ORAL NICOTINE COMMISSION

The Government of the Netherlands

The Hague, Netherlands

10th January 2023

Submission of the Oral Nicotine Commission to the Government of the Netherlands on the proposed legislation to ban oral nicotine pouches

To: Policy makers in the Dutch Government

Honourable Members of the government of the Netherlands,

We are a group of international health professionals and harm reduction experts, and some signatories form part of the Oral Nicotine Commission[1]. Several of us have sub-specialised in harm reduction science and policy matters, relevant to alcohol, tobacco, food, drugs, HIV and Covid-19. We argue the case for oral nicotine pouches, as a powerful example of "harm reduction strategies" as outlined in the FCTC,[2] Article 1(d): *"tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke*".

Oral nicotine pouches can contribute towards the prevention and control of tobacco-related disease and death, in adult Dutch smokers. Prohibiting oral nicotine pouches, will lead to unnecessary tobacco-related disease and premature death. On the other hand, risk-proportionate regulation of this critically important adjuvant to tobacco control can and will save lives in the Netherlands. As part of the Oral Nicotine Commission's work, we have summarised some of the potential benefits of oral nicotine pouches as part of tobacco control: Prevent Disease, Save Lives - An Introduction to Oral Nicotine Delivery Systems (ONDS)[3]

[1] https://oralnicotine.com/

[2] https://fctc.who.int/who-fctc/overview

[3] Prevent Disease, Save Lives - An Introduction to Oral Nicotine Delivery Systems (ONDS)

Our sincere plea to the Dutch government is not to ban oral nicotine pouches.

It will be diametrically opposed to the central objective of the FCTC, to prevent and control tobacco-related disease and premature death. More importantly, it is likely to perpetuate tobacco-related mortality amongst Dutch smokers.

Although our main plea to the Dutch government is NOT to ban oral nicotine pouches, this submission will also address some aspects of other *"nicotine apparaten"* as it is depicted in the proposed changes to the "Tabaks-en Rookwarenwet".

It is essential for the Dutch government to take a holistic view of harm reduction, reduced risk products and especially recognise the critical difference between combustible and non-combustible tobacco and nicotine products. As you will hear repeatedly from health advocates - "People smoke for the nicotine, but die from the tar" as Professor Michael Russell pointed out in 1976.

We are deeply concerned that the proposed changes to the "Tabaks-en Rookwaren" seem to disregard the key issue - that harms from smoking are due to the toxic products of combustion (the delivery method - smoking) and not from nicotine use.

Banning oral nicotine pouches, while leaving combustible cigarettes freely available in the Netherlands, seem to be incoherent, inconsistent, misaligned with current evidence and frankly, represent a death sentence to some of the 3,3 million Dutch adult smokers, who cannot or will not quit smoking, but wish to switch to less harmful nicotine products.

1. "WHOLE-OF-SOCIETY" ACTION - THANK YOU FOR CONSULTING STAKEHOLDERS

The Oral Nicotine Commission (ONC) and its partners wish to thank the Dutch Government for the opportunity to submit comments on the proposed changes to the Dutch Bill amending the Tobacco and Tobacco Products Act regulating non-tobacco nicotine products and nicotine devices.

This is fully aligned with the United Nations Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases[4], calling for "whole-of-government" and "whole-of-society" action. "Effective non-communicable disease prevention and control require leadership and multisectoral approaches for health at the government level, including, as appropriate, health in all policies and whole-of-government approaches across such sectors as health, education, energy, agriculture, sports, transport, communication, urban planning, environment, labour, employment, industry and trade, finance and social and economic development.

The ONC is one of the voices representing the approximate 1,1 billion smokers on earth, including the 3,3 million adult combustible cigarette smokers in the Netherlands[5]. In addition, we speak for the

[4] United Nations Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases (Attached)

[5] https://gsthr.org/countries/profile/nld/

approximate 100 million users of safer nicotine products worldwide, 27million of which reside in the European Union (EU).

We are pleased to see that the Dutch government fundamentally want to support smokers who want to quit. The trend is clear: harm reduction is essential to meeting the tobacco control goals of the Dutch Government. Reduced risk products, such as oral nicotine pouches and ENDS have an important, life-saving role to play in this strategy. We hope and trust that the Dutch Government will consider our strong opposition to the ban of oral nicotine pouches, as it will remove a potential lifesaver for Dutch smokers, who cannot or will not quit altogether.

