

Tobacco Harm Reduction

Regulatory, Economic and Taxation Perspectives



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Proceedings of the 2020 Dubrovnik Consultation

Foundation for a Smoke-Free World

An outline of goals and areas of opportunity in regulatory policies, including taxation, for tobacco harm reduction.

FOUNDATION FOR A
SMOKE-FREE WORLD

Foreword



Dr. Derek Yach, President
Foundation for a Smoke-Free World

On behalf of the Foundation for a Smoke-Free World, I am pleased to share with you the initial results of a virtual consultation that supports all three pillars of our activity – Health, Science and Technology, Agriculture and Livelihoods, and Industry Transformation, and our commitment to advancing global progress to end smoking in our generation.

Farmers, consumers and industry’s daily activities are impacted by an unavoidable externality: regulation. Smart regulations, including product, consumer regulation as well as taxation, serves as a catalyst for positive change and interacts constructively with the economics dynamics of the market. It helps consumers make healthy choices and companies’ transition to products that do not harm health or the environment. Impulsive regulation, such as product bans and exorbitant taxation levels, on the other hand, plays directly to the benefit of dark forces. At the most extreme, prohibition damages health and fuels illicit trade and criminality. And it undermines corporate innovation.

The Foundation’s “Dubrovnik Consultation” project – named after the beautiful city on the Adriatic that was meant, and is still planned, to be the seat of our expert group’s first in-person meeting, delayed due to the COVID-19 pandemic - is designed to bring diverse world-famous expert perspectives on regulation, taxation and economics to the ideal intersection – the “sweet spot” of the three that will accelerate tobacco harm reductions and the demise of smoking. Eventually it will lead to model regulation, appropriate and tailored for various legal systems, that would best accomplish both public health and, realistically, overall government economics goals.

Our ultimate goal for this project is to create toolkits that include optimal regulation and taxation models that support public health goals in the area of smoking cessation and overall tobacco harm reduction, and which are tailored to the various legal systems around the world. This meeting and the work focused on better regulations to accelerate an end to smoking draws upon substantive work recently published that shows how we could save millions of lives over the next four decades if we were to accelerate access to effective tobacco harm reduction and cessation products. With smarter regulations-that vision could be possible and our call to action, articulated in a recent publication,¹ can make it happen.

The first phase in this journey was to identify a pool of experts and listen to their opinions and expertise on regulatory, economics and taxation topics. This report contains the summary of the initial consultation, which took place remotely over a period of a few months and resulted in expert papers. We will keep you updated of additional proceedings as they happen, and we hope to have your support along this transformative effort!

¹ Yach, D. (2020), “Accelerating an end to smoking: a call to action on the eve of the FCTC’s COP9”, *Drugs and Alcohol Today*, available at <https://www.emerald.com/insight/content/doi/10.1108/DAT-02-2020-0012/full/pdf?title=accelerating-an-end-to-smoking-a-call-to-action-on-the-eve-of-the-fctcs-cop9>

I am also pleased to share thoughts by the two project leaders, Dr. Ayda Yurekli, Senior Economist of the Foundation for a Smoke-Free World, as well as Patricia Kovacevic, attorney and regulatory expert, our external consultant and project initiator.



Dr. Ayda Yurekli

“Policies and regulations that do not rely on evidence can damage public health, and many current regulations put place on harm reduction products (HRPs) for tobacco use are examples of this trend.

While tobacco control regulatory measures have been debated for over a half-century and have a wealth of scientific evidence behind them, their implementation is still incomplete. Yet many countries are now rushing to regulate HRPs in the absence of research evidence about their near-term and long-term health risks, and growing evidence for their positive role in smoking cessation.

As the debate about HRPs shifts from health to economic issues, we also need to be mindful of the public health impact of economic interventions. High excise taxes on combustible cigarettes, in appropriate tax systems and supported by comprehensive tobacco control measures, are a win-win situation for both public health and economies. This is not the case for HRPs, however, and in this case such regulations are a sample of ignorance that serves special interests but not public health.”



Patricia I. Kovacevic, Esq.

“This, above all, is true and demonstrated time and again: the regulatory framework for products, industry and initiatives is the single most impactful factor capable to move consumers away fastest from the highest risk products, towards the lowest risk products on a spectrum and ultimately accomplishing global health goals. A country that is held hostage to irreparable harm by a regulatory ban on all other products except for the highest risk products is, in my opinion, violating that country’s citizens’ human right to life. Often, there is no nefarious intent, just lack of information and understanding on the side of the government. We need to redress this harm by every available legal, knowledge and education means, and we need to do it NOW.”

