



Position Paper on Nicotine Pouches

Executive Summary

Nicotine pouches have significant potential to reduce the global death toll from toxic combustible and smokeless tobacco, and should not be banned

“Nicotine pouches” are smoke-free oral products. They are similar in appearance and use to snus, but contain no tobacco. The pouches contain biologically harmless cellulose, flavourings that are safe for oral use, and nicotine. As such, they are consumer products with many similarities to nicotine gum, including – in all probability – their safety profile.

There is no biologically plausible argument that nicotine pouches are anything other than vastly safer than smoking and the use of toxic smokeless oral tobacco products (e.g. gutkha, pan masala, chew, etc.), which result in 8 million deaths per year (WHO, 2020).

As a comparison, low-harm snus pouches do contain tobacco, but based on extensive epidemiological evidence, the US Food and Drug Administration (FDA) has authorized a reduced risk claim for eight snus products. Using these products instead of smoking “puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis.” (FDA news release, October 2019)

Tobacco-free nicotine pouches are relatively new, although they are increasingly popular harm reduction options in many countries. While regulations in many parts of the world are still in their infancy, some countries are taking a prohibitionist stance toward these safer alternatives.

The concerns raised about nicotine pouches appear similar to initial concerns raised about nicotine patches and gum (nicotine replacement therapies or “NRTs”). But after three decades of safe use, it is now clear that NRTs are not subject to abuse. Similarly, snus has led users away from smoking rather than toward it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe (Bates, 2003).

INNCO’s position is clear. Nicotine pouches have significant potential to reduce the global death toll from smoking and other toxic tobacco, which result in 8 million deaths per year (WHO, 2020). Because every person who uses toxic tobacco products is different, access to all safer nicotine alternatives should be seen in the light of a human rights based approach to health (UN 2019 31 org. common position). Nicotine pouches should not be banned. INNCO does, however, support the establishment of appropriate safety standards for nicotine pouches.

Nicotine pouches can contribute to tobacco control’s public health goals, but only if they remain affordable and accessible to people who use toxic tobacco products. Therefore, INNCO strongly objects to heavily taxing or banning these products, particularly because such policies protect the sales of cigarettes, bidis and toxic smokeless tobacco products.

INNCO is a non-profit organization that supports the rights of 98 million adults worldwide who use safer nicotine to avoid toxic forms of tobacco. INNCO is funded by individual contributions from thousands of adult ex-smokers, and by a grant from the Foundation for a

Smoke-Free World (FSFW). The Foundation is a US nonprofit 501(c)(3) private foundation with a mission to end smoking in this generation. For more information, see their website. FSFW had no role in the planning or execution of this document. INNCO is independent of FSFW. Our mission, purpose and goals are driven by our Member Organizations all over the world. Those organizations are led by unpaid volunteers (ex-smokers) who, as a condition of membership, agree not to accept funding or direction from industry. The contents, selection and presentation of facts in this article are the sole responsibility of the authors.

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Nicotine pouches: the facts

What are they and what do they contain?

Nicotine pouches are tobacco-free products, designed to deliver nicotine to the user. They are similar in appearance and use to snus – an oral tobacco product popular in Sweden and Norway – but unlike snus, they contain no tobacco. The pharmaceutical-grade nicotine within the pouch is often derived from tobacco, but the pouches contain no tobacco leaf, dust or stem (Meagan, 2019). Pharmaceutical-grade nicotine is also used in smoking cessation products such as nicotine patches and nicotine gum. Some nicotine pouches contain synthetic nicotine, not derived from tobacco plants.

As well as nicotine, the pouches contain biologically harmless cellulose and flavourings that are safe for oral use. As such, they are consumer products with many similarities to nicotine gum, including – in all probability – their safety profile.

They are sometimes known as “all-white portions” because of their contrasting appearance to traditional snus, which is brown and looks like tobacco wrapped in cellulose, resembling a tiny teabag (there are also loose versions of snus without the bag). Because nicotine pouches do not contain tobacco – and the bags are instead filled with white powdered cellulose – their appearance is “all white.”

Nicotine pouches come in a variety of flavours and strengths.

How are they used?

Nicotine pouches are applied by placing the pouch between the upper lip and gum. The nicotine is absorbed into the body from the oral cavity. The user may feel the mild nicotine effect and taste a few seconds after placing a pouch behind a lip.

