



FOUNDATION WORKING REPORT
CONFERENCE OF PARTIES NINTH SESSION, OCTOBER 2021

Expert Review of WHO EURO Reports Related to Electronic Nicotine and Non-Nicotine Delivery Systems and Heated Tobacco Products

A collaborative effort

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Table of Contents

Table of Contents.....	1
1. Overview	2
2. Introduction.....	3
3. Terminology and Classification	3
3.1 APPROPRIATENESS, ACCEPTABILITY, AND ADOPTION	3
3.2 SUMMARY OF TERMINOLOGIES FINDINGS AND RECOMMENDATIONS	4
4. Trends and Usage Patterns	4
4.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS	4
5. Assessment of Health Effect	7
5.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS	7
5.2 HEATED TOBACCO PRODUCTS	8
5.3 SUMMARY OF HEALTH EFFECTS FINDINGS AND RECOMMENDATIONS	9
6. Regulatory and Policy Options	10
6.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS	10
6.2 HEATED TOBACCO PRODUCTS	10
6.3 COUNTRY CASE STUDIES	11
6.4 SUMMARY OF REGULATORY/POLICY FINDINGS AND RECOMMENDATIONS.....	12
7. Key Considerations Where We Already Have Data Available.....	13
8. Next Steps	Error! Bookmark not defined.
9. References.....	17

1. Overview

In May 2020, ahead of the ninth Conference of the Parties (COP9) of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), the WHO Regional Office for Europe (WHO/Europe) announced the release of three reports on “the current state of scientific knowledge, and regulatory and policy options available on novel tobacco products” such as electronic nicotine and non-nicotine delivery systems (ENDS and ENNDS, or EN&NDS), and heated tobacco products (HTPs).¹ The three reports include:

1. Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief²
2. Heated Tobacco Products: A Brief³
3. Country Case Studies on Electronic Nicotine and Non-Nicotine Delivery Systems Regulation, 2019: Brazil, Canada, the Republic of Korea, and the United Kingdom⁴

These reports are especially relevant to ending smoking across the globe, and to the FSFW mission.⁵ In response to their publication, FSFW worked with both internal staff and external experts to undertake a substantive review and critique of the reports and to identify potential synergies, gaps in knowledge, and areas where research could be strengthened or accelerated. The following document summarizes our key findings, opinions, and recommended action strategies. We hope this document will inspire further work in specified areas.

2. Introduction

In recent years, health authorities have become increasingly interested in, and sceptical of, the potential of ‘novel tobacco products’ in reducing morbidity and mortality associated with tobacco use. However, substantial barriers to the development and implementation of sound recommendations and policies exist; these include limited understanding of short- and long-term health effects as well as regulatory approaches and/or best practices. WHO/Europe purportedly launched its three reports to bridge the gap between science and policy. This review identifies numerous weaknesses in the reports — from untenable assumptions to faulty science — and highlights opportunities for urgent work, research, and messaging. Such activities are particularly important ahead of COP9, which will now take place in November 2021.

3. Terminology and Classification

Health-related terminology and classification should be unambiguous. If terms and categories are not articulated objectively and broadly, the margin of error increases for clinical and public health practitioners. Furthermore, such lack of clarity could negatively impact acceptance and adoption of forward-thinking solutions among policymakers, peers, and the general public. The recent WHO/Europe reports present key terminology for classifying products that purportedly serve as smoking substitutes and/or are linked to tobacco use. These terms include: “novel tobacco products,”⁶ “electronic nicotine delivery systems,” (ENDS) “electronic non-nicotine delivery systems,” (ENNDS)⁷ and HTPs⁸.

3.1 APPROPRIATENESS, ACCEPTABILITY, AND ADOPTION

The term ‘EN&NNDS’ incorporates ENDS and ENNDS devices and first appeared in the 2014 WHO “Report of the sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control.”⁹ These terms are commonly used by WHO and by other major funders or organizations working in the field of tobacco control to refer to “a heterogenous class of products that use an electrically powered coil to heat and turn a solution (e-liquid) into an aerosol, usually dissolved into Propylene Glycol and/or Glycerine, which is inhaled by the user.”¹⁰ WHO defines HTPs as “tobacco products that produce an emission containing nicotine and other chemicals, which is then inhaled by users.”

WHO has used ‘novel tobacco products’ to refer collectively to ENDS, ENNDS, and HTPs.¹¹ Article 1 of the WHO FCTC¹² defines ‘tobacco products’ as “products entirely or partly made of the leaf of tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.” But WHO has not addressed how and why ENDS and NNDS have been communicated/categorized in its brief.¹³

The WHO/Europe reports, and these definitions, operate on the premise that ENDS and ENNDS are functionally similar as alternatives to cigarette smoking, and that these products are inextricably linked to tobacco. WHO ignores the fact that people who use ENDS are generally seeking nicotine and/or smoking alternatives, whereas NNDS users might have entirely different and possibly unrelated motivations for use. Additionally, the authors do not convincingly show

why WHO discusses EN&NNDS in parallel, or why ENNDS are discussed in connection with tobacco- or nicotine-containing products at all.

