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European Tobacco Harm Reduction Advocates
Response to the Call for Evidence
Tobacco products and tobacco advertising – revision of EU rules
15th June 2026

Our submission is on behalf of the European Tobacco Harm Reduction Advocates (ETHRA). ETHRA is the voice of 27 million EU consumers of safer nicotine products (SNPs). The safer nicotine products we use include vapes, nicotine pouches, snus, and heated tobacco products. ETHRA is a consortium of 24 grassroots consumer associations in 17 European countries, supported by experts in tobacco control and nicotine research. We are a voluntary operation with no industry funding or conflicts of interest. Our transparency registration number is 354946837243-73. ETHRA expects to be part of any consultation process going forward.

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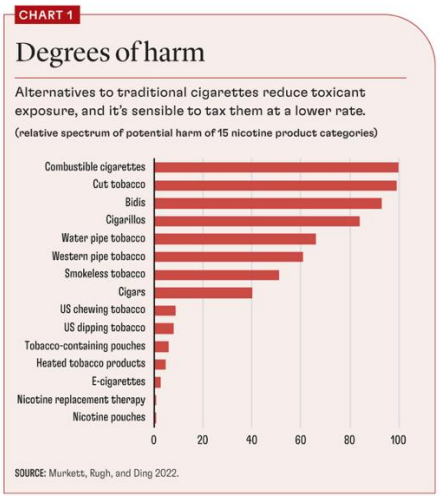
1 Framework for assessing evidence

Our main concern is that the Commission's framework for interpreting evidence is not aligned with how the nicotine market functions in practice and how consumers respond to restrictions. We draw attention to the following foundational concepts that should inform the evaluation of evidence gathered in the call for evidence.

- **The market for consumer nicotine is large and will persist**. Demand for nicotine exists because a substantial number of people wish to use it for its psychoactive effects, including pleasure, mood control and cognitive improvements. In this sense, it is like alcohol or caffeine; people use nicotine because of its effects. Around 100 million Europeans (about 1 in 4 adults) currently use nicotine, mostly through the most dangerous method: smoking tobacco. Nicotine has been used for 12,000 years, and the market for nicotine is not going to disappear in the foreseeable future. Attempts to suppress supply through regulation or prohibition do not necessarily modify demand, and those seeking nicotine will either continue to smoke or revert to smoking, access an illicit market in the products they wish to use, or find risky workarounds, such as home mixing.

- **The risks of nicotine use vary by more than one hundred-fold depending on the method of delivery.** Nicotine may be the most important psychoactive agent, but it is not the cause of most of the harm to health and welfare. The following chart, which provides rough estimates of risk relative to cigarette smoking, is from research on optimal taxation conducted by experts at the International Monetary Fund.[1]



  The report shows how different risks can be reflected in policy, in this case through variations in tax rates. The most important feature of the bar chart is the *discontinuity between combustible and non-combustible products*. The highest risks arise from combustion and smoke inhalation. From that observation, it is possible to achieve substantial gains in public health by shifting nicotine use from high-risk (combustible) to low-risk (smoke-free) products. The main public health goal should be to reduce *smoking* as deeply and rapidly as possible.

- **Nicotine use will persist, but consumers will use it with far lower risks**. Nearly one quarter (24%) of Europeans still smoke, and over 100 million use nicotine; a legal market for consumer

[1] MF, Van Oordt & Rosenberg, Taxing harmful habits, 2026. Graphic derived from Murkett et al. 2022

nicotine will inevitably persist for the foreseeable future and at least over the likely time frame of updates to the Tobacco Products Directive and Tobacco Advertising Directive. Fortunately, it is possible to migrate this market, over time, from high-risk products like cigarettes to low-risk smoke-free products like vapes, pouches, and heated or smokeless tobacco. This is already happening through consumer preference under the existing regime, and it is essential that new legislation does not interrupt that process.

- **The transformation of the nicotine market proceeds through two main mechanisms:** (1) existing smokers switching to safer products, and (2) new nicotine users diverting from smoking to safer products at the point of initiation and then ageing into the population without ever smoking. Where smoking rates are the lowest, for example, in Scandinavia, young people with a propensity to use nicotine take up safer nicotine products such as snus or pouches without ever smoking in the first place.

- **E-cigarettes are a popular and effective tool for smoking cessation**. An independent 2026 "umbrella" review summarised the systematic reviews of e-cigarettes for smoking cessation, concluding:[2]

  > *Meta-analyses of electronic cigarettes (EC) for smoking cessation report point estimates favouring higher ≥6-month smoking cessation rates with nicotine EC compared with nicotine replacement therapy, non-nicotine EC/placebo, behavioural or no support and mixed support.*

  In England, a study of methods used for smoking cessation found that the most commonly used smoking cessation aid was e-cigarettes, used in 40% of quit attempts, and that e-cigarettes and heated tobacco were the most effective:[3]

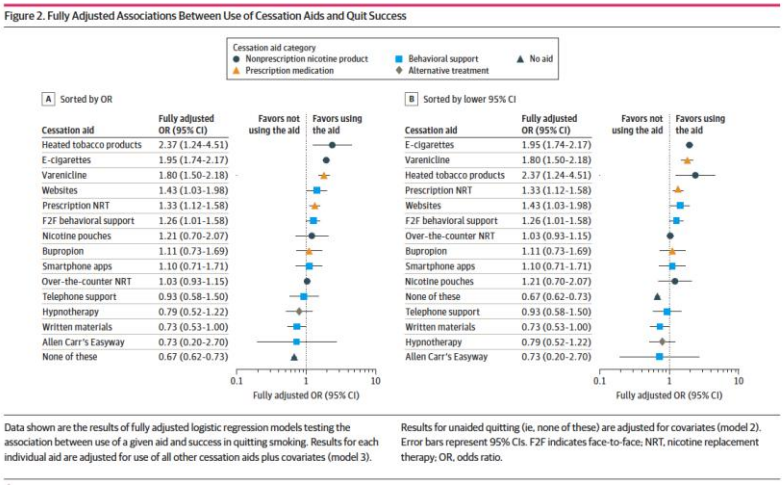


Figure 2. Fully Adjusted Associations Between Use of Cessation Aids and Quit Success

Cessation aid category: Nonprescription nicotine product; Prescription medication; Behavioral support; Alternative treatment; No aid

A Sorted by OR

Cessation aid	Fully adjusted OR (95% CI)
Heated tobacco products	2.37 (1.24-4.51)
E-cigarettes	1.95 (1.74-2.17)
Varenicline	1.80 (1.50-2.18)
Websites	1.43 (1.03-1.98)
Prescription NRT	1.33 (1.12-1.58)
F2F behavioral support	1.26 (1.01-1.58)
Nicotine pouches	1.21 (0.70-2.07)
Bupropion	1.11 (0.73-1.69)
Smartphone apps	1.10 (0.71-1.71)
Over-the-counter NRT	1.03 (0.93-1.15)
Telephone support	0.93 (0.58-1.50)
Hypnotherapy	0.79 (0.52-1.22)
Written materials	0.73 (0.53-1.00)
Allen Carr's Easyway	0.73 (0.20-2.70)
None of these	0.67 (0.62-0.73)

Favors not using the aid | Favors using the aid

0.1 1 10

Fully adjusted OR (95% CI)

B Sorted by lower 95% CI

Cessation aid	Fully adjusted OR (95% CI)
E-cigarettes	1.95 (1.74-2.17)
Varenicline	1.80 (1.50-2.18)
Heated tobacco products	2.37 (1.24-4.51)
Prescription NRT	1.33 (1.12-1.58)
Websites	1.43 (1.03-1.98)
F2F behavioral support	1.26 (1.01-1.58)
Over-the-counter NRT	1.03 (0.93-1.15)
Bupropion	1.11 (0.73-1.69)
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Allen Carr's Easyway	0.73 (0.20-2.70)

Favors not using the aid | Favors using the aid

0.1 1 10

Fully adjusted OR (95% CI)

Data shown are the results of fully adjusted logistic regression models testing the association between use of a given aid and success in quitting smoking. Results for each individual aid are adjusted for use of all other cessation aids plus covariates (model 3). Results for unaided quitting (ie, none of these) are adjusted for covariates (model 2). Error bars represent 95% CIs. F2F indicates face-to-face; NRT, nicotine replacement therapy; OR, odds ratio.

An American economic analysis showed e-cigarettes to be more *cost-effective* relative to nicotine replacement therapy from a societal point of view.[4] Users generally bear the cost of e-

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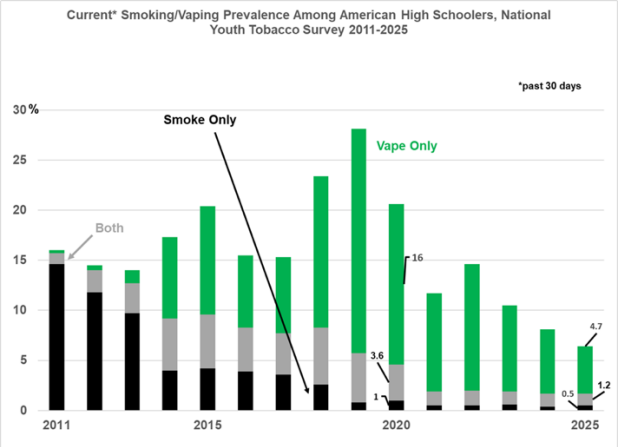
2 Wu, A. D., Conde, M., Butler, A. R., Knight, E., Lindson, N., Livingstone-Banks, J., Hajek, P., McRobbie, H., Begh, R., Theodoulou, A., Notley, C., Turner, T., Zhitnik, E., & Hartmann-Boyce, J. (2026). Electronic cigarettes for smoking cessation: An overview of systematic reviews and evidence and gap map. *Addiction*. https://doi.org/10.1111/add.70388

3 Jackson, S. E., Brown, J., Buss, V., & Shahab, L. (2025). Prevalence of Popular Smoking Cessation Aids in England and Associations With Quit Success. *JAMA Network Open*, *8*(1), e2454962. https://doi.org/10.1001/jamanetworkopen.2024.54962

4 Chen, A. W., & Fishman, P. A. (2025). Cost-Effectiveness Analysis of E-cigarettes Compared to Nicotine Replacement Therapy for Smoking Cessation Among Medicaid Users in California. *Nicotine & Tobacco Research*, *27*(3), 466–474. https://doi.org/10.1093/ntr/ntae219

cigarettes, so the cost-effectiveness from the healthcare system's perspective would be even greater.

- **In framing proposals and considering their impact, the Commission needs a more sophisticated approach to youth uptake.** No one is recommending that young people vape or use pouches. However, policymakers must assess the impact of these products by considering what would happen in their absence – the counterfactual. If a young person is vaping today, but would have smoked in the absence of vapes, then that is a public health benefit. The process of migration of youth nicotine use from high-risk to low-risk use has been highly visible in the United States. See the dramatic decline in smoking shown in the chart below,[5] which experts regard as a cause for celebration.[6]



- **The concept of a gateway effect has been thoroughly debunked**. The idea that uptake of vaping would cause a subsequent move to smoking has been based on a misreading of the evidence. The proper explanation for the observed data is "common liability" – the idea that vaping and smoking have the same confounding risk factors.

- **Evidence for the gateway hypothesis is better explained by a "common liability" to nicotine use.** Claims that vapes are a gateway to smoking are based on a misunderstanding of the evidence (i.e. that youth who use vapes are also more likely to smoke cigarettes). Rather than vapes *causing* youth to also smoke cigarettes (which confuses correlation and causation), it is more likely that vape use and smoking are both explained by pre-existing characteristics which predispose some youth to use nicotine. There are dozens of these "common liability" factors (e.g., other substance use, poor mental health, risk-seeking personality) which are not accounted for in most studies. [17] The apparent gateway association becomes successively weaker as more common liability factors are accounted for[7] [8] – in some cases becoming not

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5 Rodu, B., & Plurphanswat, N. (2024). Joint smoking–vaping prevalence rates among American youth and young adults 2011–2022. *Harm Reduction Journal*, *21*(1), 209. https://doi.org/10.1186/s12954-024-01125-4 Graphic (Figure 1) updated for 2025 data by Brad Rodu [Tobacco Truth].

