GLOBAL QUALITY AND MANUFACTURING CONTROLS FOR NICOTINE POUCHES

White Paper

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Executive Summary

This White Paper outlines the current landscape of nicotine pouches, emphasizing the need for standardised regulations across global markets. With the increasing popularity of nicotine pouches as a smokeless alternative a global standard is essential to ensure product quality and safety, and appropriate marketing and consumer education. A transparent, non-biased global standard would provide a platform to work with regulators to ensure nicotine pouches are considered as a product distinct from tobacco or nicotine preparations of the past. This paper discusses the existing regulatory frameworks and some national standards highlighting some inconsistencies and deficiencies.

The key recommendations include the development of a product quality standard using impartial parties with sound scientific evidence and validated testing methods, development of key consistent product information to create consumer awareness and prevent uptake in the youth population and ensure the nicotine pouch industry remains at the forefront in the development of regulation of nicotine pouches globally.

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Background

Nicotine Pouches – the new nicotine product

Over the past 40 years nicotine products, predominantly marketed as nicotine replacement therapy (NRT) have evolved. Nicotine gum was the first NRT approved by the FDA in 1984, followed by transdermal patches in 1992, nasal spray in 1996 and an inhaler in 1997 (Rigotti 1998). More recent products include lozenges, e-cigarettes, vapes and nicotine pouches.

The availability of different product types has led to many and varied forms of regulation and control of these products and their marketing throughout the world.
A new product category is emerging with several large tobacco companies now selling tobacco-free nicotine pouches, such as British American Tobacco(BAT), Velo (RJ Reynolds Vapor Company), Swedish Match, Kretek International and Japan Tobacco International (JTI). (Robichaid 2020). Nicotine pouches are small permeable pouches containing synthetic nicotine usually mixed with a base material, sweeteners and flavours. The pouches are placed in the mouth between the gum and lip for a short period of time, resulting in oromucosal absorption of nicotine. (Duren 2024).

Snus was the very first nicotine pouch, widely used by consumers in Sweden over the past four to five decades. Unlike the new nicotine pouches, snus is a pouch containing smokeless tobacco. Within the European Union (EU) the sale of snus is prohibited by legislation in all countries except Sweden which has an exemption. (Clarke 2019). Oral nicotine pouches or white pouches first became available in the US in 2016, although no nicotine pouch products have been approved by the FDA. (Centre for Disease Control 2024).

Regulation and control of nicotine pouches

The classification and regulation of oral nicotine pouches varies significantly between countries. Some countries classify oral nicotine pouches as nicotine replacement therapies which are regulated as a therapeutic good or medicinal product, other countries regulate the pouches as tobacco products and some countries regulate the pouches as food or novel food products. Some countries also fail to regulate nicotine pouches at all. A recent summary of regulatory approaches to nicotine pouches across 67 countries found that only 34 countries actually regulate nicotine pouches, and 16 of these regulate the pouches as a tobacco product. Of the 34 countries with regulation in place, nicotine pouches were sold in 20 countries, however they were not sold in the remaining 14 countries due to the restrictive nature of the policies and regulation. (Duren 2024).

Regulation in some countries:

United States:

The U.S Food and Drug Administration (FDA) consider nicotine pouches as a type of tobacco product. The FDA regulates the manufacture, sale and distribution of tobacco products under the Federal Food, Drug and Cosmetic Act (FDCC Act).

Manufacturers of nicotine pouches are required to submit a pre-market application for FDA approval before marketing their products. The Tobacco Control Act was enacted in 2009, amending the FDCC Act, providing the FDA with authority to regulate tobacco products. A tobacco product is defined as any product made or derived from tobacco that is intended for human consumption, including any part, component or accessory of a tobacco product. The FDCC Act excludes from the definition of a tobacco product any article that is defined as a drug, a device or a combination product. (FDA Rule 2017; FDA Regulation NTN Products 2023)

Sweden:

Tobacco free nicotine products are regulated by the Act on Tobacco Free Nicotine Products, which was enacted in 2022. This legislation regulates product requirements, sales and marketing of tobacco free nicotine products. Medical products or medical devices as described in the Medicinal Products Act or Act with Supplementary Provisions to Regulations (EU) on Medical Devices, are not considered tobacco free nicotine products according to the Act on Tobacco Free Nicotine Products.

