All-Party Parliamentary Group on Vaping - Inquiry into the WHO Framework Convention on Tobacco Control (FCTC) Conference of the Parties (COP)

Memorandum by Clive Bates
February 2021

Table of Contents

All-Party Parliamentary Group on Vaping - Inquiry into the WHO Framework Convention on Tobacco Control (FCTC) Conference of the Parties (COP)

Memorandum by Clive Bates[1]
February 2021

Summary

- The FCTC text was settled in 2003 and does not provide a satisfactory framework for regulating tobacco and nicotine products in the 2020s. It is not designed to capture the opportunities arising from vaping and other non-combustible consumer nicotine products that present much lower risks than smoking, which remains by far the dominant causes of harm globally. Though the FCTC includes harm reduction in its definition of tobacco control, it is not designed for 'risk-proportionate regulation'.

- The Conference of the Parties, the WHO, FCTC Secretariat, and approved observers have adapted to the fundamental weakness of the FCTC itself by adopting a highly hostile approach to tobacco harm reduction. The approach implicitly favoured by WHO is to normalise the prohibition of vaping products or, if that is not possible, press for excessive regulation, such as regulation comparable to cigarettes. The effect is to protect the global cigarette trade. *This is profoundly harmful and in conflict with UK interests and global public health aims.*

- The hostility is evident in COP decisions, papers and guidelines; in the approach taken to science and regulation; and in speeches, reports, events, awards, and advocacy conducted by WHO and the Secretariat. It is backed by a well-funded network of non-governmental organisations (NGOs), many of which rely on a small number of American foundations with intensely negative views about tobacco harm reduction. In the case of Bloomberg Philanthropies, the most significant funder, the proprietor favours outright prohibition of vaping, and many grantees are pursuing that agenda with his support.

- The policy and science postures of WHO, Secretariat and COP are selective and cherry-picked, are based on minimal or inadequate justification, and are largely blind to obvious perverse unintended consequences. Most of what passes for scientific synthesis and policy analysis would not withstand even cursory scrutiny. However, there is little real scrutiny and accountability.

- The FCTC institutions have carefully cultivated a self-referential bubble by approving only a small number of like-minded NGOs to participate as observers at COP meetings. To gain observer status, NGOs are required to pledge allegiance to the FCTC. The COP requires them to report on how they support the FCTC, and any Party can veto observer status for any organisation. The result is pronounced group-think from hand-picked, compliant and sycophantic observers. This is in marked contrast to other UN conventions such as the UNFCCC on climate change.

[1] The author has had a diverse career in the public, private and not-for-profit sectors. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003 he joined Prime Minister Blair's Strategy Unit as a civil servant and worked in senior roles in the public sector and for the United Nations in Sudan. In 2013, he founded Counterfactual, a consulting and advocacy practice focused on sustainability and public health. He has no conflicts of interest with respect to tobacco, vaping or pharmaceutical industries.

- Much of the FCTC insularity is justified with reference to preventing 'tobacco industry interference', However, this is both a tactical excuse and a strategic mistake. While vested interests should not distort policymaking, this concern should not be used as a tactical reason to exclude people or organisations affected by the FTCTC, with a critical perspective on the FCTC, or with legitimately different views on how to secure public health objectives. Strategically, tobacco companies have a significant role in tobacco harm reduction. The transformation of this industry to non-combustible technologies would be a very significant public health achievement. The tobacco industry is already present though delegations with state-owned tobacco enterprises. It should be possible for the COP to engage with tobacco, vaping, and other relevant industries with safeguards to prevent excessive influence while gaining from their experience.

- The UK government is no longer required to follow the EU common positions at COP meetings. It should no longer play a passive role in what is becoming a public health circus. It should take an assertive stance to rescue the FCTC and COP from counterproductive and harmful policies and distorted messaging. As a party to the FCTC and a member of the World Health Assembly, the UK should press WHO to restore respect for science, open-mindedness and curiosity in response to the public health impact of smoking. The UK should encourage WHO, the FCTC Secretariat and the Conference of the Parties towards developing a credible approach to innovation, risk and opportunity. It will be unable to do this as a bystander or by merely objecting if its own red lines are crossed. The UK needs to adopt an assertive evidence-based approach to comprehensive reform. The government should base its engagement strategy on:

    1. The world-class research and analysis by UK universities and non-profits, and the high-quality synthesis reports produced by Public Health England and others.

    2. The policy measures and communications needed to meet the demanding domestic goal of smoke-free status by 2030, taking advantage of smoke-free alternatives to cigarettes.

    3. A recognition that the critical public health distinction is not between tobacco and non-tobacco products, but between combustion and non-combustion products. The public health problem is overwhelmingly smoking, and all smoke-free products are beneficial.

    4. The principles of proportionality and non-discrimination in regulation and a sound approach to precaution and uncertainty. The regulation of tobacco and nicotine products should be "risk-proportionate".

    5. The importance of the credibility, responsibility and trust in FCTC institutions and the accountability of these agencies to their stakeholders, including the UK government.

    6. Openness, transparency and diversity. FCTC needs much greater intellectual diversity in its observers and greatly increased media access. The UK delegation should reflect broader interests and should consider including public health and consumer representatives.

- It is premature to reopen the text of the FCTC, and this would be counterproductive at this point. The challenge for COP-9 and COP-10 is to shape the 'discourse' surrounding the FCTC and win over individuals and organisations to a more constructive and pragmatic approach to tobacco harm reduction and vaping.

1. What problems are FCTC policies and positions supposed to address

A brief introduction to the Framework Convention on Tobacco Control is provided at Annex 1. The body of this document follows the five themes of the APPG Inquiry.

1.1 FCTC objective

The objective of the FCTC. The objective is expressed in Article 3.[2]

> *The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.*

This text is not as clear as it could be. The convoluted framing mixes aims, causes and means. As expressed, it does not easily allow for the idea that some tobacco products are much less risky than others and that low-risk products (snus, heated tobacco) could substitute for high-risk products. So aspects of this objective – the proposed means - are internally contradictory. Contradictions should be resolved by reference to the overriding primary objective:

> *protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke*

A focus on smoked tobacco. The objective essentially establishes a broad harm reduction agenda. Because the overwhelming cause of the harms described here comes from smoked tobacco, it follows that *smoked tobacco* should be the primary focus of the FCTC. It is not focussed on creating a tobacco-free or nicotine-free society, destroying the tobacco industry, or preventing people from reducing risk while continuing to use nicotine.