2. ISSUES WITH THE DRAFT REGULATIONS AND WHY AN OVERHAUL OF REGULATION IS NEEDED TO SAVE DUTCH LIVES

"Wat verandert deze wet?

Door de wetswijziging zullen nicotineproducten zonder tabak en nicotineapparaten worden gereguleerd. Nicotineproducten zonder tabak voor oraal gebruik zullen niet langer in de handel mogen worden gebracht. Voor nicotineproducten zonder tabak en nicotineapparaten zullen onder meer de leeftijdsgrens en reclameverbod gaan gelden".

Frankly, a ban will take away the "fire escape" for adult Dutch cigarette smokers, to switch to vastly safer, non-combustible nicotine alternatives. As a country and government, the Netherlands is widely respected for its pragmatic and evidence-based approach to policy-making, so it was surprising to review these proposed changes, especially with its prohibitionist approach to Oral Nicotine Pouches.

We strongly argue that it will be detrimental to public health if these draft amendments were to be accepted by the Dutch Government, as outlined in the points made below:

2.1 Failure to recognise evolving products supporting tobacco harm reduction (THR) – an evolving solution for adult smokers to reduce risk

For those adult smokers who cannot or will not quit tobacco (primarily cigarettes), a range of much safer products has emerged over the last 10 years, acting as a “fire escape”. These products also make tobacco harm reduction a realistic and practical public health strategy for most smokers. There are broadly four categories of products that support tobacco harm reduction. Their common defining feature is that they allow for nicotine use, but with no combustion of tobacco and inhalation of smoke. These are:

a. Nicotine vaping products (Electronic Nicotine Delivery systems or e-cigarettes)
b. Oral nicotine pouches
c. Heated tobacco products
d. Oral tobacco pouches (such as “Swedish snus”)

Switching from smoking to smoke-free products greatly reduces risk. All the low-risk products share a common characteristic – they do not involve combustion (burning) and there is no smoke to inhale. They however, do provide nicotine and can satisfy smokers who would not otherwise wish to quit or would find it hard to quit. They are much less harmful – with likely risk reductions of one to two orders of magnitude – though not harmless. When a smoker completely switches from smoking to a low-risk product, he/she avoids nearly all the incremental health risks of continued smoking. This allows for "harm reduction", a well-established concept in public health policy, for example with drugs, alcohol and HIV.

Smoke free products and smoking cessation products have a different public health model. Tobacco control activists often fail to appreciate the underlying mechanism by which smoke free products create a public health benefit. Smoke free consumer products work by replacing one pleasure with another, but at much lower health risk. This is the reason for their success: they do not involve a loss, and for many smokers, they offer a superior experience. In contrast, smoking cessation products aim to assist a smoker in moving from smoking to abstinence by managing withdrawal and craving. While both are legitimate approaches, they are very different and will suit different people in varying circumstances. Oral Nicotine Pouches have been working well in other countries and could be a compelling alternative to smoking in the Netherlands.

Alternatives needed to save lives. Dutch tobacco control policies demand all possible alternatives to help smokers quit. Tobacco harm reduction is supportive, not antagonistic to conventional tobacco control. The smoke free products greatly expand the range of options to quit smoking without reducing or compromising any of the more traditional options. In England[6], the government promotes vaping as part of its quit smoking strategy, as the case study will show.

2.2 Banning Oral Nicotine Pouches will lead to unnecessary tobacco-related disease and premature death

The Oral Nicotine Commission fully supports the comments already submitted by Prof. Brad Rodu[7] during this consultation:

"If the Dutch government bans nicotine pouches, this will inevitably perpetuate high mortality rates among Dutch smokers. To illustrate my statement, I compared mortality rates for lung cancer, the sentinel disease of smoking, among men and women in The Netherlands and in Sweden, where vastly safer smoke-free options such as snus and nicotine pouches are widely available and consumed. I derived estimates for the year 2020 from the World Health Organization's International Agency for Research on Cancer mortality database (2). The rates for the two countries are completely comparable because IARC provides individual country rates that are calculated using a standardized population age structure (3). All the rates in the following paragraph are reported as deaths per 100,000 among men or women age 40+ years. The lung cancer mortality rate (LCMR) among men in the Netherlands is 92, which is twice as high as the rate for Swedish men (45.1). Similarly, the LCMR among women in the Netherlands is 72, which is 60% higher than the rate for Swedish women (45). In short, a Dutch government ban on nicotine pouches would deny Dutch smokers vastly safer cigarette substitutes, thereby needlessly increasing their risk for premature smoking-attributable diseases and deaths"