6 Warner, K. E. (2024). Kids No Longer Smoke Cigarettes. Why Aren't We Celebrating? *American Journal of Public Health*, *114*(11), 1191–1194. https://doi.org/10.2105/AJPH.2024.307841

7 Leventhal AM, et al. Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence. *JAMA*. 2015;314(7):700-707. [link]

8 Sun R, et al. Is Adolescent E-Cigarette Use Associated With Subsequent Smoking? A New Look. *Nicotine Tob Res*. Mar 26 2022;24(5):710-718. [link]

statistically significant[9] – suggesting that it is better explained by a pre-existing propensity to use nicotine. A 2024 analysis of the gateway effect concluded:[10]

> *Evidence offered in support of the gateway hypothesis does not establish that ENDS use causes youth to also smoke cigarettes. Instead, this evidence is better interpreted as reflecting a shared liability to use both ENDS and cigarettes. Population-level trends are inconsistent with the gateway hypothesis, and instead are consistent with (but do not prove) ENDS displacing cigarettes. Policies based on misinterpreting a causal gateway effect may be ineffective at best, and risk the negative unintended consequence of increased cigarette smoking.*

- **If there is a gateway, where are all the smokers?** If vapes were a gateway to cigarette smoking, then youth smoking trends would be higher than otherwise expected as vape use increases. However, population-level studies show the opposite: youth and young adult smoking prevalence declined *faster* after the use of vapes became common,[11] and this pattern is remarkably consistent across countries, including the US,[19 12 13] UK,[14 15] Canada,[16] and New Zealand.[17 18] These declines have been drastic and unexpected: in the US, youth smoking in 2020 was far lower (3.3%)[19] than what was thought possible in 2010, according to the US Healthy People 2020 target (16%).[20] These trends are consistent with vape use diverting youth with a predisposition for nicotine use away from more harmful combustible cigarettes.

2 Taking an ethical perspective

- **The EU must act ethically in its approach to tobacco and nicotine policy**. This means it must carefully weigh benefits and detriments, consider distributional effects, and recognise an appropriate relationship between the institutions and the citizen. There is a trade-off between paternalism and autonomy that is rarely discussed in Brussels. As well as asking the question "will it work as intended?" (discussed below), politicians must also ask "is it right?" (a question of values). There is a substantial body of literature on the ethics of harm reduction. Lund and

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9 Kim S, et al. The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. *Nicotine Tob Res*. Jun 12 2020;22(7):1123-1130. [link]

10 Selya, A. (2024). The "Gateway" hypothesis: Evaluation of evidence and alternative explanations. Harm Reduction Journal, 21(1), 113. [link]

11 Levy DT, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control*. Nov 2019;28(6):629-635. [link]

12 Meza R, et al. Trends in Tobacco Use Among Adolescents by Grade, Sex, and Race, 1991-2019. *JAMA Network Open*. 2020;3(12):e2027465-e2027465. [link]

13 Selya AS, et al. Trends in electronic cigarette use and conventional smoking: quantifying a possible 'diversion' effect among US adolescents. *Addiction*. 2021;116(7):1848-1858. [link]

14 Levy DT, et al. England SimSmoke: the impact of nicotine vaping on smoking prevalence and smoking-attributable deaths in England. *Addiction*. 2021;116(5):1196-1211. [link]

15 Tattan-Birch H, et al. Rapid growth in disposable e-cigarette vaping among young adults in Great Britain from 2021 to 2022: a repeat cross-sectional survey. *Addiction*. Feb 2023;118(2):382-386. [link]

16 Levy DT, et al. Comparison of smoking prevalence in Canada before and after nicotine vaping product access using the SimSmoke model. *Canadian Journal of Public Health*. 2023/08/04 2023. [link]

17 Walker N, et al. Use of e-cigarettes and smoked tobacco in youth aged 14-15 years in New Zealand: findings from repeated cross-sectional studies (2014-19). *Lancet Public Health*. Apr 2020;5(4):e204-e212. [link]

18 ASH (New Zeakand) Year 10 Snapshot Survey 2023 Topline – Youth Smoking and Vaping, [link]

19 Gentzke AS, et al. Tobacco Product Use Among Middle and High School Students - United States, 2020. *MMWR Morb Mortal Wkly Rep*. Dec 18 2020;69(50):1881-1888. [link]

20 Healthy People 2020. Tobacco Use Objectives. [link]

Saebo (2024) discuss the limits of anti-smoking measures if not backed by promotion of safer alternatives:[21]

> *We problematize the "help" argument and discuss the authorities' right to elevate the zero-vision of smoking as universally applicable while at the same time setting up barriers to switching to alternative nicotine products with reduced risk.*

Parker and colleagues discuss e-cigarette availability (ECA) in the context of a bioethics framework:[22]

> *ECA is a population-level intervention consistent with respecting individual autonomy by using the least restrictive means to accomplish public health goals, and it supports equity and justice. Second, ECA is supported by four principles that form a biomedical ethics framework. By reducing smokers' health risks and not harming them, ECA fulfills principles of beneficence and non-maleficence. Because ECA allows smokers to make informed health decisions for themselves, it fulfills the principle requiring respect for persons and their autonomy. Here, we consider whether nicotine addiction and thus ECA undermine autonomy, and also discuss the ethical warrant for special protections for youth. Finally, ECA can also advance justice by providing a harm reduction alternative for disadvantaged groups that disproportionately bear the devastating consequences of smoking.*

The Royal College of Physicians (London) has also framed its consistent support for tobacco harm reduction through an ethics perspective since 2007.[23] Its 2016 report concludes: [24]

> *The evidence summarised in this report demonstrates that the emergence of e-cigarettes has generated a massive opportunity for consumers as well as a healthcare-led revolution in the way that nicotine is used in society. As the technology of these and other non-tobacco nicotine products improves, so the vision of a society that is free from tobacco smoking, and the harm that smoking causes, becomes more realistic.*

3 Unintended consequences of excessive regulation – illicit trade

- **Excessively restrictive policies on safer alternatives are constrained by illicit trade**. If people cannot access the products they want, especially if they believe the restrictions are unjustified or likely to harm them, they will resort to illicit supply. Illicit suppliers see taxation and regulation as an opportunity. In March 2026, the Fraunhofer Institute published an estimate that 48% of the European Union e-cigarette commerce is "irregular", comprising a grey market (private personal consumption of non-compliant products) of 13% and a black market (commercial illegal trade) of 38%.[25] The Fraunhofer Institute highlights a likely **large and growing illicit market in Europe**, anticipating a 64% increase in value by 2030.

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21 Lund, K. E., & Saebo, G. (2024). Challenges in legitimizing further measures against smoking in jurisdictions with robust infrastructure for tobacco control: How far can the authorities allow themselves to go? *Harm Reduction Journal*, *21*(1), 33. https://doi.org/10.1186/s12954-024-00951-w

22 Thomas, R., Parker, L. S., & Shiffman, S. (2021). The Ethics of Tobacco Harm Reduction: An Analysis of E-Cigarette Availability From the Perspectives of Utilitarianism, Bioethics, and Public Health Ethics. *Nicotine & Tobacco Research*, *23*(1), 3–8. https://doi.org/10.1093/ntr/ntaa198

23 Royal College of Physicians (2007) Harm reduction in nicotine addiction: helping people who can't quit, Chapter 11: Ethics, human rights and harm reduction for tobacco users, RCP London [full report PDF]

24 Royal College of Physicians (2016) Nicotine without smoke: tobacco harm reduction Chapter 12: Ethics and conclusions. RCP London [full report PDF]

25 Fraunhofer Institute, The irregular market for e-cigarettes in Europe, February 2026 [Fraunhofer Institute]

Irregular trade in e-cigarettes in Europe has risen to a significant 48%, equal to a volume of €6.6 billion.

The irregular e-cigarette market is expected to exhibit significant annual growth of 8.6 per cent. This translates into a market value of €10.83 billion in 2030.

The global illicit share of the vape market was 75% in 2025 and is growing, according to the business information service Euromonitor: [26]

The illicit e-vapour market is valued at 47 million litres, equivalent to 605 billion sticks and accounts for three-quarters of total e-vapour volume globally.

Global illicit e-vapour sales exceeded the equivalent of 600 billion sticks last year and are forecast to grow a further 10% in 2025

The rise of single-use products has driven the illicit market, with 89% of disposable e-vapour volumes being illicit globally

31% of global e-vapour consumers reside in markets where e-vapour products are prohibited

- **There is a considerable danger that further taxation and regulation in the European Union will drive even more illicit trade, which is already out of control for vapes**. Despite the obvious problem, the Commission's evaluation report and research programme are silent on the European Union's illicit trade in tobacco and nicotine products. Several member-state policies have exacerbated illicit trade. According to research commissioned by the Netherlands Ministry for Health, Welfare and Sport, nearly all of the Dutch vape market is illicit following its ban on vape flavours. The report concludes:[27]
    - *87 per cent of vapers appear to use illegal vapes and/or vapes obtained through an illegal sales channel.*
    - *Vapes are sold in physical shops in the Netherlands, online shops and physical shops abroad, but also via social media and dealers (mainly among young people).*

  Despite Belgium's 2023 ban on nicotine pouches, these products are still easy to find in regular stores,[28] and nicotine analogues have been used as a workaround.[29] Finland provides a useful example of liberalisation *reducing* illicit trade: it went from a strict pharmaceutical regime for pouches to allowing their sale in shops in 2023. The result was an 80% decline in illicit snus activity as measured by seizures.[30] However, further restrictions imposed in 2025 caused a rebound in illicit activity. The Commission has failed to synthesise evidence from member states on the impact of the policies it is now considering for harmonisation at the EU level.

- **The European Commission must learn from Australia**. It is essential to learn lessons from Australia's mishandling of tobacco and nicotine policy. Once regarded as a leader in tobacco

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26 Euromonitor, Over 75% of global e-vapour volume is driven by illicit market, 28 August 2025. [Euromonitor]

27 Bureau Beke, "Donkere Wolken" (Dark Clouds), 10 April 2026 [Bureau Beke]

28 Brussels Times, A year on, nicotine pouches still available in shops despite ban, 26 November 2024 [Brussels Times]

29 Vanhee, C., et al. (2025). *The Emergence of a Novel Synthetic Nicotine Analog 6-Methyl Nicotine (6-MN) in Proclaimed Tobacco- and Nicotine-Free Pouches Available in Europe*. https://doi.org/10.1002/dta.3841

30 YLE news, Snus smuggling plummets after nicotine pouch law reform, 3 October 2023 [YLE news]

control has now descended into a chaotic, lawless fiasco: it is important to understand why.[31] Following Australia's restrictive and punitive approach to tobacco control, 50-60% of tobacco and 97.5% of e-cigarettes were sold illegally in 2024-25.[32] More recent estimates from the Australian Bureau of Statistics suggest that 80% of the nicotine market (by weight of nicotine) is now illegal and that the nicotine market has grown by 40% since 2017, despite highly restrictive policies (e-cigarettes) and punitive taxation (cigarettes). According to the ABS:[33]

> *Greater accessibility and affordability of illicit tobacco products are likely to have enabled higher tobacco consumption. In 2025, illicit sources accounted for 80% of all nicotine consumption.*
>
> *The quantity of nicotine consumed in Australia increased by almost 40% from 2017 to 2025, with most of the increase occurring since 2021. Population growth over the period 2017-25 was 14%.*

Australia's authorities have lost control of its tobacco and nicotine market and are now experiencing the exact opposite of their intended objectives.[34] Given Europe's greater openness and the presence of established organised crime groups, the Impact Assessment must consider Australia's experience and the likely illicit response to restrictive or prohibitive measures at the European level.

- **Illicit trade in nicotine pouches could easily reach the same levels as vapes**. A very high penetration of illicit trade has been experienced for vapes. There is every reason to expect that excessive regulation or taxation of nicotine pouches would lead to a similar scale of illicit trade,

- **The negative consequences of illicit markets are severe**:
  - The aim of the restrictions or taxes that caused the illicit trade is defeated
  - The products are unregulated and may be dangerous, out of date, or defective
  - The sellers are unscrupulous commercial operators and will sell to anyone of any age
  - Criminal networks operate through violence, corruption and extortion
  - The consumer has no protections or recourse; disputes are settled through violence
  - Enforcement actions are expensive, often excessive, and do little to limit supply
  - Penalties to deter supply and use become disproportionate to the risk
  - Young people are drawn into criminal supply chains as bottom-tier suppliers
  - Consumers are exposed to other illegal products or services, such as illicit drugs
  - Large illicit profits finance flourishing organised crime groups and terrorism

  The UN Office on Drugs and Crime has documented the harms arising from criminal infrastructure that underpins the illicit drug trade.[35] The UNODC chart maps the actors involved:

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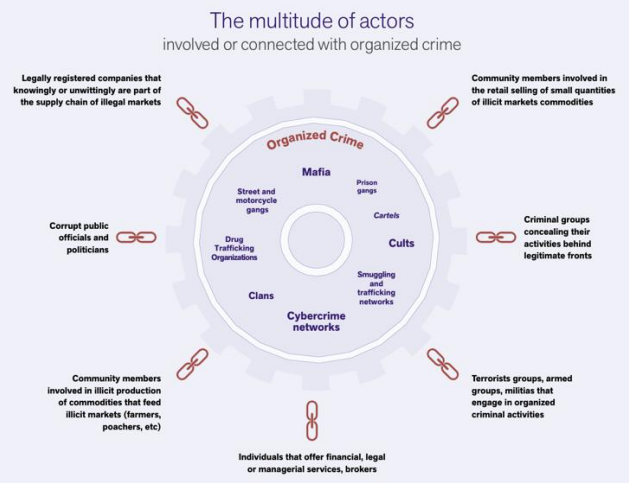
31 Martin, J., & Jegasothy, E. (2025). Fanning the flame: Analysing the emergence, implications, and challenges of Australia's de facto war on Nicotine. *Harm Reduction Journal*, *22*(1), 42. https://doi.org/10.1186/s12954-025-01163-6

32 Illicit Tobacco and E-cigarette Commissioner, Report 2024-25. Table 4, March 2026 [ITEC website]

33 Australian Bureau of Statistics, Household consumption of illicit tobacco and nicotine products, June 2026 [ABS website]

34 Borland, R., Martin, J., Jegasothy, E., Youdan, B., & Hall, W. (2026). Has Australia lost control of its tobacco and nicotine markets? *Addiction*. https://doi.org/10.1111/add.70428

35 UN Office on Drugs & Crime, Research Brief on Transnational Organized Crime, November 2025 [UNODC]



The European Union should learn from the experience of the illicit drug trade and avoid replicating it for tobacco and nicotine.