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Executive Summary

This document is a summary of expert contributions to the 2020 Dubrovnik Consultation, a summit meeting on regulatory issues, taxation and other perspectives in tobacco harm reduction sponsored by the Foundation for a Smoke-Free World (www.smokefreeworld.org).

This summit was originally planned as a live meeting in Dubrovnik, Croatia in mid-2020. Due to the global COVID-19 pandemic, this live meeting has been postponed, but the expert contributions to this meeting are summarized here in print form.

The Dubrovnik Consultation is a unique opportunity to bring together top economists and legal experts from various geographies to identify areas of intervention in tobacco harm reduction regulation and to enable the Foundation of the Smoke-Free World to prioritize future areas of research in the field of tobacco harm reduction regulation. Here are some of the key takeaways from their contributions:

We must address market and information failures in tobacco harm reduction products (THRPs)

Future gains in smoking cessation require public education on effective harm reduction approaches, as well as economic policies that do not penalize tobacco harm reduction products. Unfortunately, THRPs are often subject to taxation policies and marketing restrictions that run counter to these goals. Expert recommendations in this area include:

- Taxation policies that reflect the true health risks and downstream costs of tobacco products
- Strategies to remediate market failures in consumer perceptions of THRPs, addressing the economic drivers of consumer behavior as well as education to support public perceptions of relative risk
- Evidence-based economic justifications for government regulatory policies

Product-specific regulations for THRPs need to be re-examined

Current regulations governing tobacco harm reduction products are often broad, overreaching and inconsistently applied between different countries. Expert recommendations include:

- Incorporate more science, expertise and open discussion into the regulatory process
- Work to have evolving regulations such as the EU's Tobacco Products Directive third revision (TPD III) differentiate better between THRPs and cigarettes
- Normalize implementation of regulatory policies between specific countries to better support cessation.

Existing international law can serve as a framework for improving smoking cessation

Many national-level bans on THRPs are discriminatory and inconsistent with current international law, providing a mechanism for legal challenges to regulations that interfere with smoking cessation. Possible areas of intervention include:

- Rules of the World Trade Organization such as the General Agreement on Tariffs and Trade (GATT)
- Issues with carving out tobacco products from International Investment Agreements (IIAs)
- Methods by which states can establish civil liability for purposes of tobacco control under Article 19 of the Framework Convention on Tobacco Control (FCTC)

In addition, future research opportunities that remain to be addressed include human rights treaty protections for consumers, country-specific constitutional protections and potential constitutional law challenges, and the impact of partial bans such as flavor bans and nicotine caps.

Our goal for this meeting was to explore the importance of harm reduction in the context of economic and taxation policy, regulations, and the regulatory framework. Its expert contributions provided important insight into these issues, as well as what information and research evidence gaps still exist, and how we can best plan to address these gaps in the future. It represents the next step in an important dialogue on the future of smoking cessation and public health.

“Switching to modern tobacco harm reduction products (THRPs) including e-cigarettes and heat-not-burn products offers the potential to prevent most, if not all, of the health consequences of smoking.”

Detailed Summary

Expert opinions submitted in print for the 2020 Dubrovnik Consultation revolved around three key areas: economics and taxation, product-specific regulation, and opportunities for addressing tobacco harm reduction under international law. The following is a summary of these opinions.

Economics and Taxation

Taxation policies form an important subset of current regulation of tobacco harm reduction products. Here are some of the key areas that were addressed in the participants' papers:

Taxation as a function of the health risk argument surrounding THRPs

Electronic nicotine delivery systems (ENDS) are often taxed in a way that is disproportionate to their relative health risk, which in turn disincentivizes their use for harm reduction purposes. ENDS are significantly less harmful than cigarettes, and switching from combustible cigarettes to ENDS or other reduced risk products preponderantly improves the health outcomes of smokers.

If consumers are not fully informed of the relative health risks of tobacco products, economists consider this to be a market (information) failure and urge governments to address this failure via taxation policies. One expert proposes that taxation policies should not focus on reduced consumption, but rather on eliminating the external and internal costs of tobacco use, including policies that target young and heavy smokers who cause the greatest external and internal costs.

Examining the justification for taxing THRPs

Beyond the argument for differential taxation for electronic cigarettes, given their lower health risks and role as a successful bridge to complete cessation of smoking, is the question of whether these products warrant taxation based on their health gains.