Before making a tobacco free nicotine product available to consumers in Sweden you must notify the sale to either the municipality or the Public Health Agency of Sweden. Additionally, a self-monitoring program is required in order to be able to conduct retail trade of tobacco free nicotine products to consumers in Sweden. (Public Health Agency Sweden, 2023).

New Zealand:

It is illegal to import oral nicotine products into New Zealand for distribution or retail sale, unless they have been approved as a medicine or a psychoactive substance by New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

Oral tobacco nicotine products (e.g. snus, chewing tobacco, dissolvable forms such as lozenges and snuff) for personal use can be imported into New Zealand by the person who is to use the product, but where the product is for retail sale or distribution it cannot be imported unless approved as a medicine.

Oral synthetic nicotine products (i.e. not derived from a tobacco plant) and are not a vaping product and are for a therapeutic use, cannot be imported into New Zealand for sale or distribution unless approved as a medicine. Where the product is for recreational use, it cannot be imported into New Zealand unless approved as a psychoactive substance.
There is no nicotine pouch products approved by Medsafe at the time of publication. (Medsafe, New Zealand 2024)

Norway:

Tobacco products are regulated under the Norwegian Tobacco Act (1975). The EU Directive 2001/37/EC concerning the manufacture, sale and presentation of tobacco products and the 2014/40/EU Tobacco Products Directive were implemented into Norwegian legislation in 2023. Like Sweden, Norway has an exception from the EC ban on the sale of tobacco for oral use (moist snuff). Regarding nicotine pouches, the regulations prohibit the import of products that have not been approved for sale in Norway. These products must be approved by the Norwegian Directorate of Health in order to be introduced and sold on the Norwegian market. The main purpose of the approval scheme is to protect children and young people from products with potential to cause nicotine addiction. No products have been approved in Norway. Two products which were rejected by the Norwegian Directorate of Health and were appealed to the Ministry of Health and Care Services, who also rejected the marketing authorisation.Advertising of approved nicotine pouches will be prohibited so as not to appeal to the youth population. (Directorate of Health, Norway 2023).

Denmark:

The regulation of tobacco products in Denmark falls under the Danish Act on Tobacco Products (Act no. 608 of 07/06/2016). The Act includes regulation of both smoke-free tobacco products and oral products. Under the current Act chewing tobacco is allowed in Denmark but must undergo assessment by the authorities before it can be sold. Snus is banned as per the EU Directive and nicotine pouches must comply with certain retail and advertising restrictions. (Tobacco Control Laws, 2023).

However, in 2024 a proposal to amend the Tobacco Products Act was presented to the Danish Parliament. This proposal included adding a definition for "smokeless tobacco products" that would cover nicotine pouches. This proposal included a recommendation that nicotine pouches be regulated in a manner similar to tobacco products and nicotine liquids. Including enforcing a nicotine limit of 9mg per consumable pouch and banning flavours. (Tobacco Insider, 2024).

The Danish government have been criticised for the proposal with a groundbreaking study by the Tholos Foundation in collaboration with IPSOS and the Harvard Business School of Economics demonstrating that if the proposal is implemented, current nicotine pouch uses will chose other purchasing channels, including switching back to cigarette smoking (18%). (Tholos Foundation, n.d).

Czech Republic:

Until recently nicotine pouches were not regulated in the Czech Republic and were only subject to general product safety legislation. In response, an amendment was made to the Act on Food and Tobacco Products effective from May 2021. A Decree was issued by the Czech Republic Ministry of Health two years later in May 2023. The Decree, in conjunction with the Act on Food and Tobacco Products follows the model of tobacco and e-cigarette legislation and requirements for the composition, appearance, quality and characteristics of nicotine sachets. It also contains a notification obligation for manufacturers and importers. In March 2023, an amendment to the Act on Health Protection from Addictive Substances resulted in a ban of the sale of nicotine pouches outside specialist tobacco shops, grocery stores and daily and periodical newspaper outlets, with a prohibition of sale to persons under 18 years of age. (Collection of Laws, Decree 2023).

The Act on Regulation of Advertising does not restrict advertising of nicotine pouches as it does for tobacco products and e-cigarettes.