Harms arising from policies – taking an integrated approach to harm reduction. A significant omission is a recognition that *tobacco policies* can cause harms. For example, taxes can be economically painful and regressive; anti-smoking campaigns can cause stigma; and measures taken to reduce the appeal of new low-risk entrants can protect high-risk incumbents. Harms can also arise from inhibiting people from exercising their autonomy and volition or degrading their experience or something they like. The approach to harm-reduction should be broad and integrated across the range of harms arising from tobacco and nicotine use.

1.2 How the FCTC, COP and WHO work against vaping and tobacco harm reduction

So far, no amendments have been made to the FCTC text itself. Consequently, it represents a view of tobacco control formed over the period it was negotiated, from the first working group meeting in October 1999 to the completion of the final text in June 2003. Though tobacco harm reduction is

[2] Framework Convention on Tobacco Control., WHO, 2003 [link]

mentioned within the definition of tobacco control in Article 1.d of the FCTC[3], this was not a significant source of discussion or negotiating effort when the FCTC text was negotiated and has not found any expression subsequently.

However, the static nature of the FCTC text does not stop the Convention from influencing the global approach to 'ENDS' (vaping products) or other recent innovations, even though some of these fall outside the literal scope of the FCTC. There are several ways in which WHO and the FCTC Secretariat influence policy on tobacco harm reduction:

- **Decisions of the COP**. These are consensus statements reached by the Parties and agreed at COP meetings. They are generally non-binding position-taking (e.g. "invites parties to consider…"), but they have the effect of 'normalising' favoured policies. For example, see the hostile decisions on ENDS at COP-6[4] and COP-7[5] and on 'novel and emerging tobacco products' at COP-8.[6] The decisions also request further information from WHO or the Secretariat: for example, the COP-7 decision on ENDS requested a new paper for COP-8.
- **Papers to support COP meetings**. The WHO or Secretariat prepare documents on issues on the agenda for COP meetings, sometimes in response to decisions made at prior COPs. There have been papers on ENDS at COP-6[7], COP-7[8] and COP-8[9]. These shape the discussion and usually come with explicit or implicit policy recommendations. We see the FCTC steadily advancing a prohibition agenda through these papers – though uncritically, and without considering unintended consequences.

---

3 FCTC 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*; [link]

4 FCTC/COP6(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems, October 2014. [link]

3. INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health; 4. URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS;

5 FCTC/COP7(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems, 12 Nov 2016. [link]

2. *INVITES Parties to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives*;"

6 FCTC/COP8(22) Novel and emerging tobacco products, 6 October 2018 [link] Paragraph 5 essentially applies all FCTC provisions to heated tobacco products, without assessing whether this would be potentially harmful to public health by reducing switching from high-risk to low-risk products..

7 FCTC/COP/6/10 Rev.1. Electronic nicotine delivery systems Report by WHO. September 2014 [link]. Though sceptical in its approach to harm reduction, this document is notable for its efforts to cite sources and debate the evidence: an approach that was dropped in subsequent COP papers and not reflected in the decision at COP-6

8 FCTC/COP/7/11 Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report by WHO, August 2016. [link] This document used a linguistic formulation to imply that prohibition of ENDS was the default regulatory option. Paragraphs 29 and 30 start: "*Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options*:"

Note: see Annex 3 for a critique of this paper by experts at the UK Centre for Tobacco and Alcohol Studies

9 FCTC/COP/8/10 Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) 66 Report by the Convention Secretariat, June 2018 [link]. This paper pursues the prohibition agenda more forcefully, for example by providing a table of countries that have done this. It does not debate the merits – and obviously unintended consequences of doing it.

- **Guidelines**. These are guidance documents approved by decisions of the COP that provide advice on the implementation of the Articles of the FCTC. For tobacco harm reduction, the most notable guidelines are those on the implementation of Article 5.3.[10] In the case of Article 5.3, the guidelines went far beyond the original FCTC article, declaring that the tobacco industry interests were in a 'fundamental and irreconcilable conflict' with public health. In doing so, they implicitly rule out tobacco harm reduction. By asserting that the industry's interests align with tobacco harm reduction, anti-vaping activists imply that tobacco harm reduction is irreconcilable with public health. Many perverse consequences arise from the over-zealous application of that principle.[11]

- **WHO tobacco regulation advisory committee**. The WHO Study Group on Tobacco Product Regulation (often known as 'TobReg') is a long-standing scientific advisory committee and has produced useful reports in the past.[12] However, its advice is a product of the group's membership, and this has changed over time. A new TobReg report is in the pipeline but has so far not been published. However, its recommendations were summarised in a paper for the February 2021 Executive Board of WHO.[13] These recommendations are *extremely contentious* but were provided to the Executive Board without any supporting evidence or indication that these measures would be controversial and have a weak evidence base and potential unintended consequences. The recommendations, if adopted, would be deeply damaging to vaping and tobacco harm reduction. The recommendations presented to the Executive Board are reproduced in Annex 2.

- **Scientific papers**. The WHO or the Secretariat can commission advice on scientific or regulatory issues, and the Parties can request technical papers via COP Decisions. WHO staff also produce papers for scientific journals, and the Director-General wrote a commentary for *The Lancet* in 2019. [14] His piece was packed with misleading science and flawed reasoning. The Director

---

10 FCTC/COP7(3) Guidelines for implementation of Article 5.3. Guidelines on the protection of public health policies with respect to tobacco control from commercial and other vested interests. November 2008 [link]

Principle 1: There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.

11 Clive Bates, *The irreconcilable conflict principle*. Tobacco Reporter. 1 November 2020 [link]

12 WHO Study Group on Tobacco Product Regulation (TobReg): History and objectives, WHO website [link]

13 EB148/27 Report on meetings of expert committees and study groups, Report by the Director-General [link] Paragraph 26-32 Tobacco Product Regulation: Report of the tenth meeting of the WHO Study Group on Tobacco Product Regulation, virtual meeting, 28 September–2 October 2020

14 Ghebreyesus TA. [Director General WHO] Progress in beating the tobacco epidemic. *Lancet* 2019 394(10198):548–549. [link]. This makes multiple misleading and contested statements drawing on flawed or debunked studies:

Although tobacco and related industries promote these products as tools for quitting, the evidence does not support their use as part of population-based cessation strategies. The aerosols of ENDS contain toxic chemicals that are harmful to both users and non-users and are, therefore, products that come with health risks of their own. And in combination with smoking, which is the practice with the majority of ENDS users, the health effects of two or more products are combined. ENDS on their own are associated with increased risk of cardiovascular diseases and lung disorders and adverse effects on the development of the fetus during pregnancy. For adolescents, the addictive nature of nicotine can lead to dependence and may harm adolescent brain development, including reduced activity in the prefrontal cortex. Use of ENDS could also lead to a new generation of nicotine and tobacco users, as seen in some countries, especially given how these products are marketed to young people. Although the specific level of risk associated with ENDS has not yet been conclusively estimated, ENDS are undoubtedly harmful, should be strictly regulated, and, most importantly, must be kept away from children. It is also incorrect to think that heated-tobacco products are the answer, as they simply move tobacco users from one harmful tobacco product to another.