When finished, the pouch is disposed of in a bin. Unlike chewing tobacco, the user does not need to spit, since the contents of the pouches stay inside the pouches during use.

How many are there, where are they available?

There are several brands that have been made commercially available in different countries, including (Meagan, 2019):

Brand	Countries available
2ONE	The US
Dryft	The US
Epok	Norway and Switzerland
LOOP	Scandinavia, Germany, UK and other EU markets
Lyft	Kenya, Denmark, Sweden and the UK
Nordic Spirit	Sweden, Switzerland and the UK
On!	Japan, Sweden and the US
Velo	The US
Zone X	The UK
Zyn	Europe, the US and Switzerland

These are just a selection of available brands. In total, there are at least 46 brands marketed in the EU. The products have been rapidly adopted throughout Scandinavia and central and eastern Europe in particular (Research and Markets, 2020).

The increase in demand for nicotine pouches in the EU may have been triggered by the ban on flavoured tobacco products and the total ban on snus products in those countries.

What is certain is that nicotine pouches have emerged alongside snus as a popular alternative to smoking and other toxic tobacco-based products and represent a rapidly growing market. The global market size for nicotine pouches is projected to reach USD 32 billion by 2026, from USD 2 billion in 2020 at a CAGR of 54.9 percent during 2021-2026 (MarketWatch, 2020).

These products, similarly low in toxicants and exposure as snus is, have seen significant uptake in traditional snus markets, Sweden and Norway. In the first quarter of 2020, nicotine pouches accounted for 6.7 percent of Sweden's "snus" market, up from 3.2 percent in 2019 (Swedish Match, 2020). In Norway, a non-EU member with a snus tradition, pouches today account for 25.8 percent of the snus market, up from 15.3 percent in 2018.

This reflects a wider accelerating shift in global consumption away from traditional combustible cigarettes towards reduced harm alternatives.

How are they regulated?

Although the use of nicotine pouches is increasing, regulation is still in its infancy. In the U.S., nicotine pouches are subject to FDA regulation, although entry barriers are low compared to tobacco-containing products. Nicotine pouches are required to carry the warning, "This product contains nicotine. Nicotine is an addictive chemical," and may be sold only to consumers over 21 years of age. Nicotine patches and gum are not required to carry this warning.

In the EU meanwhile, there is no regulation that covers these products, although it is likely in development. Containing no tobacco, the products are not covered by the EU Tobacco Product Directive nor do they belong to any other regulated product category. INNCO and its global network of members have not identified any reputable producers or sellers that knowingly digress from strictly employing a voluntary +18 age limit also for these newer products since day 1.

In the EU, snus sales have been prohibited since 1992, except for in Sweden, which negotiated an exemption when it joined the EU in 1995. Will the EU go the same way with nicotine pouches? The way e-cigarettes were regulated may give an indication of how the EU will regulate nicotine pouches in the future. This would indicate a focus on warning texts and introducing a strict maximum nicotine level. Future regulation of nicotine pouches in the EU may leave considerable room for further regulation by Member States, and even national bans (Fjellner, 2020).

National bans

Some countries have already made the decision to ban nicotine pouches outright. These include:

- New Zealand (Vaping Post, 2020)
- Russia (Tobacco Intelligence, 2020)
- Canada – in Canada, nicotine is considered a prescription drug, therefore personal imports of nicotine are prohibited (Notice: PDL, 2018)

Do they reduce harm compared to toxic tobacco products?

Yes. Significantly. Nicotine itself does not directly cause cancer, heart or lung disease, so nicotine pouches offer considerable potential for tobacco harm reduction because they do not involve combustion of tobacco. There is no biologically plausible argument to suggest these safer nicotine alternatives will cause cancer, heart or lung disease.

Their use by smokers will reduce or eliminate smoking, the number one cause of preventable non-communicable diseases. It is exposure to the toxic chemicals, solid particulates (TAR) and carbon monoxide released when tobacco is combusted (e.g. when a cigarette is lit), and the fumes from burning tobacco leaves are inhaled, that primarily causes life-threatening diseases and premature deaths.

Already about 100 million tobacco deaths have occurred this century and there will be another 250 million tobacco deaths before 2050. The vast majority of the deaths before 2050 will occur among current smokers (Jha, 2020). Hence, the major public health priority is to increase the proportions of adults who quit smoking or switch to a safer product.