[6] https://health-diplomats.ams3.digitaloceanspaces.com/pdfs/Tobacco_Harm_Reduction_2021.pdf#page=59
[7] https://www.internetconsultatie.nl/nicotineproducten/reactie/d7f211b4-4e34-48e8-a014-526aa5790c90

In addition, we draw to your attention the ground-breaking work by Dr. David Levy, of the Lombardi Comprehensive Cancer Center, Georgetown University, USA, well-known tobacco control expert and developer of a simulation model to derive public health implications from smoking and vaping prevalence. He stated that if cigarette smokers were to switch to nicotine vaping products in the USA a significant number of smoking-attributable deaths can be averted and life years gained. The basic simulation model, its assumptions, and sensitivity analyses are outlined in an important recent article[8].

2.3 Ignoring the potential benefits of Oral Nicotine Pouches for the Netherlands

- Could *help users of combustibles* (cigarettes) switch affordably to clean forms of nicotine. This would affect a billion users globally and the 3.3 million cigarette smokers in the Netherlands
- Could affordably *displace toxic oral tobacco* products, commonly used in regions such as South Asia, but also prevalent in the EU and support the elimination of oral cancer
- Could lead to *new combinations of vapes and pouches* being offered to smokers unable to quit with nicotine replacement therapy and who seek nicotine options to either quit or switch to less harmful nicotine products
- In an era where the environmental effects of consumer goods are under the spotlight, nicotine pouches offer a solution when derived from green chemistry, which would *cut GHG losses* associated with tobacco, *cut impurities* associated with plant derived nicotine, and *cut back on the growing concerns about disposable vapes* and the complex electronics finding their way into waste streams

2.4 Overestimating the risk of Oral Nicotine Pouches and other THR products

There is justified concern about the safety of novel products, such as Oral Nicotine Pouches. The Dutch government mentions toxins such as tobacco specific nitrosamines (TSNAs). As nicotine pouches do NOT contain tobacco , the risk from TSNAs is minimal. We encourage the Dutch policymakers to carefully study the report of the German Federal Institute for Risk Assessment (BfR)[9] and its assessment of oral nicotine pouches. The analysis found that some pouches contained trace amounts of TSNAs at levels which were over 100-fold lower compared to unlit cigarettes. The BfR concluded that pouches can act as a harm reduction product for smokers. In addition, the BfR report also recognises the harm reduction potential of snus, which will be discussed later in this submission.

2.5 Not recognising the reduced population harm, if cigarette smokers were to switch to reduced risk products

Evidence from various scientific sources, shows reduced risk products are a substitute for smoking and reduce population-level harms. Initially, we should expect these smoke free products to displace smoking. That is because they provide much of what smokers are looking for (nicotine, sensory effects and flavour,

[8] Public health implications of vaping in the USA: the smoking and vaping simulation model. Levy et al. 17 April 2021
[9] Bundesinstitut für Risikobewertung. Oktober 2022. Gesundheitliche Bewertung von Nikotinbeuteln. Page 5

hand-to-mouth movement, ritual aspects etc.) but without many of the costs (harm to health, financial burdens, stigma and marginalisation). The evidence of beneficial population effects is sourced from:

- Randomised controlled trials – comparing vaping with Nicotine Replacement Therapy (NRT) in a clinical setting;
- Observational studies – studying how behaviours change over time;
- Population trends – low and rapidly falling smoking prevalence where there is uptake of alternative nicotine; and
- User testimony – many users eloquently testify that vaping was the reason they quit smoking.