There is no basis for or benefit to WHO recommendations discussing EN&NNDS in conjunction. By their very definition, ENNDS could include anything from vaporisers filled with oil-based liquids containing tetrahydrocannabinol (THC) or cannabidiol (CBD) to liquid mosquito repellents, essential oil diffusers, and kerosene lighting. These products present their own set of potential health risks and regulatory challenges that arise from different policy considerations (e.g., the EU Biocidal Products Regulation, BPR Regulation (EU) 528/2012)¹⁴. For ENNDS, discussing general consumer protection laws would also be necessary for comprehensively addressing population-level risks from chemical inhalation.

Including products that are not necessarily used as smoking substitutes in ENDS analyses could be misleading and confusing. The term ‘EN&NNDS’ is vague and invites potentially erroneous interpretations and/or applications. Such misperceptions have had negative consequences in the past. This was particularly clear during the 2019 e-cigarette, or vaping, product use-associated lung injury (EVALI) epidemic in the United States, where broad misconceptions confused widespread understanding of the condition’s aetiology and muddled attempts at regulatory framework proposals for nicotine delivery products.

Clear, consistent, and universal definitions are necessary to develop accurate analyses of product usage and precise short- and long-term predictions. Such definitions, particularly those linked to use (e.g., ‘regular use’), are discussed below.

3.2 SUMMARY OF TERMINOLOGIES FINDINGS AND RECOMMENDATIONS

- ‘ENDS’, ‘ENNDS’, ‘HTPs’, and ‘novel tobacco products’ are **ambiguous terms**. There is a need to define and understand perceptions of these terminologies and to consider the role impact of the language used. The concepts surrounding products classes are not clearly delineated and may not be understood or interpreted identically by all.
- To adequately direct and support global efforts towards ending smoking, **clear and globally acceptable definitions for EN&NNDS, HTPs, and novel tobacco products are required**. For example, to generate comparable data and to provide a true and accurate assessment of use.
- **NNDS should be discussed, researched, and regulated separately from conventional nicotine or non-nicotine e-cigarettes.**

4. Trends and Usage Patterns

4.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS

In its EN&NNDS brief, WHO defines regular use of these products as “at least once in the last month.” According to a July 2016 Public Health England report¹⁵, smoking is defined both clinically and legally, and e-cigarette use does not

fall under either definition. Generalizing the way 'use' is defined could lead to inaccurate usage reporting, which could in turn reflect an incorrect landscape of use.

The global tobacco control community has developed a consistent questionnaire with definitions for 'Global Adult Tobacco Use' (GATS) and 'Global Youth Tobacco Survey' (GYTS), which is led by the US Centers for Disease Control and Prevention (CDC)¹⁶. The definitions they use were developed through consultations and pilots. These surveys are now conducted by national governments with support from WHO. A similar approach by all stakeholders is needed to keep information on ENDS and ENNDS consistent and accessible worldwide before collated results are presented to researchers and policymakers. The disaggregation of data into subcategories will illustrate a clear picture of use in all age groups for countries to assess the prevalence and appropriate risk-based regulations and policies.

The WHO EURO Brief does not provide an in-depth assessment of population-level e-cigarette usage. It neither clarifies the link between usage and smoking status nor does it forecast potentially adverse public health effects from the possible decrease in use of e-cigarettes among smokers. Of course, the prevalence of e-cigarette use (in relation to smoking status and frequency of e-cigarette use other than 'current use') has been poorly documented in most countries. This is particularly problematic for interpreting the prevalence of data in a public health context. One exception to this pattern is England, who has paved the way for examining and presenting data on the prevalence of e-cigarette use at the population level.¹⁷

Data from countries featured in the WHO reports highlight the interplay of regulations with public perceptions about tobacco-related harm and the availability of products like ENDS and HTPs. Below we outline some of the trends our analysis has uncovered (see Attachments for full data, review, and references).

South Korea

The initial decline in tobacco consumption in South Korea can be attributed to the policies adopted and implemented by the country, such as its 2015 ban on indoor smoking. The continuous decline from 2017 to 2019 coincides with the availability of HTPs in late 2017. The retail volume and value of HTPs in South Korea also increased over these two years. The consumer acceptability for HTPs is high in South Korea, which has become one of the biggest HTP markets within a year. The growth rate of HTP retail volume slowed from 2018 to 2019, following the Ministry of Food and Drug Safety's announcement that HTPs were not considered risk-reduction products. Such evidence indicates a direct correlation between HTP availability and HTP-regulation policies in South Korea.

