ETHRA submission to Norway TRIS notification - Amendments to the Tobacco Control Act and the labelling regulations

Thank you for the opportunity to comment on the proposed amendments to the Tobacco Control Act and the labelling regulations, which would introduce standardised packaging and a flavour ban for vaping products.

European Tobacco Harm Reduction Advocates (ETHRA) is the voice of 27 million[1] European consumers of safer nicotine products. ETHRA is a consortium of 25 grassroots consumer associations in 17 European countries, supported by experts in tobacco control and nicotine research. We are mostly ex-smokers who have used safer nicotine products, such as vapes, nicotine pouches, heated tobacco products, and snus, to quit smoking and to remain smoke free. We are a voluntary operation with no industry funding or conflicts of interest. Our EU Transparency Registration number is 354946837243-73.

As people with lived experience of using safer nicotine products to quit smoking and remain smoke free, we have serious concerns about the proposed amendments. Vaping products are a direct competitor to combustible tobacco, a point noted in the Impact Assessment: *"use among never-smokers is almost non-existent"*. The implementation of a vape flavour ban would severely restrict adult access to the products people are using to improve their health by switching to a low-risk alternative to smoking.

The consequences of removing adult access to the most popular and effective smoking cessation tool will be negative to public health. Smoking prevalence will increase, current vapers may relapse to smoking, and it is highly likely that a black market will emerge including massive cross border shopping.

Below we set out our reasoning in nine points.

1. The justification for the proposed amendments lacks a solid foundation

The rationale for the proposed amendments, as set out in the Statement of Grounds, is the *"protection of children and young people from the harms of tobacco and nicotine addiction".* This is problematic for a number of reasons. First of all, no distinction is made between the use of high-risk combustible tobacco and low-risk non-combustible nicotine products. Smoke inhalation, not nicotine, is the primary cause of smoking-related ill health, and there are, beyond any reasonable doubt, significantly lower risks in using non-combustible forms of nicotine products.

The same issue is present in the Impact Assessment which states: *"Tobacco use is the main preventable source of disease and mortality in Norway".* It has been known for decades that people smoke for the nicotine but die from the tar.[2] In other words, it is the toxic products of combustion that cause the harms from smoking, not tobacco use per se. Proof of concept for this theory can be found in Sweden, which has become the first EU country to achieve smoke-free status. Swedish men increasingly use snus as a low-risk alternative to smoking, leading to Sweden having the lowest instances of tobacco related cancers in the EU.[3]

When discussing the potential harms of using vaping products the impact assessment relies heavily on the deeply flawed SCHEER Opinion[4]. The overwhelming problem with this assessment was its failure to evaluate e-cigarette use (vaping) in relation to smoking. The Special Committee on Beating Cancer report[5] attempted to rectify this by recommending: *"the assessment of the risks of using these products compared to consuming other tobacco"*. Numerous comments made about the SCHEER Opinion highlighted problems with framing.[6]

2. Plain packaging increases misperceptions of harm

The justification for requiring plain packaging for cigarettes is based on the harms done by smoking and the very high risk to health. That justification does not apply to vaping products and does not stand up to scrutiny in a risk-proportionate regulatory system. Plain packaging gives the impression that combustible and non-combustible products carry the same level of risk, which simply isn't true. There must be a clear distinction in risk communication between these products in order to avoid deterring potential switchers.

3. Vaping is significantly less harmful than smoking

The most robust evidence comes from the UK, a global leader in tobacco control policy. A 2020 review by the UK's Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT)[7] concluded that smokers who switch completely to vaping will get a substantial health benefit and that there is a considerable reduction in the risk of lung cancer due to lower exposure to harmful compounds.

In 2018, Public Health England[8] conducted a comprehensive independent evidence review on e-cigarettes which found:

> *"Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking"*

The most recent report from the Office for Health Improvements and Disparities[9] (formerly PHE) concurred that the 95% less harmful statement was still an appropriate way to communicate the relative risk of vaping compared to smoking. It also went on to add.

> *"The evidence suggests there is significantly lower exposure to harmful substances from vaping compared with smoking, as shown by biomarkers associated with the risk of cancer, respiratory and cardiovascular conditions".*

The UK's Royal College of Physicians landmark paper, Nicotine without smoke[10], concluded:

> *"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." (Section 5.5 page 87)*

A study by Stephen WE[11], published in the British Medical Journal, estimated that vaping had a cancer potency of 0.4% compared to smoking. The French Cancer Institute[12] also recognises the huge harm reduction potential of vaping in their latest campaign, stating:

> *"Without tobacco, without smoke and without combustion, the electronic cigarette represents an opportunity to reduce cancer mortality related to tobacco. It should be used with a view to quitting smoking for good".*

4. Vaping and smoking cessation

Vaping and tobacco harm reduction should be viewed as an opportunity to drive down smoking prevalence and achieve smoke-free status, much as has happened in Sweden with snus. There is strong evidence of the effectiveness of vaping for smoking cessation. A Cochrane systematic review[13] of over 70 studies finds high certainty evidence that vaping is significantly more effective for smoking cessation than Nicotine Replacement Therapy (NRT). Population data trends from the Santé Publique France report[14] finds vaping to be an effective means for smoking cessation. The Special Committee on Beating Cancer (BECA) Report[15] clearly states that vaping products could allow some smokers to progressively quit smoking.

