

Response to consultation on marketing of nicotine products without tobacco for oral use

Helix Sweden AB,¹ a manufacturer of tobacco-free nicotine pouches, is grateful for the opportunity to submit a consultation response regarding the proposed product ban for nicotine products without tobacco for oral use (NZT for oral use). Helix Sweden AB has significant experience in tobacco-free nicotine products and operates in seven European markets.

While Helix Sweden AB welcomes regulation for tobacco-free nicotine products, it is our view that this proposal does not adequately consider the role that emerging nicotine products without tobacco can play in reducing the harms of tobacco by providing less harmful alternatives to adult smokers who can't, or won't, quit. We believe that product regulation should be evidence-based and balance the goals of preventing new nicotine product initiation and preserving the opportunity these products offer to adult smokers. Finally, we believe a common European approach to tobacco-free nicotine product regulation would be beneficial.

Policymakers should consider the harms of continued smoking in addition to nicotine-related concerns.

While nicotine is addictive, it's the exposure to smoke – not nicotine – that causes most tobacco-related disease including lung cancer, heart disease and emphysema.²

Nicotine is not without risk and those not currently using tobacco or nicotine products, especially young people, should not start. Focusing only on the risks of nicotine, though, ignores the harms encountered by adult smokers. As recently put by one public health expert, "If all smokers in the world...would switch to one of [the] less harmful alternative smoke-free, nicotine-based products, it could prevent disease and save millions of lives worldwide."³ By banning NZT for oral use on the Dutch market, the proposal risks undermining this potential public health benefit.

A new policy should consider the potential health benefits to adult smokers who can't or won't quit.

The proposal materials identify several important nicotine policy stakeholders including youth who must be prevented from accessing nicotine products and smokers who have quit, or who desire to quit, nicotine product use.⁴ These focus areas are appropriate. Young people should not use any nicotine

¹ Helix Sweden AB is a subsidiary of Altria Group, Inc. Helix Sweden AB manufactures nicotine pouches without tobacco under the brand name of on!®. "We" or similar pronouns are used throughout to refer to Helix Sweden AB.

² See, Gottlieb, S., & Zeller, M. (2017). A nicotine-focused framework for Public Health. *New England Journal of Medicine*, 377(12), 1111–1114. <https://doi.org/10.1056/nejmp1707409> ("Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year."); Blog: Nicotine is why tobacco products are addictive, U.S. Food & Drug Administration, retrieved January 10, 2023, from <https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive> ("Nicotine is what keeps people using tobacco products. However, it's the thousands of chemicals contained in tobacco and tobacco smoke that make tobacco use so deadly.").

³ Tobacco Reporter. "Sweden Approaching Smoke Free Goal." Retrieved January 11, 2023 from: <https://tobaccoreporter.com/2022/12/07/sweden-approaching-smoke-free-goal/>

⁴ Explanatory Memorandum, page 1

containing product, and we support efforts to prevent youth product access and support smokers seeking to quit.

The proposal materials, though, are silent on the group at most immediate risk of the harms of tobacco product use – adult smokers who can’t or won’t quit smoking. Many public health policymakers weigh the risks of product initiation by unintended audiences, especially by minors, against the potential public health benefits of adult smokers switching to smoke-free products.⁵ The current proposal, though, disregards half of this equation, failing to meaningfully consider adult smokers who can’t or won’t quit in the policy evaluation.

The unrealized public health benefits of the products subject to a ban under the proposal are potentially significant. Recent peer-reviewed literature shows a profound difference in risk between combustible and smoke-free product categories, frequently referred to as a “risk cliff.”⁶ Emerging data for specific NZT for oral use products shows marked reduction in exposure to harmful and potentially harmful constituents among smokers who switch.⁷ Under the rigorous product authorization review in the United States, multiple nicotine products for oral use have been deemed “appropriate for the protection of the public health.”⁸

Further, recent case studies illustrate that the goals of preventing youth initiation while offering reduced harm opportunities to adult smokers need not be in conflict. Sweden, a leader in progressive policymaking which preserves smoke-free products for adults, achieved “the lowest level of mortality attributable to tobacco” among men in European Union Member States,⁹ even as smoking among youth and young adults virtually disappeared.¹⁰

⁵ See, e.g., Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing youth access to flavored tobacco products and banning menthol in cigarettes. November 15, 2018 (“The policies I’m outlining now strives to strike a careful public health balance between our imperative to enable the opportunities to transition to non-combustible products to be available for adults; and our solemn mandate to make nicotine products less accessible and less appealing to children.”) Retrieved December 12, 2022 from: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>; David J. K. Balfour, Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, et al. (2021). Balancing Consideration of the Risks and Benefits of E-Cigarettes. *Am J Public Health*, vol. 111 (9), 1661-1672. doi:10.2105/ajph.2021.306416.

⁶ See, Nutt, et. al Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. *Eur. Addict Res* 2014; 20:218-225. Clark, B. Presentation to GTNF: *Risk Continuum or Risk Cliff: Appropriate Evidence for Appropriate Claims*. 2016.

