16 April 2020

Dear Christina Dziewanska-Stringer,

We are writing on behalf of European Tobacco Harm Reduction Advocates (ETHRA).

ETHRA is a group representing 21 consumer associations across Europe, supported by four scientific partners. We are mostly ex-smokers who have used safer nicotine products to quit smoking. We have been following the progress of the TPD review with keen interest, as we know from our own experience that prudent regulation of safer products can offer huge gains to health, at population and individual level. We note, and have experienced, that countries where safer products are popular and regulated sensibly have seen huge drops in smoking prevalence.

We are writing with a view to making the following points about the questionnaire submitted to member states on the review of TPD2:

- The TPD promises to ensure a high level of health protection.
- Smoking kills but reduced risk products are far safer
- The Member States Questionnaire on the Assessment of the Tobacco Products Directive does NOT examine whether the TPD has fulfilled the purposes for which it was intended (instead, it focuses solely on policing)
- Regulations that make reduced risk products more inconvenient, less satisfying, or which increase perceptions of harm or addiction may cause harm through continued smoking and counteract the aims of the regulations.

We believe that the Questionnaire should be investigating the potential unintended consequences of the TPD with regards to its provisions for safer nicotine products. A failure to regulate vaping and other safer nicotine products well is a win for the incumbent combustible tobacco trade and could trigger more smoking.

We would like to draw attention specifically to these five areas of the Questionnaire:

1. Who is using safer nicotine products? What is the relationship between use of safer nicotine products and smoking?

The Questionnaire asks about national data on the level of prevalence of use in under 25's and whether the TPD has changed tobacco and related product use in young people (1.4.1 Effectiveness). It also asks whether Member states have evidence that electronic cigarette use "is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers" (1.5.12 Article 20).

The questions do not examine the relationship between smoking and safer nicotine use. Are smoking rates decreasing as electronic cigarette use is increasing? This is a crucial consideration. There is evidence to show that vaping is displacing smoking, from countries which are collecting data, for example, France, Ireland and the UK.

The question on whether electronic cigarettes are "a gateway to nicotine addiction and ultimately traditional tobacco consumption" is a leading one and presupposes an effect that is not supported by the evidence. This is a highly controversial policy area and this question lacks neutrality. It would be more beneficial for public health if there was also a call for evidence that vaping is a gateway away from traditional tobacco consumption. There is, indeed, considerable evidence demonstrating this.

A headlong approach to restricting youth access - while worthy - will have far greater negative effects on health if it also restricts adult access and deters smokers from switching to a safer alternative. It is important to note that a key influence on why children begin to smoke is whether their parents do. Encouraging adults to move to less harmful products will have a knock-on effect in discouraging youth to embark on a lifetime of smoking a deadly product. Vaping and other harm-reduced products are in the region of at least 20 times less harmful than smoking, is it therefore sensible to throw the baby out with the bath water rather than study the issue more diligently?

We believe the questionnaire does not adequately ask for evidence to balance risks against benefits in this vital area of policy.

2. Is the TPD relevant and future proof?

The TPD should be a beacon of good policy-making taking into account the nicotine market as it is currently evolving. An exciting recent development has been the emergence of oral nicotine pouches onto some markets in Europe. These products are of huge benefit to smokers and are generally very safe. However, we have had reports that some nicotine pouches are being manufactured and sold in Russia with extremely high nicotine levels, which is putting consumers at risk. Regulating to limit the nicotine concentration is therefore appropriate and the limits should be set to benefit consumers, allowing them to benefit from the nicotine but without the potentially harmful effects. A test of whether the TPD is relevant and future proof will be in whether it can respond to this market development in a way which maximises the potential to replace smoking whilst minimising any risks to consumers.

3. Tobacco for oral use (1.5.9 Article 17)

The Questionnaire asks whether Member States have encountered any difficulties in implementing the ban on tobacco for oral use and whether they are aware of efforts to circumvent the ban.