- **A critical goal for all tobacco and nicotine policies must be to keep the market legal.** The likely consequences of illicit trade constrain European policymakers' flexibility to impose restrictive or prohibitive policies. Such trade undermines the policy's original purpose, leaves the market unregulated, and causes a wide range of social harms. It is NOT adequate simply to call for more enforcement without explaining why this failed to stop around half the European market in vapes becoming illicit or irregular by 2025.

- **Many commentators overstate the importance and effectiveness of enforcement in controlling illicit trade.** With good policing, large-scale seizures and arrests are possible and desirable. However, the illicit supply is adaptable, innovative and competitive – supply reconfigures and continues, and prices stabilise. If a container is seized, it will be replaced. If non-compliant shops are shuttered, internet commerce and courier services will step in. The arrest of a gang creates an opportunity for rival suppliers. If there is a crackdown on one brand, others will emerge. The digital economy has increased the flexibility of illicit supply through encrypted messaging apps, pop-up online stores, international payment systems, cryptocurrency, social media for marketing, long supply chains, and containerisation.

- **Focus regulation on upholding consumer interests.** There is a simple way to avoid illicit trade. Regulation should be designed in the interest of the adult consumer and be welcomed by consumers as protecting their consumer rights, health, and welfare, given that they have decided to use these products.

- **The Impact Assessment must consider the implications of any policy package for illicit trade**. It is unacceptable to continue ignoring this harmful, unintended consequence of taxation and regulation. Policy should be constrained to avoid excessive illicit trade rather than proceed by ignoring it.

4 Unintended consequences of excessive regulation – more smoking

- **Restrictions on safer products can increase smoking.** There is now considerable evidence, mostly from the United States, that vapes function as economic substitutes for cigarettes. This should not surprise the European Commission: both are methods of delivering nicotine, and

users generally seek a satisfactory level of nicotine from whatever source they are using. But several implications follow that must be accounted for in policymaking. If the safer products become relatively more expensive, less accessible, or otherwise unappealing, then a rebound to cigarette smoking should be expected. As the Royal College of Physicians put it in its groundbreaking 2016 report:[36]

> *If [a risk-averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer-friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking.*

- **Vape flavour bans increase smoking**. Quasi-experimental economic research has shown that vape flavour bans have increased smoking at the state level in the United States. For example, Friedman et al (2026) show:[37]

  > *Our findings reveal that ENDS flavor restrictions yield substantial decreases in total ENDS sales, primarily owing to significant declines in flavored ENDS sales alongside nonsignificant increases in unflavored ENDS sales.* ***Further analyses find that ENDS flavor restrictions increase sales of combustible cigarettes, a more harmful product: 11 to 15 additional cigarettes are purchased for every 1 less 0.7 mL ENDS pod sold because of these policies.*** [emphasis added]

  Other U.S. studies showed that vape flavour bans had the effect of increasing smoking:

  > "*… state restrictions on flavored ENDS sales were associated with a 3.6–percentage point (ppt) reduction in daily vaping as well as a 2.2 ppt increase in daily smoking relative to trends in states without restrictions*." Friedman et al. (2024)[38]

  > "*We find a trade-off of 12 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions*". Friedman et al. (2023)[39]

  > *"Our findings suggest that statewide comprehensive flavor bans may have generated an unintended consequence by encouraging substitution towards traditional smoking in some populations*. Saffer et al. (2024)[40]

  > *"… we find that the adoption of an ENDS flavor restriction reduces frequent and everyday youth ENDS use by 1.2 to 2.5 percentage points. […]. However, we also detect evidence of an unintended effect of ENDS flavor restrictions that is especially clear among 18-20-year-olds: inducing substitution to combustible cigarette smoking"* Cotti et al., 2024)[41]

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[36] Royal College of Physicians. (2016). Nicotine without smoke: Tobacco harm reduction. RCP (London). https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

[37] Friedman, A. S., Liber, A. C., Crippen, A., & Pesko, M. F. (2026). E-Cigarette Flavor Restrictions' Effects on Tobacco Product Sales. *American Journal of Health Economics*, *12*(2), 377–411. https://doi.org/10.1086/734689

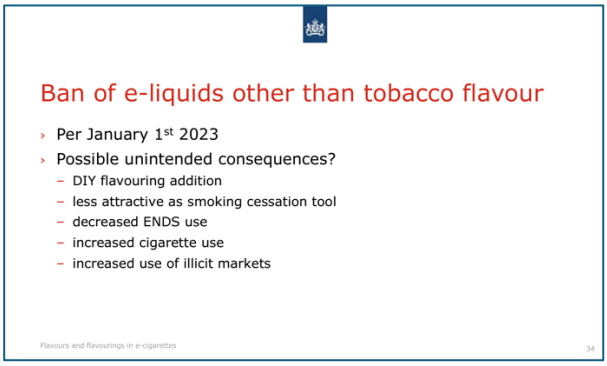
[38] Friedman, A. S., Pesko, M. F., & Whitacre, T. R. (2024). Flavored E-Cigarette Sales Restrictions and Young Adult Tobacco Use. *JAMA Health Forum*, *5*(12), e244594. https://doi.org/10.1001/jamahealthforum.2024.4594

[39] Friedman, A. et al. (2023). *E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales*. SSRN [link]

[40] Saffer, H., Ozdogan, S., Grossman, M., Dench, D. L., & Dave, D. M. (2024). *Comprehensive E-cigarette Flavor Bans and Tobacco Use among Youth and Adults* (Working Paper 32534). National Bureau of Economic Research.[link]

[41] Cotti, C. D., Courtemanche, C. J., Liang, Y., Maclean, J. C., Nesson, E. T., & Sabia, J. J. (2024). *The Effect of E-Cigarette Flavor Bans on Tobacco Use* (Working Paper 32535). National Bureau of Economic Research. [link]

- **The dangers are recognised in Europe but have been ignored.** A ban on flavours makes alternatives to cigarettes less competitive with cigarettes and, in doing so, protects and aids the cigarette trade. In December 2023, in a presentation on the Netherlands' approach to banning flavours, the Dutch public health agency RIVM summarised the plausible negative responses to a flavour ban.[42]



These concerns prompted no further analysis and did not cause the Dutch government to pause to assess the possible adverse consequences, though these are now clear. As well as the market becoming 87% illicit,[43] a 2026 study of the impact of the Netherlands vape flavour ban showed there had also been an *increase in cigarette smoking*.[44]

> *A research agency with a certified participant pool recruited 548 adolescents and young adults (ages 13–24) and 457 adults (25+ years), all of whom used e-cigarettes pre-ban.*
>
> *Most consumers (73%) who quit vaping due to the ban did not switch to a substitute product.* ***Six per cent of all participants started cigarette smoking and attributed this initiation to the e-cigarette flavour ban***. [emphasis added]

- **Surveys show consumers' intention to overcome excessive restrictions.** A survey of French consumers found that half said they would source flavours illegally, and about one-quarter said they would return to smoking.[45] Several academic studies have identified risks with flavour bans: Posner et al. (2021)[46] found that one-third of e-cigarette users would be likely to switch to cigarettes. Gravely *et al.* (2021)[47] examined possible responses to flavour restrictions in the United States, Canada, and England, finding that 28.8% would obtain their preferred flavours through illicit means and 17.1% would stop vaping and switch to smoking instead.

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42 Reinskje Talhout, Flavours and flavourings in e-cigarettes, National Institute for Public Health and the Environment (RIVM), Ministry of Health, Welfare and Sport, The Netherlands. Presentation [presentation PDF] to French National Cancer Institute Conference, International Scientific Conference on E-cigarette, Paris, 5-6 December 2022.

43 Bureau Beke, "Donkere Wolken" (Dark Clouds), 10 April 2026 [Bureau Beke]

44 Hellmich, I. M., Havermans, A., Pauwels, C. G. G. M., Boesveldt, S., & Talhout, R. (2026). Reduced vaping and smoking prevalence among people using e-cigarettes after implementation of an e-cigarette flavour ban in the Netherlands. *Tobacco Control*. https://doi.org/10.1136/tc-2025-059567

45 AIDUCE, SOVAPE, La Vape du Coeur and FIVAPE, Communiqué: Première synthèse de l'enquête MERCI LA VAPE – 40000 réponses + 1 alerte sanitaire, 3 November 2023 [link] Full report (French) [PDF link]

46 Posner H, Romm KF, Henriksen L, Bernat D, Berg CJ. Reactions to Sales Restrictions on Flavored Vape Products or All Vape Products Among Young Adults in the United States. Nicotine Tob Res. 2021 https://bit.ly/30aAdOn

47 Gravely S, Smith DM, Liber AC, Cummings KM, East KA, Hammond D, et al. Responses to potential nicotine vaping product flavor restrictions among regular vapers using non-tobacco flavors: Findings from the 2020 ITC Smoking and Vaping Survey in Canada, England, and the United States. *Addict Behav*. 2021 https://bit.ly/3oRuSo3

- **Bans on disposable vapes may trigger a rebound to smoking**. There has also been little evaluation of bans on disposable vapes, but a survey conducted following the ban in Britain suggested a decline in the use of disposable vapes, but also a rebound to smoking.[48]

  > *There had been concerns that the ban on disposable vapes could lead some adults to return to smoking. While 70% of people who vaped using mainly disposables just ahead of the ban reported that the change in law had no impact on their smoking,* ***13% reported that it led to an increase in smoking***. [emphasis added]

  Given that around 2.6 million people were affected by the ban on disposable vapes,[49] this 13% would amount to around 340,000 people increasing their smoking in response. Is this a large number? It compares with 98,000 self-reported successful smoking cessation attempts delivered through England's stop-smoking services.[50] It is also worth noting that suppliers responded to the ban with pseudo-reusable products, so the negative effects are likely to have been muted by these workarounds.

- **The public health impact of policies regarding vaping or other smoke-free products is dominated by their impact on smoking**. The policy-driven rebound to smoking arises via several mechanisms: relapse from vaping to smoking, migration from dual use to exclusive smoking, maintaining dual use when instead of migrating to exclusive use of a safer product, not switching and sticking with exclusive smoking, and taking up smoking instead of a safer alternative. Other, less direct, adverse effects may apply; for example, excessive regulation may be a brake on innovation, meaning that more effective cigarette substitutes are unavailable, or users may access substandard products if the market is largely illicit. The key point is that smoking is so much more harmful than the alternatives, and the effect of a small uptick in smoking could easily outweigh any benefits from reduced vaping or pouch use. The idea that a small increase in the use of a very harmful product can offset the benefits of reducing the use of low-risk products has been described as a risk-use equilibrium.[51] The concept is critical in weighing the benefits and detriments of a policy proposal that may reduce vaping but increase smoking.

5 Unintended consequences of excessive regulation – risky workarounds

Consumers respond to regulations or taxation that they perceive as obstructive, unfair, or excessive with a range of behavioural responses. These could include accessing an illicit supply or adverse behavioural changes, such as smoking instead. Other strategies are possible and may involve consumer or producer innovations. These include:

- DIY home mixing of flavoured liquids
- DIY home mixing with flavourings intended for cooking or aromatherapy
- DIY mixing with nicotine concentrates to overcome nicotine strength thresholds
- Shortfills to overcome container size limits

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48 Action on Smoking and Health (UK) and YouGov. Disposable vape use falls sharply during the first year of the ban**.** 29 May 2026 [ASH(UK)]

49 Jackson, S. E., et al. (2024). Who would be affected by a ban on disposable vapes? A population study in Great Britain. *Public Health*, *227*, 291–298. https://doi.org/10.1016/j.puhe.2023.12.024

50 NHS England. Statistics on Local Stop Smoking Services in England, April 2025 to December 2025 (Q3), 23 April 2026 [NHS England]

51 Kozlowski, L. T., Strasser, A. A., Giovino, G. A., Erickson, P. A., & Terza, J. V. (2001). Applying the risk/use equilibrium: Use medicinal nicotine now for harm reduction. *Tobacco Control*, *10*(3), 201–203. https://doi.org/10.1136/tc.10.3.201

- Cards or capsules to reintroduce menthol flavour into cigarettes
- Use of nominally removable tanks and rechargeable batteries to overcome disposable bans
- Use of nicotine analogues to overcome restrictions on nicotine
- Use of more than one pouch concurrently to overcome pouch nicotine content limits

6 Smoking and harm reduction

There is no serious dispute that vaping, pouches, and other forms of non-combustible tobacco and nicotine products are far less harmful than smoking, and a wide range of evidence confirms this. The key difference between combustible and non-combustible products is the formation of thousands of combustion byproducts. Tobacco smoke contains around 7,000 identifiable chemical agents, of which at least 158 are known to be toxic or carcinogenic.[52] Measures of toxicant exposure in the bodies of those using smoke-free products show levels that are much lower compared to those of people who smoke, close to background, or undetectable to people.