Germany:

There is no dedicated legislation governing the regulation of nicotine pouches in Germany. Since the ingredients of nicotine pouches are ultimately orally ingested by humans these products are currently classified as food by the federal state authorities in Germany. Food, however, must not cause any sort of detrimental effect on human health according to the general food law (Regulation (EC) No. 178/2002). (Reimann 2024). Therefore, nicotine pouches are not available to buy in Germany.

The German Federal Institute for Risk Assessment published a health risk assessment of nicotine pouches in 2022 suggesting nicotine content of the pouches is comparable to conventional cigarettes. (BfR, 2022) The health minister of Germany has therefore suggested a ban of nicotine pouches may be imminent, noting the increased popularity of nicotine pouches posed serious public health concerns.

Australia:

Nicotine pouches can only be imported, supplied and advertised in accordance with the Therapeutic Goods Act 1989 and state and territory medicines and poisons law. Supply of nicotine pouches is prohibited unless approved as a therapeutic good with a therapeutic claim (e.g. smoking or vaping cessation) by the TGA following a rigorous assessment of quality, safety and efficacy data. The TGA note that no nicotine pouches have yet been approved and to date there is no strong evidence to support the use of nicotine pouches for smoking or vaping cessation. Advertising of nicotine pouches will be prohibited. If approved a nicotine pouch will be a prescription medicine and advertising of all prescription medicines is banned in Australia. (TGA, 2024)

Other Countries:

Recently, possible bans on nicotine pouches, predominantly in Europe, have been reported. Already banned in Belgium and the Netherlands, bans are being considered in Poland and France. The EU are considering a full-scale ban on nicotine pouches via an update to the EU Tobacco Products Directive.

Other countries, such as Finland propose to bring the nicotine pouches under the current tobacco laws to discourage their use, and the Ministry of Health Canada propose to pursue legislative and regulatory mechanisms to restrict advertising, flavours and places of sale of nicotine pouches. (Tobacco Insider, 2024)

Development of nicotine pouch national standards and specifications

Many technical specifications and standards for nicotine pouches have been developed. These specifications have been valuable in providing some control of the manufacture and supply of nicotine pouches throughout the world. However, the use of these standards and specifications are limited:

- Some standards are prepared for national use only, for example the "Swedish Institute for Standards (SIS), Technical Standard Nicotine-containing, tobacco-free oral products – safety and quality related requirements", is considered a technical standard specifically prepared to supplement to Swedish legislation and applies to nicotine pouches supplied in Sweden only.

- HYAPP Group, headquartered in Scandinavia, has established standards for marketing nicotine-containing consumer products. They own 11 e-commerce brands and assert a market share exceeding 60% in non-tobacco pouches. While these standards offer a framework for manufacturing and supplying nicotine products, they have not yet been evaluated by regulators and policy makers.

- Other specifications and standards have been developed under country specific standards institutions. These standards have been very helpful in providing sounds scientific guidance for nicotine pouches. Well established, ISO compliant analytical experts such as the Broughton Group, Inter Scientific and Hall Analytical (now acquired by Element) provide subject matter experts in next generation nicotine delivery products, combined with their application of well validated analytical methods and certified laboratory facilities have developed sound specifications and standards for nicotine pouches. Unfortunately, the standards for nicotine pouches, while providing some manufacturing and supply framework, were primarily developed with sponsorship from Big Tobacco companies.

"The British Standards Institute Publicly Available Specification (BSI PAS) for tobacco-free oral nicotine pouches" was sponsored by British American Tobacco (BAT), with contributions from other multinational industry players like Philip Morris International, and Japan Tobacco International. This industry involvement may lead regulators and policy developers to question the standards' objectivity, as they were shaped by companies with vested interests in the cigarette market.

- CORESTA (Cooperation Centre for Scientific Research Relative to Tobacco) a French based organisation, has a large global membership, with 38 countries represented in the membership of 165 members. The membership of CORESTA includes both private and government organisations that have a scientific activity related to tobacco and tobacco products. CORESTA have prepared a draft "Technical Guide for Nicotine Pouch Safety and Quality". This technical guide covers pouches containing either synthetic nicotine or nicotine derived from tobacco. The CORESTA standard has gained widespread international recognition, leading to its frequent adoption in national regulatory specifications. While the standard's technical framework is robust, it's worth noting that its development is influenced by major tobacco industry players who make up its membership base.

