

ETHRA submission for the APPG for Vaping Inquiry into Achieving a Smoke-Free 2030

Introduction

We would like to thank the APPG for Vaping for holding this important inquiry. This submission is made on behalf of European Tobacco Harm Reduction Advocates (ETHRA). We are an alliance of 22 grass root consumer groups in 16 European countries, representing approximately 27 million consumers across Europe and supported by scientific experts in tobacco control or nicotine research¹. We are ex-smokers who have used safer nicotine products, such as vapes, heated tobacco products and snus, to quit smoking and to remain smoke-free. ETHRA is not funded and has no industry conflicts of interest. We have a unique pan European perspective on how smokers are using safer nicotine products.

Consumers in Europe are looking to the UK for independent leadership

Consumers in Europe are looking to the UK for independent leadership on tobacco harm reduction, to move beyond the obstacles presented by the TPD and provide a regulatory framework for all safer nicotine products. If the UK does this the ambitious 2030 smoke free target of >5% or less will be attainable. Sweden is the only country in the EU which has reached this target², and this is thanks to snus³, a popular consumer nicotine product which is currently banned in the UK.

For safer nicotine products to win smokers over and drive down smoking prevalence, smokers need access to a wide variety of appealing and affordable alternatives to combustible cigarettes. The Royal College of Physicians pointed this out in 2016:

... 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. Getting this balance right is difficult.

(Nicotine Without Smoke: Tobacco Harm Reduction, Section 12.10 page 187)

This statement refers to vaping products, which are the most widely available and popular alternative to smoking in the UK, but it could equally apply to any safer nicotine product. These products include vapes, snus, nicotine pouches, heated tobacco products; all of which have the potential to get smokers off the combustibles.

Table of Contents

Introduction.....	1
Consumers in Europe are looking to the UK for independent leadership	1
Vaping has delivered huge gains in the UK, but more can be done	3
<i>The 20mg/ml nicotine limit is failing entrenched smokers.....</i>	<i>3</i>
<i>Restrictions on refill bottle sizes and tank sizes are pointless and obstructive</i>	<i>3</i>
<i>The excessive mandatory health warnings prevent smokers from switching.....</i>	<i>3</i>
<i>Overly restrictive advertising regulations hinder smoker awareness of safer alternatives</i>	<i>4</i>
The UK must take a different course from the WHO and EU	4
<i>Flavours are crucial for winning over smokers</i>	<i>4</i>
<i>Open tank systems are essential for choice and for affordability</i>	<i>4</i>
<i>Vaping is still too expensive for many of the people who are still smoking.....</i>	<i>5</i>
The UK must embrace all safer alternatives to smoking and regulate them equally	5
<i>The ban on the sale of snus should be overturned.....</i>	<i>5</i>
<i>Heated tobacco products should be regulated in the same way as vaping products.....</i>	<i>5</i>
<i>The regulatory distinction should be between combustion and non-combustion.....</i>	<i>6</i>
<i>Nicotine pouches should be included in an appropriate regulatory framework</i>	<i>6</i>
Concluding comments	6
References	7

Vaping has delivered huge gains in the UK, but more can be done

We know that vaping products are far more accessible to adult smokers in the UK than in many other European countries and we commend the UK government for maximising the opportunities offered by e-cigarettes. Smoking rates plummeted in the UK after e-cigarettes became widely available⁴. However, uptake of vaping has now slowed. We believe that there are regulatory barriers to smokers wanting to use vaping products to quit and we outline some of those below.

The 20mg/ml nicotine limit is failing entrenched smokers

The nicotine limit of 20mg/ml means that many smokers do not find vaping sufficiently satisfying and it prevents the convenient pod devices from giving an effective nicotine hit. The 20mg/ml limit on nicotine e-liquid concentrations was negotiated in TPD negotiations in 2013 but since then evidence has become available which shows that it is needlessly low. The limit should be raised in order to make vaping more satisfying for dependent smokers. ETHRA recently conducted a survey of nicotine users in Europe which received 37,000 responses. 30% of the UK respondents who had tried vaping but who were not current vapers said that the nicotine delivery was not sufficiently effective and 23% of dual users said that they continued to smoke because vaping does not satisfy their nicotine needs⁵.

Restrictions on refill bottle sizes and tank sizes are pointless and obstructive

The restrictions on refill bottle sizes and on tank sizes make vaping more fiddly than it needs to be and are a huge barrier for those with dexterity issues, including older people. These restrictions also create more environmental waste. The arbitrary restrictions that were placed on refill bottles and tanks have no basis in science. Professor Lynne Dawkins, whose research was cited by the EU in their justification document for these restrictions, stated that *“officials have distorted my words and taken my statement out of context”*⁶.

