

11 October 2023

European Tobacco Harm Reduction Advocates (ETHRA)

Memo: Tobacco *acquis* evaluation validation workshop, 6th October 2023

We write to thank Open Evidence for the inclusive discussion on the effectiveness, relevance and efficiency of the EU tobacco control *acquis* held on 6th October 2023. We thought it would be helpful to (1) summarise our stance briefly and (2) share further relevant evidence that underpins our position.

- Consumers (smokers, vapers, and other nicotine users) are by far the most significant stakeholders. The economic analysis presented by Open Evidence shows that consumers 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 that arise from proposed policies to control products like 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.

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- 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, 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 guiding principles of the EU. 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.
 - *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, 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.
 - *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 a uniquely dangerous product. It has been implemented for cigarettes but is not applied to other consumer products like alcohol. Smoke-free products do not have the risk profile to justify plain packaging. For that reason, such a measure would be a form of harmful and misleading risk communication.
 - *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 and ensuring that descriptors are not deliberately appealing to children.

- *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.

Further supportive evidence

1. Nicotine regulation must reflect substantial differences in risk between products.

- **UK Office for Health Improvement and Disparities (OHID): [Nicotine vaping in England: an evidence update including health risks and perceptions](#) (September 2022)**

This latest update of the UK-commissioned report on nicotine vaping in England is considered the most comprehensive and rigorous, particularly regarding health risks. It presents strong evidence that nicotine vaping is far less harmful than smoking and that switching away from smoking substantially reduces risk. The report found, among other things, that vaping poses only a small fraction of the risks of smoking, that public perceptions of vaping harm are not in line with the evidence and influence subsequent vaping and smoking behaviours, and that vaping is effective for stopping smoking. It also concluded that non-tobacco flavours, particularly sweet flavours, may play a positive role in helping people switch from smoking to vaping. The report also found that vaping continues to increase and smoking to decrease.

- **Peer-reviewed publication: [What are the harms of vaping in young people who have never smoked?](#) (May 2023)**

“Population and modelling studies also suggest that vaping and smoking are substitutes and that vaping displaces smoking at a population level. Studies of the effects of tax increases on vaping products also support a diversion effect. Higher taxes on vapes are associated with increased cigarette smoking, while higher cigarette prices are associated with increased vaping. Bans or purchasing restrictions on the sale of vapes to teens are also associated with increased adolescent smoking.”

- **New Zealand [Smokefree Environments and Regulated Products \(Vaping\) Amendment Bill Health Committee Commentary:](#)**

“The bill acknowledges that vaping products and heated tobacco products have lower health risks than smoking, and aims to support smokers to switch to these less harmful products.”

“The bill also recognises that many smokers need support and advice to successfully move to less harmful alternatives, so the Bill allows for the provision of information and advice for those wishing to switch from smoking to vaping.”

- **Cochrane review: [Electronic cigarettes for smoking cessation](#) (November 2022):**

“There is high-certainty evidence that ECs with nicotine increase quit rates compared to NRT and moderate-certainty evidence that they increase quit rates compared to ECs without nicotine... For every 100 people using nicotine e-cigarettes to stop smoking, 8 to 12 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy, 7 of 100 using e-cigarettes without nicotine, or 4 of 100 people having no support or behavioural support only.”

2. Gateway effects

- **Peer-reviewed publication:** [Dramatic Reductions in Cigarette Smoking Prevalence among High School Youth from 1991 to 2022 Unlikely to Have Been Undermined by E-Cigarettes](#) (September 2023)

“Concerns about a potential rise in adolescent cigarette use following the introduction of e-cigarettes to the US market in the early 2010s are not supported by the data. In fact, the emergence of e-cigarettes has coincided with the most rapid declines in cigarette use over the past thirty years.”

- **Peer-reviewed publication:** [A critique of the Australian National Health and Medical Research Council CEO statement on electronic cigarettes](#) (February 2023):

“There is no convincing evidence that e-cigarette use is a gateway to smoking. [...] A more plausible explanation is that young people who engage in one form of risky behaviour, such as vaping, are more likely to engage in other risky behaviours such as smoking, hazardous alcohol consumption and illicit drug use.”

- **Invited commentary in JAMA:** [e-Cigarette and Cigarette Use Among Youth: Gateway or Common Liability?](#) (March 2023):

“At the population level, e-cigarettes do not appear to be a gateway to cigarette smoking... Collectively, concerns about a gateway effect and a potential increase in youth cigarette use following the introduction of e-cigarettes to the US market are not supported by the data.”

- **Cancer Research UK:** [E-cigarette FAQs](#):

“Regular use of e-cigarettes remains largely confined to current or ex-smokers. Experimentation with e-cigarettes in ‘never smokers’ remains low and coincides with the continuing decline in youth smoking.”

- **Action on Smoking and Health UK:** [Addressing common myths about vaping](#) (August 2023):

“If vaping were a gateway into smoking at population level, as vaping increased smoking rates would be expected to show a reduced rate of decline or start to increase. To the contrary between 2010 and 2021, when e-cigarette use grew rapidly from a low base in England, smoking rates among children continued to fall at least as rapidly as previously, which does not support the gateway hypothesis at population level.” [...] “Moreover survey data shows that children who tried vaping in the US between 2014 and 2017, compared with matched children who did not try vaping, were equally likely to try a cigarette but less likely to progress to regular smoking.”