- The SIS, BSI PAS and CORESTA technical guides have all detailed technical parameters required to establish nicotine pouch safety and quality. These parameters include nicotine content, pouch pH, water activity, material of the pouch, ingredients, undesirable constituents, packaging, product information and labelling. Generally, the three specifications were consistent with some minor variations. Notably a maximum 20mg nicotine content per consumable pouch was permitted in the SIS and BSI PAS compared to only 16mg nicotine content permitted under the CORESTA technical guide.

- The CORESTA technical guide also provided reference to suitable methods for determination of some of these parameters. Generally, these methods were developed by Coresta. Technical methods were not described in SIS or BSI PAS.

- The nicotine content proposed in the standard of the SIS, BSI PAS and CORESTA did not appear to be guided by sound scientific evidence regarding the pharmacokinetics of nicotine pouches. Pharmacokinetic studies have been conducted comparing nicotine pouches to lozenges and gum. Azzopardi 2022 reported similar Cmax and AUC values for lozenges and pouches, but plasma levels achieve with the pouches was reported two-fold greater than that achieve with nicotine gum. When nicotine pouches containing no more than 10mg of nicotine were compared to cigarettes they demonstrated higher AUC0-6h and Cmax than the cigarettes. Such data will be integral in determining a safe limit of nicotine content, particularly if the pouches are marketed as a nicotine replacement therapy. In contrast Chapman 2022 reported nicotine pouches as having lower plasma and time to peak slower than cigarettes suggesting 5-10mg nicotine content of pouches acceptable for nicotine replacement therapy.

- The German Federal Institute for Risk Assessment (BfR, 2022) presented an assessment of the health risks of nicotine pouches based on existing studies and data. The BfR is a government body under public law within the portfolio of the German Federal Ministry of Food and Agriculture. While this review considered factors liked nicotine content and the pharmacokinetics of nicotine pouches, it also considered toxicity factors such as tobacco- specific nitrosamines and associated toxicities. This report was presented as research of hazard risk, not so much as a standard that should be applied to a nicotine pouch product. The data was prepared solely by a transparent government research institution.

Scientific evidence for product standards

Pharmacopeial standards are an example of technical standards applied to pharmaceutical ingredients and are often considered the gold standard. The main purpose of these standards is to help ensure that medicines and their ingredients are safe, effective and appropriate quality. The standards contain detailed information about the quality attributes of medicines and their ingredients. The standards not only include the limits applied to the products aspects but also the test methods applied and preferred techniques to determine such limits in the products quality.

The WHO recommend that the standards should be the result of an unbiased public process which has included stakeholders from regulatory agencies, academia, healthcare practice, industry and other members of related advisory groups. The impartial nature of members contributing to the standards is critical in providing a transparent well developed quality standard. (WHO, IMWP, n.d)

Recommendations for control of E-cigarettes and vapes

In many countries the regulation and control of nicotine pouches falls within the current legislation and regulations relating to either nicotine or tobacco products. It is therefore reasonable to expect that some controls enforced on more recent nicotine products such as e-cigarettes and vapes may be considered applicable to nicotine pouches. E-cigarettes and vapes, either with or without nicotine have been heavily scrutinised due to the uptake in the youth population. This has resulted in significant changes in regulation and control of these products in some countries, with specific focus on the youth enticing flavours and colourful packaging.

Like nicotine pouches e-cigarettes and vapes do not contain tobacco but also typically contain additives and flavours. The World Health Organisation have published concerns over the safety of some additives and flavours. In 2024 the

WHO noted that 74 countries had no regulations in place for these harmful chemicals. The WHO has recommended that where e-cigarettes and vapes are permitted in a country that strong regulations are applied to reduce their appeal and harm to the population, including banning all flavours, limiting the concentration or nicotine and taxing suppliers.

Data of the National Youth Tobacco Survey, presented by the Centre for Disease Control and Prevention (CDC) reported a decline in use of e-cigarettes among youths from 2023 to 2024, most likely attributable to the public health education campaigns and introduction of more stringent controls on the supply of e- cigarettes. The same report noted that there had not been an increased uptake in nicotine pouches in the youth population between 2023 and 2024. The report also noted that 8 in 10 youths who use either e-cigarettes or nicotine pouches used flavoured products. This data supports the notion that health campaigns are critical in managing the uptake of these products in the youth population. (FDA 2024).

