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For the attention of the Ministry of Finance and Civil Service.

Thank you for the opportunity to comment on the Draft Law for Tobacco and Related Products. We write as the European Tobacco Harm Reduction Advocates (ETHRA), of whom Spanish consumer association Anesvap is a partner.

European Tobacco Harm Reduction Advocates is the voice of 27 million EU consumers of safer nicotine products.¹ 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 (SNPs), such as vapes, nicotine pouches, heated tobacco products, and snus, to quit smoking and to remain smoke free. ETHRA is a voluntary operation with no industry funding or conflicts of interest. Our EU Transparency Register number is 354946837243-73.

Our comments relate to provisions within the draft law which aim to bring the sale and distribution of safer nicotine products, such as vapes and heated tobacco products, under the control of the State Monopoly. This raises serious concerns as it would restrict the sale of SNPs to tobacconists, force vape shops to either close or transition into tobacconists, and drastically reduce adult access to the products they use to remain smokefree.

The main points of our submission are:

1. Regulation must be risk proportionate
2. Safer nicotine products provide a public health gain by facilitating smoking cessation
3. Restricting access to safer nicotine products harms public health
4. The unintended but predictable consequences
5. Conclusion

EU TRANSPARENCY REGISTER: 354946837243-73

1. Regulation must be risk proportionate

The justification for including safer nicotine products in the State monopoly can be found at chapter two of the draft law,² which cites *“the serious impact on the health of the population that the consumption of tobacco and other related products have”*. This highly misleading statement ignores the fact that the serious impact on population health is due to smoking, the inhalation of the toxic products of combustion, and not the use of nicotine products.³ This was explained as far back as 1976 by Professor Michael Russel:⁴

“People smoke for nicotine, but they die from the tar. Their risk of lung cancer and bronchitis might be more quickly and effectively reduced if attention were focused on how to reduce their tar intake, irrespective of nicotine intake”

We know beyond any reasonable doubt that non-combustible nicotine products are orders of magnitude safer than combustible tobacco. The most compelling and 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)⁵ 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 conducted a comprehensive independent evidence review on e-cigarettes which found:⁶

“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”

Regulations or laws that relate to tobacco or nicotine products must be science based and risk proportionate. Treating safer nicotine products in the same way as harmful combustible cigarettes sends the false message that the products are equally as harmful. This discourages people from switching, which results in more smoking.

2. Safer nicotine products provide a public health gain by facilitating smoking cessation

As we have demonstrated above, SNPs carry a fraction of the risk of smoking (at least 95% less harmful). This is very important in the context of the draft law as public health impacts are mentioned a number of times. So, how does the use of SNPs impact public health? There is an ever-increasing body of evidence which shows that using SNPs as a means to quit smoking and remain smoke free is both popular and effective.

A 2019 large-scale randomised control trial, considered the gold standard, found that vaping was 83% more effective than nicotine replacement therapy (NRT).⁷ A Cochrane living review of vaping for smoking cessation, which includes over 60 studies and over 15,000 participants, has consistently found that vaping was substantially more effective than NRT’s.⁸

Evidence that SNPs are a substitute for combustible tobacco and a driver of smoking cessation is clear from official EU data. Special Eurobarometer 506⁹ found that 31% of ever smokers say that vaping or similar product helped them quit smoking completely, a huge increase of 121% from 2017.

Use of SNPs, according to Eurobarometer, is almost exclusively among former or current smokers. 98% of current SNP consumers initiated with a combustible product.

A recent study conducted by Sigma Dos,¹⁰ which examined the habits of Spanish vapers, found that 76% of current vapers had completely quit smoking. A survey of over 35,000 EU consumers of nicotine products, conducted by ETHRA in 2020, found that 83.5% of vapers had successfully stopped smoking.¹¹ Both surveys came to the same conclusion as Eurobarometer regarding first initiation, with 93.1% and 97.8% respectively initiating with combustible tobacco.

It's evident from the data that SNPs are an effective gateway out of combustible tobacco use, and provide a huge gain for public health.

3. Restricting access to safer nicotine products harms public health

Special Eurobarometer 506 estimates that there are approximately 460,000 consumers of safer nicotine products, and over 11 million smokers in Spain¹². The Spanish Ministry of Health estimates that smoking is responsible for 50,000 deaths per year.¹³ Given those alarming figures it's clear that more needs to be done to reduce the burden on health from smoking. Unfortunately, the draft law will do the opposite as it intends to restrict access to SNPs, which are a proven method of smoking cessation, and outlaw online sales. This policy decision, if enacted, will inevitably lead to the protection of the cigarette trade and prolong smoking.

The Royal College of Physicians expertly communicated the unintended consequences of policies which are designed to restrict low-risk alternatives to smoking [emphasis added]:¹⁴

*"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."* (Section 12.10 page 187)

4. The unintended but predictable consequences

Vape shops offer smokers a specialised service that goes far beyond just selling a product. They offer expert advice and guidance on the best products to use for each individual on their journey to quit smoking, and provide support on that journey. They offer a wide variety of flavours which have been shown to be vital in transitioning away from smoking.^{15 16} When San Francisco reduced the availability of flavours for consumers of SNPs the inevitable outcome was an increase in smoking.¹⁷

Forcing vape shops to transition to tobacconists will negate the public health benefits they provide. There will be a legal obligation to stock a large variety of combustible tobacco products, but no obligation to do the same for low-risk alternatives to smoking, the variety of SNPs available will undoubtedly be greatly reduced. Consumers will be faced with the very products they have been trying to escape from, combustibles, which could increase risks of relapse to smoking. All of which will increase smoking and public health harms.

As the cost-of-living spirals throughout the EU, the economic impact of the draft law should not be overlooked. Specialised vape shop generate an estimated €60 million a year for the economy. The draft will force many or all to close, leading to the loss of 1,200 direct and 3,000 indirect jobs.¹⁸

Chapter two of the draft law specifically mentions helping to fight effectively against all kinds of illicit trade. The reality of including SNPs in the State monopoly is that it will encourage illicit trade. When the products people want to use are no longer accessible or available, because of bans (online sales or product categories bans), people will seek them out by other means. This was the experience in Estonia, where a flavour ban and high taxation led to an explosion of grey-market products, reported to account for 62-80% of all sales.¹⁹

Another example of the perverse consequences of restricting access to safer nicotine products by means of an online sales ban can be found in Belgium. Restrictions that were put in place in the height of the COVID pandemic meant that vape shops were forced to close, but cigarettes remained widely available. A survey by Adriaens et al found that a significant number of exclusive vapers returned to smoking due to a lack of availability of vaping products.²⁰

5. Conclusion

The draft law will achieve none of its objectives, rather, it is more likely to do the exact opposite. If enacted the law will increase smoking and harm public health by making safer nicotine products less accessible. The wide variety of products that are available to ex-smokers who use SNPs to remain smokefree will be greatly reduced, impacting Spain's 460,000 consumers of SNPs and the 11 million smokers who have yet to find SNPs. Business closures and job losses will have a negative impact on the economy. The probability of an illicit market emerging is very high as people seek out the products they want and need to remain smokefree.

We urge you to listen to the experience of consumers as we are the ones that will be most affected by the unintended but entirely predictable consequences of the draft law.

Yours sincerely,

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On behalf of ETHRA & Partners

References

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