Several high-quality, independent assessments conclude that exclusive smoke-free nicotine use poses a small fraction of the risks of cigarettes:

- *Scientific studies show that e-cigarettes themselves are much less hazardous than conventional cigarettes*—Bundesinstitut für Risikobewertung, [Federal Institute for Risk Assessment], Germany (2025)[53]
- *When you vape, the flavoured liquid (which may contain nicotine) is heated and turns into droplets of vapour and air. This way, you avoid most of the carcinogenic substances found in cigarettes*—Institut National du Cancer, France.[54]
- *Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes*—National Academies of Sciences, Engineering, and Medicine, United States (2018).[55]
- *…vaping poses only a small fraction of the risks of smoking*—Office for Health Improvement and Disparities, England (2022).[56]
- *Vaping exposes vapers to a far narrower range of toxins than does smoking cigarettes, and levels of toxins absorbed from vaping are generally low. It is therefore likely that vaping poses only a small fraction of the risk of smoking*—Royal College of Physicians, London (2024).[57]
- A detailed discussion of the health impacts of e-cigarettes compared to cigarettes is part of a paper by 15 former presidents of the independent Society for Research on Nicotine and Tobacco

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52 Fowles, J., & Dybing, E. (2003). Application of toxicological risk assessment principles to the chemical constituents of cigarette smoke. *Tobacco Control, 12*(4), 424–430. [link]

53 Bundesinstitut für Risikobewertung [German Federal Institute for Risk Assessment] Are e-cigarettes actually less harmful than conventional cigarettes? [link]

54 République Française, Institut National du Cancer, Agir pour sa santé contre les risques de cancer, 2024 "*Quand vous « vapotez », le liquide aromatisé (qui peut contenir de la nicotine) est chauffé et se transforme en gouttelettes dans de la vapeur et de l'air. Vous évitez ainsi la plupart des substances cancérogènes de la cigarette*." [link]

55 National Academies of Sciences, Engineering, and Medicine ("NASEM"), United States, *Public Health Consequences of E-Cigarettes*, National Academies Press (2018), Summary at 1, [link]

56 Office for Health Improvement and Disparities ("OHID") (formerly Public Health England), *Nicotine Vaping in England: 2022 evidence update summary* (2022), at chapter 16 [link].

57 Royal College of Physicians (2024). *E-cigarettes and harm reduction: An evidence review*. at 67. [link].

(SRNT).[58] These authors, some of the world's leading authorities, summarise the safety case as follows:

- *Many scientists have concluded that vaping is likely substantially less dangerous than smoking because of the following:*
- *The number of chemicals in cigarette smoke, greater than 7000, exceeds that of e-cigarette aerosol by 2 orders of magnitude.*
- *Among potentially toxic substances common to both products, cigarette smoke generally contains substantially larger quantities than e-cigarette aerosol. However, e-cigarette aerosol contains some substances not found in cigarette smoke.*
- *Biomarkers reflecting exposure to toxic substances are present at much higher levels in exclusive cigarette smokers than in exclusive vapers, and studies of smokers who switch to e-cigarettes find decreases in toxicant exposures.*
- *Tests of lung and vascular function indicate improvement in cigarette smokers who switch to e-cigarettes. Exclusive users of e-cigarettes (most being former smokers) report fewer respiratory symptoms than do cigarette smokers and dual users.*

- *The use of oral nicotine pouches, as recommended by the manufacturer, as a replacement for cigarette smoking, is likely to be associated with a reduction in overall risk of adverse health effects*—Committee on Toxicology (UK government) 2023.[59]
- *The profound reduction (>99%) of key carcinogens [...] as well as substantial overall reduction of toxicants is expected to affect health risks, if people abstain completely from other tobacco products*—Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. Bundesinstitut für Risikobewertung, Germany (2019).[60]
- The United States Food and Drug Administration has authorised a range of e-cigarettes, nicotine pouches, heated tobacco products, and snus as "*appropriate for the protection of public health*" under its exacting population health standard.[61]
- It is common to cite Professor Michael Russell's 1976 insight, "*People smoke for the nicotine but die from the tar*",[62] to convey the idea that it is not the nicotine that is the primary direct cause of disease and death arising from smoking. Nicotine is the reason people smoke and, as a result, expose themselves to thousands of toxicants in cigarette smoke. That insight still holds today. U.S. Food and Drug Administration leadership reiterated this point in 2017, setting out a strategic approach to nicotine: [63]

> *Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year.*

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58 Balfour, D. J. K.et al. (2021). Balancing Consideration of the Risks and Benefits of E-Cigarettes. American Journal of Public Health, 111(9), 1661–1672. [link]

59 Committee on Toxicology (UK). (2023). *Statement on the bioavailability of nicotine from the use of oral nicotine pouches and assessment of the potential toxicological risk to users* (Statement 2023/01). Committee on Toxicology. [link]

60 Mallock, N., Pieper, E., Hutzler, C., Henkler-Stephani, F., & Luch, A. (2019). Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. *Frontiers in Public Health*, *7*. [link]

61 Food and Drug Administration (United States) Searchable Tobacco Products Database [here] Accessed 27 January 2026, 85 PMTA authorisations for vapes, pouches (designated 'other'), heated tobacco and smokeless tobacco products.

62 Russell, M. A. H. (1976). Low-tar medium-nicotine cigarettes: A new approach to safer smoking. *British Medical Journal*, *1*(6023), 1430–1433. [link]

63 Gottlieb, S., & Zeller, M. (2017). A Nicotine-Focused Framework for Public Health. *New England Journal of Medicine*, *377*(12), 1111–1114. [link]

7 Priorities for European Union regulation: the consumer perspective

It is often assumed that consumers oppose all regulation or are simply reflecting the views of tobacco or nicotine companies in the sector. Neither is correct. Consumers are a distinct population of at least 100 million Europeans. Though we cannot speak for all, we are reflecting a distinct perspective on policy that we believe will serve the interests of this group and the people who will join it in future. We have a strong interest in health and well-being, as it is our own. We have a strong locus in the debate as the policies most directly and immediately affect our personal interests. We expect to be taken seriously, and we expect third parties who make judgments on our interests to be treated with a measure of scepticism.

- Consumers (smokers, vapers, and other nicotine users) are by far the most significant stakeholders. The economic analysis presented by Open Evidence shows that smokers bear the overwhelming share of the economic burden through disability and premature death (€595 billion, 90% of the total). Consumers have interests that are distinct from economic actors and from professional activists who support the elimination of all nicotine use. We should not be bracketed with either.
- Consumers believe that the European Union should do what it is supposed to do: promote the free movement of goods with a high level of human health and consumer protection while respecting the long-established principles of proportionality and non-discrimination – with a focus on reducing cancer (*Europe's Beating Cancer Plan*) and reducing the burden of non-communicable disease (*Healthier Together*). If it did so, it would recognise smoke-free forms of nicotine and tobacco as significant opportunities with minimal and manageable risks, with the potential to expedite the obsolescence of the cigarette through the smooth functioning of a competitive internal market.
- Consumers believe the most important distinction from a policy perspective is between combustible and non-combustible products, not between tobacco and non-tobacco or between traditional and novel products. Smoke inhalation is overwhelmingly responsible for the health and other risks of tobacco or nicotine use and should be the basis for defining proportionate regulation and taxation.
- Consumers raise concerns about a range of likely unintended consequences arising from proposed policies to regulate products such as vapes, heated tobacco, nicotine pouches, and snus. There are essentially three forms of risk: (1) reversion to cigarettes or reduced switching or other adverse behavioural response; (2) stimulation of illicit and unregulated trade; (3) potentially risky workarounds by users or suppliers, such as making or adding flavours. In each case of a proposed new regulation, EU institutions must recognise and evaluate these effects and be realistic about the damage they could do.
- Consumers believe the concern about youth vaping is excessive and has become a moral panic, aided by tobacco control activists. Most youth use is experimental, infrequent, and likely to be transient. More intensive and frequent use by adolescents is mostly displacing smoking, and hence, is beneficial in the longer term. There is no evidence for a gateway effect – all the evidence points the other way: vaping is an exit route from smoking.
- Consumers are not hostile to all regulation but draw a distinction between regulation designed to protect consumers (e.g., from chemical, electrical, or thermal hazards or misleading information) and regulation intended to deter use. The latter diminishes the consumer

experience. As a result, it is highly prone to the unintended consequences described above and raises costs to users of finding and maintaining alternatives to smoking.

- Consumers believe regulation should be risk-proportionate and non-discriminatory, and that this is consistent with the EU's guiding principles. While risks arising from combustible products are sufficiently severe to justify many tobacco control measures, no such equivalent risk applies to non-combustible products. The following issues were discussed:
    - ***The snus ban***. There is no basis for this ban and a solid rationale to lift the ban, given the highly beneficial effect of snus on smoking rates and related disease in Scandinavia. Many premature deaths would have been avoided had the ban been reversed years ago.
    - ***Banning flavours***. While characterising flavours play some role with combustible products, most of the flavour is imparted by the burning tobacco. For vape products or pouches, added ingredients impart all the flavour. A ban on flavours would be highly prone to unintended consequences. Recent evidence from economic studies in the United States shows that bans on vaping flavours *increase cigarette consumption*. It should not be surprising that flavour bans favour cigarettes: a flavour ban aims to make an alternative to cigarettes less attractive.
    - ***Controls on flavours***. Flavours can be conceptualised as either:
      (1) a chemical recipe,
      (2) a sensory experience (e.g., "apple", "mint"), or
      (3) a descriptor: the language, trademarks or iconography used to describe a product.
      Regulation should focus on banning or restricting known toxicants, CMRs, and respiratory sensitisers in the chemical recipe and ensuring that descriptors are not deliberately appealing to children. It should not ban broad classes of sensory characterisation.
    - ***A possible ban on nicotine pouches***. Pouches offer the prospect of generalising the public health successes of snus to more EU member states. There is no reason (ethical, legal, or health) to deny smokers anywhere in the EU the option to switch to these products (snus or pouches). A ban on pouches would compound the serious errors made when the snus ban was introduced.
    - ***Low nicotine content thresholds for nicotine pouches***. This brings the danger of setting thresholds too low for many smokers and therefore triggering behaviour change, leading to illicit supply or more smoking. A further danger would be workarounds, such as using two pouches simultaneously. The consumer ultimately controls nicotine uptake by how long they hold the pouch in their mouth and how many they use.
    - ***Extending the ban on advertising, promotion and sponsorship***. The Tobacco Advertising Directive was justified with reference to 700,000 Europeans dying annually from *smoking*. No such justification exists for smoke-free products, including the smoke-free *tobacco* products included in the Directive by default. The advertising of these 'entrant' alternatives allows them to challenge the incumbent cigarette trade and is essential to the smooth functioning of the internal market.
    - ***Extending plain packaging to smoke*-free products.** Consumers regard plain packaging and related imagery as signalling that a product is uniquely dangerous. It has been implemented for cigarettes, but is not applied to other consumer products like alcohol.

Smoke-free products do not have a risk profile that justifies plain packaging. For that reason, such a measure would constitute harmful and misleading risk communication.

- ***Controls on tar, nicotine, CO, etc.*** The provisions of Articles 3 & 4 of the TPD2 cannot and should not be extended to smoke-free products. Any efforts in this area should focus on toxicant exposure experienced by users. Efforts to control nicotine exposure (such as the 20mg/ml concentration limit in TPD2) are likely futile, given that the users tend to control nicotine exposure through compensatory behaviour or product selection.

8 The challenge for the European Union's internal market

- **Consumers favour risk-proportionate regulation focused on consumer protection**. We expect regulation to support the interests of the users of tobacco and nicotine products, while creating proportionate deterrence to uptake by new users. In our view, aggressive attempts at behaviour change through regulation will largely drive unintended consequences such as increased smoking, more illicit trade, and risky workarounds. For consumers, the focus should be on consumer protection, safety, quality, and accurate information. A further objective should be to facilitate the migration of the nicotine market from high-risk products to low-risk products, but through the consent and choice of consumers, not be coercive, punitive or stigmatising policy. A high priority must be assigned to keeping the market legal, and policy choices should be constrained accordingly.
- **The challenge for EU decision-makers is to harness the internal market to migrate supply and demand for nicotine to safer forms of use.** Once policymakers accept that there will be a market for nicotine, the question becomes how it should be supplied. Under Article 114 of the TFEU, which concerns the development of the internal market, the Commission must aim to reduce harm to health, enhance safety, protect consumers, and support the uptake of relevant innovations if they serve these aims.