Smokeless tobacco meanwhile is consumed by more than 300 million people worldwide. The highest rates of consumption are in South and Southeast Asia where the products are also dramatically more dangerous due to additives and methods of production. In 2017, at least 2.5 million DALYs (disability-adjusted life years, a measure of overall disease burden) and 90,791 lives were lost across the globe due to oral, pharyngeal and esophageal cancers that can be attributed to toxic forms of smokeless tobacco. Over 6 million DALYs and 258,006 lives were lost from ischaemic heart disease that can be attributed to toxic forms of smokeless tobacco. Geographically, over 85 percent of the smokeless tobacco-related burden was in South and Southeast Asia, India accounting for 70 percent, Pakistan for 7 percent and Bangladesh for 5 percent of DALYs lost (Siddiqi, 2020). Conversely, even tobacco based Swedish snus was in the Lancet's Global Burden of Disease 2017 reports not found to have higher RRs for any form of disease whatsoever than 1.0 compared to no use.

Non-combustion nicotine products such as e-cigarettes, HTPs, snus and nicotine pouches, are all significantly less harmful than smoking and toxic smokeless tobacco. An expert independent evidence review published by Public Health England (PHE) concluded that e-cigarettes are at least 95 percent less harmful than smoking (PHE Review, 2019). Another PHE report on HTPs concluded that "the available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than electronic cigarettes".

In its ruling on HTPs, the U.S. Food and Drug Administration (FDA) concluded that marketing the product is "appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than

combustible cigarettes” (FDA news release, April 2019). The issue of removal of IQOS HTP products from the US marketplace is not health related but a patent infringement legal dispute.

Similarly, the U.S. FDA has concluded that completely switching from smoking cigarettes to using certain snus products lowers health risks (FDA news release, October 2019). Eight snus products are now authorized by the FDA to advertise with the message: Use of this product “instead of cigarettes puts you at lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

In Sweden, snus has both contributed to decreasing initiation of smoking and, when used subsequent to smoking, appears to facilitate smoking cessation. It is clear that the availability and use of snus has been a major factor behind Sweden’s record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe (Rodu, 2009; Ramström, 2018). Sweden has a smoking prevalence of just 7 percent compared to the European Union average of 26 percent (Eurobarometer, 2017).

Studies investigating nicotine pouches are beginning to appear in the scientific literature. A recent toxicological assessment study showed that tobacco-free nicotine pouches showed reduced toxicity compared to both Swedish-style snus and cigarette smoke (Bishop, 2020). Another showed that a nicotine pouches product delivered nicotine as quickly, and to a similar extent as, other smokeless products, with no significant adverse effect (Lunell, 2020). Another showed that current and former tobacco users may perceive nicotine pouches as reduced-risk products, while nonusers of tobacco had very little interest (Plurphanswat, 2020).

Why are some advocating for a ban?

There appear to be four main reasons why some are advocating for a prohibitionist stance to these products:

The first is that they are made by tobacco companies. This is a political stance, not one that has the best interests of smokers in mind. It is not a valid reason to ban the products and the only people who suffer from this approach are current and ex-smokers who have, want to, or would want to quit or dramatically reduce their risks.

The second is that they contain nicotine, which is dependence-forming. But nicotine itself does not cause smoking-related diseases (Nicotine without Smoke, 2016). It is exposure to the toxic chemicals released when tobacco is combusted (e.g. when a cigarette is lit) and the smoke from burning tobacco leaves is inhaled that primarily causes life-threatening diseases and premature deaths. Therefore, nicotine pouches – just like nicotine gum and other forms of NRT – are a valid alternative to cigarettes that can significantly reduce harm likely to below measurable levels as seen in the GBD 2017 reporting by The Lancet.

There is a misconception that nicotine pouches contain more nicotine than cigarettes and provide a quicker ‘hit’ of nicotine, making them more addictive than cigarettes. In fact, nicotine pouches usually contain between 2mg and 6mg of nicotine. A standard cigarette contains 8-12 mg nicotine. The uptake of nicotine from a traditional cigarette is actually much

faster than from snus and nicotine pouches (Foulds, 2003), which means users get a more instant 'hit' of nicotine from a cigarette. The nicotine from nicotine pouches is absorbed through the lining of the cheek and gum, which delays the uptake of nicotine.