The overall smoking prevalence in South Korea has consistently declined, likely given a confluence of factors that include government tobacco-control policies, the 2015 tax increase on combustibles, enhanced package warnings in 2018, and the number of smokers who switch to HTPs.

Brazil

Based on analysis of the Euromonitor data, Brazil's lack of economic stability led to the fast growth of the country's illicit cigarette market. More than half of cigarette total volume sales in the country from 2014-19 is accounted for by illicit products.

According to the FSFW 2017 Global Poll, 66% of smokers, 82% of ex-smokers, and 82% of non-smokers in Brazil thought smoking e-cigarettes and vaping devices could be harmful. Of respondents familiar with heat-not-burn tobacco products, 23% reported their belief that heat-not-burn products are more harmful than combustible cigarettes, while 43% reported thinking that heat-not-burn products were less harmful. The pursuit of healthier lifestyles, combined with comprehensive harm-reduction legislation, has contributed to the decline in smoking rates.

Canada

In Canada, cigarette sales increased in value given manufacturer's pricing power, but declined by 6% in retail volume in 2017. Tobacco market trends have indicated a shift in tobacco use because of the increasing retail value of e-cigarettes and HTPs. The sales value of ENDS increased by 101% in 2019 to US\$1.026 billion; this matched the value of HTPs, which reached US\$47.9 billion in 2019. Major tobacco players turned their attention to ENDS and HTPs to maintain revenue growth. Imperial Tobacco Canada Ltd, Rothmans Benson & Hedges Inc, and JTI MacDonald Corp — the three biggest tobacco companies — have all launched products under a 'reduced harm' category.

After its strong tobacco control policies, Canada has experienced an overall decrease in smoking prevalence. The awareness of harms of smoking according to Canadian Tobacco, Alcohol and Drugs Survey, 85% of Canadians recognize the harms of smoking cigarettes regularly with 65% of Canadians referring to regular use of ENDS as a moderate to great risk of harm.

United States

Both the retail volume and value of cigarettes has declined in the United States over recent years (2017-19). The increased retail value of ENDS is reflected by an increased prevalence of vaping for the same time period. According to the FSFW 2019 Global Poll, fewer than half of US participants believed that ENDS were either equally or more harmful than combustible cigarettes.

As predicted by Euromonitor data and FSFW analysis, HTPs are expected to see a double-digit volume Compound Annual Growth Rate (CAGR) through 2023, as a result of consumers' switching intention. The recent FDA [announcement](#) categorizing HTPs as Modified Tobacco Risk Products (MTRPs) will also impact the market; this should be closely monitored by stakeholders in US and globally.

United Kingdom

The UK has decreased cigarette use in its population through stringent adoption and implementation of tobacco control laws. The UK also constitutes a unique environment in that people who smoke combustible cigarettes were encouraged to switch to alternative nicotine products (see CCS section for more details). The percentage of people who believe that ENDS products are equally or more harmful than combustible cigarettes is low, given trends towards ENDS usage, which were boosted by health experts' recommendations and a consistent messaging by health departments, civil society, and health organizations. UK authorities and health experts were quick to react to the 2019 US EVALI outbreak and, despite the impact on ENDS usage in the same year, the EVALI outbreak and corresponding news was not significant enough to lead to a fall in ENDS use.

5. Assessment of Health Effect

5.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS

The main findings and conclusions of a comprehensive health effects assessment and EN&NNDS brief review are presented below (see Attachment 1 for review and references). Note that this response avoids using the term ENDS/ENNDS; instead, the term ‘e-cigarettes’ is used. This is because, as mentioned above, including other products — particularly NNDS, which might not be used as smoking substitutes — in ENDS analyses could be confusing and could lend unnecessary complication for both future analysis and regulatory framework proposals for nicotine-containing products.

In its EN&NNDS brief, WHO acknowledges lower toxin exposures and the relatively lower harm e-cigarettes may pose if they are used as substitutes for combustible cigarettes. In general, WHO acknowledges the potential benefits of promoting e-cigarettes as exclusive replacements for combustibles use. However, their [Report](#) has several limitations:

- It lacks a detailed assessment of e-cigarette population-use patterns that specifically address the frequency of use and smoking status of users, therefore misses making a recommendation for accurate recording of e-cigarette use.
- It fails to provide a detailed assessment of e-cigarettes use patterns by youth in not addressing frequency of use or the rapid decrease in youth smoking rates during the period of growing e-cigarette popularity.
- Instead of suggesting potential benefits for all individuals who switch to exclusive e-cigarette use, the report seems to exclude youth and pregnant women who smoke. This omission is inadvisable at best, since smoking is a well-documented concern among these population subgroups.
- While it correctly argues that regulatory policies should work to minimize tobacco harm and optimize public health, the report fails to consider that a regulatory framework must be risk proportionate and must clearly differentiate restrictions, taxation, and marketing possibilities for e-cigarettes in relation to other cigarette types. Balanced, evidence-based communication strategies must be designed so that individuals who smoke have the opportunity to make informed decisions based on long-term well-being.