General's paper was criticised for its hostility to innovation and failure to provide a reasoned analysis of risks (which are negligible) and opportunities (substantial)?[15]

- **Global Tobacco Regulators Forum.** WHO convenes a forum for tobacco regulators, the Global Tobacco Regulators Forum (GTRF).[16] The forum is funded by the US Food and Drug Administration, which has an exceedingly heavy-handed approach to regulation. However, the WHO uses this forum to influence regulators. Though its proceedings are kept secret, leaked papers prepared by WHO EMRO regional office revealed promotion of regulatory proposals for vaping and heated tobacco products that are extremely hostile through this forum.[17]
- **Advocacy by the FCTC Secretariat and WHO**. The FCTC Secretariat and WHO signal their policy preferences in many ways through various forms of advocacy. This advocacy includes speeches,[18] reports,[19] social media posts[20], WHO awards[21], WHO events,[22] and web resources such as the e-cigarette Q&A.[23] The original version of the E-cigarette Q & A was so deeply biased

---

15 Beaglehole R, Bates C, Youdan B, Bonita R. Nicotine without smoke: fighting the tobacco epidemic with harm reduction *Lancet*. 2019 394(10200):718–720. [link]

Vaping and other smoke-free products have the potential to reduce the enormous harm of smoked tobacco products. The stakes of getting policy responses to smoke-free products wrong are high, especially if such restrictions stop millions of the world's smokers accessing safer alternatives. It is disappointing that in its latest tobacco report, WHO clings to outdated orthodoxy when it could embrace innovation. Equating smoke-free products with cigarettes only serves to protect the stranglehold of the cigarette trade on the world's nicotine users and will nullify the potential of modern tobacco harm reduction strategies

16 Global Tobacco Regulators Forum, Terms of engagement, accessed 18 February 2021 [link]

17 Clive Bates, Leaked papers: WHO to intensify its pointless and destructive war against innovation - expect many dead, 9 September 2019. [link]

18 Dr Adriana Blanco Marquizo, Head of FCTC Secretariat. 15 year of the entry into force of the WHO Framework Convention on Tobacco Control. 5 March 2020 [link]

As known to many of us, the youth are the favorite target of the tobacco industry, especially through the novel and emerging tobacco products that are flooding the markets. We must act now. That is why, youth will be the focus of the ninth session of the Conference of the Parties to the WHO FCTC

19 WHO Report on the Global Tobacco Epidemic, 2019. [Archive link]

These products [ENDS, heated tobacco] are aggressively marketed or promoted as cleaner alternatives to conventional cigarettes, as smoking cessation aids, or as "reduced risk" products. They have proliferated in several markets around the globe and present a unique challenge to regulators. While some of these products have lower emissions than conventional cigarettes, they are not risk free, and the long term impact on health and mortality is as-yet unknown. There is insufficient independent evidence to support the use of these products as a population level tobacco cessation intervention to help people quit conventional tobacco use. HTPs contain tobacco, and the use of these products constitutes tobacco use, thereby contributing to the burden of tobacco in countries where they are sold. In addition, the available evidence does not support the tobacco industry's claim that these products are less harmful relative to conventional tobacco products

20 WHO SEARO Tweet: *WHO congratulates #India for banning #ecigarettes* 18 September 2019 [link]

21 World No Tobacco Day Awards 2020 [link]. Finland was rewarded for its exemplary hostility to e-cigarettes [link]

WHO is pleased with Finland's exemplary actions, which have helped to reduce the appeal of e-cigarettes among young people in particular. Finland has strictly regulated the use of e-cigarettes and prohibited characterising flavours in liquids for e-cigarettes.

22 WHO World No Tobacco Day, 2020 [link] – key theme:

Tobacco and related industry tactics to attract younger generations: Flavours appealing to children in smokeless tobacco, shisha and e-cigarettes.

23 WHO web site Q & A. E-cigarettes 29 January 2020. [link] accessed 17 February 2021. For example:

2. *Are e-cigarettes more or less dangerous than conventional tobacco cigarettes? It is difficult to generalize on the risk to health of ENDS as compared with cigarettes or other tobacco products, as this is contingent on a range of factors. Both tobacco products and ENDS pose risks to health. The safest approach is not to use either*

and flawed that even WHO found it necessary to replace it within a few days[24]. These activities are all hostile to vaping and tobacco harm reduction. Positions taken by WHO regional offices can also be influential.

Figure 1: WHO tweet following India's ban on e-cigarettes

India has over 100 million smokers and 200 million smokeless tobacco users. The WHO is congratulating the Indian government for denying these tobacco users safer alternatives.

The WHO and the FCTC Secretariat are notionally there to serve the parties to the FCTC and members of the World Health Assembly, but they are far from being passive policy-takers. They play a considerable influencing role too. This begs the question: how do the WHO and the FCTC Secretariat form their positions, who scrutinises them, and how are they accountable? There is little doubt that the FCTC COPs would be quite different if WHO and the FCTC Secretariat had a different, more constructive and pragmatic, perspective on tobacco harm reduction.

1.3 The UK approach to tobacco harm reduction differs sharply from the FCTC

The UK and especially England, take a much more positive approach to vaping and tobacco harm reduction. There are many compelling examples of the UK/England approach showing a highly positive approach.[25]

The government's stated aim is to go smoke-free and make smoked tobacco "obsolete" by 2030. This is generally taken to mean reducing adult smoking prevalence to below 5%. The goal was raised in a July 2019 government consultation on its preventative health approach in the following form.[26]

[24] Clive Bates, WHO fails at science and fails at propaganda, Counterfactual. January 2020. [link]

[25] See Clive Bates. Vaping and tobacco harm reduction – highlights from England. The Counterfactual. [link]

[26] Cabinet Office & Department of Health and Social Care: Advancing our health: prevention in the 2020s. July 2019. [link]

> We are setting an ambition to go 'smoke-free' in England by 2030. This includes an ultimatum for industry to make smoked tobacco obsolete by 2030, ***with smokers quitting or moving to reduced-risk products like e-cigarettes***. Further proposals for moving towards a smoke-free 2030 will be set out at a later date. (emphasis added)

The government clearly intends to make reduced-risk products integral to its strategy – precisely the opposite of the approach from WHO, the Secretariat and COP. This is likely to be essential given that the goal requires cutting smoking prevalence by approximately two-thirds in the 2020s, compared to the approximately one-third cut achieved in the 2010s.