The excessive mandatory health warnings prevent smokers from switching

The excessive mandatory health warnings overstate the risks of vaping and are deterring smokers from trying vaping. The prominence of the warnings and the alarming wording suggest far greater risk than there is. The warnings are similar in style to those used on cigarettes, yet the health risk from vaping is a small fraction of the risk of smoking. This tilts perceptions in favour of the dangerous cigarette. The warnings about nicotine have the effect of reinforcing the widespread misunderstanding that it is nicotine, not smoke, which is the most significant cause of harm. E-cigarettes only represent a fraction of the risk of combustible tobacco products and the warning labels should reflect this difference in risk.

PHE's [Vaping in England: 2021 evidence update summary](#) states: *“Perceptions of the harm caused by vaping compared with smoking are increasingly out of line with the evidence”*, with 38% of smokers believing vaping to be as harmful as smoking⁷.

As ex-smokers we know that having the knowledge that vaping is less harmful to health is a prime motivator to switch. Some of the TRPR regulations are feeding the misperceptions and preventing smokers from switching.

Overly restrictive advertising regulations hinder smoker awareness of safer alternatives

Advertising regulations are overly restrictive. Health or quit claims are not permitted but there is now sufficient evidence to explore potential regulatory change there. The UK leads the way with research into safety and use - notably, the Cochrane review and the annual PHE evidence updates. This knowledge should be used to develop effective public health strategies. Canada and New Zealand developed government approved risk statements and the UK should consider doing the same. These statements could be used in advertising and in cigarette pack inserts. We believe this would give more smokers the confidence to switch.

The UK must take a different course from the WHO and EU

The EU's Tobacco Products Directive is responsible for all the barriers to switching which we outlined above. The European Commission has very recently published its TPD implementation report⁸, in which they signal intentions to impose further barriers on vaping, including on flavours and open tank systems. In December 2020 recommendations from the Report of the tenth meeting of the WHO Study Group on Tobacco Product Regulation included a complete ban on open systems⁹. The same WHO study group published a report on 4 May¹⁰ which includes recommendations to ban flavours and open systems. The WHO and the EU are misapplying the precautionary principle and keeping people smoking. It is crucial for the UK to take a different course from the WHO and the EU now, if the Smoke-free 2030 goal is to be reached.

Flavours are crucial for winning over smokers

To ensure that vaping products are as palatable as possible for smokers, it is essential to permit a wide variety of flavours to be sold, as flavours are intrinsic to vaping's success at winning over smokers¹¹. This is demonstrated in studies that have shown vaping non-tobacco flavours is associated with increased smoking cessation among adults¹². Having a wide range of flavours to choose from is even more important for long term smoking cessation as adults commonly migrate to fruit or sweet flavours¹³. For ETHRA's soon to be published survey of nicotine users in Europe¹⁴ 74.2% of UK vapers ranked flavours as "important or very important" for their adoption of vaping, and out of our 1065 UK based vaping respondents, only 5.8% exclusively vape tobacco flavours.

It should be noted that flavours were introduced in nicotine gum for the same reason, to make them more appealing to adult smokers, and to increase efficacy¹⁵.

Open tank systems are essential for choice and for affordability

Vaping products are affordable for most people. It is crucial for open tank systems to remain on the market because these are far cheaper for consumers than closed pod systems, which require expensive pod refills. Open tank systems also enable vapers to use a wide variety of flavours. They are very flexible and can accommodate different types of vaping without the need to buy a new device. The high level of user control with open systems means the consumer can tailor the vaping experience to suit their needs. Open systems are by far the most popular choice among vapers, they were the device of choice for 72% of people surveyed in Special Eurobarometer 506¹⁶.

Vaping is still too expensive for many of the people who are still smoking

However, even though vaping products are affordable for many, this is not the case for everyone - and it is well established that smoking prevalence in the UK is highest amongst those in the lowest socio-economic groups. The UK's ambitious aim to be smoke free by 2030 will not be realised unless the least well off can access affordable and attractive alternatives to smoking. It is regrettable that most stop smoking services are still reluctant to recommend vaping to smokers. The UK government will need to think creatively to find strategies to tackle these issues.

The UK must embrace all safer alternatives to smoking and regulate them equally

Vaping is a success story in the UK, but e-cigarettes are not the only product out there - other products include snus, nicotine pouches and HTPs, all less harmful alternatives to smoking and attractive to smokers. Having a wide variety of alternatives to smoking available will give the UK the best chance of reaching its smoke free target.

