Written evidence submission from Global Institute for Novel Nicotine (GINN) to the Tobacco and Vapes Public Bill Committee (TVB35).

1. Executive Summary

Safer nicotine products (SNPs), such as nicotine pouches, lozenges, gums, dissolvables and other reduced-risk nicotine alternatives, should not be regulated in the same manner as combustible smoking tobacco products and nicotine vaping products because they–

- are smokeless and do not pose the same relative health risks;
- readily contribute to a smoke-free environment that minimizes risk to non-users;
- provide opportunities for innovation and economic growth in a marketplace that is switching from traditional inhalable products;
- require regulations and guidelines that accommodate the products' unique reduced risk characteristics and labelling and marketing that impart less harmful benefit information to adult consumers.

2. **The Global Institute for Novel Nicotine (GINN)** is a membership-based association dedicated to advancing collaborative standards, innovation, research, and advocacy in the field of novel nicotine products. Under the leadership of Director Shem Baldeosingh, who brings over eight years of senior leadership experience in the nicotine industry and extensive experience working with Commonwealth parliaments and national governments, GINN supports the development and adoption of reduced-risk alternatives, such as nicotine pouches and non-combustible heated products, to engender a potentially safer choice of future products for adult consumers worldwide. GINN collaborates with consumers, policymakers, scientific and technical researchers, product innovators and the industry-at-large, to address regulatory challenges, promote harm reduction, and encourage responsible product development. Our commitment to collaboration and scientific integrity positions us as a trusted voice in the evolving landscape of tobacco harm reduction and nicotine innovation.

3. Regulatory Landscape of Modern Nicotine Products

The regulatory approach to nicotine-containing products is evolving globally, with increasing recognition of the need for risk-proportionate regulation based on product characteristics and intended use. This regulatory framework can be broadly categorized into three main segments:

Traditional NRT Products:

Nicotine gum and lozenges have established themselves as conventional Nicotine Replacement Therapy (NRT) medicines, with comprehensive regulatory oversight worldwide. These products have:

- Extensive clinical validation through rigorous testing protocols
- Regulatory approvals from major authorities like the US FDA and European EMA
- OTC status in most jurisdictions
- Integration into national healthcare systems
- WHO endorsement under the FCTC framework

Emerging Nicotine Pouches:

Modern oral nicotine products like pouches represent a new category requiring distinct regulatory consideration. Recent developments include:

- Canada's landmark authorization of Zonnic nicotine pouches as cessation aids
- Growing regulatory interest in their harm reduction potential
- Recognition of their unique characteristics distinct from traditional tobacco products
- Need for specific regulatory frameworks addressing their novel nature

Risk-Proportionate Regulation:

The rationale for differentiated regulation of safer nicotine products (including pouches, lozenges, gums, and other reduced-risk nicotine alternatives) from combustible tobacco and vaping products is based on:

- Lower risk profile compared to combustible products
- Different usage patterns and consumer behavior
- Distinct manufacturing standards
- Varied intended purposes (cessation vs. harm reduction)

Model Implementation - UK Approach:

The United Kingdom exemplifies a sophisticated regulatory framework with:

- NHS integration of NRT into cessation services
- MHRA oversight ensuring product safety and quality
- Dual availability channels (OTC and prescription)
- Demonstrated cost-effectiveness (£2,000-£4,000 per QALY)

WHO Framework:

The WHO FCTC provides overarching guidance through:

- Recognition of NRT as essential cessation tools
- Guidelines for member nations on implementation
- Integration requirements in national tobacco control strategies
- Evidence-based policy recommendations

4. SNP's fall within the definition of "nicotine product" in clause 49 of the Tobacco and Vapes Bill;

5. Nicotine products are generally categorized with vaping products [cf. clauses 10 (sale of vaping or nicotine products to under 18s), 11 (purchase of vaping or nicotine products on behalf of under 18s) and 12 (vaping and nicotine products vending machines)]. In clauses 13 (displays of products or prices in England), 16 (Prohibition of retail sales of tobacco products etc in England without a licence), 23 (restricted premises orders), 28 (restricted sale orders) nicotine products are grouped with tobacco products, herbal smoking products, cigarette papers and vaping products.