A comprehensive review of available evidence (see ANNEX 1 for details and references) unveiled conclusive evidence that most adults who use e-cigarettes, especially those who do so regularly, smoke or have smoked combustible cigarettes in the past. E-cigarette use is uncommon among adults who have never smoked; e-cigarette popularity with youth has increased over the past decade. However, most use is experimental and infrequent; regular use is confined largely to youth who have smoked in the past. Rates of smoking among youth populations have decreased rapidly and considerably during the period that e-cigarettes grew in popularity.

There is some preliminary evidence that e-cigarettes contributed to reduced smoking rates by distracting from smoking, but no conclusive evidence is currently available. There is conclusive evidence that e-cigarettes promote smoking cessation in smokers when used regularly as part of a broader smoking-cessation attempt. There is also evidence that switching to e-cigarettes results in strong reductions in toxin exposure. Chemistry, toxicology, and

clinical data support the reasonable expectation that substantial health benefits will be experienced by smokers who switch to exclusive e-cigarette use.

There is conclusive evidence that smoking cessation and exclusive use of e-cigarettes leads to lower toxin exposure than that experienced in dual use. However, individuals who use dual products should consider changes in their smoking consumption and understand the potential risk difference between dual use and exclusive use of e-cigarettes. Additionally, dual use is an expected transition period, and it should not be discouraged if dual users are expected to become exclusive smokers and continue previous levels of smoking consumption, especially if dual use is related to substantial smoking reductions.

5.2 HEATED TOBACCO PRODUCTS

The main findings and conclusions of a comprehensive health effects assessment and HTP brief review are presented below (see Attachment 2 for full review and references).

Main findings: Our review uncovered substantial evidence that HTPs emit far fewer toxins than combustible tobacco cigarettes. In addition to measurements of emissions using machine-puffing conditions, clinical data show substantial reductions in human exposure to toxins through measurements of exposure biomarkers of exposure. Furthermore, preliminary data suggest reductions in biomarkers of harm within a period of few months of switching from smoking to HTP use. There is currently no evidence that individuals who have never smoked are drawn to HTPs, or that these products encourage such individuals to take up smoking. In our opinion, regulatory decisions presenting HTPs as equally harmful to combustible tobacco cigarettes could discourage smokers from switching to these products as smoking substitutes and could indirectly and unintentionally protect tobacco cigarette sales.

There are substantial weaknesses and imbalances in the WHO HTP brief. It focuses narrowly on potential harms while it ignores potential benefits of using these products as smoking substitutes. Additionally, while the brief mentions that toxic emissions are lower in e-cigarettes than in combustible cigarettes, it makes no attempt to quantify this reduction by doing a comparative analysis between the two. The argument that it is unknown how toxicological profile of nicotine delivery systems translates into short- and long-term health risks, although technically correct, falls short of a reasonable and practical approach as evidence on health risks can only be generated after several years of long-term use by a substantial part of the population.

Conclusions: The following flaws are observed in the WHO HTP brief:

- Overestimation and focus on potential absolute risks of HTPs without sufficiently addressing overwhelming evidence on e-cigarettes' relatively low-risk potential.
- Failure to acknowledge that HTPs seem to displace combustible tobacco cigarettes from the market.
- Failure to acknowledge that most users are individuals who smoke, which justifies focusing on the relative risks of HTPs compared with those of tobacco cigarettes.

- Recommendations to prevent initiation of HTP use that neglect to clarify that this should be addressed only to individuals who have never smoked; whereas individuals who smoke should be encouraged to initiate HTP use as part of a comprehensive effort to quit smoking.
- Presentation of public-health recommendations to restrict or inhibit the development, manufacture, and sales of HTPs that would leave combustible tobacco cigarettes as the only option for individuals who smoke and are unable or unwilling to quit in accordance with current guidelines.
- Failure to suggest a reasonable regulatory framework that should be risk proportionate and address relative risks of HTPs in relation to combustible tobacco cigarettes.
- Unreasonable suggestions to curb health claims, which would mean that available data indicating HTPs' lower harm potential would not be communicated to aid individuals in making informed health decisions.
- Misleading claim that the suggestions in the Brief are based on a high level of protection for human health, because the health of individuals who cannot quit smoking with other methods is overlooked.

Monitoring HTP use in the population by regulatory authorities, researchers and civil society, focusing on usage in relation to smoking status, and conducting industry-independent research will expand our knowledge about these products.