One expert argues that the rationale for current taxation policies centers on the origin of the nicotine present in electronic cigarettes, leading them to be considered as tobacco products. In addition, there has been an expectation that these products are expected to replace potential losses in cigarette tax revenues, although evidence suggests otherwise. Applying taxes to these products followed widespread regulation in many instances, especially as consumer acceptance of e-cigarettes continued to grow and these novel products emerged as substitutes for conventional cigarettes.

One expert explored how tax policy can balance public health benefit by making ENDS less affordable and accessible to youth, while increasing their affordability to the most economically disadvantaged adult smokers, including women and poor smokers. Another proposed how tax policy could be designed by considering the impact of "renormalizing" of smoking: in other words, if e-cigarettes become socially acceptable and reduce the stigma attached to smoking, would smokers smoke more combustible cigarettes, or would the emergence of new, cleaner products increase the stigma attached to smoking and lead to more people switching from combustibles to e-cigarettes?

Another perspective involves whether the benefits to society from regulating tobacco product markets exceed the costs. Consumers make choices about tobacco products based on the “full price,” or the sum of the monetary price plus health costs, and higher taxes on combustible tobacco products could encourage smokers to switch to THRPs. Alternatively, THRPs could be subject to negative taxes, i.e. purchases could be subsidized. There is already a precedent for this in the United States, which provides subsidies for nicotine-replacement therapies to lower-income consumers enrolled in Medicaid.

Another issue discussed was the current lack of information on what the comparable basis is for taxation policies between combustible cigarettes, e-cigarettes and HT products. Future discussions with epidemiologists, clinicians and economists will be needed to determine the comparable tax base among these products.

Economic justifications for government interventions

What regulatory measures are needed by governments to correct market and information failures surrounding THRPs? Economic studies have established that many consumers are poorly informed on the health risks of these products, and associate risk perception according to their current risk perception of combustible cigarettes.

One such solution involves an approach to tobacco market regulation that addresses the harms of combustible cigarettes and the potential of THRPs. This reflects that information failure is the most important problem of tobacco market, where consumers are poorly informed about the health consequences of combustible tobacco products and the harm-reduction potential of THRPs, and regulation can only be justified when they correct market failures or individual failures to optimize this messaging.

Current restrictions on the ability for THRPs to make therapeutic advertising claims limit the ability to educate the public about harm reduction, and target older smokers about cessation and health risks. Public policies to improve consumer information have great potential to improve tobacco market outcomes and yield societal benefits that far exceed the social costs, and improved information is a policy intervention that encourages consumers to make better decisions in their own self-interest.

“Public policies to better inform consumers about THRPs continue to show great potential. Unfortunately, many consumers have inaccurate risk perceptions and mistakenly believe that harm reduction products are as harmful, or more harmful, than combustible cigarettes. As a result, smokers may be reluctant to switch to THRPs, even though THRPs are an effective way to help smokers quit. Evidence from a discrete choice experiment suggests that correcting consumer misperceptions of the risks of e-cigarettes would substantially increase the number of subjects who choose e-cigarettes and substantially reduce the number who choose combustible cigarettes”

Selected Product-Specific Regulation

Areas of product regulation addressed in the participants' papers to date include:

Why bans are a failed tobacco harm reduction policy

One case study paper discusses how Turkey's ENDS ban is not science-based and also counterproductive for harm reduction. Its recommendations include identifying and eliminating blockages in the regulatory process, leaving regulation in the hands of competent and objective people including the input of scientists, creating a free discussion environment so that radical views on smoking can be challenged, and public consultation.

The EU regulatory model

Another paper analyzed the comparative regulatory approaches in the UK, the most progressive country in terms of encouraging harm reduction through the use of commercially available, non-medicinal ENDS, and Romania, an EU country that took a more stringent approach. It presented selected differences with respect to the United Kingdom's implementation of the Tobacco Products Directive (TPD II) regulating the sale and merchandising of tobacco products in the EU. It also discussed a summary of media and government communication trends on comparative risk vis-à-vis combustible cigarettes regarding various alternative nicotine products, ENDS and HT, both types of products being well represented on the Romanian market.

The author, a practicing attorney, makes the following practical recommendations:

- A "macro-solution" of how the Tobacco Products Directive third revision (TPD III) presents an opportunity at the EU level to differentiate between ENDS, HT and cigarettes;
- In-country solutions: even before TPD III adoption, Romania has the discretion to amend its national TPD II transposing legislation to allow ENDS remote sales and point of sale advertising for both ENDS and HT like other EU countries and further differentiate product taxation, and
- A public awareness campaign solution communicating reduced risk and cessation opportunities.