2.6 Precautionary Principle should not be misapplied

The draft regulations seem to place a disproportionate emphasis on the so-called "precautionary principle". We believe that its misapplication will deny Dutch smokers access to safer alternatives to cigarettes. Many tobacco control activists claim that because of uncertainty about the future, regulators should take a “precautionary approach” and prohibit or apply excessive regulation to smoke-free nicotine products. In fact, in a situation where it is uncontroversial that the current dominant product in the marketplace –cigarettes – is very harmful, the main risk is not the introduction of much safer products (albeit with some residual uncertainty about risk). The main risk comes from excessive or prohibitory policies that limit access to much safer products, thereby causing harm by protecting the cigarette trade and denying smokers safer options to quit. The precautionary principle demands assessment of both the risks of no intervention and the perverse consequences of intervention and weighing the consequences of uncertainty.

2.7 Youth Risk Behaviour: Unbalanced Approach

Unfortunately it seems as if the draft regulations take a rather simplistic approach to youth risk behaviours and fails to demonstrate net benefits to public health. The rationale offered is grounded in a perhaps naïve account of youth risk behaviours, which do not stop simply because adults in authority disapprove of them or pass laws to prevent them. There is a long and complicated chain of causation from a ban on e.g. oral nicotine pouches and e-cigarette flavours to improved health, with many possible diversions into perverse and harmful consequences. Legislating to ban something does not make it go away or necessarily cause its existing users to become abstinent – it provokes a variety of responses on the part of consumers. Illicit drugs are subject to prohibitions and strong sanctions yet are still widely used and supplied by criminal enterprise. The proposed changes lack justification of the measure as a successful youth-orientated public health intervention. Without realistic insights into youth risk behaviours, the government is likely to regulate in a way that increases harm to young people – for example, by tacitly encouraging young people to revert to smoking.

2.8 Plea to consider tobacco harm reduction (THR) as part of tobacco control.

From the consultation paper, it is clear the intention is to further restrict adult smoker access to reduced risk products, including Oral Nicotine Pouches, and introduce further regressive measures that stand against all principles of tobacco harm reduction. This document is a plea for the consideration and inclusion of tobacco harm reduction science, preferred regulatory frameworks and regulated products in tobacco control. These elements should enable consumers to move from the most harmful to least harmful products containing tobacco and / or nicotine.

In essence, our plea to the Dutch government is to complement tobacco control with tobacco harm reduction (THR), in order to save more adult smokers' lives. We call on the relevant policymakers:

- to consider the potential benefits of THR science and THR products (including electronic nicotine delivery systems or ENDS, oral nicotine pouches and heated tobacco products);
- to consider risk-based, proportionate regulation of reduced risk, non-combustible nicotine products;
- that adult smokers are informed about the potential benefits of THR and that access, affordability and acceptability to such reduced risk categories are validated.

In this regard, we would like to site an exceptionally important "Letter from one hundred specialists in nicotine science, policy and practice"[10], directed to World Health Organization(WHO) during 2021. Highlighting the "urgent need to reduce deaths from smoked tobacco: parties should challenge WHO to modernise its approach to tobacco policy". In this appeal, the scientists recommend to the parties to the Framework Convention on Tobacco Control (FCTC) :

"We recommend that Parties to the FCTC take a more questioning and assertive approach to WHO's advocacy on smoke-free alternative to smoking and undertake the following:

- Make tobacco harm reduction a component of the global strategy to meet the Sustainable Development Goals for health, notably SDG 3.4 on non-communicable diseases.
- Insist that any WHO policy analysis makes a proper assessment of benefits to smokers or would-be smokers, including adolescents, as well as risks to users and non-users of these products.
- Require any policy proposals, particularly prohibitions, to reflect the risks of unintended consequences, including potential increases in smoking and other adverse responses.
- Properly apply Article 5.3 of the FCTC to address genuine tobacco industry malpractice, but not to create a counterproductive barrier to reduced-risk products that have public health benefits or to prevent critical assessment of industry data strictly on its scientific merits.
- Make the FCTC negotiations more open to stakeholders with harm-reduction perspectives, including consumers, public health experts, and some businesses with significant specialised knowledge not held within the traditional tobacco control community.
- Initiate an independent review of WHO and the FCTC approach to tobacco policy in the context of the SDGs. Such a review could address the interpretation and use of science, the quality of policy advice, stakeholder engagement, and accountability and governance. The Independent Panel for

[10] "Letter from one hundred specialists in nicotine science, policy and practice"

Pandemic Preparedness and Response (IPPPR), initiated to evaluate the response to the COVID-19 pandemic, offers such a model.[11] "

This letter was apparently also sent to the Ministry of Health of the Netherlands, and we strongly encourage the Ministry to examine these recommendations and allow for constructive debate on the evidence base for these recommendations.