5.3 SUMMARY OF HEALTH EFFECTS FINDINGS AND RECOMMENDATIONS

- **The EN&NNDS brief is, on balance, negative** and categorically depicts these products as unsafe for “young people, pregnant women and adults who have never smoked.” The report does offer lukewarm agreement that ENDS may provide some value in smoking cessation; however, it contains a number of omissions.
- **The brief could make an important contribution moving forward if it were to emphasize the reduced health risks of ENDS products.** Instead, it implies that WHO remains opaque on its stance regarding the use of EN&NNDS for ending smoking. The brief sidesteps important health considerations to focus instead on tangential issues of inefficient or faulty batteries related to EN&ENNS.
- **The EN&NNDS brief leans heavily on the conclusions of a 2018 paper**¹⁸. It notes the paper’s conclusion that “there is insufficient evidence from randomized controlled trials about the effectiveness of ENDS as cessation aids compared with no treatment or approved smoking-cessation treatments.” Evidence in the supplementary review, (see attachments) could challenge this claim.
- **The HTP brief features major omissions.** This piece homes in on potential harms and sidesteps the potential benefits HTPs offer as smoking substitutes. Additionally, while the paper notes that HTP toxin emissions are lower than those from tobacco cigarette smoke, there is no attempt to quantify this reduction.
- **Evidence indicates that HTPs emit far fewer harmful or potentially harmful compounds than combustible tobacco cigarettes.** Monitoring HTP use in the population, focusing on use relative to smoking status, and industry-independent research are necessary for expanding our knowledge about these products.
- **The WHO/EUROPE Brief correctly note that regulatory policies should aim to minimize consequences that might contribute to the tobacco epidemic and to optimize potential public-health benefits.** However, these documents do not emphasize that a proper regulatory framework should be risk proportionate and should clearly differentiate among restrictions, taxation, and marketing possibilities for e-cigarettes.

- Balanced, evidence-based messages are needed so that policymakers and members of the public can make more informed health decisions.

6. Regulatory and Policy Options

6.1 ELECTRONIC NICOTINE & NON-NICOTINE DELIVERY SYSTEMS

While the EN&NNDS brief outlines several sensible regulation considerations, it categorically avoids making the important distinction between ENDS and NNDS. Further, the regulatory recommendations disregard scientific findings quoted in the brief regarding substantial comparative reduced risk. It also fails to adequately weigh the minimal risks of progression to smoking by those who initiate with ENDS versus the great and quantifiable benefit in educating adults who smoke about ENDS' comparative risk profile and potential benefit in quit attempts.

Although some policy recommendations in the WHO/EUROPE Brief are useful, others will likely result in continued use of cigarettes. Glaringly absent from the recommendations are government obligations to proactively and accurately communicate the reduced risk profiles of ENDS and NNDS products. The necessity of such government action is overlooked in all three reports, which shift this communication burden to the industry as governments ban comparative risk communication. The net result of such recommendations will be a massive lack of information for consumers, who will thus not be incentivized to switch from combustible cigarettes to ENDS products. Coupled with the tax recommendations in the EN&NNDS brief, which also fail to distinguish among products based on risk profiles, the net result of these recommendations will be a virtually unchanged incidence of smoking across the globe.

Policy regulations affect the availability, accessibility, and affordability of e-cigarettes, factors that can in turn encourage individuals to switch from smoking combustible cigarette. The proposals in the WHO/EUROPE Brief are vague and suggest that e-cigarette regulations should be similar to those placed on combustible tobacco cigarettes. Lack of communication and marketing messages on the relatively low health risk posed by e-cigarettes could curtail the number of successful cessation attempts. An approach that would equate e-cigarettes with tobacco cigarettes within the regulatory framework has proven unreasonable following implementation in several countries. Striking a perfect balance between maximizing public health minimizing risk would necessitate regulations encouraging individuals who smoke combustible cigarettes to try e-cigarettes, and it would discourage use among youth and individuals who have never smoked.

6.2 HEATED TOBACCO PRODUCTS

The HTP brief makes three important policy recommendations in its conclusion. These are discussed below.

- “Governments should introduce a system for the pre-market assessment of novel tobacco products, including HTPs. Marketing of HTPs should not be permitted unless there is conclusive evidence that compared to conventional cigarettes, the product reduces exposure to harmful and potentially harmful components and

reduces health risks.” This recommendation in the WHO/EUROPE Brief assumes that HTPs are more harmful than conventional cigarettes, but this assumption is not supported by evidence. It also ignores the fact that the sale of conventional cigarette products is essentially unimpeded by regulation in most countries. To date, not even the United States — which arguably has the most stringent anti-tobacco legislation — poses an obstacle to the introduction of new cigarettes. In fact, the United States does not require cigarette manufacturers to carry out human studies before they introduce new cigarettes into the marketplace, following the Substantial Equivalence premarket authorization pathway under the 2009 Family Smoking Prevention and Tobacco Control Act. The net result of this policy recommendation is a de facto monopoly of combustible cigarettes.