  > *[Commission proposals…] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.*[64]

  This Treaty obligation, if taken seriously, *requires* the Commission to adopt a tobacco harm reduction approach. If there is a continuing market in nicotine, then policy and legislation should aim to make it safer and better for consumers of nicotine. There is no case in any of the principles that underpin the internal market to ban or severely restrict far safer alternatives than the market norm, cigarettes.

- **The EU cannot regulate tobacco and nicotine products as if they are all the same**. The fundamental EU principle of non-discrimination has been elegantly articulated by the Court of Justice as follows:[65]

  > *… the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.*

[64] Treaty on the Functioning of the European Union, Article 114 [Eur-Lex]
[65] Case 304/01 September 2004, Spain v European Commission para 31

The purpose of regulation is to manage risks and ensure fair competition. If different products have dramatically different risks, they cannot be treated the same way. The EU must regulate in proportion to risk and cannot apply the same restrictions to cigarettes as to far safer smoke-free products.

An outline of a risk-proportionate regulatory system for tobacco and nicotine

Measure	**Cigarettes, hand-rolling tobacco, and other combustibles**	**Vaping, heated and smokeless tobacco and oral nicotine**
Overall aim	Reduce appeal and deter use	Consumer protection
Taxation	Relatively high taxes	Low or zero tax (sales tax only)
Advertising	Prohibit other than within trade	Control themes and placement
Warnings	Graphic warnings depicting disease	Messages encouraging switching
Public places	Legally mandated controls	Up to the discretion of the owner
Plain packaging	Yes	No. Controls on imagery and branding
Risk communication	Major risks to health	A far safer alternative to smoking
Age restrictions	No sales to under-21s	No sales to under-18s
Flavours	Ban characterising flavours	Control flavour *descriptors*
Product standards	Control risks and reduce appeal	Control safety risks to the user

- The policy aim should be to take the toughest, most restrictive measures to address the risks of smoking to the user and bystanders. The regulation of safer nicotine products should focus on consumer protection (chemical, electrical, and thermal safety, and reliable information) and on limiting youth uptake through measures to ensure responsible supply, retailing, and marketing.

9 The public consultation survey: "impossible by design"

On 22 May 2026, the European Commission published a survey to support the development of the next round of tobacco and nicotine product regulation, with proposals expected later in 2026.[66] The survey is impossible to answer for anyone with an understanding of the differences in risk between different tobacco and nicotine products and a rational public health interest in the role that low-risk alternatives to smoking could play in reducing the burden of cancer, cardiovascular and respiratory disease in the European Union. Around one hundred million European Union adult citizens are currently smokers, vapers, or other nicotine users, and around 700,000 die from smoking-related disease each year. The survey betrays a lack of seriousness about the size of this population, the toll of disease and death, and the options available to address it. In particular, it signals a contemptuous attitude towards the views of citizens who have an evidence-based, nuanced public health case for tobacco harm reduction. Our critique of the survey is attached as Appendix A to this submission. In this briefing, we identify eight generic problems with the consultation questionnaire and provide more specific comments on the twenty-three questions.

[66] European Commission Tobacco products and tobacco advertising – revision of EU rules 26 May 2026.

10 Misleading statements about tobacco and nicotine by the European Commission

Consumers have been justifiably concerned that the European Commission has been making statements that betray a dangerously flawed understanding of risks and apparent indifference to the consequences of being so wrong. Recent claims made by Commissioner Várhelyi that the use of smoke-free products has comparable risks to smoking cigarettes are wrong. There is no scientific basis for this claim, and a strong scientific basis to assess smoke-free tobacco and nicotine products as posing only a small fraction of the risk of cigarettes.

Given that smoking kills around 700,000 European Union citizens annually, this misrepresentation of risks has multiple negative consequences for public health and European Union policymaking. It would, for example, undermine the Tobacco Excise Directive, an updated Tobacco Products Directive, Europe's Beating Cancer Plan, and the Cardiovascular Health Plan. More fundamentally, it would distort the development of the internal market by imposing high levels of health and consumer protection, and make it impossible to apply the principles of proportionality, non-discrimination, and precaution in practice.

We have seen a letter to the Commission President from 23 European experts in tobacco and nicotine science and policy regarding the costs and consequences of such misrepresentation and misinformation. We have included this letter as Appendix B and would like this to be considered in the call for evidence.

Appendix A: Impossible by design: the EU survey on future tobacco and nicotine policy

ETHRA commentary on the European Commission's public consultation questionnaire.

9th June 2026

The EU survey on tobacco and nicotine regulation

On 22 May 2026, the European Commission published a survey [Tobacco products and tobacco advertising – revision of EU rules] to support the development of the next round of tobacco and nicotine product regulation, with Commission proposals expected later in 2026.

The survey is impossible to answer for anyone with an understanding of the differences in risk between different tobacco and nicotine products and a rational public health interest in the role that low-risk alternatives to smoking could play in reducing the burden of cancer, cardiovascular and respiratory disease in the European Union.

Around one hundred million European Union adult citizens are currently smokers, vapers, or other nicotine users, and around 700,000 die from smoking-related disease each year. The survey betrays a lack of seriousness about the size of this population, the toll of disease and death, and the options available to address it. In particular, it signals a contemptuous attitude towards the views of citizens who have an evidence-based, nuanced public health case for tobacco harm reduction. Finally, it shows the Commission has fixed views about the development of tobacco and nicotine legislation. The questionnaire's design shows that it does not intend to conduct a genuine consultation but is determined to frame questions that will create the illusion of support for a simplistic prohibitionist policy agenda.

In this briefing, we identify eight generic problems with the consultation questionnaire and provide an annex with more specific comments on the twenty-three questions.

Generic issues with the consultation questionnaire

1. Inadequate breadth or subtlety of available answers. There are multiple questions for which the only credible answer is "it depends". For example, Question 1 asks whether tobacco and nicotine measures and policies are beneficial for society. The appropriate answer is "it depends on what the measure is and whether it works as intended". In reality, there are three classes of measures:

1. those that may be beneficial if specified carefully and proportionately (e.g. controls on toxicants and ingredients, as long as these are risk-based);
2. those that may be well-intentioned but subject to unintended consequences (nicotine limits that cause deeper inhalation or flavour bans that trigger illicit trade); and
3. those that are unambiguously ill-conceived and harmful, and without any supporting evidence of benefits (the EU's ban on oral tobacco since 1992).

Faced with simplistic choices, the informed respondent can only answer “Neither agree nor disagree”. But that renders their response irrelevant, suppresses their insights, and lends weight to responses from those holding simplistic views on policymaking issues.

2. Inappropriate aggregation of very different products. Multiple questions group together all tobacco and nicotine products as if they have the same risks and consequences, and that all products should be regulated in the same way as the most dangerous products. In fact, there are likely two orders of magnitude differences in risk between the most and least dangerous. The survey respondent is unable to provide differentiated responses across product categories based on their riskiness, yet this is the most important emerging feature of the nicotine market that the European Union seeks to regulate. This risk-blind framing leaves the respondent with only the option to answer “neither agree nor disagree.”

3. No recognition of likely unintended consequences. The survey does not provide any context or even recognise that some forms of regulation can have harmful unintended consequences, nor does it invite views on these risks. It is, therefore, shielding the respondent from one of the most important policy design considerations and encouraging them to ignore the real-world consequences of their choices. The likely unintended consequences include:

1. Adverse behavioural responses leading to a rebound to more smoking,
2. Growth of illicit trade and criminality, and loss of regulatory control
3. Risky workarounds, such as home-mixing flavours.

Compelling evidence exists for all three, yet it has been ignored in the survey. For example, the Fraunhofer Institute recently estimated that 48% of European Union vapes are now sold via irregular or illicit channels. There is evidence from the United States indicating that vape flavour bans have increased smoking. There have been multiple workarounds to overcome the EU menthol cigarette ban.

4. Missing counterfactual to youth vaping: many young people would otherwise have smoked. Several questions are asked about the attractiveness, uptake or marketing of certain low-risk nicotine products (vapes, pouches, heated tobacco) as if the intent is to define this as problematic and justify intervention to control it. However, this is a gross simplification, without any acknowledgement that these products are, at least to some extent, displacing cigarette use among young people. None of the questions is framed to even recognise this possibility, but it means that youth uptake of vapes may be beneficial if the young person would otherwise have started smoking in the absence of vapes. It also means that more punitive regulation could easily be counterproductive. No questions recognise the concept of a counterfactual or that a significant impact of vapes is to divert young people from smoking at the point of initiation.

5. No recognition of trade-offs in framing questions. One of the most useful functions of policymaking surveys is to test opinion on how trade-offs would be made, though the framing of a trade-off must be done carefully. This survey has a high degree of focus on young people taking up newer nicotine products (vapes, pouches, heated tobacco). However, that near-exclusive focus has several values-based trade-offs embodied in its framing. For example, there is a trade-off between the interests of young people who would otherwise have smoked and those who would never have used nicotine in any form. There is a trade-

off between the interests of middle-aged adults who smoke and are at immediate and far greater risk of serious disease than young people who take up smoke-free products, with low risks and a distant and small risk of serious disease. Nothing in the survey engages the respondent in these trade-offs.

6. Asking for opinions on factual matters. In several places, the survey asks for respondents' opinions on objective data rather than presenting the data and asking how it should be interpreted (e.g. by asking at what age young people take up tobacco or nicotine use). The aggregate opinions of survey respondents offer worse-than-useless input to the formulation of EU policy because respondents have no way of knowing what happens at the population level, the sample will not be representative of the population, and many respondents will approach the survey with strong policy biases.

7. Ignoring respondent risk perceptions. A key question missing from the survey concerns respondents' risk perceptions. If respondents (incorrectly) believe that vapes, pouches, or heated tobacco have similar or greater risks than smoking, then they are likely to hold beliefs about regulation that would be counterproductive for health and the smooth operation of the internal market. If they believe there is no difference in risk, they would see no merit in encouraging people who smoke to migrate to vaping, pouches or heated tobacco. Any analysis of the survey results should be disaggregated by risk perceptions, and the views of those with false risk perceptions should be treated accordingly.

8. No deregulation options are considered. There are existing EU tobacco and nicotine measures in the 2014 Tobacco Products Directive (2014/40/EU) that may be incompatible with public health or the smooth functioning of the internal market. These include:

- The ban on oral tobacco or snus (Article 17), even though snus has successfully displaced smoking and reduced smoking-related disease in Sweden and Norway.
- The 2 ml tank size limit for e-cigarettes (Article 20.3(a)) means more filling or more waste per unit of nicotine consumed compared to large-capacity devices supplied in the illicit trade and in other jurisdictions, which are now typically 10-16 ml.
- The requirement not to suggest "*that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke*" (Article 13.1(b)) is misinformation by omission. It prevents realistic risk communication with consumers and likely sustains smoking and protects the cigarette trade.
- There are plausible unintended consequences and distortions arising from e-liquid nicotine concentration limits (Article 20.3(b)), advertising bans (Article 20.5), and the warnings required on ENDS (Articles 20.4 and 12.2), which may be deterring switching to safer products by failing to present realistic risk communications.

To summarise, the questionnaire is not fit for purpose. It is unlikely to elicit useful or representative views from anyone. In particular, it will exclude the views of approximately 1 in 4 European Union citizens who smoke or use other nicotine products and whose interests are most affected by regulation in this area. The questions appear to have been designed to provide affirmation for simplistic, indiscriminate prohibitionist policies favoured by Brussels-based health lobbyists with little interest in whether the measures will work, or do more harm than good.

Annex: Comments on the individual survey questions

The text below reproduces the 23 survey questions and available answers, with a brief critique of the questions (in red) from the perspective of a rational policymaker.

1. To what extent do you agree with the following statement:
Measures and policies aimed at protecting people from the effects of tobacco and nicotine consumption, as well as from second-hand tobacco smoke and aerosols, are beneficial for society.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q1 Comment
The question is unanswerable because it depends on what the measures and policies are. Some policies are beneficial, others cause unintended consequences such as illicit trade and increased criminality, or adverse behavioural change such as a rebound to smoking, or encourage users or suppliers to engage in risky workarounds. Some measures are unambiguously harmful, such as prohibiting the safest products in a market dominated by the most dangerous.

All policies involve trade-offs: some policies place undue weight on addressing relatively minor problems (youth vaping or pouch use) at the expense of much larger and more immediate public health problems in far larger populations at risk, for example, the 94 million European Union adults who still smoke - almost 1 in 4.

2. In your view, which products are most attractive to young people
Between 1 and 3 selections

- Nicotine e-cigarettes, including e-cigarettes with flavours and disposable e-cigarettes
- Nicotine-free e-cigarettes, including those with flavours
- Heated tobacco products
- Nicotine pouches, including those with flavours
- Cigarettes/roll-your-own tobacco
- Waterpipe tobacco, including those with flavours
- Other (specify)
- Don't know

Q2 Comment
The question seeks opinions on objective data that the Commission should already have answers to. It should not be asking for public opinions on data questions. Respondents to this questionnaire will not be representative and are likely to have a prior policy agenda that will affect their answers.

The question does not recognise a counterfactual: whether these new products are positive for the internal market operating with a high level of health protection depends on what these young people would do in the absence of each product. Many would have smoked.