This is built on a foundation of science, policy analysis and organisational support. For example:

- Department of Health, Tobacco Control Plan (2017)[27] and Delivery Plan (2018)[28]
- Public Health England E-cigarette evidence reviews (2105-2020)[29]
- NHS guidance on e-cigarette[30]
- E-cigarette consensus statement[31]

1.4 Why the FCTC does not work for vaping products – insensitive to risk

There is no text in the FCTC that relates to or anticipates the rise of low-risk consumer alternatives to cigarettes. This starts with the scope of the FCTC, which does not include consumer nicotine products. However, the parties have determined that they should bring these products into the norm-setting process of the FCTC, and they are free to do this if they do it by consensus.

The lack of risk-sensitivity is evident, even though smokeless tobacco products such as snus had an observable harm reduction effect that was clear at the time the text was finalised. The European Union ban on snus and the American activist position that there was no meaningful difference in risk contributed to this design failure. Then, as now, many tobacco control advocates simply did not

---

[27] Department of Health, Towards a Smokefree Generation, the tobacco control plan for England. [link]

The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products.

See blog on the plan: Clive Bates, English tobacco control plan embraces tobacco harm reduction - world first. July 2017. [link]

[28] Department of Health, Tobacco control plan: delivery plan 2017 to 2022, 2018 [link]

Continue to provide smokers and the public with clear, evidence based and accurate information on the relative harm of nicotine, e-cigarettes, other nicotine delivery systems and smoked tobacco, to enable informed decisionmaking

Support local areas looking to implement local smokefree policies differentiating the levels of harm caused by existing tobacco products including e-cigarettes and other novel products

[29] Public Health England E-cigarette evidence reviews 2015-2002. [link]

[30] NHS Using e-cigarettes to stop smoking [link] Smokefree NHS E-cigarettes/vapes Q&A. [link]

[31] Joint statement on e-cigarettes by Public Health England and other UK public health organisations, E-cigarettes: a developing public health consensus. [link] Signed by: Public Health England, Action on Smoking and Health, Association of Directors of Public Health, British Lung Foundation, Cancer Research UK, Faculty of Public Health, Fresh North East, Healthier Futures, Public Health Action (PHA), Royal College of Physicians, Royal Society for Public Health, UK Centre for Tobacco and Alcohol Studies, UK Health Forum

wish to acknowledge that it was possible to use tobacco or nicotine with very low risks. This is because harm (arising from smoke inhalation) is the key argument against nicotine use.

As a result, there is no *architecture* in the FCTC that allows for differential measures according to radically different levels of risk. The FCTC text is always exhorting the parties to go as far as possible within the confines of national legislation or constitutional constraints. There is no text at all that reflects the pronounced difference in risk between combustible smoked products and smoke-free products (vaping, heated and smokeless tobacco and nicotine pouches). There is no recognition that policymakers should use different measures to reflect different risks.

1.5 Why the FCTC does not work for vaping products – unintended consequences

As a result, there is also nothing that recognises that policies designed to restrict low-risk alternatives to smoking may have unintended and perverse consequences, as carefully outlined by the Royal College of Physicians in 2016:

> 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, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)

These considerations ("getting this balance right") do not find any expression in the FCTC text and do not feature in COP decisions or papers. See the discussion of unintended consequences in section 4 below.

1.6 Why the FCTC does not work for vaping products – no consensus on policy or science

The original concept of the FCTC was to generalise established policies for which the scientific and public health community broadly agreed. These are supposed to be effective and proportionate public health measures that every government ought to take in some form. However, for vaping, there is no consensus on what these policies should be. Many of the policy measures so far adopted or proposed are strongly contested – either because they have a contested science base (for example, claiming a gateway effect), they are prone to unintended consequences (for example, relapse to smoking), or they encode particular priorities or objectives (for example, a focus on nicotine use rather than disease). So this is not about normalising and creating an authorising environment for established policies but promoting one side in a debate where the science and policy is highly contested. There is little data on the effectiveness or harms arising from policy choices. The FCTC COP – a theatrical setting for health bureaucrats – is wholly unsuited to advancing new policies and measures that have not been tried, tested or validated.

1.7 Why the FCTC does not work for vaping products – excluding legitimate perspectives

Instead of recognising that the debate over harm reduction is polarised and polarising, the FCTC has simply tried to exclude one side of this debate, by its system for approving observers, the way it commissions scientific advice and who it chooses to listen to, the biases in its COP papers and advocacy. The WHO is wide open to conflicts for interest, for example, through its support from Bloomberg Philanthropies. Michael Bloomberg is on record favouring outright prohibition of vaping.

2. Justification of proposals

The quality of justification of proposals implicitly or explicitly advanced by WHO and the FCTC Secretariat is wholly inadequate. For example, in 2016, WHO published four documents on ENDS as background for its COP-7 paper on ENDS.[32] However, these were commissioned from hand-picked tobacco control activist-academics and not subject to peer review or challenge – and the biases were obvious and pronounced. The resulting WHO paper for COP-7 was subject to a blistering critique by UK experts from the UK Centre for Tobacco and Alcohol Studies.[33] The executive summary of this critique is available in Annex 3.

Almost all policymaking involves trade-offs of some sort – between the interests of different population groups and between different public policy objectives. Almost all policymaking is subject to risks of unintended perverse consequences. The WHO and the FCTC Secretariat act as though they are oblivious to these basic policymaking concepts: they are never adequately reflected in the papers and other WHO and the Secretariat communications.

This is most obviously the case with outright prohibitions of vaping, which WHO both openly and tacitly supports. It never cautions about the risks of prohibitions, despite the well-known effects of drug and alcohol prohibitions and the dismal experience of tobacco prohibition where it has been tried, for example, in South Africa[34] and Bhutan.[35] In its report on Bhutan, WHO summarised the situation:

> Despite efforts on the part of relevant authorities, a tobacco black-market, as initially feared, has emerged. Shops that thrive on illicit sale of tobacco and its products have found a way around the law. A steady stream of loyal customers continue to sustain these shops that have, over the years, grown into a network of black market. Recent studies have found Bhutanese youth, who are among the highest in the region to be using tobacco and its products, to be at the centre of this burgeoning contraband good. (WHO 2020)

WHO appears to have learnt nothing from this experience and is determined to repeat the development of black markets for vaping products by endlessly advancing the case for prohibition.