- “Governments that cannot prevent the introduction of HTPs in their markets or decide to allow the marketing of HTPs in the absence of such evidence should ensure the tobacco industry cannot claim government authorization of the product as its endorsement.” This recommendation implies that preventing the introduction of HTPs in the market is a desirable outcome, again, without having conducted any relevant modelling. However, the suggestion against claiming government endorsement is sensible and should hold true for any consumer product.
- “HTPs should be taxed similarly to other tobacco products.” This recommendation is so generic as to become inactionable, as there are many subtypes of tobacco products that are taxed in a differentiated manner (such as smokeless tobacco, roll-your-own products, etc.). Because taxation should align with efforts to reduce population-level risk and to change health outcomes, more evidence and population-level modelling must be performed in support such a recommendation.

Regulation is necessary, acknowledging the fact that it is too early to have epidemiological evidence about long-term health risks. However, the latter cannot justify overly restrictive measures that would undermine the precautionary principle. Sufficient evidence is available to justify a risk-proportionate regulation, which is a common-sense approach that should be the hallmark of any regulatory framework. The public-health effects of HTPs should consider both the intended benefits in individuals who smoke and the unintended effects they could have among individuals who have never smoked. Authorities should consider the totality of evidence and all possible aspects in different population subgroups when preparing the regulatory framework for HTP products.

6.3 COUNTRY CASE STUDIES

In its Country Case Studies (CCS) report, WHO presents case studies that detail regulatory schemes in Brazil, Canada, South Korea, and the UK, and that from strict to active endorsement. The report reiterates the position of the WHO FCTC to “consider prohibiting or regulating ENDS/ENNDS... taking into account a high level of protection for human health.” Unlike many other WHO documents, the CCS report is on the surface largely factual with minimal ‘authorial’ opinions or recommendations. However, while there seems to be very little that is inaccurate or contentious in terms of what is included in the report, it could be argued that the report cherry picked its data. For example, the report fails to present the three types of evidence crucial in determining whether a de facto ban is appropriate. Moreover, WHO’s initial recommendation makes clear that the underlying premise that EN&NNDS are a health hazard and that regulatory schemes that favour EN&NNDS over cigarettes are unacceptable.

Regulatory models lead to different health risks, benefits, and harms. The WHO studies do not acknowledge that the different regulatory options they present could have widely different results in terms of smoking and smoking-related health effects. Understanding these health benefits and harms remains incomplete and we need only look to recent studies that explore the link between smoking and COVID-19 outcomes and indicate nicotine's possible protective role against the novel coronavirus.¹⁹ While such research and data remain incomplete, such observations exemplify how our understanding of differences between nicotine and tobacco is still developing.

To maximize public-health benefits, the regulation of tobacco and nicotine products must distinguish between these two products. But such a distinction is impossible unless regulators are provided with the most convincing evidence on the success rates of differing regulatory approaches. Regulators and health advocates would be better served with information that shows how changes in smoking and smoking-related harm have differed among countries using different regulatory approaches ranging from complete bans on safer nicotine products to treating all nicotine products as tobacco products.

Prohibiting ENDS products would restrict what many are reporting to be a powerful mechanism that drives smoking cessation. Past bans on ENDS products have encouraged illicit trade and associated outcomes like unregulated products, lost public revenues, escalating enforcement costs, and damage to social capital. Imperfect regulation is also likely to lead to suboptimal benefits and unnecessary risks to public health. As in the United States, interactions between an imperfectly regulated ENDS marketplace and illicit cannabis markets, ineffective or evaded product safety standards, and imperfect labelling can lead to negative public-health outcomes. Harm-reduction critics suggest that such risks show that e-cigarettes are unsafe and should be banned but these risks are absent to have been largely or wholly absent in other regulated ENDS markets (notably the UK). This absence suggests that such risks are not a necessary feature of regulated ENDS markets but are instead contingent on features of specific regulatory environments.

By presenting prohibition and three models of regulation, these case studies present a false equivalency between prohibition and regulation, and between different regulatory frameworks. The international public health community needs more than a brief catalogue of regulatory options, and it is not sufficient to say that the different regimes have led to different rates of ends use. Instead, different regulatory frameworks should be presented with an analysis of associated risks and benefits, so that regulators and public health professionals can understand how to secure the optimal balance for their constituents. Finally, the CCS report excludes evidence from countries in which pre-existing consumer-protection laws, coupled with more generic recommendations (such as a conspicuous nicotine ingredient disclosure requirement), might represent a more practical regulatory option (see Attachment 3 for full review and references).

6.4 SUMMARY OF REGULATORY/POLICY FINDINGS AND RECOMMENDATIONS

- There exists an underlying premise that 'novel tobacco products' are a health hazard and that regulatory schemes favoring EN&NNDS over cigarettes, for example by prohibiting their sale, constitute an unacceptable public health opinion.