A realistic framing of the youth use of these products is that many will be using safer products as an alternative to cigarettes. For them, there is a major health benefit. There may be some users of new products who would never have used nicotine, who have taken up vaping. For them, there is a small detriment and their use is more likely to be transient.

The question is framed in terms of attractiveness, not risk or harm. The purpose of regulation is to manage risks, not consumer preferences. Risks depend on the behaviour change triggered by changes in consumer preferences. Making safer products more attractive could benefit health.

3. In your view, which products are most attractive to those aged 25 and over
Between 1 and 3 selections

- Nicotine e-cigarettes, including e-cigarettes with flavours and disposable e-cigarettes
- Nicotine-free e-cigarettes, including those with flavours
- Heated tobacco products
- Nicotine pouches, including those with flavours
- Cigarettes/roll-your-own tobacco
- Waterpipe tobacco, including those with flavours
- Other (specify)
- Don't know

Q3 Comment
The question seeks opinions on objective data that the Commission should already have answers to. The people answering this survey do not constitute a representative sample, and many will have prior political preferences regarding the policy outcomes of the TPD revision. No useful information can be drawn from the responses to this question.

The issue here is that smoking does remain popular for older smokers. However, it would be better if far safer nicotine products were more attractive to this group, especially those over 35. This group contains the population at greatest risk of serious harm - middle-aged adults who have smoked for two or more decades.

4. Are you a current user or ex-user of tobacco, nicotine or non-nicotine products?

- Yes
- No

Q4 Comment
The question flattens the experience of nicotine use into a poorly defined single binary status [ever-use or never-use]. It is hard to see what possible use could be made of such information. If there were any interest in the nicotine use status of respondents, it would be important to distinguish between use of different categories, between current and past use, between recent and distant past use, and between inconsequential use and sustained use.

The question is seemingly neutral, but on past form, it is likely to be used to disregard or dismiss the views of people disclosing their nicotine user status as organised consumer activism. In fact, this group bears by far the greatest costs of tobacco use and tobacco policy. They are the primary stakeholders, not the medical and health activists. The views of people who use nicotine products should be given the greatest weight.

Further, taken literally, the question is nonsensical; all respondents use “non-nicotine products”.

6. At what age do you think young people start using tobacco, nicotine or non-nicotine products?

	Under 16 years	16-18 years	19-24 years	Don't know
*Tobacco products	○	○	○	○
*Nicotine products	○	○	○	○
*Nicotine-free e-cigarettes and herbal products	○	○	○	○

Q6 Comment

The question is meaningless. Young people start at different ages, with the age of initiation usually conditioned by underlying psychosocial risk factors, such as their mental health, rebelliousness, or parental smoking. Even if the question made sense and the respondent could enter a percentage in each box, there is still nothing to be gained from asking for opinions about objective facts.

Eurobarmeter 539 (2023 data) provides some data. The average age of initiation in the youngest age group (15-24) is 17.

QD12a How old were you when you started smoking or using regularly these products? (% - EU)

	Less than 15 years old	Between 15 and 18 years old	Between 19 and 25 years old	Refusal	Don't know	Average
EU27	13	40	39	1	1	18
Gender						
Man	15	42	38	1	1	17
Woman	11	38	41	1	1	18
Age						
15-24	15	50	30	2	2	17
25-39	12	41	41	1	1	18
40-54	13	39	41	1	1	18
55 +	14	38	40	1	1	18

Why waste respondents’ time asking for their opinions when there is an EU survey that has relevant data?

Nevertheless, that is not the main issue with this question. The date at which a young person starts experimentation is less important than their established smoking or nicotine use status as they enter adulthood.

7. In your view, through which channels do young people most commonly obtain tobacco, nicotine and non-nicotine products?

	Friends	Family members	Retail shops (in-person)	Online retailers from the young people's country	Online retailers other than from the young people's country	Sellers on social media/messaging apps	Informal sellers/black market	Other (specify)	Don't know
*Tobacco products	☐	☐	☐	☐	☐	☐	☐	☐	☐
*Nicotine products	☐	☐	☐	☐	☐	☐	☐	☐	☐
*Nicotine-free e-cigarettes and herbal products	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q7 Comment

The question seeks opinions on objective data that the Commission should already have answers to. The anecdotal experiences of individual respondents who choose to complete this survey cannot provide any reliable evidence for the process of formulating a revised TPD.

8. The heated tobacco products market (including tobacco heating devices) reached 12.5 billion EUR in 2023, compared to just 4 million EUR in 2013. The EU e-cigarette market grew from 909 million EUR in 2012 to 5 billion EUR in 2023. Nicotine pouches have seen a similar surge, with sales value increasing from 61 million EUR in 2018 to 1 billion EUR in 2023.

To what extent do you agree with the following statement:
Market developments and consumption trends have increased the availability, popularity and use of heated tobacco products, e-cigarettes, and nicotine pouches, particularly among the following groups.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*Among people aged 24 years or less (young people)	○	○	○	○	○	○
*Among people aged between 25 and 34 years	○	○	○	○	○	○
*Among people aged between 35 and 54 years	○	○	○	○	○	○
*Among people aged 55 years or more	○	○	○	○	○	○

Q8 Comment

It is obvious that new (safer) products that have entered the market and grown since 2013 have become more popular and attracted a greater share of the nicotine market. That is what happens with new and better products. The question is what behaviours have they

displaced or added to, and what effect have they had on the pattern of nicotine use. Again, the question is posed without appropriate contextual framing. The available answers are uninformative if the questions are not framed correctly.

9. New forms of digital promotion of tobacco and nicotine products have emerged since the adoption of the TAD in 2003. These include promotion on social media platforms, online marketplaces, through influencers, on streaming services, in online video games, in music videos, and in user-generated content without any financial consideration. User-generated content is any content made by individuals without any financial consideration, not by a brand or professional publisher.
To what extent do you agree with the following statement:
The exposure of young people to these new forms of digital promotion of tobacco and nicotine products influences their use and/or uptake of use.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q9 Comment
Again, this is a scientific question, not something that the aggregated opinions of the respondents can establish.

The question asks respondents to assert a causal relationship, which is difficult to establish scientifically. The key problem is that people interested in tobacco and nicotine products may be drawn to content that aligns with this interest (reverse causation), or to content that presents such information because they fall into a broad “rebel” category (confounding).

Better questions would address the limitations of the definitions of “commercial communication” used in the TAD and TPD2. It would be useful to seek opinions on whether it is right to intervene to address content for which there is no commercial basis.

10. To what extent do you agree with the following statement:
Further EU action under the EU tobacco control legislation is needed regarding the following promotion practices to reduce the uptake of tobacco, nicotine and non-nicotine products.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*User-generated content from individuals other than influencers	○	○	○	○	○	○
*Brand or corporate promotion including through influencers	○	○	○	○	○	○

Q10 Comment
The first question (user-generated content) raises broader questions about policing the internet and would raise many issues of principle that extend beyond tobacco. The user-

generated content in the tobacco and nicotine field is relatively innocuous compared to violent, pornographic, bigoted, and manipulative content related to self-harm, suicide, etc.

The second question should be informed by the Commission, which needs to explain any shortcomings of existing legislation before asking whether respondents agree to further powers of intervention.

A further question is whether this promotional activity is beneficial for public health. If it causes people to switch from smoking to a lower-risk product, then it is likely beneficial.

11. Across the EU Member States, there are differing national laws covering different aspects of tobacco, nicotine, and non-nicotine products. This means that economic operators must comply with these different rules to place their products on the markets of the various Member States.

To what extent do you agree with the following statement:
Differing national laws create legal complexities and hinder the smooth functioning of the EU single market.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q11 Comment

Generally, harmonisation is a good, enduring principle in EU policy. However, it must be aligned with other EU principles: subsidiarity, proportionality, conferral and equal treatment. While harmonisation can be valuable, that is only so if the harmonised regulation is welfare-enhancing. The smooth functioning of the internal market should not involve prohibitions (such as on snus) or restrictions on consumer choice (flavour bans), which cause European citizens to defect from the internal market and seek the products they want from illicit suppliers with unregulated products and commercial practices.

12. How important is it to you that the EU tobacco control legislation supports the following objectives with regard to tobacco, nicotine and non-nicotine products?

	Not important	Barely important	Moderately important	Very important	Essential	Don't know
*Preventing the initiation of use	○	○	○	○	○	○
*Supporting the cessation of use	○	○	○	○	○	○
*Ensuring that these products do not have attractive features and do not appeal, particularly to young people	○	○	○	○	○	○
*Ensuring that consumers are well informed about the health risks	○	○	○	○	○	○
*Minimising the administrative burden on Member States	○	○	○	○	○	○
*Minimising the administrative burden on business	○	○	○	○	○	○
*Ensuring that the same conditions for the manufacture, presentation, sale and advertising apply across the EU	○	○	○	○	○	○
*Ensuring that manufacturers and importers can report the necessary information easily and quickly to national and EU authorities	○	○	○	○	○	○

Q12 Comment

The question is heavily loaded. It does not differentiate between different tobacco and nicotine products that have very different levels of risk. A reasonable public health strategy would aim to substitute high-risk use (smoking) with low-risk use (vaping pouches, etc.) among people who are likely to use nicotine, including those likely to initiate nicotine use. So, for example, good public health outcomes arise from smoking cessation using smoke-free nicotine products. It is a public health gain if a young person takes up vaping instead.

The question mixes regulatory outcomes (initiation and cessation) with outputs (attractive features, information) and inputs (administrative burdens). Yet, it misses major outcome objectives (reducing the burden of smoking-related disease) that can be attained by switching from high-risk to low-risk products.

13. To what extent do you agree with the following statements:
The following measures are effective in reducing the uptake and/or harmful effects of consuming nicotine and non-nicotine products.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*Prohibiting flavours	○	○	○	○	○	○
*Prohibiting flavour descriptions and visuals on the packaging	○	○	○	○	○	○
*Reducing nicotine concentration in the product	○	○	○	○	○	○
*Standardising the form and size of tanks, refill containers and cartridges for e-cigarettes	○	○	○	○	○	○
*Setting limits for the nicotine content and/or dose of nicotine pouches	○	○	○	○	○	○
*Strengthening product standards for device safety (e.g. leakage, overheating, battery safety)	○	○	○	○	○	○
*Introducing product design requirements to reduce appeal (e.g. restrictions on device appearance, lighting, “toy-like” features)	○	○	○	○	○	○
*Introducing restrictions on disposable products	○	○	○	○	○	○
*Introducing a ban on disposable e-cigarettes	○	○	○	○	○	○
*Requiring mandatory child-resistant and tamper-evident packaging	○	○	○	○	○	○
*Strengthening restrictions on the ingredients to be used in nicotine and non-nicotine products	○	○	○	○	○	○
*Requiring reporting and testing by manufacturers and importers on product composition and, emissions or aerosol constituents	○	○	○	○	○	○
*Introducing requirements on the traceability	○	○	○	○	○	○

Q13 Comment

This question is both the most facile and consequential of all the questions asked. For policymakers, each of these raises multiple issues that cannot be reduced to a simplistic agree/disagree response. The question and answers do not allow for risk-proportionate regulation or for a regulatory system designed to migrate the internal market for nicotine from high-risk to low-risk use. The options offered are unclear and leave no room for nuance. Let us consider some of the policies on offer:

- Prohibiting flavours: the question is unclear. Does this mean banning every flavouring ingredient, everything but tobacco flavour, some flavours thought to be youth-

appealing, or just flavouring agents that may be toxic? For a policy like a flavour ban, many nuances go beyond agree/disagree answers. What if the respondent supported this ban for some categories, but not others? The questionnaire does not provide any opportunity to comment on likely unintended consequences or trade-offs, nor does it include this in its framing.

- Prohibiting flavour description might be justified if they are frivolous, misleading, or child-oriented, but not if they accurately describe the flavour in neutral terms. Again, a rational answer is precluded, or relegated to irrelevance by requiring the answer, “Neither agree nor disagree”.

- Whether nicotine concentration should be reduced depends on which product and several other considerations. For example, would this apply to cigarettes? If so, any reduction would need to be deep enough to make compensatory smoking impossible, but that would amount to a prohibition of cigarettes with significant implications for illicit trade and excise revenues. Conversely, there is no case for reducing the concentration of nicotine e-liquids, which were already limited to 20mg/ml under TPD-2, and, if anything, there is a case for relaxing this limit, especially when linked to the liquid’s pH. In the case of pouches, there is a case for limiting total nicotine content, but not concentration, at 15-20 mg to exclude rogue products, but not so low to make pouch products uncompetitive with cigarettes, to cause people to use two at once, or generate an illicit market. There is no pattern of boxes to tick that would capture these reasonable evidence-based positions.

- Whether product safety standards should be “strengthened” depends on which standards are being referred to and how the strengthening would affect the user experience. For example, a standard that improved battery safety would be welcome, but a standard that made refilling difficult or impossible to reduce leakage would not.

- Whether “strengthening” ingredient restrictions (or any other restriction) makes sense depends on which restrictions, to which products they apply, the degree of strengthening, the likelihood of achieving the policy aim, and the plausibility of unintended consequences.