The third and fourth reasons are that the products may be used recreationally by never-smokers, and may be used by teenagers as a gateway product to smoking. These concerns were raised for nicotine patches and nicotine gum (Wagner, 2000), which are now on the World Health Organization's Essential Drugs List, and have been used safely for three decades. The U.S. FDA's official position on nicotine replacement therapies (NRTs) is that over-the-counter "NRT products do not appear to have significant potential for abuse or dependence" (Federal Register, 2013), while a comprehensive review of NRT uptake among never-smokers and teenagers found the prevalence of NRT use to be close to 0percent (Gerlach, 2008).

Similar concerns have been raised around snus (Melika, 2009). But a review of the evidence which examined gateway effects in Sweden suggested that snus appeared to lead users away from smoking rather than towards it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe (Bates, 2003).

We acknowledge that nicotine pouches may generate a certain level of unintended uptake and use over longer time in younger adults, the use would be more likely to follow similar patterns as for snus however, in protecting against smoking initiation, not in any way being a gateway to smoking, and not in themselves generating measurable levels of adverse health consequences in the users. Mid horizon data from the use of e-cigarettes with nicotine also suggest that Nicotine when 100% decoupled from tobacco and tobacco constituents pose a far lower addiction potential than smoking does

Are there any genuine concerns?

This is not to say there are no concerns about nicotine pouches (see below), or that we should simply take a laissez-faire approach to their production and sale. We fully support fair and appropriate regulation of these products, and the development of safety standards.

High nicotine content of products in illicit markets

Nicotine pouches usually contain between 2mg and 6mg of nicotine. In 2020, the Russian State Duma passed a bill prohibiting the sale of tobacco-free nicotine products for oral use, mainly affecting popular nicotine pouches (Tobacco Intelligence, 2020). This was partly in reaction to the emergence of extreme-strength pouches, which appeared on the illicit market, with nicotine strengths over 100mg and as high as 250mg. Illicit markets generally result in high dose products that are dangerous, especially to children (although high-dose ingestion generally induces vomiting so is unlikely to be fatal (Felson, 2020)).

The potential impact of flavours on youth uptake of smoking

There are some fears that nicotine pouches may entice youth as well as young adult never-smokers because they are available in an array of fruit flavours and may be used unobtrusively. This may then act as a gateway to smoking.

However, while e-cigarettes have become popular among American youth, smoking rates have continued to plummet, suggesting they do not act as a gateway (FDA, 2020). Similarly in Sweden, snus has appeared to lead users away from smoking rather than towards it (Bates, 2003).

There is currently limited research on the impact of flavoured nicotine pouches on youth uptake of the products. But it is important to note that the pharmaceutical industry's nicotine gum does not come in tobacco flavour. These products are available in mint, menthol and "fruit medley" flavours.

What is INNCO's position on nicotine pouches?

Nicotine pouches offer considerable potential for tobacco harm reduction because they do not involve combustion or highly toxic formulations of tobacco in smokeless formats. There is no biologically plausible argument that nicotine pouches are anything other than vastly safer than smoking and the use of toxic smokeless oral tobacco products (e.g. gutkha, pan masala, chew, etc.) which result in 8 million deaths per year (WHO, 2020).

INNCO's position is clear. Nicotine pouches have significant potential to reduce the global death toll from smoking and other toxic tobacco. Because every person who uses toxic tobacco products is different, access to all safer nicotine alternatives should be seen as a human right. Nicotine pouches should not be banned. INNCO does, however, support the establishment of appropriate safety standards for nicotine pouches.

Nicotine pouches can contribute to tobacco control's public health goals, but only if they remain affordable and accessible to people who use toxic tobacco products. Therefore, INNCO strongly objects to heavily taxing or banning these products, in particular because such policies protect the sales of cigarettes, bidis and toxic smokeless tobacco products.

This position is based on 5 key points:

1. The potential benefits of nicotine pouches for tobacco harm reduction (THR) should be encouraged and are complementary to tobacco control efforts

There is currently a global trend toward THR. Today, several, safer non-combustion nicotine products, such as e-cigarettes, HTPs and snus, are available, and are significantly less harmful than smoking. For example, an expert independent evidence review published by Public Health England (PHE) concluded that e-cigarettes are at least 95% less harmful than smoking (PHE Review, 2019). Snus has been given modified risk tobacco product (MRTP) status by the FDA (FDA news release, October 2019). IQOS has become the first new HTP tobacco product to be approved by the FDA for sale (FDA news release, April 2019).