A huge opportunity is being missed here. Snus is a smokeless tobacco product which is widely used in some parts of Scandinavia. In Sweden, where snus use has been displacing smoking, adult daily smoking prevalence has already fallen to five percent. The disease burden from tobacco is almost entirely due to smoking. People smoke for the nicotine in cigarettes but die from the tar and toxic gases inhaled from burning tobacco. So, the key point is not whether a product contains tobacco but whether there is combustion involved.

The Questionnaire focuses on the policing of a ban which is detrimental to health and fails to examine whether the ban is denying smokers access to a safer nicotine product and preventing them from quitting. The Questionnaire starts with an assumption that the ban on snus is justified when the evidence shows that it clearly is not. It would be far better for the health of Europeans if the ban on snus was revisited and the evidence examined as to whether it should be lifted. It is important to note that snus is not only legal in the US but has now been granted reduced risk status.

The EU is ignoring evidence and lagging behind much of the world by banning snus. A review of the TPD should necessarily examine the evidence on snus but the questionnaire does not do so.

4. Nicotine limit for e-cigarette refills, refill bottle sizes, advertising

These are referred to in the background to the questions on Article 20 but, again, the approach is solely as an issue of enforcement and neglects to examine the potential unintended consequences of the limit being set to 20mg/ml. This is a controversial area of the TPD and the scientists whose evidence was cited wrote at the time to complain that they had been misrepresented.

The right questions to ask are

- Does the 20mg/ml limit reduce satisfaction and increase the chances of smokers relapsing?
- Does the limit send the false message that nicotine is harmful?
- Does the limit result in compensatory behaviour which increases the user's exposure to toxins?

Why are these questions not being asked? Why are we at the stage of reviewing the TPD yet no data has been harvested on these issues from TPD2? The EU had a chance to evaluate how the nicotine limit was effective or otherwise but has singularly failed to do so.

Issues around the 10ml limit on refill containers should also be examined. Mandating small bottles is problematic in many ways:

- It leads to more frequent refilling, therefore more chance of spillage
- It increases the cost to the user for no discernible benefit
- It results in more packaging waste, most of which is plastic and in direct conflict with the EU's environmental campaigns.

Again, why does the questionnaire not weigh up the benefits and disadvantages of the 10ml limit? Why has data not been studied and why is this review not attempting to do so?

Why, also, has there been no examination of TPD2's draconian approach to advertising? Vastly safer nicotine products are on the market which could have a dramatic positive effect on smoking prevalence by publicising alternatives. By restricting advertising on the same level as combustible tobacco, the EU is hiding safer products from smokers who could otherwise choose to reduce their risk if they were aware of them, and how to use them.

As a side note, at 1.5.12 there is a reference to “unit packets of electronic cigarettes”. Combustible cigarettes are sold in packets, but we have never seen units of electronic cigarettes referred to in this way. This betrays a deep misunderstanding of vaping products and accessories and does not inspire confidence that those drafting the questionnaire are fully knowledgeable about what is being regulated.

5. Health warnings on electronic cigarettes

The Questionnaire asks whether Member States have faced issues implementing various packaging provisions, including health warnings. Again, the focus is on policing and fails to explore whether the health warnings are actually doing more harm than good.

There is clear evidence that alarmist health warnings can be misleading and misunderstood by the public. Data shows that the nicotine addiction warnings are scaring smokers away from using e-cigarettes and that the proportion of adults incorrectly perceiving e-cigarettes to be as harmful or more harmful than smoking is increasing.

Why does the questionnaire not examine if the warnings are having a positive or negative effect on public health? There is no justification for the warnings to be exactly the same size and as those for far more dangerous tobacco products. It is also baffling - and embarrassing to the EU - that hardware including batteries and glass tanks should carry a warning that they contain nicotine when they quite clearly do not. Why is there no investigation as to why those products require a warning at all?

Consumers are stakeholders

On a final note, ETHRA is a Europe-wide advocacy organisation, collectively representing thousands of association members and many millions of consumers in 21 countries. We are the people who use the products which are being regulated and have great knowledge about them. We are the public.

We are not funded by the tobacco or vaping industry; our only motivation is to ensure that products we have found to be vastly beneficial to our health are not regulated irresponsibly.