The WHO does not approach its role as an impartial mediator trying to secure a healthy policy discourse but as an advocate with talking points and preferred policy postures. To support its policy agenda, it selectively uses and misuses scientific citations to argue its case. This represents a fundamental failure in an international agency and convention secretariat.

---

[32] Background papers to the WHO report on electronic nicotine delivery systems and electronic non-nicotine delivery systems (ENDS/ENNDS). [link] Commissioned as background to Document FCTC/COP/7/11 [link].

[33] Britton J, Bogdanovica I, McNeill A, Bauld L. UKCTAS Commentary on WHO Report on Electronic Nicotine Delivery Systems and Electronic Non-nicotine Delivery Systems UKCTAS, 26 October 2016. [link] Critique of FCTC COP-7 paper on ENDS FCTC/COP/7/11 [link]

[34] Van Walbeek, C., Filby, S. and van der Zee, K. 2020.Lighting Up the Illicit Market: Smoker's Responses to the Cigarette Sales Ban In South Africa. Report, Research Unit on the Economics of Excisable Products (REEP), University of Capetown, May 2020. [link - PDF]

[35] World Health Organization. Country Office for Bhutan. (2020) The Big Ban: Bhutan's journey towards a tobacco-free society. [link]

3. Transparency and consultation

The FCTC COP has developed highly restrictive and opaque practices that ensure that it operates in an echo chamber populated by compliant and sycophantic observers. It chooses so-called "civil society" organisations according to their willingness to support the FCTC and contribute to its implementation. Any NGO can be refused observer status at the request of a single party. NGOs are required to file reports on their activity with the Secretariat. The Secretariat then makes recommendations about who should be granted observer status, retained, or expelled. The "civil society" organisations chosen are mainly grant-funded tobacco control organisations, often with bizarre views about public health that bear little relationship to the norms in the countries they come from or anything like good practice in policy and science.

This insularity is not a feature of all UN treaties. A comparison with the UN Framework Convention on Climate Change is instructive.

FCTC (tobacco control)	UNFCCC (climate change)
Number and type of observers 21 non-governmental organisations (NGOs) [source] 28 Intergovernmental organisations (IGOs) [source] The Framework Convention Alliance (FCA) is a holding group for 300 smaller organisations. Any can attend under the FCA umbrella - but they must meet FCA's membership requirements and support its tobacco control vision and mission. No business or consumer organisations have been granted observer status. No organisations critical of the FCTC, its interpretation by COP, WHO, the Secretariat, any parties or tobacco control generally have been admitted. They are ruled out by selection criteria, veto and reporting requirements.	**Number and type of observers** As of 2018, over 2,200 NGOs and 130 IGOs are admitted as observers. The NGOs represent a broad spectrum of interests. They include representatives from business and industry, environmental groups, farming and agriculture, indigenous populations, local governments and municipal authorities, research and academic institutes, labour unions, women and gender and youth groups. [source] [list] Includes Business NGOs likely to be hostile to the aims of the UNFCCC, such as the World Coal Association, International Association of Oil and Gas Producers (IOGP), Organisation of International Automobile Manufacturers and International Council for Mining and Metals (ICMM). Does not admit for-profit businesses.
Criteria for observer status Applicants must be international and must have aims and activities be "in conformity" with the FCTC "spirit purpose and principles". This effectively excludes critics. Rules of procedure 31(2) *31.2. ... international and regional non-governmental organisations whose aims and activities are in conformity with the spirit, purpose and principles of the Convention, may apply for observer status, which may be granted by the Conference of the Parties, based on the report of the Secretariat, and taking into account the 17th and 18th preambular paragraphs as well as Article 5.3 of the Convention. Such applications should be submitted to the Secretariat not later than ninety days before the opening of the session.*	**Criteria for observer status** Applicants may be a national body and only have to show they have relevant knowledge, not necessarily a particular policy perspective. UNFCCC Article 7(6) *Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by the Convention, and which has informed the Secretariat of its wish to be represented at a session of the Conference of the Parties as an observer, may be so admitted unless at least one third of the Parties present object.*

FCTC (tobacco control)	UNFCCC (climate change)
Decision-making on observer status The Secretariat reviews conformance with criteria and makes a recommendation to the COP, which has to agree by consensus. As a result, any party has a veto. Rules of procedure 31.2 *"granted by the Conference of the Parties, based on the report of the Secretariat, and taking into account the 17th and 18th preambular paragraphs as well as Article 5.3*	**Decision-making on observer status** The Secretariat reviews applications and makes recommendations to the COP based on capabilities. An applicant can only be blocked by one-third of the parties. UNFCCC Article 7(6) *may be so admitted unless at least one third of the Parties present at the session object*
Qualifiers Observers should contribute to 'tobacco control' efforts. From rule 31.2 on observers- referring to FCTC text **17th recitation:** *Emphasising the special contribution of non-governmental organisations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,*	**Qualifiers** None
Reporting requirement The accredited NGOs must provide reports on their activities in support of the FCTC implementation. These form the basis of their continued participation Rules of Procedure rule 31.3 *31. 3. The Conference of the Parties shall review the accreditation of each non-governmental organisation at any of its regular sessions and thus determine the desirability of maintaining its observer status.* What this means was set out at COP6 *NGOs with observer status to the COP will be requested to submit a report on their activities to the Secretariat every two years. Such reports shall be submitted at the latest six months before the opening of the next session of the COP. In this regard, the COP adopted a standard reporting questionnaire to be used by NGOs which will be available on web-based format in due course.* (FCTC/COP/6/26) See NGO reports for 2020.	**Reporting requirement** None

Admission to the FCTC as an observer is problematic in several ways:

- FCTC observers must support the aims of the Convention. It is not enough that they are affected by it or that they may be well-informed critics. UNFCCC observers have to be 'qualified in the matters covered by the Convention'. This is a radically different approach, and it means that a much broader range of stakeholders has access to the meetings and delegates: a far more democratic process.

- FCTC requires observer organisations to be transnationals. UNFCCC admits national bodies. FCTC has a loophole for small organisations it finds supportive, but not for small consumer organisations or individuals who have specialised knowledge but do not operate internationally.
- FCTC observers must be approved by consensus by the Parties (i.e. each Party has a veto, whereas UNFCCC requires one-third of the parties to block an observer. This FCTC has a strong filter against critics, including critics of any party. This is a very tame view of 'civil society'.
- FCTC emphasises contribution to tobacco control. UNFCCC does not require any particular approach. FCTC requires its observers to be working on behalf of the treaty. Again, being affected by it or having critical views is not enough.
- FCTC requires observers to report on activities undertaken to implement the Convention. UNFCCC does not require reporting by observers or expect them to implement the Convention. The FCTC effectively enforces compliance among its "civil society" observers by demanding reports on their activity and commitment, backed by the threat of deselection.
- The "civil society" organisations involved have no incentives to press for greater transparency, broader consultation, more comprehensive access or all the usual things that we would expect genuine civil society organisations to pursue. They are compromised beneficiaries of the FCTC's exclusive, undemocratic and unaccountable *modus operandi*.

