers are buying, who is supplying the products, and how the market is operating.

Davidson's report uses a Total Regulatory-Failure Cost model to estimate the measurable annual economic displacement created when lawful nicotine markets are suppressed while demand persists. The model includes four categories: forgone fiscal capture, enforcement escalation, displaced lawful-market activity, and criminal-market rents. It does not fully monetise broader harms such as violence, neighbourhood disorder, insurance repricing, youth informalisation, or counterfeit-product risk. Even with that limitation, the estimated annual measurable costs are substantial: AUD 12 billion to AUD 20 billion in Australia, R\$3 billion to R\$15 billion in Brazil, €250 million to €1.2 billion in Belgium, €500 million to €3 billion in the Netherlands, and DKK 250 million to DKK 1.5 billion in Denmark.

These figures should not be treated as ordinary compliance costs. They are estimates of recurring economic displacement. They describe what happens when markets move out of lawful commercial systems and into illicit and enforcement-intensive channels. They also show why a narrow fiscal analysis is inadequate. A government may focus on the excise it has lost, but that is only one part of the ledger. Police see organised-crime caseloads. Customs sees smuggling and seizures. Regulators see permanent inspection burdens. Lawful retailers see lost sales

^{x1} <https://www.prohibitiondoesnotwork.com/news/new-gfn-report-vape-prohibition-hands-markets-to-criminals>

and closures. Communities see firebombings, extortion and disorder. Public-health agencies lose reliable information about products, consumption patterns and user behaviour.

Australia provides the clearest fiscal and enforcement warning. A PDNW report on Australia estimates the illicit vape market at AUD 1 to 2 billion annually and describes a market marked by widespread non-compliance, unsafe products, underage access and violent criminal competition. Davidson's broader cost model places Australia's annual regulatory-failure cost far higher, at AUD 12 billion to AUD 20 billion, once forgone tax, enforcement escalation, lawful retailer displacement and criminal-market rents are included. This distinction matters. The cost to government and society is not merely the value of illegal products sold. It is the cost of the parallel criminal market that prohibition creates and then forces the state to chase.

The same pattern appears in Brazil. A PDNW and Livres Mercado report on Brazil shows that the country has maintained a national vape ban since 2009, yet now has up to 2.9 million e-cigarette users and a market worth over USD 1 billion. Because all supply is illegal, there are no licensed retailers, no legal product standards, no age verification and no regulatory visibility. Youth access remains widespread, while smoking prevalence has risen from 9.3% in 2020 to 11.6% in 2024. Davidson's report estimates Brazil's annual measurable regulatory-failure cost at R\$3 billion to R\$15 billion when fiscal leakage, enforcement costs, lawful-market displacement and criminal rents are considered.

Mexico, while not included in Davidson's five-jurisdiction cost table, shows the same mechanism in a more dangerous form. A PDNW report, *Vapes and Violence: Mexico's Prohibition Problem*, shows that prohibition has failed to eliminate demand. The illicit vapour market is estimated at USD 658 million to USD 1.39 billion, adult use has risen to 1.8 million, and youth vaping has reportedly increased by more than 400%. The report also documents the involvement of criminal groups including Los Chapitos and CJNG, with violence, extortion and cartel-controlled distribution. In such a market, the fiscal cost is not only lost revenue. It is the creation of a recurring income stream for organised crime.

The European examples are especially relevant to the Commission. Belgium banned disposable vape sales from January 2025. Davidson's report notes that Belgium's Federal Public Health Service seized 140,019 disposable vapes in 2025, conducted almost 2,400 inspections, identified illegal products in 680 cases, filed nearly 600 official reports, and temporarily closed 18 shops. Illegal disposable vapes were found in nearly 60% of Brussels inspections and roughly one in five inspected shops in Flanders. This is not evidence of a market disappearing. It is evidence of a continuing market that now requires permanent inspection and seizure activity.

The Netherlands shows the same enforcement problem through flavour restrictions. Dutch regulators prohibited flavoured vapes and expanded enforcement across retailers, distributors and online sellers. In the first half of 2024, the Dutch Food and Consumer Product Safety Authority conducted 513 retailer inspections and found 107 violations, a 21% violation rate. Regulators also removed 1,059 online posts advertising illegal vape or tobacco products in the same six-month period. The PDNW report on the Netherlands similarly shows widespread non-compliance, continued use of banned flavours, cross-border and illicit sourcing, and seizure activity. Again, the legal market was weakened, but demand continued.