- The EN&NNDS brief does not distinguish between ENDS and NNDS in its regulatory recommendations. More so regarding NNDS, all countries have some form of general consumer-protection law regarding many classes of chemical-containing products that could expose users to divergent levels of the same toxins in NNDS (or even ENDS). A discussion of general consumer-protection law would also be necessary to comprehensively address population-level risks from chemical inhalation.
- Whereas some of their policy recommendations are sensible, none of the three documents acknowledges government responsibility to provide truthful comparative risk communication. The result of such a recommendation – or absence thereof – will be a massively uninformed consumer basis who is only familiar and comfortable with the deadliest product – cigarettes – and is unaware of potential reduced risk. Coupled with the tax recommendations in the EN&NNDS brief, which also fail to distinguish among products based on risk profiles, the net result of all EN&NNDS brief regulatory recommendations would be a virtually unchanged smoking incidence among population, with the nefarious consequences it entails.
- The CSS report excludes a thorough analysis of the impact that regulatory choices may have had upon tobacco and nicotine use, and presents a false equivalency between prohibition and regulation, different regulatory frameworks, and the public health outcomes that can be expected of each model. A more useful set of studies would present the different regulatory frameworks along with an analysis of the associated tobacco and nicotine related risks and benefits, so that regulators and public health professionals could understand how to secure the optimal balance for their constituents.
- Some country-level data evaluating the success of ENDS as smoking cessation tools is included in the recently completed FSFW report, “Assessing the impact of smoking cessation interventions on smoking prevalence.” These data could be used to complement the CSS report.
- Authorities should be guided to consider the totality of evidence and all population subgroups when preparing regulatory frameworks for all ‘novel tobacco’ products, including ENDS and HTPs

7. Key Considerations Where We Already Have Data Available

FSFW commissioned work for ‘*Assessing the impact of smoking cessation interventions on smoking*’, the report of this work is attached as Annex 4. Below are key considerations from the commissioned work.

- A. The health debate around alternative options to cigarettes (e.g. ENDS and HTPs) is ongoing and countries are taking varied stances in response
- The growing popularity of ENDS, HTPs and (in specific regions) snus, is the subject of a public health debate. Whereas some welcome these alternatives as a potential pathway to the reduction or cessation of tobacco smoking, others view them as undermining efforts to de-normalize tobacco use and potential gateways to smoking for younger smokers.
 - The products are either assessed as consumer products or medicinal products, depending on the health claims made.
 - The UK is an example of a country that has taken a pragmatic approach, seeing the potential for reduced harm. The NHS and Public Health England have endorsed ENDS as viable and ‘safer’ alternatives to smoking. Public Health England concluded in a review “e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit.”²⁰ This is in stark contrast to almost all other countries in the FSFW report research, who have not publicly acknowledged any potential benefit of ENDS or alternative tobacco products such as snus and HTPs, preferring to lump them all together in “anti-smoking” governance.

B. A tough stance on alternative products limits options for potential quitters and will lead many back to combustible cigarettes

- The experience of smoking – and attempting to quit – is multifaceted and deeply individual, and there are a wide range of options available to quitters to assist them. The evidence suggests that smoking substitution alternatives should be a part of this armory.
- For example, in South Korea, HTPs were having a positive impact on smoker numbers, with 2.3% of tobacco cigarette male smokers switching to a sole consumption of HTPs. In addition, dual users of both tobacco cigarettes and HTP had a higher quit attempt rate than cigarette-only smokers by 9.8%.²¹
- However, since a tougher stance by the country’s Ministry of Food and Drug Safety on HTPs and a significant increase in taxes in 2018, many South Koreans seem to be returning to combustible cigarettes.²²
- The FSFW report assessed five “high success” countries that have had significant success in reducing smoking prevalence and five “low success” countries that have not yet, despite implementing several interventions. It is noticeable in the FSFW report that in low success markets, non-combustible tobacco options, such as snus and HTPs, which could facilitate smoking substitution and / or reduction, are generally heavily legislated against.

C. Reduction or substitution is a valid goal for many smokers who are unable to quit

- Smoking reduction is a promising intervention and may lead to complete cessation.²³
- Quitting smoking altogether is always the preferable aim. But several of the high success countries in the FSFW report have demonstrated that substitution may be a viable goal if complete abstinence is too difficult for smokers.
- The increasing use of ENDS in the UK has broadly correlated with the reduction in smoking prevalence in the UK population since their introduction in 2005. Around 5%-7% of adults in the UK used e-cigarettes in 2019, up from 0.5% in 2008.²⁴
- In Sweden and Norway, many smokers have made the switch from cigarettes to snus, a Nordic cultural phenomenon that is apparently a reason behind the record-low tobacco-related mortality in Sweden.²⁵ Around 30% of people who attempt to quit smoking in Norway use snus and it is more common than cigarettes among both men and women between the ages of 16 and 24 in the country.²⁶
- In Japan, heat-not-burn products have been rapidly replacing cigarettes, with approximately 28.9% of the total smoker population only using HTPs in 2018.²⁷