There is no point in any organisation interested in tobacco harm reduction or concerned about the perverse consequences of FCTC measures trying to gain access to the meetings. The COP and Secretariat have established insurmountable barriers to access and a selection process that will only admit compliant and obedient organisations to participate in the proceedings.

4. The threat of unintended consequences arising from FCTC decisions

The fundamental challenge with regulating a low-risk product (e-cigarettes) that is a substitute for a high-risk product (cigarettes) is that excessive regulatory measures will have the effect of protecting the cigarette trade from competitive pressure. E-cigarettes are a low-risk entrant facing a high-risk incumbent. As the Royal College of Physicians put it:[36]

> if [a risk verse 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, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)

There is no sign that WHO, the FCTC Secretariat or the network of influencers that surround the FCTC have understood and internalised this critical insight. However, it is not hard to imagine the perverse effects of applying FCTC policies to vaping and other THR products.

[36] Tobacco Working Group. Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [link]

Measure	Nearest relevant FCTC Article	Plausible unintended consequence of applying excessive measures to vaping
Taxation	Article 6	Fewer smokers switch, more vapers relapse, more continue dual use, black market activity
Illicit trade	Article 15	Vaping supply concentrates to tobacco multinationals who already have the track and trace infrastructure for tobacco products
Advertising	Article 13	Protects incumbent cigarette trade from entrant vaping products, prevents communication of advantages and innovation
Warnings	Article 9	Disincentivises switching, plays on fears, by being physically large and bold or graphic, implicitly overstates the risk
Public places	Article 8	Mandatory bans remove a significant advantage of vaping over smoking, situate vapers with smokers, stigmatise vaping
Plain packaging		Prevents brand building and degrades the appeal of an alternative to smokers
Ingredients	Article 9	May compromise pharmacokinetic effects and make the products less satisfying than smoking
Flavours	Article 9/16	Flavour bans remove a crucial element of the appeal to smokers and how smokers migrate away from tobacco
Flavour descriptors	Article 16	Prevents communication of brand value and appeal to smokers
Age restrictions	Article 16	Could prevent smokers under 18 or 21 from accessing much safer products and increase teenage smoking.
Internet sales	Article 13	Denies vapers the full range of liquids and technologies, reducing choice to commodity products sold in convenience stores
Product standards	Article 9	Degrades appeal an imposes a brake on innovation

5. Are the FCTC and COP fit for purpose?

Is the FCTC delivering on its promise? The FCTC itself reflects a model of tobacco control that was formed more than twenty years ago. The marketplace for nicotine has changed very significantly since then, creating new opportunities, new risks, and also new risks from poorly designed policies designed to address the products introduced in the last decade.

How should vaping and other reduced-risk products be regulated? The appropriate form of regulation would be 'risk proportionate', meaning the degree of regulation (costs, obligations, restrictions etc.) should reflect risk and opportunity. More stringent regulation should be applied to the riskiest products. Less stringent or enabling regulation should be applied to the low-risk alternatives that can be net beneficial for health.

Such a scheme could look as outlined in the following table.

Figure 2: Risk proportionate regulation - an illustration

Measure	Nearest relevant FCTC Article	Smoking products	Smokefree products
Taxation	Article 6	Relatively high taxes	Low or zero tax (VAT or sales tax only)
Illicit trade	Article 15	Track and trace (FCTC protocol)	Complaint-driven
Advertising	Article 13	Prohibit other than within trade	Control themes and placement
Warnings	Article 9	Graphic warnings depicting disease	Messages encouraging switching
Public places	Article 8	Legally mandated controls	Up to the discretion of the owner
Plain packaging		Yes	No
Ingredients	Article 9	Control reward-enhancing additives	Blacklist material health hazards
Flavours	Article 9/16	Prohibit	Allow, restrict ingredients that could be hazardous for inhalation
Flavour descriptors	Article 16	Not applicable if flavours banned	Control appeal to youth/trademarks
Age restrictions	Article 16	No sales to under-21s	No sales to under-18s
Internet sales	Article 13	Banned	Permitted with age controls
Product standards	Article 9	Control risks and reduce the appeal	Control risks

Should the FCTC be amended? In an ideal world, the FCTC should be recast to recognise the very large differences in risk between tobacco products and exploit the harm reduction opportunities while managing any residual risks. I do not recommend attempting to amend the FCTC. Given the disposition of the COP, the WHO, the FCTC Secretariat, and the so-called civil society participants, any change is more likely to bake in language that is hostile to tobacco harm reduction.

How could risk proportionate regulation be introduced? The essential means to shift the FCTC towards a better public health model embracing tobacco harm reduction would be initially through the COP working papers, the COP decisions, guidelines, the scientific and advocacy stance of WHO. All the mechanisms currently adopting a hostile approach to tobacco harm reduction and vaping will need to change to reflect a more pragmatic approach to tobacco harm reduction.

Annex 1: Introduction to the Framework Convention on Tobacco Control

Background to the Framework Convention on Tobacco Control

The Framework Convention on Tobacco Control. The FCTC is the only international treaty brokered by the World Health Organisation. The text was finalised and open for signature and ratification on 30 June 2003. It entered into force on 27 February 2005 after it had been ratified by 40 parties. The first Conference of the Parties was arranged for the following year, 2006, and scheduled for every two years since. Currently, there are 182 Parties covering more than 90% of the world population. The most notable exception is the United States, which is not and never has been a party to the FCTC.

The Conference of the Parties. The decisions and policymaking in FCTC are the responsibility of the parties to the FCTC, and the policymaking forum is the Conference of the Parties, which occurs every two years. The FCTC was incubated by WHO, but it now has a separate institutional foundation. It is managed by the FCTC Secretariat, which is independent of the WHO and funded directly by the parties to the FCTC. The WHO retains a tobacco programme, the *Tobacco Free Initiative*, financed from member states of the WHO and voluntary contributions, including from private foundations. The WHO Tobacco Free Initiative is part of the Noncommunicable Diseases and Mental Health cluster of WHO.

