Catania, 6th August 2024

To the Ministry of Health
Government of Spain
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RE: Contribution to the Public Consultation on the Proposed Amendment to the Spanish Anti-Tobacco Law

We, the signatories, are public health experts and socio-health professionals committed to the fight against smoking, members of the Center of Excellence for the Acceleration of Harm Reduction (CoEHAR), an international, multidisciplinary research center established in 2018, which currently includes more than 80 academics globally. **CoEHAR's mission is to accelerate efforts to study and reduce health burden and deaths from tobacco smoking, both locally and internationally, through the use of approved pharmacological approaches and innovative technologies**.

Premise
Following the latest EDADES 2022/2023[1], Spain has now the highest tobacco rates, 33.1% of the population between 15 and 64 years old, compared to 32.8% in 2005, just before the first approval of the anti-tobacco law. **There are many smokers in Spain and, at least, 6 million people are unable of stopping smoking even if they want to quit it and only 35% of smokers succeed with traditional approaches, with a very high relapse rate.** The Spanish government has implemented various tobacco control measures, including bans on smoking in enclosed public spaces and restrictions on tobacco advertising. Despite these efforts, smoking remains a leading cause of preventable diseases and deaths. The proposed amendments to the Anti-Tobacco Law aim to further reduce smoking rates by expanding smoke-free areas, regulating e-cigarettes, and restricting tobacco advertising and sales.

We appreciate the intent of the Spanish Government as we need to further strengthen current anti-smoking policies and renew the Government's strong commitment to reducing the prevalence of smoking and the harms associated with it. Nevertheless, we consider that the announced initiative of amend the Anti-Tobacco Law in terms that smoke-free alternatives are compared to traditional cigarettes is still anchored in the pillars of prevention and cessation, which have already shown themselves to be stagnant and to have a limited impact on the fight against smoking, as demonstrated by the most recent data.
It is necessary to complement the existing tobacco control policies with new approaches, particularly for smokers who do not intend to quit or are unable to do so.

Harm reduction is a public health strategy aimed at minimizing the negative consequences of risky behaviors. In the context of road safety, mandating the use of seat belts in cars and helmets for motorcyclists and bicyclists has significantly reduced injuries and fatalities resulting from road accidents. In the context of tobacco smoking, harm reduction refers to strategies and practices designed to prevent or reduce the health risks associated with smoking, particularly for those who are unable or reluctant to

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stop, rather than focusing solely on complete abstinence from nicotine use[2]. This approach involves providing adult smokers with combustion-free alternatives to conventional tobacco cigarettes (e.g. e-cigarettes, heated tobacco products, nicotine replacement therapies), that can mitigate the harm caused by the exposure to the toxic substances from tobacco combustion and help to cope with cravings and withdrawal symptoms.
The World Health Organization's Framework Convention on Tobacco Control (FCTC) [3] acknowledges harm reduction as an integral part of a comprehensive approach, but it does so only by eliminating or reducing consumption. Concerning tobacco use itself, the FCTC program is abstinence-based[4].

According to the top public health authorities in the UK[5,6] and US[7,8], e-cigarettes are significantly less harmful than traditional tobacco cigarettes. They have also stated that adults who smoke can gain health benefits from switching to e-cigarettes, even though there may be some residual exposure, but at much-reduced levels. Therefore, these public health authorities are promoting e-cigarettes, heated tobacco products and oral nicotine/tobacco products as safer alternatives and effective tools for quitting smoking. Regarding effectiveness for smoking cessation, the latest Cochrane review found high evidence that e-cigarettes are among the most effective intervention for smoking cessation[9].

A paradigmatic example of the successful impact of tobacco harm reduction at the population level is that of the **"Swedish Experience"**. **In Sweden, "snus"** (a type of oral tobacco that delivers nicotine but not any of the toxic combustion products) **consumption has progressively replaced cigarette smoking over the past 30 years.** As a result of the significant reduction in cigarette smoking, a marked decrease in lung cancer and cardiovascular disease mortality rates have been reported in recent years. Sweden is not an isolated case. **Other countries, such as United Kingdom, Norway, Japan, and New Zealand, which have adopted harm reduction principles, have all seen a significant reduction in smoking prevalence, even among young people, well beyond what was estimated with the simple application of traditional prevention and cessation measures.** In the case of Sweden, its commitment to harm reduction tools has reduced daily smoking to 5.6%, which has resulted in a 41% lower incidence of cancer in this country than in other EU countries, and a 38% lower total number of deaths from cancer; nevertheless, sometimes smoking is at 4.3% so there is still room for improvement[10,11]. For its part, the United Kingdom has managed to reduce the smoking rate by five points in just five years to 12% today[12]. In the case of New Zealand, the latest data showed that the number of people smoking has fallen from 15.1% in 2018 to 8% in 2022[13]. This would place it among some of the lowest smoking rates in the world and would be on track to achieve "smoke-free" status by 2025.

Since its foundation, **CoEHAR has published more than 150 peer-reviewed papers** investigating the toxicological effects of combustion-free products, their effectiveness and tolerability among smokers, but also their impact on health conditions among individuals with chronic obstructive pulmonary disease who have switched to these products. What we have found is that **combustion-free products:**

1) **help smokers quit smoking**;
2) **offer a significant reduction in exposure/risk compared to traditional cigarettes;**
3) **are associated to clinically relevant improvements in users with smoking-related diseases, such as in those who suffer from chronic obstructive pulmonary disease**.