6. SNPs should not be regulated within the same product category as combustible tobacco products and nicotine vapes for the following reasons:

    - unlike combustible tobacco products, SNP's lack the harmful smoke and total aerosol residue (TAR), particulate matter and ambient sensory effects that may contribute to broader public health issues;

    - unlike vaping products, SNP's do not involve the inhalation of combinational vapor, flavourants and additives which likely cause vaping products to share some regulatory overlap with traditional tobacco products and other inhalable products;

    - SNP's eliminate smoke-exposure and the risk of harm from ambient smoke and vapor;

    - the very use of SNP's actively creates a smoke-free environment, so it is not necessary to regulate SNPs in the context of social smoking and vaping;

    - SNPs are innovative, have exhibited demonstrable reductions in tobacco smoking and tobacco use in countries such as Sweden and Norway, and provide consumers with a diverse range of potentially safer choices;

- the promotion of innovation in the SNP sector would promote a domestic UK industry to help drive positive economic growth through product advancement, investment in research and development and the creation of improved SNP's that better meet adult consumer preferences and demands;

- SNP's have unique use and features of consumption that warrant distinct regulatory treatment;

- placing SNPs in a separate product category within the proposed statute, would better facilitate the development of highly tailored regulation that would encourage adult adoption of a reduced risk product, and diminish the potential social and public health impacts of tobacco use, as well as ensuring full legal compliance and broad consumer protection;

- specific product labelling and marketing regulation to diminish youth appeal and designed specifically for adult consuming SNP's, would allow receptive adult consuming switchers to receive accurate information about the contents and usage of SNP's. This would, in turn, promote fuller consumer understanding, enhance responsible compliance, facilitate informed decision-making towards future regulation of SNP's and encourage responsible adult consumption.

7. Some of the **potential benefits of regulating SNPs in a separate product category** are as follows:

    a. **Regulation and Compliance**: new measures may be introduced to regulate nicotine levels and ingredients in SNP's, ensuring product verifiable acceptable low toxicity thresholds and responsible adult consumer protections;

    b. **Marketing Restrictions**: there could be more carefully considered regulation on advertising and promotion that balances the broader societal benefits of switching to potentially lower risk profile SNPs, and that also moves to eliminate the potential appeal to young or vulnerable audiences;

    c. **Health Warnings**: mandatory informative health warnings on packaging should be required to inform consumers about potential risks associated with any form of nicotine use. Such labelling should be based on independent scientific validation and communicated in part, as a smoking alternative to reduce risk, similar to the Modified Risk Tobacco Product (MRTP) messages permissible on FDA authorized products in the USA;

d. **Age Restrictions**: selling SNPs to minors should be illegal, aligning with other societal age restrictions for products such as alcohol in order to protect youth;

e. **Innovation and Market Impact**: the industry may face challenges in product innovation and distribution, impacting market dynamics, adult consumer choices, but importantly the broader public health goal of encouraging switching, to reduce the impacts of tobacco use;

f. The responsible regulation of SNP's would ameliorate safety concerns, mitigate public health impacts, and balance adult consumer interests in the evolving nicotine product landscape.

8. Some of the **key elements of a regulatory framework for SNP's** should include:

a. **Market Access**:
o Implement a notification process where manufacturers must provide detailed information about the product, including ingredients, chemical toxicological data, and total nicotine content.
o Ensure that products meet minimum quality and safety standards by mandating registration, before a new product can be commercially marketed.

b. **Differentiated Product Category**:
o Create a separate product category that includes SNP's and other alternative nicotine-containing products.

c. **Product Standards**:
o Set responsible product standards for ingredients, materials, total nicotine content and manufacturing processes to enhance safety and quality.
o Require compliance with standards for total nicotine delivery and qualify the absence of combustion.

d**. Communication with Adult Smokers**:
o Allow communication about SNP's and other alternative nicotine products at points of sale, through digital platforms, and in product comprehension sessions.
o Permit manufacturers to provide substantiated information on the reduced risk profile of SNP's and other alternative nicotine products compared to tobacco smoking and tobacco use.
o Implement appropriate control mechanisms to limit youth exposure to SNP's and other alternative nicotine products communications.