COP-9. The FCTC's Ninth Conference of Parties (COP-9) is due to be held in the Netherlands from 8-13 November 2021, following a postponement from 2020 due to COVID-19. At this stage, in February 2021, we can only estimate the likely outcomes of COP-9 by looking at the positions adopted by various stakeholders and the general direction that the FCTC has been taking. New policy papers are usually published sixty days before the COP meetings. COP-9 is scheduled to start on 8 November 2021, so new documents should be available on or before 6 September 2021.

The Protocol on Illicit Trade. The FCTC has a subsidiary instrument that functions like a separate treaty, the Protocol to Eliminate Illicit Trade in Tobacco Products. The protocol develops Article 15 of the FCTC (Illicit Trade) using the machinery of FCTC Article 33 (Protocols). The protocol entered into force in 2018. The protocol has a periodic Meeting of the Parties (MOP), which follows straight after COP meetings. The first MOP was in 2018, the second MOP (MOP-2) will be directly after COP-9, 15-17 November 2021.

An example of how the FCTC works: tobacco taxation

The FCTC does not generally create strong, legally-binding obligations, and it has no enforcement mechanism or sanctions. The underlying concept of the FCTC is to normalise and generalise across all countries proven anti-tobacco policies. Most international treaties regulate relations between states, but FCTC includes norm-setting for purely domestic policy (smoke-free places) as well as measures that facilitate the management of transboundary issues, such as illicit trade or aspects of advertising and promotion. The idea was to help, especially developing countries, to implement policies and overcome tobacco industry pressure through a kind of international solidarity. The

FCTC contributes to establishing what scholars call an "authorising environment".[1] This enables officials to press for domestic measures with the endorsement of WHO and the backing of a treaty, though without creating a firm obligation to implement such measures.

Tax policy provides an example of how the FCTC works. The FCTC at Article 6 recognises that its parties jealously guard tax-setting. So it raises tobacco taxation as a relevant policy but does not make it mandatory or set a preferred tax level. Article 6 provides a preambular statement and then a range of qualifications while aiming to establish a norm.[2]

> 1. The Parties recognise that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons.
>
> 2. Without prejudice to the sovereign right of the Parties to determine and establish their taxation policies, each Party should take account of its national health objectives concerning tobacco control and adopt or maintain, as appropriate, measures which may include: […]

The norm-setting continues as the FCTC develops. The original Article 6 is subsequently supplemented with 'guidelines', and these are endorsed by a decision of the COP (at COP-6 in 2014)[3]. These guidelines concentrate on tax design and administration, but they stop short of recommending tax *levels*. However, the guidelines do include a footnote pointing to a WHO technical manual on tobacco tax administration. This manual recommends that tobacco tax should account for at least 70% of the retail price.[4] So without making this mandatory, the FCTC and WHO try to normalise this tax policy and set a benchmark tax level – providing an authorising environment for tax officials who can draw on the FCTC, the guidelines, and the technical manual as a source of legitimising authority, depending on how far they want to go.

Where the FCTC does have firm requirements, these tend to relate to 'soft' commitments like reporting to the COP, having a tobacco control plan, or making financial commitments. There are some cases where they do endorse firm policy measures for which there was already near-universal agreement and no costs to the parties. For example a mandatory minimum warning size of 30% of the principal pack surface is established in Article 11(1)(b)(iv).

---

1 For example, see Andrews M, Pritchett L, Woolcock M. Building State Capability: analysis, evidence, action. Managing your authorizing environment Chapter 10. Oxford University Press; 2017 [link]

2 See full text for FCTC Article 6 [link]

3 WHO Framework Convention on Tobacco Control, Conference of the Parties to the WHO Framework Convention on Tobacco Control, sixth session. (2014). DECISION(FCTC/COP6(5): Guidelines for implementation of Article 6 of the WHO FCTC (Price and tax measures to reduce the demand for tobacco) [link]

4 See: WHO technical manual on tobacco tax administration, 2010 [link]

Annex 2: TobReg recommendations presented to the WHO Executive Board[1]

29. The main recommendations to policymakers and all other interested parties include, but are not limited to, the following:

(a) to maintain focus on evidence-based measures to reduce tobacco use as outlined in the WHO Framework Convention on Tobacco Control and seek to avoid being distracted from these actions by the promotion of novel tobacco products such as heated tobacco products;

(b) to use existing regulations for tobacco products to regulate heated tobacco products (including the device) and consider broadening the scope of the existing regulations, where regulatory loopholes may be exploited by the tobacco industry, including in countries in which these tobacco products are currently not legally available;

(c) to apply the most restrictive tobacco control regulations to heated tobacco products (including the device), as appropriate within national laws, taking into account the need for a high level of protection for human health;

(d) to prohibit all manufacturers and associated groups from making claims about reduced harm of heated tobacco products, compared with other products, or portraying heated tobacco products as an appropriate approach for cessation of any tobacco product and ban their use in public spaces unless robust independent evidence emerges to support a change in policy;

(e) to ensure that the public is well informed about the risks associated with use of heated tobacco products, including the risks of dual use with conventional cigarettes and other smoked tobacco products, and also their use during pregnancy; to correct false perceptions, counter misinformation and clarify that reduced exposure does not necessarily mean reduced harm;

(f) to rely on independent data and to support continuing independent research on the public health impact of heated tobacco products, along with critically analysing and interpreting tobacco industry-funded data, including but not limited to research data pertaining to emissions and toxicity of heated tobacco products and associated exposures and effects in users and non-users;

(g) to require tobacco manufacturers to disclose all product information – including product design, chemical profile, total nicotine content, nicotine forms, toxicity, other findings of product testing and testing methods – to appropriate regulatory agencies at least once a year; any modifications to products should require an updated report;

(h) to ban all activities related to the commercial marketing of electronic nicotine delivery systems, electronic non-nicotine delivery systems and heated tobacco products, including in social media and through organisations funded by and associated with the tobacco industry;

(i) to prohibit electronic nicotine delivery systems and electronic non-nicotine delivery systems over which the user can control device features and liquid ingredients (that is, open systems);

(j) to prohibit the sale of electronic nicotine delivery systems that have a higher abuse liability than conventional cigarettes, for example by restricting the emission rate or/flux of nicotine; and

(k) to prohibit the addition of pharmacologically active substances (in jurisdictions where they are legal) other than nicotine in electronic nicotine delivery systems, such as cannabis and tetrahydrocannabinol to electronic nicotine delivery systems and electronic non-nicotine delivery systems

[1] EB148/27 Report on meetings of expert committees and study groups, Report by the Director-General [link] Paragraph 26-32 Tobacco Product Regulation: Report of the tenth meeting of the WHO Study Group on Tobacco Product Regulation, virtual meeting, 28 September–2 October 2020