- **Action on Smoking and Health New Zealand:** [Harm reduction and vaping](#):

“Whilst there are concerns about vaping being a gateway into smoking, there is no evidence of this, particularly for youth.”

- **Peer-reviewed publication:** [What are the harms of vaping in young people who have never smoked?](#) (May 2023)

“It is well established that young people who try vaping are more likely to later try smoking. There is a tendency in policy discussions to assume that this association is causal (the gateway hypothesis). However, it is not the only possible or the most plausible explanation. A more likely explanation is that the association is explained by shared risk factors for vaping and smoking, such as a genetic liability to develop nicotine addiction and environmental, psychological and social causes e.g., peer group or parental smoking that create a ‘common liability’ for risk taking. In studies that adjust for these confounders, most of the association between vaping and subsequent smoking has disappeared.”

“The gateway hypothesis also predicts that increased vaping will increase cigarette smoking among youth. However, increases in youth vaping have been accompanied by an accelerated decline in smoking since vaping became popular in the US, UK and New Zealand, suggesting either no overall gateway effect or at most, a small gateway effect that is outweighed by the much larger number moving from smoking to vaping.”

3. The primary driver of harm (exposure to toxicants) is smoking, not e-cigarette use:

- **Peer-reviewed publication: [Biomarkers of potential harm in people switching from smoking tobacco to exclusive e-cigarette use, dual use or abstinence: secondary analysis of Cochrane systematic review of trials of e-cigarettes for smoking cessation \(October 2022\)](#)**

The studies analysed in this review showed no evidence that biomarkers of potential harm increased in people who continued to smoke combustible tobacco while also using EC. In fact, dual use was associated with statistically significant reductions in CO, nitrosamines (mixed evidence), some metabolites of polyaromatic hydrocarbons and some mercapturic acids.”

4. Flavours are important to help adults quit smoking, with studies showing that e-cigarette flavour restrictions increase smoking:

- **[E-cigarette Flavor Restrictions’ Effects on Tobacco Product Sales \(September 2023\)](#)**

“Matching new flavor policy data to retail sales data, we find a trade-off of 15 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions. Further, cigarette sales increase even among brands disproportionately used by underage youth. Thus, any public health benefits of reducing ENDS use via flavor restrictions may be offset by public health costs from increased cigarette sales.”

“**Conclusion:** In this study, we find that ENDS flavor policies reduce flavored ENDS sales as intended, but also increase cigarette sales across age groups. As cigarettes are much more lethal than ENDS, the high rate of substitution estimated here suggests that, on net, any population health benefits of ENDS flavor policies are likely small or even negative.”

- **[ETHRA EU Nicotine Users Survey Report \(June 2021\)](#)**

This survey assessed potential consumer reaction to flavour bans or the unintended consequences of such an action. The ETHRA Survey, which had over 37000 responses, found that only 5.4% of current vapers used tobacco or unflavoured vapes. On potential flavour bans, ***28% of vapers said they are likely to restart smoking again, and 71% would consider using the black market or other alternative sources.*** It’s important to note that ETHRA and our partners conducted the ETHRA Survey. It is not peer-reviewed, although we did take advice on design from our scientific partners.

5. Nicotine pouches

- **[German Federal Institute for Risk Assessment \(October 2022\):](#)**

“For people who have not previously smoked or otherwise consumed nicotine, any form of nicotine consumption represents an increased risk to their health. Keeping this model of risk minimisation in mind, switching from cigarettes to nicotine pouches could represent a reduction in health risks for a person who smokes.”

- **[UK Committee on Toxicity \(February 2023\):](#)**

“The use of oral nicotine pouches, as recommended by the manufacturer, as a replacement for CC smoking is likely to be associated with a reduction in overall risk of adverse health effects,

although the magnitude of the decrease will depend on the effect in question. Use of oral nicotine pouches by nicotine-naïve users is likely to be associated with some adverse health effects to which the user would not otherwise have been subject, as a pharmacologically active dose of nicotine is delivered. Concurrent use of oral nicotine pouches with CC smoking or other nicotine-containing products could increase and prolong nicotine exposure compared to a single source.”

▪ [ASH UK survey \(August 2023\)](#):

“Nicotine pouches (which include brands such as Zyn and Nordic Spirit) appear to have greater public awareness with 54% of smokers reporting they have heard of these products in 2023. Ever use of nicotine pouches is at 15% among smokers in 2023. Fewer than 1% of never-smokers have tried nicotine pouches, and only 0.2% say they are still using them.”

As people with lived experience of using Safer Nicotine Products (SNPs), we generally choose to use these terms:

- ‘vapes’, ‘vaping products’ and ‘vaping’, rather than ‘e-cigarettes’ or ‘ENDS’.
- ‘HTPs’ to refer to Heated Tobacco Products.
- ‘Nicotine pouches’ for non-tobacco containing oral sachets.
- ‘snus’ to refer to the pasteurised Scandinavian oral tobacco product, either in loose or pouch form.

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