D. Alternative options such as ENDS, HTPs and snus have been proven to have a positive impact on smoking cessation

I. ENDS:

- There is a strong case that ENDS have helped to increase smoking cessation at the population level.²⁸
- UK:
 - The increasing prevalence of ENDS in the UK has broadly correlated with the reduction in the smoking population. As many as 6% of the UK population used e-cigarettes in 2018, up from 0.5% in 2008.²⁹
 - In total, ENDS use can be held accountable for over 2 million cessations since 2008.^{30 31 32}
- South Korea:

- The large tax increase on cigarettes in 2015, combined with a sudden expansion of local vaping shops, led to a significant increase in ENDS use.
- Nearly half (45.2%) of all users choose ENDS for cessation, with a further 19.4% choosing them as a less harmful option compared to cigarettes.³³
- ENDS have had an impact on the smoking prevalence in South Korea, leading to a higher number of quit attempts and a higher successful quitting rate. Dual users of cigarettes and ENDS were found to have a 25% higher quit attempt rate than tobacco cigarette-only smokers (Euromonitor), and ENDS users were found to have a successful quitting rate of 7.3% after 6 months, which is a higher rate compared to nicotine patches (5.8%).³⁴
- Since 2012, ENDS have had a total impact of around 0.4 million cigarette cessations in South Korea.^{35 36}
- Germany:
 - In 2016, 9.1% of smokers said that ENDS were their most recently used smoking cessation tool, which made ENDS the most popular evidence-based smoking cessation tool in Germany.³⁷
 - 1.6% of ex-cigarette smokers in Germany successfully switched to ENDS while 7.2% of former ENDS users are also ex-tobacco smokers and therefore can be considered successful quitters.³⁸
- France
 - In 2017, 7.2% of smokers were using ENDS.³⁹
 - 76.3% of ex-smokers who use, or used, ENDS daily for at least one month, said that it helped them to quit smoking.⁴⁰ Extrapolated, this represents 870,000 smokers who have quit since 2010 (6.1% of the ex-smokers in 2017).

II. Snus:

- Snus has been used as a tool for smoking cessation for several decades.
- Norway:
 - Every fourth smoker who attempts to quit uses snus alone or in combination with other smoking cessation methods.
 - The chance of successfully quitting smoking is significantly higher for snus users compared to smokers with no former snus use⁴¹. Although as use of snus has increased and use of cigarettes has declined in Norway, overall tobacco consumption has remained relatively consistent.
- Sweden:
 - In Sweden, snus is probably the major feature of the country's dramatic changes in tobacco use resulting in tobacco-related mortality in men being the lowest in all European Union countries.⁴²

III. HTPs:

- HTPs have some parallels with snus in being alternative tobacco products that have made an impact in specific countries.
- Japan:
 - HTPs have become popular very quickly in Japan with around 28.9% of smokers using them in 2018.⁴³
 - Only around 4% of HTP users have never smoked cigarettes, implying that the majority of HTP users were former smokers.⁴⁴
- South Korea:
 - 2.3% of tobacco cigarette male smokers switched to a sole consumption of HTPs and dual users of both tobacco cigarettes and HTP have a higher quit attempt rate than cigarette-only smokers by 9.8%.⁴⁵

E. Availability is key to use

- The success of ENDS in the UK market is largely due to availability, with a wide product range available both online and across a variety of mainstream, high-street grocers and retailers.

F. Measures to disincentivize the use of alternative products among young non-smokers fully in line with traditional cigarettes should be supported

- The key value of alternative products is to aid smoking cessation.
- Data from some countries have suggested they do not increase the risk of young smokers using combustible tobacco (e.g. in Japan, only around 4% of HTP users have never smoked cigarettes, implying that the majority of HTP users were former smokers. However, other countries have seen a relatively high uptake of alternative products among youth, increasing concerns about their potential as gateway products.
 - In one survey in Italy, of all people potentially interested in using an HTP, 43% were non-smokers. Furthermore, 39.6% of people who experimented the product were non-smokers.⁴⁶
 - In Germany, the dominant reason for using ENDS among smokers over the age of 25 was smoking cessation and reduced harmfulness, compared to under 25s, who predominantly mentioned fun and taste⁴⁷ which could suggest a potential gateway into cigarette smoking amongst younger smokers.

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10. Supplementary Attachments

Developed by FSFW convened collaborative group

1. EN&NNDS Health Assessment (PDF)
2. HTPs Health Assessment (PDF)
3. Country Case Studies Assessment (PDF)
4. Executive Insights – Review (PDF)
5. Trends Data – South Korea-Brazil-Canada-US-UK (PDF)