In addition, we direct your attention to an important booklet on "Balancing the risks and benefits of tobacco harm reduction": "Saving Lives - an advocate's Guide to Tobacco Harm Reduction".[12] For too long, the net public health benefit of tobacco harm reduction has been overshadowed by ideological discussions rather than a balanced, science-driven discourse about evidence, risk and benefit. This booklet provides a framework for a civil dialogue between all stakeholders on this subject.

2.9 Lessons to be learned from the European Union

We would also like to refer to recent EU-related publications, of highly reputable institutions and / or researchers, that address some of the concerns you have raised:

- The Special Eurobarometer 506[13] on "Attitudes of Europeans towards tobacco and electronic cigarettes", published in 2021, recognised two important facts:
    - **Vaping is an important tool in the quest to quit smoking:** 58% of repondents who smoke or used to smoke, and use or used e-cigarettes (n=1.321) said that the use of the e-cigarette helped them to stop or reduce their tobacco consumption (+27% compared to 2017, page 129);
    - **Vaping is not a gateway to smoking:** Among those who currently smoke, used to smoke, or who have tried smoking at least once (n=16.787; page 97), only 2% said they tried e-cigarettes first, which is far from the "epidemic" that many claim is currently ongoing with vaping.
- In a follow-up publication of an earlier 2015 Report[14], where it was already stated that the best estimates show e-cigarettes are 95% less harmful than normal cigarettes, Public Health England[11] published its 7th review on the evidence of vapour products, stating:
    - **Using a vaping product is the most popular aid used by people trying to quit smoking;**
    - **Most young people who had never smoked, had also never vaped.** Between 0.8% and 1.3% of young people who had never smoked were current vapers. Most current vapers were either former or current smokers.

[11] WHO, Independent evaluation of global COVID-19 response announced, 9 July 2020
[12] "Saving Lives - an advocate's Guide to Tobacco Harm Reduction"
[13] Special Eurobarometer 506. Atitudes of Europeans towards tobacco and electronic cigarettes. February 2021
[14] Public Health England Report. Vaping in England: 2021 Evidence Update Summary. 23 February 2021

- As an additional example of the value of e-cigarettes in smoking cessation, a study "ECSMOKE"[15] by Public Health France and the University Hospital Pitié Salpêtrière published in January 2021 found that, of those trying to quit, 14.8% of smokers or ex-smokers declared having used an electronic cigarette without nicotine replacement therapy (NRT), while 11.7% used NRT without an electronic cigarette, and 2.8% used an electronic cigarette in combination with NRT. It was further observed that amongst men who had previously tried to quit: "smoking cessation was associated with the use of an e-cigarette (with or without NRT) and that using NRT without an e-cigarette did not appear associated with tobacco cessation beyond six months".

- THR to fight cancer: Several Experts directed comments to the European Union, notably concerning the EU Consultation on the Roadmap to Europe's Beating Cancer Plan[16]. The letter to Dr. Véronique Trillet-Lenoir, Member of the European Parliament, on "**Preventable cancer deaths due to the under-utilisation of harm reduction"** is attached.

- Use of flavours in smoking cessation: Dr. Konstantinos Farsalinos, cardiologist and well-known E-cigarette researcher, published a report on *"The case for flavours in tobacco harm reduction to save lives"*[17], which examines the science, consumer insights, risks and regulatory considerations relating to flavours in ENDS. This includes the use of flavours in Nicotine Replacement Therapy (NRT). The review concludes that restrictions on vaping flavours would risk seriously reducing the life-saving potential of these innovative products.

Our first concern in addressing you as greatly respected lawmakers, is to make prevention the absolute top priority in policymaking to prevent and control tobacco-related disease and premature death. The possibility for significantly reducing disease and cancer morbidities and mortalities is under-addressed and under-utilised in traditional tobacco control, due to a failure to fully include evidence-based harm reduction strategies. The Netherlands has an opportunity to lead the world with a strategy that puts prevention first, by significantly reducing pathways to combustible tobacco, that inevitably lead to cancer and other chronic diseases.