Annex 3: UKCTAS critique of WHO paper on ENDS for COP-7

This annex reproduces the executive summary of the UK Centre for Tobacco Alcohol Studies detailed critique of WHO scientific advisory paper on ENDS provided for COP-7 in 2016.[1]

EXECUTIVE SUMMARY

The World Health Organisation has commissioned a scientific assessment and policy options report on electronic cigarettes (referred to in the report as Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS)) for the Seventh Conference of the Parties of the Framework Convention on Tobacco Control (FCTC COP-7). This paper provides a critique of that assessment. The main concerns with the WHO report are as follows:

- **Positioning ENDS as a threat rather than opportunity.** Overall, the WHO report does not correctly position ENDS primarily as an alternative to smoking and instead focusses excessively on risks of ENDS use without adequately recognising the deep reductions in health risks when a smoker switches to ENDS. The FCTC itself recognises 'harm reduction' as a key strategy in tobacco control. But with minor exceptions, the WHO report discusses ENDS as a threat, whereas in fact they represent a major opportunity for public health.
- **Failure to quantify risk.** The WHO paper provides a poor assessment of ENDS risks. In terms of toxicology, the discussion is naïve and places excessive emphasis on negligible risks arising from very low exposures. In toxicology, the presence of a potentially harmful agent does not necessarily establish a material risk. This is because the level of exposure matters and "the dose makes the poison".
- **Inadequate comparisons with smoking.** The WHO paper does not systematically make meaningful comparisons with exposures arising from inhaling tobacco smoke or refer to other useful comparators such as occupational exposure limits. However, data from around the world shows that almost all ENDS users are smokers, ex-smokers or would-be smokers. The most relevant comparison for health policy purposes is with smoking.
- **Misrepresenting second hand ENDS vapour risks.** The section on risks of second-hand exposure to ENDS aerosol provides no evidence that such exposures pose any material risks to bystanders. The claim that ENDS have the *"potential to lead to adverse health effects"* in bystanders does not reflect the science behind the cited source unless 'potential' is taken to mean any exposure, no matter how trivial. Again, the issue is not the presence of particular chemicals, but the magnitude of exposure.
- **Discounting the evidence that ENDS do help smokers quit.** The WHO paper does not properly assess the role that ENDS play in quitting smoking and uncritically repeats a number of methodological errors found in the literature. Taking the totality of evidence including controlled trials, observational studies, changes in population smoking and ENDS use, the experience of nicotine replacement therapy, and widely reported user experience, there is confidence that ENDS are helping many smokers to quit smoking and not having negative effects like renormalising smoking, reducing quit rates or creating gateway effects
- **ENDS marketing can be anti-smoking advertising.** The vast majority of ENDS marketing is truthful promotion of a low-risk alternative to smoking and targeted at adult smokers. The evidence cited by WHO has been misrepresented and does not make the case for any systematic malpractice by ENDS vendors. However, the WHO paper overlooks that most fundamental point, which is that ENDS marketing is promoting an alternative to smoking and may therefore be promoting desirable changes in smoking behaviour. It may also reach people who do not engage with conventional stop-smoking interventions.

[1] Britton J, Bogdanovica I, McNeill A, Bauld L. UKCTAS Commentary on WHO Report on Electronic Nicotine Delivery Systems and Electronic Non-nicotine Delivery Systems UKCTAS, 26 October 2016. [link] Critique of FCTC COP-7 paper on ENDS FCTC/COP/7/11 [link]

- **Flavours are essential to the appeal of ENDS as alternative to smoking.** The section on 'product characteristics' attempts to demonstrate a problem with flavours appealing to teenagers. In fact, flavours are integral to the appeal of ENDS to adults as an alternative to smoking. The citations are selective and findings misinterpreted and do not support this claim. Several citations simply reflect opinions or speculation, while important studies have been overlooked. These do not show that any interest amongst teenagers in ENDS flavours is resulting in regular use of ENDS in this age group.
- **Mischaracterisation of the ENDS market and role of tobacco transnationals.** The WHO paper misinterprets the ENDS market, makes misleading and unreferenced statements about the role of transnational tobacco companies in the market and is not grounded in an understanding of how competitive markets function. WHO's report fails to acknowledge the threat of disruptive technology such as ENDS to the commercial viability of the traditional cigarette business. Ironically, the only references given to published papers point out how regulations, such as those favoured by WHO, actually help the cigarette trade. WHO should be aware of the danger that its policy proposals may provide the traditional tobacco industry with a twin advantage: (1) slowing down the disruption of the cigarette market by ENDS; (2) shaping the ENDS market to suit the ENDS business model favoured by the tobacco industry.
- **Unjustified support for ENDS prohibition.** In the discussion of policy options, the opening paragraph for each policy set implicitly endorses ENDS prohibition. It does this by stating that "Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options". Prohibition is one regulatory option among many that ought to be discussed on its own merits, not taken as a default. The merits of prohibition are exceedingly poor given the pervasive availability of cigarettes in all jurisdictions. WHO should not be endorsing prohibitions, explicitly or implicitly. It is unethical to deny smokers much lower risk options than cigarettes, and there is no scientific support for ENDS prohibition as a public health intervention. The WHO's framing suggests that a prohibition is something for Parties to progress towards and should not be undone once done. In fact, it is a policy that should be reversed
- **Policy proposals made with no supporting policy analysis.** Numerous policies are proposed without any supporting evidence for their effectiveness or cost-effectiveness. Any policy proposal should be subject to evidence-based justification, options appraisal and analysis of trade-offs or distributional effects, and impact assessment. Policies should be tested for proportionality and possible unintended consequences. The WHO has not applied any policymaking disciplines to its menu of proposed policy options.
- **No assessment of unintended consequences.** There is no recognition of the likelihood of 'unintended consequences' arising from the policies proposed in the WHO paper. However, it is very likely that some of the proposed policies would have the effect of increasing smoking. The Royal College of Physicians explains this in its 2016 *Nicotine without Smoke*[2] report as follows:

  > *"A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this 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, then it causes harm by perpetuating smoking. Getting this balance right is difficult."*

  Almost every policy listed in the WHO's paper could easily have the effect of protecting the incumbent cigarette trade, promoting smoking rather than vaping, and lead to increases in non-communicable diseases. It is very likely that widespread uptake of WHO's policy proposal would 'reduce harm reduction' and therefore increase harm.
- **Transparency and quality.** The WHO report has been made available without the four supporting papers upon which it is supposed to be based. These papers are still undergoing revision during peer review. This is poor scientific practice and does not provide a reliable basis for policy advice.