Knowledge.Action.Change. *No Fire No Smoke: Global State of Tobacco Harm Reduction 2018*. Retrieved January 11, 2023 from: <https://gsth.org/resources/thr-reports/no-fire-no-smoke-global-state-tobacco-harm-reduction-2018/1/en/>

⁷ Mohamadi Sarkar, Maria Gogova. (2023). “Review of: ‘Nicotine Pouch Sales Trends in the US by Volume and Nicotine Concentration Levels From 2019 to 2022’””. *Qeios*. doi:10.32388/K7XOHU

⁸ U.S. Food & Drug Administration. Premarket Tobacco Product Applications. Retrieved on January 11, 2023 from: <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>; Premarket Tobacco Market Granted Orders. Retrieved on January 11, 2023 from: <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>

⁹ Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Sep 1;12(1):14. doi: 10.1186/1617-9625-12-14. PMID: 25191176; PMCID: PMC4154048. Retrieved on January 11, 2023 from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154048/>.

¹⁰ Folkhälsomyndigheten. “Adults’ use of tobacco and nicotine products”. Retrieved on January 11, 2023 from: <https://www.folkhalsomyndigheten.se/livsvalkor-levnadsvanor/andts/utveckling-inom-andts-anvandning-och-ohalsa/anvandning/tobaks--och-nikotinprodukters-utveckling/vuxnas-bruk-av-tobaks--och-nikotinprodukter/>

A prohibition would not be in line with current nicotine regulatory efforts.

Policymakers, guided by science and evidence, should consider a tailored regulatory approach designed to encourage adult smokers to transition to smoke-free products while addressing unintended consequences including youth initiation. The proposal materials reference policy areas warranting further assessment as part of this framework including age limits, warning language, product standards, and marketing restrictions.¹¹ Indeed, while we believe the final policies may not appropriately reflect the science and evidence, lawmakers have opted for nicotine product regulation, not prohibition, in recent years.¹²

In the absence of data to support an outright ban on NZT for oral use, the proposal relies upon the “striking similarities” between snus, a currently prohibited tobacco product, and NZT for oral use.¹³ While we believe data likely supports a revisiting of the snus policy, this comparison is a fallacy, and each product should be evaluated based on its unique attributes.

Snus and NZT for oral use are fundamentally different products. While we can speak only for the products we manufacture, Helix’s NZT for oral use products contain nicotine and non-tobacco ingredients and are tobacco leaf-free. As such, most harmful and potentially harmful constituents are either absent or substantially reduced compared to certain snus products.¹⁴ Policymaker analysis should move beyond superficial comparisons, instead reviewing each nicotine-containing product independently to identify the appropriate set of regulatory responses that preserve the opportunity for adult smoker transition to smoke-free products while protecting against initiation by unintended audiences.

Regulation of NZT for oral use, rather than prohibition, is also consistent with the approach of many international policymakers. Sweden, as discussed above, permits the sale of smoke-free nicotine products subject to various marketing and sales restrictions¹⁵ and recently announced the lowest smoking rate in Europe and is “well ahead of the European Cancer Plan’s goal of a ‘smoke-free generation’ by 2040.”¹⁶ NZT for oral use remains widely available in additional countries including Denmark, United Kingdom, Ireland, Czechia, Slovakia, Austria, Poland, Switzerland, and the United States.

Finally, a full category prohibition is not without policy risks including a potential illicit market and associated presence of perhaps dangerous unregulated products, implications for law enforcement,

¹¹ Explanatory Memorandum, page 1.

¹² See, “Dutch ban on flavored e-cigarettes to begin on October 1; Only tobacco flavor allowed”, <https://nltimes.nl/2022/12/01/dutch-ban-flavored-e-cigarettes-begin-october-1-tobacco-flavor-allowed>.

¹³ Explanatory Memorandum, page 5.

¹⁴ “A Comparison of HPHCs in on!® Nicotine Pouches to HPHCs in Cigarettes and Swedish Snus”. Wagner et al., September 2022. Retrieved on January 11, 2023 from: https://sciences.altria.com/-/media/Project/Altria/Sciences/presentations/2022/Wagner_Comparison-of-HPHCs-in-on-to-Cigarettes-and-Snus.pdf

¹⁵ Public Health Agency of Sweden. “Tobacco free nicotine products.” Retrieved on January 12, 2023 from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/andtg/rules/tobacco-free-nicotine-products/>

¹⁶ St George, Henry. “EU should look at how Sweden achieved the lowest smoking rate in Europe.” EU Reporter. December 13, 2022. Retrieved <https://www.eureporter.co/health/2022/12/13/eu-should-look-at-how-sweden-achieved-the-lowest-smoking-rate-in-europe/>; Data accessible: http://fohm-app.folkhalsomyndigheten.se/Folkhalsodata/pxweb/sv/A_Folkhalsodata/A_Folkhalsodata__B_HLV__aLevvanor__aagLevvanortobak/hlv1tobaal.d.px/

future excise collections and harm to legitimate businesses. This may be especially true for products readily accessible through e-commerce.

Nicotine product policymaking is undeniably complex and, for this reason, must be based in scientific evidence. We believe emerging data convincingly shows the role smoke-free products, including products with flavors and various nicotine levels, can play in reducing the risks faced by adult smokers who can't or won't quit. Lawmakers should aim to prevent youth access and other unintended consequences through targeted regulation, while supporting the Netherlands' approximately 3 million adult smokers¹⁷ by allowing the sale of regulated, responsibly marketed, smoke-free nicotine products with the opportunity to greatly reduce the harms associated with smoking.

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¹⁷ Smoking in the Netherlands: Key Statistics for 2020. Netherlands Expertise Center for Tobacco Control. Retrieved on January 11, 2023 from: <https://www.trimbos.nl/wp-content/uploads/2021/11/AF1898-Smoking-in-the-Netherlands-key-statistics-2020.pdf>