- Requirements for traceability might have superficial appeal, but if they were excessively burdensome, they would cause concentration in the marketplace in favour of high-volume commodity products. They may lead to other products being supplied illegally.

- There is no option to state where regulation is excessive or counterproductive. For example, since the snus ban of 1992, twenty million European Union citizens have died from smoking-related disease. Yet, snus has enabled Sweden to have the lowest smoking rates and the lowest rates of smoking-related disease.

The questionnaire does not allow for realistic or nuanced answers to the questions for informed consumers. Again, it favours those with a simplistic and hostile policy agenda. It does not allow the directly affected stakeholders to contribute reality-based insights.

14. The scope of the current EU tobacco control legislation covers only tobacco products, nicotine-containing e-cigarettes, and herbal products for smoking. It does not include other nicotine products, herbal products not used for smoking and nicotine-free e-cigarettes, which have been introduced in the market since 2012.
As observed in the evaluation of the TPD (https://health.ec.europa.eu/tobacco/evaluation-legislative-framework-tobaccocontrol_
en), nicotine pouches' sales value has increased from 60.8 million EUR in 2018 to 1.09 billion EUR in 2023, whereas traditional tobacco products' sales value has decreased from 153.87 billion in 2012 to 140.75 billion in 2023.

To what extent do you agree with the following statement:
The scope of the EU tobacco control legislation has not kept pace with market developments.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q14 Comment
The Commission provides the data to support the obvious answer. However, whether the EU should have jurisdiction depends on what form of regulation should apply. If the EU proposes a ban on pouches, following some member states and by analogy with the oral tobacco ban, then it will simply be repeating the mistakes of past regulation.

The relevant question regarding the scope of European regulation is which considerations should inform regulatory design. But no questions are asked about this.

15. How important is it to you that the following products – currently not covered by the legislation – would fall within the scope of the EU tobacco control legislation?

	Not important	Barely important	Moderately important	Very important	Essential	Don't know
*Nicotine pouches and other nicotine products without tobacco	○	○	○	○	○	○
*Nicotine-free e-cigarettes, including their devices and tanks, refill containers and cartridges	○	○	○	○	○	○
*Heated herbal products and other new types of herbal products	○	○	○	○	○	○
*Devices, accessories and items used for the consumption of tobacco and nicotine products	○	○	○	○	○	○
*Future products	○	○	○	○	○	○

Q15 Comment
Again, the answer depends on the regulatory objectives and the likelihood that it would work as intended. If the aim is to ensure a reasonable level of consumer protection and safety

standards, then the EU has a valuable role to play. If, on the other hand, the regulatory intent is to deny adults products they wish to use in their own interests, in the mistaken belief that this will protect children, then member states should be free to reject such measures or deny the European Union a role.

16. To what extent do you agree with the following statement:
EU rules need to include a regulatory mechanism that allows the European Commission to react quickly to market, scientific, and technical developments.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q16 Comment
Again, the appropriate response depends on how the Commission would respond to what sort of developments and with what limits to its competence. A generalised answer is not possible. The EU must not create pockets of unaccountability in which the Commission can unilaterally extend its powers in response to technological developments as it sees fit. Further, it should not be able to use technological advances as a pretext to bypass the legislature.

17. Technology-neutral definitions focus on the general characteristics of a product and could help ensure that all products of the same definition are covered by the legislation, regardless of technological developments. This would allow products which are not on the market when the legislation came into force to also be covered if they fall under the specified technical definition.
To what extent do you agree with the following statement:
Technology-neutral definitions for products are important in ensuring the objectives of the tobacco control legislation.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q17 Comment
The question is obscure and conceals complexity. There is an argument for technology-neutral definitions in regulation generally, as they are less vulnerable to technological innovation and change. However, providing this flexibility must be contingent on carefully characterising important differences between product categories. So if the general characteristic chosen is “all products containing nicotine”, then that would be inadequate to reflect the two orders of magnitude difference in risk between products. A better 4-segment general characterisation would be:

- Nicotine products that involve combustion and smoke inhalation
- Nicotine products that involve heating and aerosol inhalation

- Nicotine products that do not involve heat
- Therapeutic nicotine products

The problem with the survey is that it is asking for an opinion on technology neutrality without specifying what the alternative system would be. In the absence of a credible scheme for segmenting technology by risk, the appropriate answer is to stick with technology-specific definitions.

18. Plain (or standardised) packaging is defined by the World Health Organisation as "measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style". The TPD allows an EU Member State to introduce further of such standardisation requirements regarding the packaging of tobacco products, including plain packaging.
To what extent do you agree with the following statement:
Mandatory plain packaging requirements under EU tobacco control legislation would strengthen the functioning of the EU internal market and/or the protection of public health.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*Functioning of the EU internal market	○	○	○	○	○	○
*Protection of public health	○	○	○	○	○	○

Q18 Comment
The questionnaire only allows a negative rejection of a positive assertion in favour of plain packaging. It does not provide any insight into potential unintended consequences, such as implicit risk miscommunication, making lower-risk products relatively less attractive, or a tendency to lower prices by favouring budget brands.

Also, it provides no option to differentiate between tobacco product categories that differ substantially in risk, such as pouches and cigarettes.

19. To what extent do you agree with the following statement:
The following labelling and packaging measures are effective in ensuring the objectives of the tobacco control legislation.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*Large health warnings with pictures depicting medical conditions associated with the use of tobacco and nicotine products	○	○	○	○	○	○
*Plain or standardised packaging of the products	○	○	○	○	○	○
*Standardised form and size of tanks, refill containers and cartridges for e-cigarettes	○	○	○	○	○	○
*Prohibition of misleading descriptors on the packaging (e.g. “natural”, “organic”, “nicotine-free”)	○	○	○	○	○	○
*Leaflets/inserts with quitting information	○	○	○	○	○	○
*Prohibition of elements that promote the product or encourage its consumption by creating an erroneous impression about its characteristics, health effects or risks	○	○	○	○	○	○

Q19 Comment

The effectiveness of policies should be a research question, not a matter of opinion. Some of these policies have been tried in the European Union or elsewhere; the Commission should present or conduct evaluation research.

There are several issues in answering these questions, mostly because the question of whether a regulation is a good idea depends on how it is specified.

- **Large pictorial warnings** convey little meaningful risk information (i.e., the likelihood that the user will experience the pictured condition and the time period over which it will occur). They rely on a shock effect to deter use and are a form of negative marketing, which is poorly scrutinised. The danger with applying such warnings to much safer products is that they misrepresent risks, present health effects for which there is little evidence, and obstruct beneficial behaviour change.

- **Plain packaging** prevents the pack from being used to create brand appeal. That could be useful for the most dangerous products, though there are potential unintended consequences, such as price reductions. For safer products, it may degrade the appeal compared to cigarettes and reduce switching.

- **Standardised tanks and refills**. Standardisation may be beneficial if it improves consumer choice through interoperability and reduces compliance costs; however, the existing limits (2ml for tanks, 10ml for containers) are too low, increasing refill activity, waste generation, and the likelihood of running out.

- **Misleading descriptors**. There is an obvious case for prohibiting anything misleading, which is normally covered by standard consumer protection legislation, including the Unfair Commercial Practices Directive 2005/29/EC (Articles 6 and 7). The question here is what additional protections are required and justified in the special case of tobacco and nicotine products. A further issue is EU mandates that

would require the consumer to be misled, for example, by exaggeration of risk in graphic health warnings or by the TPD-2 provision Article 13.1(b), which does not allow manufacturers to suggest "*that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke*" even though there is a two-orders of magnitude span in risks.

- **Leaflets**. It depends on what the leaflets say, and whether they are required for all products. They could potentially help users understand risks, or they could add to confusion and risk misperceptions. The TPD requires an information leaflet for vapes (TPD-2 Article 20.4(a)) but not for cigarettes. Why?
- **Prohibiting elements that mislead about characteristics or risks**. Again, it depends on what is defined as misleading and whether the regulation would prevent communication of genuine differences in risks or characteristics that would be beneficial to the user.

20. E-cigarettes and nicotine pouches can come in variety of flavours (such as fruit, herb, candy or ice cream). The evaluation of the tobacco control framework has shown that flavours seem to play a key factor influencing young people's decision to start using these products. Flavours can create the impression that the product is less harmful and make the product more attractive and easier to use. Some EU Member States have prohibited flavours in e-cigarettes and refill containers, while others have not.

To what extent do you agree with the following statement:

A prohibition of flavours in e-cigarettes and nicotine pouches would strengthen the functioning of the EU internal market (by eliminating different approaches across the Member States) and/or the protection of public health.

	Agree	Partly agree	Neither agree nor disagree	Partly disagree	Disagree	Don't know
*Functioning of the EU internal market	○	○	○	○	○	○
*Protection of public health	○	○	○	○	○	○

Q20 Comment

The context provided with the question is highly selective and strongly leading, presenting a series of contested causal claims that relate only to youth and offer no consideration of trade-offs, counterfactuals (vaping is beneficial for young people who would otherwise smoke), or unintended consequences of such bans (increased smoking, more illicit trade, and workarounds such as adding flavours sold separately).

21. The EU tobacco traceability system records the movements of legal tobacco products across the EU. It allows EU Member States to determine whether a product has been diverted into the illicit market. The traceability system currently covers only tobacco products and does not extend to e-cigarettes and other nicotine or non-nicotine products.

To what extent do you agree with the following statement:

The EU tobacco traceability system should also cover products other than tobacco products.

- Agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Disagree
- Don't know

Q21 Comment

The issue will be too technical for most respondents, so the clear aim of the question is to encourage unqualified positive responses to a complex question. Far too little information is contained to allow any non-specialist to answer this question. The requirement for a traceability system would likely favour large companies with established distribution systems. While it might help verify legal products or detect illicit ones, it may ultimately increase illicit trade as more supply falls outside the traceable system. It's like asking the public for its views on any other specialised technical subject: preferred methods of heart surgery, protection of undersea cables or pipelines, or cryptography standards. Similar questions are asked in Q13 and in Q22.

22. How important is it that the EU tobacco control legislation be strengthened in the following areas?

	Not important	Barely important	Moderately important	Very important	Essential	Don't know
*Reporting of accurate and complete information on the products by manufacturers and importers for the European Commission and the Member States' enforcement authorities	○	○	○	○	○	○
*Traceability tools to assist Member States in detecting illicit trade practices	○	○	○	○	○	○
*The adaptability of the legislation to respond to new market developments	○	○	○	○	○	○

Q22 Comment

The question is unanswerable. In each case, it depends on the specific measures envisaged - some of which might be helpful, others might do more harm than good.

- **Reporting**. The only reporting required should have a definable purpose - consumer protection or regulatory oversight - and regulation should be efficient. The danger is that the Commission sees compliance burdens as a benefit rather than a cost.
- **Traceability tools.** Whether these are worthwhile demands a value-for-money assessment, not an arbitrary opinion poll. The question is what works and to what

end (does it validate legal products, assist in the seizure of illegal products, or reduce illicit supply?). The distorting effects of regulatory burdens may undermine the smooth operation of the internal market.

- **Adaptability of legislation.** The value of adapting (i.e., changing) legislation depends on what falls within the scope of delegated powers and on the conditions under which the Commission can exercise these powers. Legislation should be technology-neutral to the extent possible, but that does not mean ignoring pronounced differences in the risk characteristics of products (such as the two orders-of-magnitude difference in risk across nicotine products).

23. If you wish to upload a concise document, please do so below. The maximal file size is 1MB.
Please note that the uploaded document will be published alongside your response to the questionnaire, which is the essential input to this open consultation. The document is an optional complement and serves as additional background to better understand your position.

Q23 Comment
There is no justifiable reason to set a file size limit at 1 MB.

END OF SURVEY – THANK YOU FOR YOUR PARTICIPATION

Appendix B: Letter regarding misleading statements by the European Commission

23 European experts' letter of complaint: "False and misleading European Commission statements about novel nicotine product safety"

25th February 2026

Ms Ursula von der Leyen
President of the European Commission
Rue de la Loi 200
1040 Brussels
Belgium

25 February 2026

Dear President von der Leyen,

False and misleading European Commission statements about novel nicotine product safety

We write to express our concern about recent statements by Commissioner Várhelyi regarding the safety of nicotine products. These statements amount to spreading damaging misinformation, and we urge you to take action to prevent further loss of trust and confidence in the European Union. This letter sets out the false statements made by the Commissioner, an overview of the evidence that demonstrates they are false, and the implications for European Union policymaking and EU citizens.

False statements made by Commissioner Várhelyi

In his interview with Euractiv,[1] [2] Commissioner Várhelyi made the following statements:

> **Euractiv:** Are you deeply convinced that alternative tobacco products are as harmful as traditional cigarettes?
>
> **Commissioner Várhelyi:** Yes, I am. Absolutely. One hundred per cent.
>
> **Euractiv:** Not less harmful, but as harmful?
>
> **Commissioner Várhelyi:** As harmful. I know they do not like this, but I am absolutely sure.