e. **E-Commerce**:
   o Allow online sales of SNP's and other alternative nicotine products with strict age verification requirements.
   o Ensure online retailers comply with the same regulations as offline retailers, including product display, mandated warnings, and advertising restrictions.
   o Require online marketplaces to verify sellers comply with existing laws and remove violating non-compliant actors.

f. **Differentiated Health Warnings**:
   o Require mandated warnings specific to the relative risk of SNP's and other alternative nicotine products as compared to smoking tobacco.
   o Ensure warnings are proportionate to the size of the packaging and do not include non-representative graphic elements.

g. **Product Regulation/Flavours**:
   o Allow flavours in SNP's and other alternative nicotine products to help adult smokers switch from smoking to alternatives.
   o Prohibit flavour descriptors that may prove appealing to youth and marketing that promotes a youth-oriented product choice.

h. **Minimum Age Requirements**:
   o Enforce strict minimum age laws of at least 18 years for the sale and supply of all nicotine-containing products.
   o Implement rigorous enforcement and penalties for violations.

i. **Post-Market Surveillance**:
   o Require manufacturers to report on product information, adverse events, and health effects.
   o Implement national surveillance systems to study market trends and collect data on product usage and health impacts.

APPENDIX

Following are some specific studies and research areas that compare the differences in health risks, behaviour, and societal impact between nicotine pouches and traditional cigarettes, often highlighting the potential benefits of nicotine pouches as a smoking cessation or harm reduction tool.

Overall, while not exhaustive, these studies collectively indicate that nicotine pouches may offer a less harmful alternative to cigarettes, owing to the absence of smoke and reduced exposure to harmful chemicals. However, the potential for nicotine addiction remains, making user education crucial.

1. **Lunell, E., & Fagerström, K. (2018)**: "*Oral Tobacco: Swedish Experience*." This study focuses on Swedish oral tobacco products, such as snus and nicotine pouches, examining their health impacts compared to smoking traditional cigarettes and noting lower health risks associated with smokeless nicotine products.

2.**Azzoni, S. F., & Drope, J. (2019):** "*Harm reduction and the evidence for nicotine replacement: a systematic review*." While focusing on harm reduction, this review includes discussions on different forms of nicotine replacement, including nicotine pouches, and compares them to the harms posed by cigarettes.

3. **Russell, J., & Ruhm, C. J. (2020):** "*Products with different nicotine levels: effects on user behavior*." This study compares the addictive potential and user behaviour associated with varying nicotine products, including oral pouches, and their comparative profile to cigarette use.

4. **Levy, D. T., Yuan, Z., & Luo, Y. (2021):** "*The public health impact of non-combustible tobacco products: a simulation modeling analysis*." This modelling study evaluates the overall public health impact if users switch from cigarettes to non-combustible products like nicotine pouches.

5. **Nutt, D. J., Phillips, L. D., Balfour, D., Curran, H. V., Dockrell, M., Foulds, J., & Sweanor, D. (2014):** "*Estimating the harms of nicotine-containing products using the MCDA approach*." This study assesses the relative risks of different nicotine products, including smokeless options.

6. **Levy, D. T., Borland, R., Lindblom, E. N., Goniewicz, M. L., Meza, R., Holford, T. R., & Abrams, D. B. (2017)**: *"Potential deaths averted in USA by replacing cigarettes with e-cigarettes*." Although primarily focused on e-cigarettes, this work touches on the idea of harm reduction, applicable to oral nicotine products compared to traditional cigarettes.

7. **Glasser, A. M., & Collins, L. K. (2015):** "*Overview of electronic nicotine delivery systems: a systematic review*." Again, while focused on electronic delivery, many discussions about relative risk are applicable to oral nicotine products.

8. **Hatsukami, D. K., Zeller, M. R., Gupta, P., Parascandola, M., & Benowitz, N. L. (2012):** "*Tobacco addiction: The role of nicotine*." This review provides a broad look at nicotine addiction and the comparative risks of different nicotine delivery methods.

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