A holistic approach is required to address social injustices, including the harm reduction approach offered by alternative and innovative technologies. The starting point is to make a clear risk differentiation between combustible and non-combustible tobacco and nicotine products. It is scientifically inappropriate, not to differentiate between the risks of combustible tobacco products vis-a-vis non-combustible products containing nicotine.

[15] L'Etude ECSMOKE. AP-HP. Lancée 2018.
[16] Public Health Key Opinion Leaders and Scientists' Response to EU Consultation on the Roadmap on Europe's Beating Cancer Plan (Letter attached)
[17] *"The case for flavours in tobacco harm reduction to save lives"*. Farsalinos K.

The trend is clear: harm reduction is essential to meeting the tobacco control goals of the Dutch Government. Reduced risk products, such as oral nicotine pouches and ENDS have an important, life-saving role to play in this strategy.

2.10 Consider lessons learned in SWEDEN and its extraordinary achievement, of decreasing smoking prevalence to 5,8% using snus and oral nicotine pouches

In the EU, Sweden has long defied tobacco-related mortality numbers due to its regulated allowance of snus, as outlined in this report: "A study of snus and tobacco-related mortality in the EU".[18] While we are not advocates of tobacco-containing products per se, we are strongly in favour of studying the related epidemiological data and evidence - to understand why Sweden has the lowest incidence of tobacco-related disease and premature death.

Over the last few years evidence has mounted about the benefits. Dr Araghi from the Karolinska Institute near here, recently released the latest update on snus based on nine major cohort studies involving over 400 000 people and covering over 9-million-person years. It showed that there was no association between snus use and oral cancer https://pubmed.ncbi.nlm.nih.gov/32466721/ [19]

This work has been extended globally by Cother Hajat and colleagues and shows that we should not classify all oral tobacco or nicotine products in the same risk camp. Snus confers no excess risks for oral and many other cancers, CVD, and chronic lung diseases. https://www.linkedin.com/pulse/systematic-review-confirms-harmful-health-outcomes-from-cother-hajat/[20]

Based on the evidence, it is not surprising that the USFDA authorized Swedish Match's snus as being appropriate for the protection of public health under its MRTP guidance. https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products[21].

2.11 Avoid making the same mistake as WHO, in not distinguishing between oral tobacco risks for cancer

WHO still fails to distinguish between snus and toxic forms of smokeless tobacco products despite the evidence. Their latest report on Oral Health during 2022 has a section on oral cancer. Their recommendations miss the opportunity to support displacement of these toxic products by snus and nicotine pouches and go further in raising unscientific concerns about nicotine from vaping having a potentially negative effect on oral cancer. https://www.who.int/publications/i/item/9789240061484 [22]

[18] "A study of snus and tobacco-related mortality in the EU" . Swedish Snus Commission
[19] https://pubmed.ncbi.nlm.nih.gov/32466721/
[20] https://www.linkedin.com/pulse/systematic-review-confirms-harmful-health-outcomes-from-cother-hajat/
[21] https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products
[22] . https://www.who.int/publications/i/item/9789240061484

2.12 Embrace Innovation

Policymakers in the Netherlands should challenge opponents of innovation. Throughout history, valuable innovations have met resistance from entrenched interests threatened by new approaches to addressing longstanding problems. The idea of innovative producers interacting with empowered and well-informed consumers in a regulated market – in which smokers control their own risks, on their own initiative, and at their own expense – is counter-cultural and simply not a level playing field. While probably not its intention, the effects of the proposed changes the Bill are that safer nicotine alternatives will be dampened and in fact protect the cigarette trade, obstruct Dutch cigarette smokers from quitting smoking, and add to the burden of smoking-related disease.

2.13 Beware of Institutional bias and inertia

Despite a robust evidence base in favour of THR, the Dutch government, regulators and public health establishment have unfortunately become more hostile and less open-minded to tobacco harm reduction. The heart of the problem is probably the institutional biases of those making and influencing the policy and regulatory decisions. Rather than to regard THR as a complementary measure to save lives, the tobacco control community has not fully embraced the potential benefits of tobacco harm reduction, most importantly, to prevent disease and premature death in cigarette smokers.