Denmark illustrates the youth-access and informal-supply dimension. Davidson's report notes that among 15- to 17-year-olds, the share purchasing e-cigarettes through social media doubled from 13% in 2023 to 25% in 2024. That is a fiscal and regulatory problem as well as a youth-protection problem. Licensed retailers can be inspected and sanctioned. Social-media sellers, peer-to-peer suppliers and informal personal networks cannot be regulated in the same way. When policy pushes supply into these channels, the government loses both revenue and practical control.

The Commission should therefore reject any impact assessment that treats black-market displacement as a secondary or speculative effect. It should be treated as a central policy risk. The relevant question is not only whether a restriction may reduce legal sales of a product. It is whether demand will persist, where that demand will go, who will supply it, what revenues government will lose, what costs enforcement agencies will inherit, what profits criminal networks will gain, and how much visibility regulators will surrender.

The EU is not identical to Australia, Brazil, Mexico, Belgium, the Netherlands or Denmark. But the economic mechanism is the same. If lawful supply is suppressed while demand remains, illicit actors supply the market. If that market is profitable, criminal and informal suppliers adapt quickly. The stricter the legal regime, the greater the premium for evasion.

A proper EU impact assessment should therefore include not only lost excise revenue, but VAT, customs duties, licensing revenue, company tax, employment income, lawful retailer displacement, enforcement escalation, criminal-market rents, insurance and community impacts, and the loss of regulatory visibility. Without that analysis, the Commission will underestimate the true cost of prohibition-style regulation and risk adopting measures that appear simple on paper but become far more expensive, less enforceable and less protective in the real world.

11. Enforcement experts warn that prohibition strengthens organised crime

The Commission's impact assessment should take seriously the views of enforcement experts.

Michael Ellis, former Assistant Director of INTERPOL and former head of INTERPOL's Illicit Trade Crime Unit, has warned in comments submitted to PDNW that illicit vapes have become one of the fastest-growing categories in global illicit markets. He estimates that illicit vape trade has reached 35% of the EU market, 68% in Asia, and 82% in Australia.

His warning is straightforward: prohibition creates market opportunities for organised crime. Illicit suppliers bypass safety standards, avoid taxation, undercut legitimate businesses, and reinvest profits into other criminal activity. Criminal networks can use informal retail, online platforms, social media, cross-border smuggling, and domestic assembly to meet demand quickly.

This should matter directly to EU policymakers. Once lawful supply is suppressed, criminal groups do not merely sell an unregulated consumer product. They acquire a recurring revenue stream, a recruitment channel, a distribution network, and an opportunity to normalise illegal supply among ordinary consumers. Ellis also warns that illicit vape markets can expose young people to wider criminal networks, including informal sales channels used to recruit minors and, in some cases, to facilitate exploitation.

Mexico shows how severe this can become. The PDNW report *Vapes and Violence: Mexico's Prohibition Problem* documents how Mexico's vapour market has been absorbed into the country's criminal economy despite prohibition. The report identifies involvement by major criminal organisations including Los Chapitos and the Jalisco New Generation Cartel, as well as local criminal networks using intimidation, extortion and violence to control distribution. It reports that retailers have been pressured to sell cartel-approved products, threatened for non-compliance, and forced to pay criminal rents. The report also notes that Mexico's illicit vapour trade has been linked to existing smuggling infrastructure and broader criminal networks involved in narcotics, firearms and people trafficking.

Australia shows the same mechanism in a different institutional setting. Our reporting on Australia describes how a highly restrictive model has helped create a large illicit market, with organised criminal groups filling the supply gap left by legal restrictions. The result has not been a controlled market, but a law-and-order problem involving

smuggling, extortion, unsafe products, and violent competition. Australia's illicit tobacco and vape market has been associated with firebombings, murders, targeted attacks, and shootouts between drug smuggling vessels and the Australian Border Force

It is not enough to ask whether a ban is intended to protect health. The Commission must ask who will supply the market afterwards, what criminal networks may benefit, what other activities those profits may fund, and whether regulators will have more or less visibility over the products reaching consumers. A policy that turns a regulated consumer market into a revenue stream for criminal syndicates cannot be considered a public-health success.

12. Sweden and Japan show that safer nicotine access can accelerate smoking decline

The call for evidence rightly situates the revision within Europe's objective of reducing smoking and achieving a tobacco-free generation. But that objective will not be achieved by treating all nicotine products like cigarettes.