The ban on the sale of snus should be overturned

In Sweden and Norway, the widespread availability of the pasteurised oral tobacco product called snus, is responsible for a very low smoking prevalence. In Sweden, smoking rates are close to the EU's target for 2040 – daily smoking is 5% and current smoking 7% of adults¹⁷. Lower smoking rates have translated to Sweden having Europe's lowest mortality attributable to tobacco¹⁸, especially among men, the main snus users. Snus is also popular in Norway, where smoking is down to 1-2% among young women now – signalling the emerging prospect of a smoke-free generation.

In 2019 the FDA granted modified risk orders to 8 snus products, concluding that “*completely switching from cigarettes to these authorized products lowers certain health risks*”. This enables the specific products to be marketed as being less harmful to consumers¹⁹. Yet, despite the body of evidence that snus is less harmful than smoking, the sale of snus is banned by the TRPR.

In ETHRA we are ex-smokers who have quit smoking using safer nicotine products. Many of us are from Scandinavia where snus is part of our cultural heritage, so we are very aware of its benefits. Many others amongst us are from countries where snus is banned, so we could only stop smoking when e-cigarettes came onto the market. We feel aggrieved that the snus ban denied us access to this popular, appealing, and much safer alternative to smoking and hope that the UK will embrace an evidence-based approach by overturning the ban.

Heated tobacco products should be regulated in the same way as vaping products

Heated tobacco products (HTPs) are regulated even more strictly than vaping products, and are subjected to a display and advertising ban. However, like vaping products, HTPs are used by people wishing to stop smoking and are far less harmful to health than smoking combustible tobacco. In October 2019, the U.S Food and Drug Administration determined that authorising IQOS (a HTP product) was “*appropriate for the protection of the public health*”²⁰. Simonavicius et al's [Heat-not-burn tobacco products: a systematic literature review 2018](#)²¹ finds that “*HnB*

exposed users and bystanders to toxicants, although at substantially lower levels than cigarettes.”

HTPs are estimated to be slightly more harmful to health than vaping products. However, in comparison with smoking, HTPs are far less harmful to health - and this is the only relevant comparator here. In [2017 The Committee of Toxicity assessed the possible risks in relation to smoking:](#)

“As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn tobacco products.”²²

HTP use is very low, [PHE's latest review](#)²³ states that: *“Since 2017, prevalence of heated tobacco products has remained under 1% and shows no evidence of increase over time.”* (page 103). This is hardly surprising, as the display and advertising bans prevent smokers from being aware that HTPs exist.

The regulatory distinction should be between combustion and non-combustion

HTPs are regulated more strictly because they are a tobacco product. However, the distinction between tobacco containing and non-tobacco containing products is meaningless in health terms. It is not tobacco itself which is especially harmful to health, it is the method of delivery - combustion - which causes smoking related disease and death. Vaping is not a magic bullet for all smokers and so all safer nicotine products, including HTPs, should be made as widely available as possible.

Nicotine pouches should be included in an appropriate regulatory framework

The TRPR framework has not been sufficiently flexible to capture new products. Nicotine pouches are an example of this. These entered the market after TPD2 and are increasingly popular amongst people wishing not to smoke. As safer alternatives to combusted tobacco, nicotine pouches should sit in the same regulatory framework as vaping products, HTPs and snus, yet in its current form the TRPR cannot accommodate them.

Concluding comments

Lots of us regularly use several safer nicotine consumer products. We know how important it is to offer smokers a wide variety to choose from, both across and within product categories. All safer nicotine products are just that - vastly safer than smoking combustible cigarettes. Those who smoke deserve to have access to as wide a range of reduced risk products as possible. Variety is key to the success of safer nicotine products in winning over smokers.

We hope that the UK can move away from having a distinction between tobacco and non-tobacco products and instead legislate according to whether products are combustible or non-combustible.

We end our submission with another quote from the Royal College of Physicians, this time from their brand-new Smoking and health 2021²⁴ report:

“A rational approach to regulating nicotine products would aim to minimise the uptake of nicotine use among nonusers, particularly children; promote complete cessation of nicotine use among current users wherever possible; and encourage as many current smokers as possible who choose or otherwise fail to stop using nicotine to reduce harm by switching from smoked tobacco to less hazardous products. The RCP has long argued that achieving this would be enabled by integrating the regulation of all nicotine products into a comprehensive regulatory framework which applies market controls on these products in proportion to their hazard to consumers.”