5. Product appeal plays an integral role in the success of vaping

A recent study[16] published in Harm Reduction Journal examined Norwegians' motivation for using vaping products. It found that the vast majority of Norwegian vapers previously

smoked, a point also noted in the impact assessment, and that they viewed vaping products as a harm reduction tool to cut down or completely quit smoking. Product appeal, including through the availability of a wide range of flavours, is a crucial element in attracting smokers to vaping in the first instance, and to avoid relapse to smoking. There is robust evidence that vaping non-tobacco flavours significantly increases the chances of successful smoking cessation.[17] [18]

Evidence from the Netherlands also points to the important role flavours play in quitting smoking. Havermans et al[19] concludes that "adults who completely substituted the use of conventional cigarettes by e-cigarettes have often initiated e-cigarette use with fruity flavours rather than tobacco flavours, or switched from tobacco to non-tobacco e-liquid flavours over time." A study of Dutch consumers of vaping products concluded that vape flavours are a contributing factor in smokers completely switching to vaping and recommended that they should remain available to adult smokers.[20]

Some smokers do initiate vaping with a tobacco flavour, but migration to fruit and sweet flavours over time is very common.[21] [22]

Norway is performing extremely well in regard to smoking cessation and smoke free targets. Data from Statistics Norway[23] indicate that only 7% of the adult population smoke daily. Flavoured vaping products could be a vital tool in actually reaching that smoke free target of less than 5% smoking prevalence.

6. The unintended perverse consequences of a flavour ban

Policymakers must consider the full range of likely behavioural responses to a flavour ban, given that the ban would not in itself lessen the drive to use nicotine. Such responses might include the following, all with higher risk than using regulated products:

- Switch from vaping to smoking.
- Initiate smoking, instead of vaping.
- Access flavoured products from outside EEA.
- Access flavoured products from the black or grey market.
- "DIY" their flavours (home mixing).

In our ETHRA 2020 survey of nicotine consumers in Europe, which was the largest survey of its kind in the EU and received over 35,000 responses, we asked how vapers would react to a flavour ban. 28% of respondents said there was a high possibility that they would relapse to smoking, and 71% would consider using the black market or other alternative sources to access flavours.[24]

Responses to a predicted flavour ban, highlighted in the 2020 ITC Smoking and Vaping Survey in Canada, England, and the United States, suggested that 28.3% of vapers would find a way to get the flavours they wanted and 17.1% would stop vaping and smoke instead.[25]

Real world evidence of consumer response to a flavour ban can be found in Estonia. In 2020 Estonia banned all flavours apart from tobacco. In 2022 almost 60% of vapers continued to use fruit, sweet and dessert flavours. Products are being sourced through the black market and by DIY mixing[26]. In response to this, the Estonian parliament voted to permit some e-liquid flavours[27]. Denmark too has seen a huge rise in the use of black-market products. Danish Health spokesperson Lars Boje Mathiesen believes the strict legislation [flavour ban] has created a large illegal market, because the demand for flavours is still there[28].

7. Flavour bans increase smoking

A study of a ban on flavoured vaping products in San Francisco[29] saw a sharp rise in teen smoking compared to districts without a ban. We should not be surprised by more smoking in response to restrictions on vaping because the products are substitutes. But because the health risks of smoking are far greater than the risks from vaping, only a small diversion of teenage vapers into smoking would overwhelm any benefits of reducing teenage vaping. This is important because the public health outcome of a flavour ban is extremely sensitive to any adverse changes in smoking behaviour. These potential negative consequences should be the dominant concern of policymakers.

8. There is no evidence that safer nicotine products act as a 'gateway' into smoking

As part of the rationale for the proposed flavour ban, the impact assessment claims that there is evidence that vaping products are a gateway to smoking. However, there is no evidence for this claim. Correlations between smoking and vaping which are commonly reported in studies are likely caused by 'common liabilities.' Meaning that young people who are predisposed to engage in risk taking behaviours such as smoking are also likely to try other things like vaping.

If there was a gateway effect, then we would expect to see an increase in smoking. However, that is not happening. Instead, we see a decline in smoking. In Norway daily youth smoking has steadily declined and is now only 2%, while snus use has increased (Impact Assessment). The data shows that the impact of increased snus use was positive in that it decreased the much more harmful use of combustible tobacco.

Further evidence that the use of safer nicotine products does not act as a gateway to smoking can be found in population trends. Youth vaping peaked in the USA at 27.5% in 2019, it has since fallen to 11.3%. During this time regular smoking among high school students fell to the lowest levels ever at <0.4%[30]. The UK's Action on Smoking and Health monitors trends in youth use of vaping products and combustible tobacco. It finds a slight increase in youth vaping in the last two years, while experimental and regular smoking continues to fall[31].

Conclusion

Norway has set ambitious goals to reduce smoking rates, and as tobacco harm reduction advocates, we share these goals. However, we must stress that the introduction of plain packaging and a ban on flavours for vaping products is likely to have the opposite effect. Policymakers must be aware that flavoured vaping products act as a direct competitor to smoking. Banning or severely restricting a rival product will only protect the cigarette trade and keep people smoking.

A note on ETHRA's preferred terms for products

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.

References:

[1] Estimate of 27 million consumers provided by ECigIntelligence/TobaccoIntelligence. The actual figure is likely to be far higher because the data for smokeless tobacco is taken from research (Leon et al 2016) using data gathered in 2010 in only 17 countries.

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