all party parliamentary group for vaping

Inquiry into the Framework Convention on Tobacco Control Conference of the Parties 9

A report by the All-Party Parliamentary Group for Vaping Inquiry (COP9)

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All-Party Parliamentary Group for Vaping

Purpose

To explore the most appropriate parliamentary and regulatory response to e-cigarettes and to raise education and literacy amongst policy makers regarding e-cigarettes and related public policy questions.

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Foreword

I am not a smoker, nor a vaper, but I launched the APPG for Vaping in 2014 because I saw the public health potential of this new technology and how it was helping people to quit using tobacco.

My introduction to vaping came via a member of my staff who had managed to quit smoking due to vaping, and also through a small local vape business in my Rugby constituency who had made me aware of the threat posed to this emerging market here in the UK, due to a piece of legislation coming through the European Union: the Tobacco Products Directive.

This legislation came into force in 2016 and limited vape juice bottle sizes to 10ml, restricted the nicotine strength in vape juices to 20mg/ml, and also restricted the tank capacity of devices. Although many of the measures within the legislation were sensible and sought to protect the consumer, at the time there were significant concerns that it would inhibit people from making the switch from smoking to vaping, and that it would make it more difficult for heavy smokers to make the transition. Thankfully, smokers here in the UK still continued to switch to vaping, reassured by Public Health England's assertion in 2015 that vaping was 95% safer than smoking tobacco.

However, it is clear that since 2016 the number of people making the switch has slowed, and last year the number of vapers declined year-on-year for the first time. This retraction in use has coincided with increased negative messaging in the media about vaping and reduced risk products, much of it fuelled in no small part by the position taken by the World Health Organisation (WHO).

There is no doubt that the WHO, primarily through the Framework Convention on Tobacco Control (FCTC) has developed a negative stance in relation to vaping over recent years. As is the norm these days, it was on Twitter where the WHO exposed its position on vaping in a series of tweets as part of a Q&A session in January 2020[1]. They went as far as to refuse to acknowledge that vaping is safer than smoking.

This was a concerning development and gave rise to the APPG launching an inquiry on the upcoming FCTC Conference of the Parties 9 (COP 9), which is being held in November of this year. It is at this conference where nation states which are signatories to the FCTC will make decisions on the future of efforts to eliminate smoking worldwide and, importantly, associated harm-reduction policies. The FCTC aims 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".* Crucially these 'control measures' include "*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."* The APPG wanted to evaluate whether the WHO's present position on vaping adhered to these guiding principles, and also if the FCTC remained fit for purpose in an evolved landscape where new technology has enabled new harm reduction strategies. The group also wanted to make recommendations to government on how to approach COP9, given the success of the UK's progressive stance on embracing vaping from a public health perspective.

This report is the culmination of that work, and I hope it will be looked upon favourably by Ministers and the UK Government's delegation to COP9.

Mark Pawsey MP
Chair of the All-Party Parliamentary Group for Vaping

[1] https://www.clivebates.com/world-health-organisation-fails-at-science-and-fails-at-propaganda-the-sad-case-of-whos-anti-vaping-qa/

About the inquiry

This inquiry was carried out by a panel of parliamentarians on behalf of the APPG for Vaping.

The inquiry consisted of two evidence sessions and included Members of the House of Commons and the House of Lords. They were:

Mark Pawsey MP (Conservative)

Mary Glindon MP (Labour)

The Viscount Ridley DL (Conservative)

Gareth Johnson MP (Conservative)

Adam Afriyie MP (Conservative)

The panel would like to thank all those who submitted evidence to the inquiry whether on a personal basis or as a representative of an organisation. The panel would particularly like to thank those who gave oral evidence to the inquiry:

Clive Bates, Director of Counterfactual & former Director of Action on Smoking and Health (ASH)

Martin Cullip, Chair, New Nicotine Alliance

Professor Lynne Dawkins, Professor of Nicotine & Tobacco Studies, London South Bank University

John Dunne, Director-General UK Vaping Industry Association | Vape & CBD Industry Consultant

Liam Humberstone, Board Member, Independent British Vape Trade Association

Mark Oates, Director, We Vape

Daniel Pryor, Head of Programmes, Adam Smith Institute

Professor Gerry Stimson, Director of Knowledge-Action-Change (KAC)

Terms of reference for the inquiry

The purpose of the APPG for Vaping inquiry was to collect evidence during two oral evidence sessions and then produce a report for Government regarding the upcoming World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC) Conference of Parties 9 (COP9) and the actions that are going to be taken on behalf of the UK.