Based on the scientific evidence collected so far, CoEHAR can provide three insights and advice on the proposed amendments to the Anti-Tobacco Law presented by the Spanish Ministry of Health, as follows:

1) ***Promoting Healthy, Smoke-Free Spaces***

While we understand the intent to protect public health by equating vaping with tobacco consumption in public places, it is important to recognize the substantial differences in harm profiles between combustible tobacco and vaping products. We demonstrated the reduced toxicity of ENDS (electronic nicotine-delivery systems) products compared to cigarettes[14]. We also showed a substantial reduction of the effects of aerosol from e-cigarettes (EC) and heated-tobacco products (HTP) on endothelial cell migration compared with cigarette smoke, confirming the importance of ECs and HTPs as a possible harm reduction strategy for cardiovascular diseases development in smokers.[15] Moreover, our research also demonstrated that lung function and respiratory symptoms[16] and muco-ciliary clearance[17] improve after switching from smoking to combustion-free products. Another study of non-smokers who vaped found no significant negative health outcomes after 3.5 years[18], and another showed consistent improvements in respiratory symptoms, exercise tolerance, quality of life, and rate of disease exacerbations in patients with COPD who abstained from smoking or substantially reduced their cigarette consumption by switching to HTP use.[19] Equating these products could discourage smokers from switching to safer alternatives, thus undermining harm reduction efforts. **We advocate for regulations that consider the reduced risks associated with vaping and support its role in tobacco harm reduction**.

2) ***Advertising, Promotion, and Sponsorship***

We acknowledge the need for regulations on advertising, promotion, and sponsorship to prevent youth uptake. The rising trend in vaping popularity among young non- smokers is a legitimate concern as there is a risk that EC use may have some adverse effects in the developing lungs of adolescents. In a study on youth vaping in the US, we examined data from the National Youth Tobacco Survey in 2015.[20] We concluded: "Although there is reasonable concern about the recent increase in ever and past 30-day e-cigarette among U.S. youth, the data reported here show that the majority of e-cigarette use is experimental or infrequent, while regular use is minimal, among never smokers." We also reviewed the 2016 Surgeon General report which concluded e-cigarette use among youth and young adults is becoming a major public health concern in the United States of America[21]. Our review concluded: "The U.S. Surgeon General's claim that e-cigarette use among U.S. youth and young adults is an emerging public health concern does not appear to be supported by the best available evidence on the health risks of nicotine use and population survey data on prevalence of frequent e-cigarette use." In 2022, we reviewed the evidence for youth vaping in the US, and concluded:[22] EC use has surged greatly among high school students and young adults over the last decade, but has declined significantly since its peak in 2019. During the same period, smoking rates have constantly fallen to new low record levels. These trends argue against EC use as a gateway to smoking. Our 2015 systematic review of the safety of e-cigarettes came to the following conclusions which appear to be still valid today:[23]

- "***Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes***"

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- "***It is obvious that some residual risk associated with EC use may be present, but this is probably trivial compared with the devastating consequences of smoking***"
- "***Due to their unique characteristics, ECs represent a historical opportunity to save millions of lives and significantly reduce the burden of smoking-related diseases worldwide***".

  Regulations should not be so restrictive as to limit adult smokers' access to accurate information about less harmful alternatives. Social media and product reviews are valuable sources of information for smokers considering switching to vaping. **Balanced regulations can ensure that while protecting youth, adult smokers are still able to make informed decisions based on reliable information**.

3) ***Sale and Consumption of E-Cigarettes***

Restricting the sale of e-cigarettes to controlled state tobacco stores could significantly limit access to these harm reduction products for adult smokers. Such a restriction may inadvertently push smokers back to traditional, more harmful tobacco products. We advocate for allowing the sale of e-cigarettes in specialized vaping stores, where staff are knowledgeable and can provide guidance on their proper use. Additionally, online sales should be permitted with stringent age verification measures to ensure that only adults can purchase these products. Banning disposable e-cigarettes could reduce environmental waste, but it also removes a convenient option for smokers looking to switch to less harmful alternatives. **Instead of an outright ban, we recommend implementing environmental regulations to address waste concerns. For example, manufacturers could be required to develop and promote recycling programs for disposable e-cigarettes. This approach ensures that harm reduction and environmental protection are both addressed effectively.**

Conclusions

Nicotine vaping products are the most popular quitting aid and have proven effective as substitutes for smoking. Because they incur substantially less risk than smoking tobacco cigarettes, tobacco harm reduction will produce better outcomes at individual and at a population level. On the contrary, a restrictive approach that severely limits access to harm reduction products within populations of consumers who currently smoke tobacco could be damaging to public health.

Access by young people should be restricted. There should be strict age verification on sale and harsh penalties and loss of license for sales to minors. However, the harm from vaping by young people is likely to be small as most use is experimental and short term. Regular vaping is rare. There is also no good evidence that vaping causes young people to take up smoking.

It is essential to educate the public about the relative risks of different nicotine products. Misleading information can prevent smokers from making informed decisions about switching to less harmful alternatives. Public health campaigns should accurately reflect the evidence supporting the reduced risk of e-cigarettes and heated tobacco products.

We also encourage the inclusion of harm reduction products in smoking cessation programs. These products can be valuable tools for smokers who have struggled to quit using traditional methods.

Providing support and guidance on the use of these products can enhance cessation efforts and improve public health outcomes.

Finally, ongoing research and monitoring are vital to understanding the long-term effects of alternative nicotine products. We advocate for continued investment in research to inform regulatory decisions and public health policies. Data collection and analysis should be prioritized to ensure that regulations remain evidence-based and adaptive to new findings.

We hope that the Spanish government will consider these points to create a balanced and effective smoking regulation framework.

We are available for any expert hearings at the Spanish Government on the subject.

Sincerely,

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