He further recommends that these steps be followed by longer term recalibration of these solutions, following 5-10 years of epidemiologic data to be initiated and collected from the country's switching population.

The Need for Harm Reduction in Romania

One expert notes the importance of practical smoking cessation strategies in Romania: current smoking prevalence rates are 37.4% among males and 16.7% among females, for a total of 4.3 million smokers, representing almost a quarter of the country's population. Total premature deaths attributable to smoking are estimated at 2.15 million people, meaning that half of Romania's smoking population and a little under one eighths of the entire country's population will die prematurely from smoking.

(Source: World Health Organization Tobacco Control Fact Sheet)

International (Treaty) Law Opportunities

Some experts examined strategies to level the imbalance between favorable treatment of cigarettes versus reduced risk products (primarily ENDS and snus). Specific areas discussed include:

World Trade Organization treatment of ENDS bans

One expert argues that banning ENDS at the national level, directly or indirectly, may be discriminatory and inconsistent with the rules of the World Trade Organization (WTO).

Member non-discrimination is one of the fundamental principles of the World Trade Organization (WTO) and its General Agreement on Tariffs and Trade (GATT). This expert argues that even if ENDS and conventional cigarettes are not physically “alike,” their end use puts them in a direct competitive relationship based on the extent to which the two products are capable of performing the same or similar functions. Thus, any treatment that is less favorable to ENDS than to cigarettes may be found inconsistent with the WTO law if challenged by a particular state where ENDS are manufactured, and litigation under GATT may be a solution to lift bans.

International Investment Agreements (IIAs) carve-outs

Another expert argues that carving out tobacco products from the scope of IIAs may have a legitimate policy objective at its core, but is problematic from a legal and business standpoint.

These exclusions have been drafted in such a manner that detract from public health goals and do not distinguish between tobacco products, which does not allow for nuanced harm reduction treatment of products. Finally, the tobacco exclusion is unnecessary as public health safeguards already exist in IIAs. Instead of singling out a single industry, the drafting of the treaty could be more nuanced, such that safeguards are introduced without compromising basic fairness.

Unexplored opportunities under the Framework Convention on Tobacco Control Article 19

Another expert discusses methods by which states can establish civil liability for purposes of tobacco control. Drawing from the experience of states that have successfully implemented FCTC Article 19, this expert focuses on three means of pursuing liability in accordance with Article 19: health-care cost recovery actions, private actions and government enforcement actions.

Based on a survey of practices by various states, it seems the most useful approaches for tobacco control under Article 19 of the FCTC are health recovery cost legislation and government enforcement actions. In particular, the area of government enforcement actions may be best for states that are unwilling to enact enabling legislation and are more interested in holding tobacco companies to account rather than seeking compensation from them. Conversely, the author concludes that, for states serious about implementing Article 19, the health recovery cost legislation approach offers advantages.

Areas for Future Research

In addition to the papers presented, the following areas remain as topics for further discussion and research, from this Consultation's invited experts and others:

Economics factors in smoking cessation

Research on policy interventions to support tobacco harm reduction and cessation of combustible tobacco products, including differential or even negative taxation (e.g. subsidies) to favor the use of THRPs versus cigarettes, as well as reduced limits on informational consumer education funded by private industry.

Human rights treaty protection for consumers

Is the right to health and life undermined by bans? To address this area we need to conduct further research in the area of human rights treaties, including who could challenge policies under a treaty, and what would be the mechanism and courts involved.

Country-specific constitutional protections

Particularly for the most populous countries, these include potential constitutional law challenges against unreasonable bans. Country-specific subject matter legal experts could analyze what are the opportunities to challenge the bans in Brazil, Turkey, and other populous countries that have enacted de facto bans or very restrictive measures amounting to a ban, as well as who has standing to challenge in these jurisdictions.

Partial bans

These include restrictions such as flavor bans, caps on nicotine, and others – what could be some potential legal remedies/challenges against these bans, and who has standing to mount them (for example., consumer organizations or individuals), based on each respective country's legal system. One proposal would be to analyze the 15 priority countries in the Tobacco Transformation Index and focus on several of these countries.

“The challenge for policy makers is to develop an approach to tobacco market regulation that addresses the harms of combustible cigarettes and the potential of THRPs.”