We see from the covering letter that consumers are not included in the list of stakeholders who will be formally consulted. If the EU purports to engage with the public, ensure transparency, and regulate with the consent of Europeans, why are consumers not invited for their input?

We hope that ETHRA - and consumers in general - will be included in the list of stakeholders for future consultations, and we would be willing to discuss any of the issues we have raised above at any time of your convenience.

Yours sincerely,

Damian Sweeney
ETHRA and NNA Ireland

Sources

Vaping is displacing smoking
Vaping in England: evidence update March 2020, Public Health England, https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020

Baromètre de Santé publique France 2017. Usage de la cigarette électronique, tabagisme et opinions des 18-75 ans
https://www.santepubliquefrance.fr/determinants-de-sante/tabac/documents/enquetes-etudes/barometre-de-sante-publique-france-2017.-usage-de-la-cigarette-electronique-tabagisme-et-opinions-des-18-75-ans

Healthy Ireland Summary Report 2019. Section 3: Smoking. November 2019.
https://assets.gov.ie/41141/e5d6fea3a59a4720b081893e11fe299e.pdf

Children are more likely to smoke if their parents smoke
Action on Smoking and Health Young people and smoking, September 2019
https://ash.org.uk/information-and-resources/fact-sheets/young-people-and-smoking/

Youth vaping rates
England: Vaping in England: 2020 evidence update summary. Section 3: Vaping among young people. March 2020.
https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary

Does e-cigarette experimentation increase the transition to daily smoking among young ever-smokers in France?
https://www.sciencedirect.com/science/article/pii/S0376871620300181

Oxford Academic. Nicotine and Tobacco Research. Youth Vaping and Tobacco Use in Context in the United States: Results From the 2018 National Youth Tobacco Survey. 13 January 2020.
https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntaa010/5701081?redirectedFrom=fulltext

Vaping and other harm-reduced products are significantly less harmful than smoking
Royal College of Physicians: Promote e-cigarettes widely as substitute for smoking. 28 April 2016.
https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report

Sweden's adult daily smoking prevalence 5%
Special Eurobarometer 458, Attitudes of Europeans towards tobacco and electronic cigarettes, March 2017
https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146

Snus is far less harmful to health than smoking

Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. Tob Control. 2003 Dec;12(4):349–59.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1747791/

Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11).
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5129320/

FDA grants modified risk status to snus

U.S Food and Drug Administration. FDA grants first-ever modified risk orders to eight smokeless tobacco products. October 22, 2019.
https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

Scientists complain that their work was misrepresented in the TPD

Scientific Errors in the Tobacco Products Directive, A letter sent by scientists to the European Union E Cigarette Research, Dr Farsalinos' scientific blog
http://www.ecigarette-research.org/research/index.php/whats-new/whatsnew-2014/149-tpd-errors

Guest blog: Lynne Dawkins puts the Commission straight The Counterfactual
https://www.clivebates.com/guest-blog-lynne-dawkins-puts-the-commission-straight/

20mg/ml nicotine limit for e-liquids, 10ml bottle limit

E-Cigarettes: Promises & Pitfalls of Policy, Lynne Dawkins' presentation at the SRNT-E 2019 conference in Oslo
https://www.slideshare.net/LynneDawkins/ecigarettes-promises-pitfalls-of-policy

E-cigarette health warnings

Kimber C, Frings D, Cox S, Albery IP, Dawkins L. Communicating the relative health risks of E-cigarettes: An online experimental study exploring the effects of a comparative health message versus the EU nicotine addiction warnings on smokers' and non-smokers' risk perceptions and behavioural intentions. Addict Behav. 2020
https://www.sciencedirect.com/science/article/pii/S0306460319308846?via%3Dihub

Kimber C, Frings D, Cox S, Albery I, Dawkins L. The effects of the European e-cigarette health warnings and comparative health messages on non-smokers' and smokers' risk perceptions and behavioural intentions 11 Medical and Health Sciences 1117 Public Health and Health Services. BMC Public Health. 2018.
https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-6161-7