Description of the Problem

Nicotine pouches represent an emerging category in nicotine delivery systems, but face several key challenges in their development and regulation:

Current regulatory frameworks are inadequate, as they simply apply existing tobacco and nicotine product rules to this new category. The global variation in these regulations further complicates efforts to establish consistent international standards.

The regulatory landscape for nicotine pouches is likely to be influenced by recent policy changes targeting e-cigarettes and vapes, potentially leading to restrictions that may not appropriately address the unique characteristics of nicotine pouch products.

While some specifications and standards exist for nicotine pouches, they have significant limitations. Current standards either:

- Apply only at national levels, lacking international scope, or
- Are predominantly developed by major tobacco companies, raising concerns about potential bias in regulatory influence

Growing youth adoption of nicotine pouches has emerged as a significant public health concern, particularly regarding addiction risk and health impacts. Similar to e-cigarettes, factors driving youth uptake appear to include:

- Product flavouring
- Marketing approaches
- Product accessibility

To avoid the strict regulatory measures already applied to e-cigarettes and vapes, the nicotine pouch industry must proactively address these concerns through responsible marketing practices and self-regulation.

Recommendations

Developing a global quality standard for nicotine pouches in a transparent and unbiased manner, backed by solid scientific evidence and validated testing methods, will be crucial for the future of the nicotine pouch market.

Implementing marketing standards that include consumer awareness campaigns and measures to manage youth uptake will be vital to ensure the safe supply of nicotine pouches.

Such standards will help establish the nicotine pouch market as distinct from other tobacco or nicotine products. High-quality and well-regarded standards will also provide a foundation for negotiating and influencing government regulations and policies concerning nicotine pouches.

Independent nicotine pouch manufacturers stand apart from Big Tobacco companies due to their singular focus on smoke-free alternatives. Unlike major tobacco corporations that continue to profit primarily from cigarette sales while marketing alternative products, these independent manufacturers are fully committed to smoke-free innovation, with no conflicting interests in traditional tobacco products.

While Big Tobacco companies maintain a complex dual position - promoting cigarette alternatives while still deriving most revenue from smoking products - independent manufacturers can pursue harm reduction goals without these competing priorities. Their business models are built entirely around developing and improving smoke-free options, allowing them to invest all resources into advancing pouch technology and safety.

This fundamental difference in business alignment means independent manufacturers can focus purely on optimizing the smoke-free experience rather than protecting an existing cigarette business. Their success depends solely on creating better alternatives, not maintaining profits from traditional tobacco products.

The input of independent nicotine pouch manufacturers is crucial for several reasons:

1. **Diverse Perspectives**: Small and medium manufacturers often bring fresh ideas and diverse perspectives to the table. They may approach product development, marketing, and safety in innovative ways that differ from larger companies. This diversity helps in creating more varied and potentially appealing products for consumers.

2. **Innovation and Agility**: Smaller companies tend to be more agile and responsive to changes in consumer preferences or emerging scientific evidence. Their ability to innovate quickly can lead to the development of new

flavours, formulations, and technologies that larger companies may be slower to adopt.

3. **Fair Competition:** Including the voices of small and medium manufacturers ensures a level playing field where competition is fair and not skewed in favour of large corporations. This fosters an environment where companies are motivated to improve their products continuously.

4. **Consumer-Centric Approach:** These manufacturers often have a closer connection with their customer base and may be more focused on meeting specific consumer needs and preferences. Their insights can be valuable in shaping standards that prioritize consumer interests and safety.

5. **Local Economic Impact:** Supporting and incorporating input from smaller manufacturers helps stimulate local economies. These companies can create jobs and contribute positively to the communities in which they operate.

6. **Counterbalance to Big Tobacco:** With the vested interests of big tobacco companies in mind, independent input from small and medium manufacturers can act as a counterbalance. It helps ensure that industry standards and policies are crafted without undue influence from major corporations that might prioritise their profit margins over public health.

7. **Customized Solutions:** Smaller manufacturers might be better positioned to offer customized solutions or niche products that cater to specific markets or consumer needs, thereby expanding the market's reach and inclusivity.

In conclusion, the involvement of small and medium-sized nicotine pouch manufacturers is essential in shaping a balanced, dynamic, and consumer-friendly market. Their input helps ensure that industry standards are comprehensive, equitable, and reflective of the entire market landscape.

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