2.14 Understand and better manage Opposition.

Tobacco control activists have gone to extraordinary lengths to try to show that introducing much safer products will somehow cause more harm than not introducing such products. This argument is so strange that its proponents should provide a high level for proof. Whereas the Bloomberg philanthropic network has contributed significantly to global public health, it remains to be seen if its active opposition to THR is actually preventing tobacco-related disease and premature death. Or as Marc Gunther of the "The Chronicle of Philanthropy"[23] puts it, whether it is doing more harm than good.

2.15 Dutch Government regulatory approach demands a thorough regulatory impact analysis.

May we request that current and future regulatory framework be subjected to adequate scrutiny. Too often, its proponents have not accounted for the negative effects that excessive regulation, or the de facto prohibition of smoke free alternatives to cigarettes has had and will continue to have by increasing smoking. The art of regulating these products rests on understanding and assessing likely perverse consequences of regulation with at least as much vigour as harmful effects of the products themselves. The Royal College of Physicians outlined this well in its 2016 report: *"However, if [a risk averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products; than it causes harm by perpetuating smoking. Getting this*

[23] https://www.philanthropy.com/article/bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-good

balance right is difficult." (Reference: Royal College of Physicians report, Nicotine without smoke: tobacco harm reduction, April 2016 (Section 12.10 page 187)[24].

3. CONCLUSION

The Dutch Government indicate that the aim of the Bill, is to advance the goal of achieving a smoke free generation by 2040. The Dutch Trimbos Institute reported that the Netherlands still had a smoking prevalence of 20.6% in 2021, an increase of 0.4% compared to 2020[24].

It is clear that the Dutch Government will not be able to achieve a smoke free generation by 2040, without embracing harm reduction strategies and well-regulated THR products.

In our humble opinion, the Dutch Government should decide strategically to exploit the opportunities of tobacco harm reduction and move to a system of risk-proportionate regulation covering all consumer nicotine products, including vaping, heated and smokeless tobacco products and novel oral nicotine pouches. Legislators and policymakers should scrutinise both the claims of tobacco control activists, as well as those of us who support THR, to test the robustness of its net benefit to public health.

As the Government now considers reforms to the regulation of nicotine vaping, we earnestly request that our submission is considered, in particular the scientific references mentioned.

We stand ready to engage with the Dutch government. In particular, we welcome the opportunity to present more scientific evidence of the benefits of tobacco harm reduction, as a complementary instrument to prevent tobacco-related disease and premature death in the Netherlands.

Thank you most sincerely for your attention.

Sincerely,

Dr. Delon Human

Dr. Kgosi Letlape

Prof. Mihaela Raescu

Dr. Jacques le Houezec

Prof. Riccardo Polosa

Mr. Francis Crawley

Mr. Joseph Magero

Dr. Anders Milton

[24] https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction
[24] Netherlands Expertise Centre for Tobacco Control. June 2022. Smoking In The Netherlands: Key Statistics For 2021. Page 3

Biographies

- Delon Human M.B.Ch.B., M.Prax.Med, MFGP, DCH, MBA is a French citizen and physician qualified in family medicine and child health, with an MBA from the Edinburgh Business School. He is a published author and health care consultant specializing in global health strategy, harm reduction and health communication. He has been active in tobacco control for decades, including advocacy for taxes on combustible tobacco to drive down consumer demand. He has acted as adviser to WHO Director-Generals and UN Secretary-General Ban Ki Moon. Formerly, he was Secretary General of the World Medical Association (WMA), the global representative body for physicians and thereafter Secretary General of the International Food and Beverage Alliance (IFBA). He is a fellow of the Russian and Romanian Academies of Medical Sciences. Delon has been involved in harm reduction in tobacco and nicotine, alcohol and drugs for the last 25 years. In clinical medicine, his work focused on tobacco cessation programs, while in medical politics, the development of the FCTC. He was Chair of the coordinating committee for NGOs in preparation of World No Tobacco Day 1999. He authored the book "Wise Nicotine".