COP9 was delayed due to the global pandemic and is now due to take place in the Netherlands in November 2021.

A call for evidence was made on 16th November 2020 and a website (www.copinquiry.co.uk) established to enable the submission of written evidence. A deadline of 1st February 2021 was given for the submission of written evidence.

As part of the inquiry the APPG for Vaping held two evidence sessions that investigated the following:

1. Evidence session held virtually on 26th January 2021 looked into (a) the previous COP meetings and objectives around reduced risk products and what new proposals are forthcoming & (b) Examined the transparency and accountability of COP9 and how the agenda is set; and whether countries are (or are not) consulted appropriately in the intersessional work (e.g. reports to COP).

2. Evidence Session held virtually on 9th February 2021 looked at whether the Framework Convention on Tobacco Control (FCTC) is still fit for purpose.

Key objectives and scope of the inquiry

The inquiry revolved around 5 key objectives:

1. **What problem are these policies and positions supposed to address?**

   Vaping has been advocated by Public Health England as a significant contributing factor in smoking cessation in the UK. As such, what is the policy rationale for intervention, and how does it compare and differ from current UK government policy? How is the UK government ensuring that its national experience and real-life evidence/data is reflected in the discussions within the WHO and with other regulators (e.g. WHO meetings, Global Tobacco Regulators Forum (GTRF), etc). What was the UK position? Are discussions taking place within the WHO and/or FCTC on the contribution of vaping in smoking cessation and risk reduction?

2. **Justification of proposals**.

   To what extent will the Framework Convention on Tobacco Control (FCTC) Conference of Parties 9 (COP9) justify any measures it proposes? What visibility will countries like the UK have in the reports to COP9 on vaping? How does the UK delegation to FCTC COP9 ensure that the totality of the scientific evidence available and experience of nation states is considered?

3. **Transparency and consultation**.

   What advice and evidence does the WHO FCTC COP9 Secretariat receive and how does this lead to their policy positions? What is WHO's and their Advisory Bodies' (TobReg and TobLabNet) criteria for inviting countries to provide inputs and/or to be consulted on relevant topics?

4. **Explore the threat of unintended consequences of proposals within the Framework Convention for Tobacco Control Conference of the Parties 9**.

5. **Fit for Purpose**.

   (a) To what extent has the WHO moved away from the fundamental objectives set forth by the FCTC, given its original commitment to Harm Reduction?

   (b) Is the FCTC still fit for purpose in its current form given that the Reduced Risk Products available on the market are now so prevalent and have moved on significantly since 2003 when the FCTC came into being?

   (c) In crafting the regulatory regime for Electronic Nicotine Delivery Systems (ENDS) under the FCTC, the objective of the Convention in Art. 3 of the FCTC is instructive as its stated goal is to *'protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke …. to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.'* If the FCTC is to remain relevant and responsive to contemporary needs, is there a need for greater flexibility and for a rapid response to new developments in ENDS in order to avoid divergent regulatory approaches?

Background to Framework Convention on Tobacco Control Conference of Parties 9

The UK is a global leader in tobacco control and has been an active contributor to the implementation of the Framework Convention on Tobacco Control (FCTC), including by providing financial support to the FCTC 2030 (a total of £15 million in Official Development Assistance funding over the period FY2016-17-2020/21).[2]

More recently, the UK has also pledged to become WHO's largest state donor with a 30% funding increase (£340m in UK funding over the next four years).[3] Thus, the UK must keep its effective approach to vaping and novel tobacco products at the forefront of the efforts to curb Non-Communicable Diseases (NCDs).

Previous sessions of the COP to the WHO Framework Convention on Tobacco Control (FCTC) have mandated intersessional work and reports on e-cigarettes and novel and emerging tobacco products to be submitted to Conference of Parties 9 (COP9). A report on e-cigarettes (ENDS) is expected to be submitted and discussed[4], as well as a report by the WHO on novel and emerging tobacco products[5]. Advisory bodies to the WHO such as TobReg[6] and TobLabNet[7] are required to develop and provide technical and scientific evidence to inform the discussions on vaping and novel products.