References

- ¹ European Tobacco Harm Reduction Advocates (ETHRA). Available at: <https://ethra.co>
- ² European Commission. February 2021. Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Kantar Belgium. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>
- ³ Royal College of Physicians. *Smoking and health 2021: a coming of age for tobacco control?* (p 95) London: RCP, 2021.
- ⁴ Action on Smoking and Health. October 2020. Use of e-cigarettes among adults in Great Britain, 2020. (p 4) Available at: <https://ash.org.uk/information-and-resources/factsheets/statistical/use-of-e-cigarettes-among-adults-in-great-britain-2020/>
- ⁵ European Tobacco Harm Reduction Advocates. October 2020. ETHRA launches major survey on nicotine use in Europe, report is currently being compiled and will be published on ETHRA's website soon. <https://ethra.co/news/51-ethra-launches-major-survey-on-nicotine-use-in-europe>
- ⁶ The counterfactual. January 2014. Guest blog: Lynne Dawkins puts the Commission straight. Available at: <https://www.clivebates.com/quest-blog-lynne-dawkins-puts-the-commission-straight/>
- ⁷ Public Health England. 23 February 2021. Vaping in England: 2021 evidence update summary. Available at: <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021/vaping-in-england-2021-evidence-update-summary>
- ⁸ European Commission. 20 May 2021. Report on the application of Directive 2014/40/EU. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=COM%3A2021%3A249%3AFIN&from=EN>
- ⁹ World Health Organisation. 23 December 2020. Report on meetings of expert committees and study groups. Available at: https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_47-en.pdf
- ¹⁰ World Health Organisation. 4 May 2021. WHO study group on tobacco product regulation: Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Available at: <https://www.who.int/publications/i/item/9789240022720>
- ¹¹ Li, Lin et al. 25 Feb. 2021. “How does the use of flavored nicotine vaping products relate to progression towards quitting smoking? Findings from the 2016 and 2018 ITC 4CV Surveys.” *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*, ntab033., doi:10.1093/ntr/ntab033
- ¹² Friedman, A. S. and Xu, S. Q. (2020) ‘Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation’, *JAMA network open*, 3(6), p. e203826. doi: 10.1001/jamanetworkopen.2020.3826

-
- ¹³ Russell, C., McKeganey, N., Dickson, T. et al. (2018). Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* 15, 33. <https://doi.org/10.1186/s12954-018-0238-6>
- ¹⁴ ETHRA launches major survey on nicotine use in Europe
<https://ethra.co/news/51-ethra-launches-major-survey-on-nicotine-use-in-europe>
- ¹⁵ Von Mulzer K, Dando S, Gustavsson G, Radley N, Sjöstedt G, Sydbom P, Waltermo A. Verbesserte Produktmerkmale der Nikotinkaugummi. Ein unerforschter Bereich zur Erhöhung der Compliance bei der Nikotinersatztherapie [Improved product characteristics of nicotine gums: an unexplored area for higher compliance with nicotine replacement therapy]. *MMW Fortschr Med*. 2011 Oct 6;153 Suppl 3:75-82. German. PMID: 22184800.
- ¹⁶ European Commission. February 2021. Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Kantar Belgium. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>
- ¹⁷ European Commission. February 2021. Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Kantar Belgium. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>
- ¹⁸ Ramström, L., & Wikmans, T. September 2014. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tobacco induced diseases*, 12(1), 14. Available at: <https://doi.org/10.1186/1617-9625-12-14>
- ¹⁹ U.S Food and Drugs Administration. October 22, 2019. FDA grants first-ever modified risk orders to eight smokeless tobacco products. Available at: <https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products>
- ²⁰ U.S Food and Drugs Administration. April 30, 2019. FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway. Available at: <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>
- ²¹ Simonavicius E, McNeill A, Shahab L, et al. Heat-not-burn tobacco products: a systematic literature review. *Tob Control* 2019;28:582–594. Available at: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/28/5/582.full.pdf>
- ²² Committee on Toxicity. 2017. Statement on the toxicological evaluation of novel heat not-burn tobacco products. Available at: https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf
- ²³ Public Health England. February 2021. Vaping in England: an evidence update including vaping for smoking cessation. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf
- ²⁴ Royal College of Physicians. 2021, *Smoking and health 2021: a coming of age for tobacco control?* London: RCP. Available at: <https://www.rcplondon.ac.uk/projects/outputs/smoking-and-health-2021-coming-age-tobacco-control>