These comments to Euractiv are not an accident, but part of a pattern of misinformation and false statements from the Commissioner. Other statements clearly show he is referring to the full range of smoke-free alternatives to cigarettes. He has made several public statements asserting or implying that vaping, nicotine pouches and heated tobacco are as harmful to health as smoking.

- On 13th May 2025, during an exchange of views with the ENVI Committee, Commissioner Várhelyi stated that "*vaping…has created completely new health risks [that are] comparable to or even bigger than smoking itself. It's enough to read some articles about the "popcorn lungs" which is a completely new phenomenon, and which is breathtakingly overtaking the young generation*".[3] The risks are not comparable, and there are no known cases of popcorn lung (bronchiolitis obliterans) caused by vaping.

- On 16th July 2025, Commissioner Várhelyi posted on X that "*For the first time ever, we acknowledge that new tobacco and nicotine products pose health risks comparable to traditional ones*".[4] It is the first time a Commission official has made such a significant error.

- Soon after the X.com post above, a European parliamentary question inquired about the basis of this scientifically untenable position.[5] The Commissioner's response doubles down on the claim, asserting that this is the Commission's official position.[6] In January 2026, these positions were restated in an answer[7] to a new Parliamentary question.[8] In this answer, the Commission asserts incorrectly that: "*Using smoke-free tobacco and nicotine products, as opposed to combustible smoking, is not reducing risk to health*", but bases this claim on a logical error: "*There are no safe levels of tobacco or nicotine consumption, including*

from smoke-free tobacco and nicotine products." There is an important difference between *safe* and *safer*: smoke-free products do not have to be 'safe' to be far 'safer' than cigarettes.

Evidence that the Commissioner's statements are false

There is no serious dispute that vaping, pouches, and other forms of non-combustible tobacco and nicotine products are far less harmful than smoking, and a wide range of evidence confirms this. The key difference between combustible and non-combustible products is the formation of thousands of combustion byproducts. Tobacco smoke contains around 7,000 identifiable chemical agents, of which at least 158 are known to be toxic or carcinogenic.[9] Measures of toxicant exposure in the bodies of those using smoke-free products show levels that are much lower compared to those of people who smoke, close to background, or undetectable to people. There is no plausible way to reconcile these observations with the Commissioner's statements. We do not claim that these products are "safe" or "harmless", just that they are, beyond any reasonable doubt, far less harmful than cigarettes.

Several high-quality, independent assessments conclude that exclusive smoke-free nicotine use poses a small fraction of the risks of cigarettes:

- *Scientific studies show that e-cigarettes themselves are much less hazardous than conventional cigarettes*—Bundesinstitut für Risikobewertung, [Federal Institute for Risk Assessment], Germany (2025)[10]
- *When you vape, the flavoured liquid (which may contain nicotine) is heated and turns into droplets of vapour and air. This way, you avoid most of the carcinogenic substances found in cigarettes*—Institut National du Cancer, France.[11]
- *Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes*—National Academies of Sciences, Engineering, and Medicine, United States (2018).[12]
- *…vaping poses only a small fraction of the risks of smoking*—Office for Health Improvement and Disparities, England (2022).[13]
- *Vaping exposes vapers to a far narrower range of toxins than does smoking cigarettes, and levels of toxins absorbed from vaping are generally low. It is therefore likely that vaping poses only a small fraction of the risk of smoking*—Royal College of Physicians, London (2024).[14]
- A detailed discussion of the health impacts of e-cigarettes compared to cigarettes is part of a paper by 15 former presidents of the independent Society for Research on Nicotine and Tobacco (SRNT).[15] These authors, some of the world's leading authorities, summarise the safety case as follows:
  - *Many scientists have concluded that vaping is likely substantially less dangerous than smoking because of the following:*
  - *The number of chemicals in cigarette smoke, greater than 7000, exceeds that of e-cigarette aerosol by 2 orders of magnitude.*
  - *Among potentially toxic substances common to both products, cigarette smoke generally contains substantially larger quantities than e-cigarette aerosol. However, e-cigarette aerosol contains some substances not found in cigarette smoke.*
  - *Biomarkers reflecting exposure to toxic substances are present at much higher levels in exclusive cigarette smokers than in exclusive vapers, and studies of smokers who switch to e-cigarettes find decreases in toxicant exposures.*
  - *Tests of lung and vascular function indicate improvement in cigarette smokers who switch to e-cigarettes. Exclusive users of e-cigarettes (most being former smokers) report fewer respiratory symptoms than do cigarette smokers and dual users.*

- *The use of oral nicotine pouches, as recommended by the manufacturer, as a replacement for cigarette smoking, is likely to be associated with a reduction in overall risk of adverse health effects*—Committee on Toxicology (UK government) 2023.[16]
- *The profound reduction (>99%) of key carcinogens […] as well as substantial overall reduction of toxicants is expected to affect health risks, if people abstain completely from other tobacco products*—Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. Bundesinstitut für Risikobewertung, Germany (2019).[17]
- The United States Food and Drug Administration has authorised a range of e-cigarettes, nicotine pouches, heated tobacco products, and snus as "appropriate for the protection of public health" under its exacting population health standard.[18]

It is common to cite Professor Michael Russell's 1976 insight, "*People smoke for the nicotine but die from the tar*",[19] to convey the idea that it is not the nicotine that is the primary direct cause of disease and death arising from smoking. Nicotine is the reason people smoke and, as a result, expose themselves to thousands of toxicants in cigarette smoke. That insight still holds today. U.S. Food and Drug Administration leadership reiterated this point in 2017, setting out a strategic approach to nicotine: "*nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year*".[20]

The absence of European Union evidence that supports the Commissioner

We are unaware of any credible estimates of the death toll from vaping in the European Union or anywhere else. We are unaware of any cases of popcorn lung (bronchiolitis obliterans) attributable to vaping,[21] even though this condition forms part of Commissioner Várhelyi's argument. The ingredient that caused it in American popcorn workers, diacetyl, is banned in lawfully marketed vapes in the European Union under existing European Union regulations.[22]

Though 11 years have passed since the 2014 Tobacco Products Directive, the European Commission has not reviewed the comparison of harms between vaping and smoking. Its own scientific committee (SCHEER) was charged with reviewing the data in 2021. However, it was mandated "*to focus only on health impacts compared to non-smoking,*" not on the all-important comparison with smoking.[23] Even the Commission's major research initiative, the Joint Action on Tobacco Control,[24] has not provided a basis for the Commissioner's claims. Though there is considerable analysis of e-cigarettes in the JATC work packages, we are unaware of any meaningful comparison between the risks of cigarettes and e-cigarettes in these analyses.

The volume of evidence supporting a case for harm reduction and refuting the Commissioner's claims is far greater than we can cover here.[25] The Commission and its officials are required to "act objectively and impartially" under the Code of Good Administrative Behaviour,[26] [27] and we expect the record to be corrected.

Consequences for European Union policymaking

These are non-trivial errors, yet they are relevant to policy decisions about a major public health issue: around 90 million EU citizens still smoke (almost one in four adults), and over 700,000 Europeans die prematurely each year from smoking-related disease.[28] Reliable evidence is integral to the Better Regulation agenda,[29] and misleading presentation of risks will have the following adverse effects for European Union decision-making:

- **Revision of the Tobacco Excise Directive (TED)**. The misrepresentation of risk in the case of smoke-free nicotine products has led to proposals for excessive levels of tax on smoke-free alternatives to cigarettes. The effect would be to distort the internal market, thereby protecting cigarettes and thus promoting ill-health. The revised excise regime proposed for tobacco and nicotine products in July 2025[30] was based on flawed assumptions about relative risk. Misrepresentation of risk violates the principles of

proportionality[31] and non-discrimination,[32] which justify taxation levels that reflect risk. The Commission's approach has created conflict with the European Council, which has been pressing for a more risk-proportionate regime. The European institutions have been generally positive and creative in their approach to "behavioural taxation" for health and environmental purposes, aiming to substitute high-risk with low-risk behaviours through differential tax rates.[33] Yet, the Commission proposal seeks "*to create a level playing field for both traditional tobacco products and new substitute products* […] *anticipating risks of substitution between products*." This interpretation of "non-discrimination" only makes sense if the Commission assumes that the risks of these products are broadly similar (they are not) and that substitution is undesirable (it is not).

- **Revision of the Tobacco Products Directive (TPD).** The Commission is expediting its proposal for a revised Tobacco Products Directive, which is currently expected in 2026. The effective regulation of novel nicotine products within this framework requires the legislature to consider both risks (uptake by people who would never otherwise have used nicotine) and benefits (smoke-free products displacing smoking). An incorrect understanding of risk will distort regulatory policymaking, leading to excessive regulation of products that Europeans wish to use to reduce risks associated with current smoking and future smoking uptake. The danger is driving a range of predictable unintended consequences: (i) more smoking than there would be otherwise; (ii) more illicit trade and ceding large parts of the novel nicotine market to illicit nicotine products with Russian or Chinese origins and sometimes supplied via criminal networks; (iii) a range of potentially risky workarounds by consumers and suppliers that may increase overall risk and undermine regulatory aims.

- **Major public health initiatives.** The European Union has established important public health objectives related to cancer (Europe's Beating Cancer Plan)[34] and cardiovascular disease (EU cardiovascular health plan: the Safe Hearts Plan).[35] In both cases, *smoking* is a major modifiable risk factor, with practical technologies that allow migration to low-risk nicotine use. The misrepresentation of the relative risks of smoking and smoke-free alternatives will undermine the potential effectiveness of these programmes.

- **The internal market.** Article 114 of the Treaty on the Functioning of the European Union states:[36] "(*3) The Commission, in its proposals [to develop the internal market], concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts*." The internal market can be made to function efficiently to combat smoking and disease by enabling low-risk alternatives to compete with cigarettes, allowing consumers to improve their own health, on their own initiative, and at their own expense. The effective functioning of the internal market can only proceed if the institutions have a realistic appraisal of the pronounced variations in risk to human health between smoked and smoke-free products. Commissioner Várhelyi is at risk of leading the Commission into harmful prohibitionist regulation based on flawed reasoning that would distort the internal market, cause the avoidable deaths of thousands of Europeans, and nurture a gigantic unregulated black market in safer alternatives to cigarettes.

- **Disinformation**. Misleading information originating from the Commission will undermine the European Union's efforts to tackle disinformation through the Code of Practice on Disinformation (2022)[37] and the Code of Conduct on Disinformation (2025)[38]. The Commission correctly states that disinformation is "*a growing threat to European democracies*." However, if the truthfulness of its own information is in question, critics will rightly doubt the Commission's sincerity, question its legitimacy, and act accordingly.

- **WHO Framework Convention on Tobacco Control (FCTC)**. False risk estimates will lead to weak and flawed EU common positions on international agreements, such as the FCTC. The Commission's efforts to override the perspective of more pragmatic Member States led to a breakdown in trust before the COP-11 meeting in November 2025. According to Euroreporter, there were several reasons for the breakdown, including this: "*There was no agreement on novel nicotine products. A growing number of governments insist that harm reduction alternatives cannot be regulated identically to cigarettes without triggering*

unintended public health consequences.[39] The misrepresentation of risks will only worsen these divides and give Member States grounds to reject negotiating positions grounded in flawed assumptions.

The Commissioner's statements are problematic because human lives and suffering are at stake. There are further implications: the functioning of the internal market and the credibility of the European Union are compromised by politicised, unsubstantiated scientific statements.

Consequences for European Union citizens

Smoking is a uniquely harmful consumer behaviour, creating significant risks for cancer, cardiovascular and respiratory disease, and numerous other conditions.[40] Nearly all the risks from tobacco use arise from *smoking*: inhaling thousands of chemical agents, many toxic or carcinogenic, produced during the combustion of tobacco leaves in the burning tip of a cigarette.[41]

The European Union has made lethal mistakes in this field in the past. In 1992, oral tobacco (also known as snus) was banned throughout the European Union,[42] yet snus presents far lower risks than smoking.[43] [44] At the time of accession, Sweden was granted an exemption from the ban. One estimate suggests that snus avoids 3,000 smoking-related deaths per year in Sweden, which has an exemption from the ban.[45] In the rest of the European Union, with a population more than forty times greater than Sweden's, smokers have been deliberately denied this life-saving option. Yet, twenty million European Union citizens have died from smoking-related diseases since the snus ban came into effect in 1992.[46] Many deaths could have been avoided through switching nicotine use from smoking to snus. If the internal market had been allowed to function correctly based on a proper appreciation of risk, the burden of smoking-related death and disease in the European Union could have been significantly lower. *The European Union must not repeat these mistakes with new and emerging alternatives to cigarettes.*

The Commission leadership, or other institutions, must move swiftly to correct dangerous, false, and misleading statements made by Commissioner Várhelyi and to ensure that policymaking with the potential to save or threaten the lives of millions of EU citizens is grounded in sound science. Fundamentally, the European institutions can back the Commissioner's posture, or they can take their policymaking responsibilities seriously. They cannot do both.

We are copying this letter to the College of Commissioners, European Council representatives and interested parties in the European Parliament.

Yours sincerely

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