- Anders Milton (Sweden) B.Sc., M.D., Ph.D. is the president of ERNA, a member of the government appointed Catastrophe Commission and a consultant within the health care sector. Dr. Milton is also on the board of publicly traded Q-Med AB and has been chairman of the Board of Vironova since 2008. Dr. Milton has a long history of elected as well as government appointed positions. He has previously been both CEO and Secretary General of the Swedish Medical Association, chairman of the Council of the World Medical Association, Chairman of the Swedish Red Cross and Chairman of the Swedish Confederation of Professional Associations (SACO), as well as Government appointed coordinator of psychiatric services in Sweden and government appointed chairman of a committee on HIV/AIDS.

- Riccardo Polosa (Italy) is the Director of the Institute for Internal Medicine and Clinical Immunology of the University of Catania, Italy. He is co-author of the recently published book "Analytical Assessment of e-cigarettes". He is also in charge of the University's Centre for Tobacco Research (CPCT) and is Honorary Professor of Medicine at University of Southampton, UK. An internationally recognized leader in the field of clinical bronchoprovocation (airway- challenge studies), he has published more than 250 peer-reviewed articles and books, mainly on respiratory medicine, clinical immunology, and tobacco addiction. After many years of service as President of the Italian Anti-Smoking League (LIAF: Lega Italiana Anti Fumo), he now serves as its Chief Scientific Advisor. Affiliations and Expertise: Institute for Internal Medicine and Clinical Immunology and Centre for Tobacco Research (CPCT), University of Catania, Catania, Italy; Faculty of Medicine, University of Southampton, Southampton, UK.

- Jacques Le Houezec (France), trained as a neuroscientist in Paris, has been working on nicotine and smoking cessation for more than 35 years. He is a Consultant in Public Health & Tobacco dependence, and a smoking cessation specialist. He is also Manager of Amzer Glas - CIMVAPE, a training and certification organisation, based in Rennes, France.

- Francis P. Crawley (Belgium) is the Executive Director of the Good Clinical Practice Alliance – Europe in Brussels, Belgium. He is the co-founder and a Steering Committee member of the Strategic Initiative for Developing Capacity in Ethical Review. He is a philosopher specialized in ethical, legal, and regulatory issues in health research, teaching at several European, Asian, and Middle East universities. He is the past Secretary General, Ethics Officer, and Chairman of the Ethics Working Party at the European Forum for Good Clinical Practice. He has acted as an author or expert for the leading international and European research ethics and GCP guidelines, as well as for several guidelines in Asia, Africa, the Americas, and Europe. Amongst other things, he is the committee chairman of the WHO guidelines on ethics committees and data monitoring committees; and was a member of the Scientific Advisory Committee for the World Health Organization's International Clinical Trials Registry Platform (ICTRP). He also served for four years on the UNAIDS Ethical Review Committee.

- Joseph Magero, BSBA (Marketing), is the Chairman of Campaign for Safer Alternatives (CASA), a pan-African organisation that advocates for the adoption of tobacco harm reduction policies in Africa. As the unifying voice for consumer organisations, CASA promotes the exchange of information and potential actions to reduce exposure to tobacco-related harm. Kenyan-born Mr Magero previously worked in the tobacco control arena for nearly a decade. His involvement entailed creating smoke-free environments, mandating bigger health warnings, making cigarettes more expensive as well as restricting advertising and marketing. Despite these efforts, smoking deaths continued to increase. This resulted in Mr Magero rethinking his approach towards tobacco control. He has since become an ardent tobacco harm reductionist, lobbying for the reduction of smoking-related diseases and mortality in Africa by advocating for reduced risk products for cigarette smokers. He is also a mentor on the Tobacco Harm Reduction Scholarships Program (THRSP) of Tobacco Harm Reduction Nigeria, which focuses on promoting safer alternatives to smoking. In 2019, Mr Magero was awarded Advocate of the Year by the International Network of Nicotine Consumer Organizations (INNCO). He holds a Bachelor's Degree in Business Administration (Marketing) from the University of Greenwich, England and is currently pursuing a Master's degree in Public policy.

- Mihaela Raescu, PhD, from Romania, is Professor of Preventive Dentistry at the Titu Maiorescu University of Bucharest. She is also a Counselor of the Dental Practitioners Association and has published extensively on preventive dentistry, tobacco control and tobacco harm reduction.