With 1.3 billion tobacco users in the world (WHO Tobacco Factsheet, 2019), there is an urgent need to scale up THR, which enables smokers to switch to safer nicotine products,

eliminating the smoke that causes death and disease. An estimated 98 million people already use safer products globally: 68 million vapers, 20 million using heated tobacco products and 10 million using U.S. smokeless or pasteurised oral snus – showing the huge demand for safer alternatives (GSTHR, 2020).

We believe this trend should be supported regardless of the method, as long as it is appropriately regulated. Unfortunately, THR is currently being opposed by many policymakers and public health bodies, being unfairly lumped together with cigarettes, and has become a political issue rather than a public health one. This is leading to significant misinformation discouraging smokers from switching to safer products.

It is clear that pragmatic approaches are needed, including the availability of a wide selection of products proven to dramatically reduce toxicant exposures and/or harm. Proven harm reduction products must be recognised as vital and complementary to traditional tobacco control measures.

2. The potential benefits of nicotine pouches FAR outweigh the risks – nicotine pouches could become a very useful part of the THR armoury for smokers

These products have significant potential for assisting global tobacco control to reach harm reduction goals. Any theoretical risks (which have not been proven) are far outweighed by the risks posed by smoking and other toxic tobacco, which results in 8 million deaths per year (WHO, 2020).

Countries with a pragmatic approach to alternative THR options appear to have significant success in reducing smoking prevalence.

In Sweden for example, snus is clearly a major driver of the country's tobacco-related mortality in men being the lowest in all European Union countries (Ramstrom, 2018). Sweden has a smoking prevalence of 7% compared to the European Union average of 26 percent (Eurobarometer, 2017).

There is no reason to believe nicotine pouches cannot contribute to similar success globally.

3. The simplicity and affordability of nicotine pouches make them particularly accessible and appropriate for low- and middle-income countries (LMICs)

Access to safer alternative nicotine products largely remains the preserve of higher income countries, while 80 percent of the world's smokers live in LMICs, many of which are poorly equipped to implement high cost and complex government organised tobacco control programs, or match UK/Sweden's views that 125,000 USD is an acceptable cost for a successful quit, or the costs we absorb in the west for to treatment of smoking-related diseases in those who did not quit or switch in time to avoid disease.

While the technology associated with some THR alternatives, including e-cigarettes and heat-not-burn tobacco products, makes them more challenging to commercialize in certain

regions with less infrastructure, the simplicity of nicotine pouches makes them a viable THR alternative for these regions.

It is clear that pragmatic approaches are needed, including the availability of a wide selection of products proven to reduce harm. Nicotine pouches may represent an excellent option for people living in LMICs.

4. Allowance to commercialise these products legally will ensure proper regulation and minimize room for illicit markets to operate profitably

Proper regulation of nicotine pouches minimises illicit markets similar to the one seen in Russia in recent years. This will ensure the strength of nicotine in the products can be limited to safe levels. We are firmly against products with extremely high strengths of nicotine and advocate a 20mg/pouch cap in standardising committees we have members on, and strongly advocate regulations to enforce this.

However, we are firmly opposed to overly restrictive regulations, high taxation and prohibitionist bans. Such approaches have been proven time and again to lead to thriving illicit markets, which in turn diverts precious resources into fruitless attempts to stop them. Enforcing sustainable regulation is simpler and significantly more beneficial than enforcing prohibition.

5. Consumers have a right to choose the THR option that is most suited to them

Ultimately, consumers should have the freedom to exercise agency and autonomy in having the right to select from all the commercially available options to reduce their own risk of harm. Because every person who uses toxic tobacco products is different, access to all safer nicotine alternatives should be seen as appropriate attention paid to a human rights based approach to health..

Every smoker should have the right to choose their own path to better health. By removing reduced harm alternatives such as nicotine pouches from the market – while leaving significantly more dangerous cigarettes available – countries would remove this right from the individual.

It is perhaps best summarised by the authors of a viewpoint famously published in leading scientific journal *The Lancet*, which concluded that “the absence of effective harm reduction options for smokers ***[in the marketplace - our addition and emphasis]*** is perverse, unjust and acts against the rights and best interests of smokers and the public health” (Britton, 2007).

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