The Tholos Foundation white paper *Safer Nicotine Works: The Cases of Japan and Sweden* provides important positive evidence. Sweden is the strongest EU example of harm reduction working in practice. The paper showed that Sweden's daily smoking rate had already fallen from 11.4% in 2012 to 5.6% in 2022, the lowest in Europe, while overall nicotine use remained broadly comparable to other countries because consumers shifted away from cigarettes and toward lower-risk oral products such as snus and nicotine pouches. Since then, Sweden has continued to move further ahead of the rest of Europe. The Swedish Public Health Agency reported daily smoking at 5.4% in 2024, and newer 2025 data from the Swedish Council for Information on Alcohol and Other Drugs has been reported as showing daily smoking falling below the smoke-free threshold, with CAN data cited at 3.7% daily smoking. Sweden is therefore not merely approaching smoke-free status; on this evidence it has effectively achieved it. That result is especially significant because Sweden did not eliminate nicotine use. It reduced smoking by allowing consumers to shift away from combustible tobacco. The public-health outcomes are significant. The same report notes that Sweden has the lowest lung cancer incidence and mortality in the EU. It also applies taxation that reflects relative risk, with cigarettes taxed more heavily than snus and nicotine pouches.

Japan provides another important example. The Tholos Foundation paper finds that after heated tobacco products became widely available, cigarette sales fell by 32% in five years. Japan's smoking decline accelerated after the introduction of heated tobacco products, with cigarette sales falling below 100 billion units for the first time in 2020.

These cases do not mean the EU should copy every detail of Swedish or Japanese policy. They do show that access to acceptable smoke-free alternatives can accelerate reductions in smoking.

The EU should therefore design a framework that encourages switching away from cigarettes, rather than one that makes all alternatives less accessible, less attractive, or less trusted.

13 An Evidence Based Progressive Policy Alternative

Instead of embracing further restrictions and regulations that shall entrench the black market and increase smoking rates, EU should pursue a harmonised, risk-based framework for nicotine and tobacco products.

Such a framework should keep combustible cigarettes as the central focus of tobacco-control policy and recognise the continuum of risk among nicotine products. It should maintain legal adult access to regulated smoke-free alternatives and create specific legal categories for vaping products, heated tobacco products, nicotine pouches, and other emerging products.

The framework should include clear product standards, ingredient rules, product notification, manufacturer accountability, proportionate labelling and warnings, and nicotine-content rules that prevent unsafe extremes without making legal products ineffective. It should prohibit sales to minors, require robust age verification for

online and physical sales, license retailers and distributors, carry out regular compliance checks, and impose meaningful penalties for sales to minors and illegal supply.

It should restrict unlawful deliberate marketing to youth in package design with untrue claims, while allowing objective flavour descriptors for adult products. It should preserve truthful risk communication to adult smokers, apply differentiated taxation and regulation based on relative risk, and strengthen enforcement against illicit imports and illegal online sellers.

This would be a genuine modernisation of EU rules. It would protect young people while keeping adult consumers in the legal market. It would support the internal market while reducing incentives for illicit trade. It would help smokers switch away from combustible tobacco while preserving regulatory oversight.

Conclusion

The Commission is right that the existing EU framework needs modernisation. The market has changed. Digital sales have changed. Product categories have changed. Member State rules have diverged. Youth access and illegal supply require serious attention. However proposals under review risk entrenching these problems, not solving them.

The evidence is clear. The PDNW report on the Netherlands shows that flavour bans can fail to reduce youth use while pushing adults toward illicit channels. The Tholos Foundation's Ipsos-based Estonia study shows that banned flavours continue through DIY and black-market supply. The PDNW report on Germany shows that legal misclassification can deprive smokers of safer alternatives. Dynata and Ipsos polling from Spain, Poland, and Denmark shows that consumers respond to bans through cross-border, online, informal, or cigarette substitution. PDNW and Tholos Foundation reports from Australia, Brazil, and Mexico show that when legal supply is suppressed, criminal markets expand. The Tholos Foundation's *Safer Nicotine Works* paper shows the alternative: when adult smokers have access to acceptable smoke-free products, cigarette use can fall rapidly. Professor Davidson's report shows the broader economic consequence: prohibition-style regulation does not eliminate the market, but displaces it into channels that are harder to supervise, harder to tax, more expensive to enforce, and more profitable for criminal suppliers.

The EU should not harmonise failure. It should build a framework that keeps adults in the legal market, keeps minors out, and keeps criminals from becoming the default suppliers of nicotine. The goal should be to reduce smoking, not to reduce the number of legal alternatives to smoking. The evidence is clear that progressive regulation, not prohibition, is the way for this to be achieved.