Meetings in 2020 where vaping and the use of novel and emerging tobacco products were discussed included a WHO Executive Board 146th session briefing session on electronic delivery systems (ENDS)[8] where a strong call to ban or restrict the use of e-cigarettes was made. The same WHO representative who made this call also co-authored an op-ed advocating openly against vaping without considering the relative risk when compared to cigarettes.[9]

In September 2019, there was a meeting of tobacco regulators under the auspices of the US Food and Drug Administration (FDA) funded WHO Global Tobacco Regulators' Forum[10] (GTRF) in the Netherlands as part of the preparations for FCTC COP9, initially scheduled for November 2020 but now to be held in November 2021 following the COVID-19 pandemic, also in the Netherlands.

Two leaked papers from WHO's Eastern Mediterranean Regional Office (EMRO)[11] suggest that the WHO is exploring whether to advocate that reduced risk products are treated in the same manner as cigarettes or to ban them outright. This meeting was aimed at promoting regulators-to-regulators dialogue on tobacco product regulation, in order to share real life national experience and expertise. Parliamentary questions have shown that the UK is a regular participant to this meeting[12].

[2] https://www.who.int/fctc/implementation/fctc2030/en/
[3] https://www.theguardian.com/world/2020/sep/25/uk-to-become-whos-largest-state-donor-with-30-funding-increase
[4] https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_10-EN.pdf?ua=1
[5] https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(22).pdf?ua=1
[6] https://www.who.int/tobacco/industry/product_regulation/tobreg/en/
[7] https://www.who.int/tobacco/industry/product_regulation/toblabnet/en/
[8] https://www.who.int/about/governance/executive-board/executive-board-146th-session
[9] https://journals.physiology.org/doi/full/10.1152/ajplung.00101.2020
[10] https://www.who.int/tobacco/industry/product_regulation/forum/conference2012.pdf?ua=1

[11] https://www.clivebates.com/leaked-papers-who-to-intensify-its-pointless-and-destructive-war-against-innovation-expect-many-dead/
[12] https://questions-statements.parliament.uk/written-questions/detail/2018-09-03/169292

Executive summary

At the Framework Convention on Tobacco Control Conference of the Parties 9 (FCTC COP), the UK has a unique opportunity to champion its progressive, successful and evidence-based, domestic policies on tobacco harm reduction on a global stage.

The UK is a world leader in this field and must fully embrace this position. Whereas in previous years the UK delegation to the FCTC COP has been obligated to adhere to the consensus view within the European Union, post-Brexit it is able not only to forge its own path in terms of domestic legislation on vaping and reduced-risk products, but also to take its place on the world stage as a leader in pragmatic and effective health regulation.

Above all the argument around vaping and reduced risk products is one of public health and the UK has a clearly stated position that vaping is 95% safer than combustible tobacco. In recent years the UK has very successfully integrated vaping into its public health policies on tobacco harm reduction. However, this position is not shared by a number of countries, the World Health Organisation itself, and the Secretariat to the FCTC.

It is clear from leaked papers, official channel social media posts and statements by the Head of the FCTC Secretariat, that the body is looking at treating vaping and reduced-risk products in the same way in which it treats combustible tobacco products. This contrary to the available scientific evidence and to the UK's domestic public health policy position.

The UK is one of the principal financial contributors to the World Health Organisation and the FCTC. If the upcoming FCTC COP9 advocates for a position on vaping and reduced risk products which is contrary to domestic UK policy, the UK should consider its options in relation to future funding.

It is imperative that the UK sends a balanced delegation of officials and experts, including proponents of evidence-based policy and harm reduction, to the FCTC COP9. It should also consider including representatives of the vaping community, or former smokers who have been able to quit tobacco because of vaping. The UK should take positive steps to ensure that the voice of the consumer is heard as part of the deliberations at the FCTC COP9.

The UK delegation to the FCTC COP9 should highlight the work and consensus opinions of UK public health bodies and NGOs on the safety and efficacy of vaping products in smoking cessation and harm reduction efforts, including issues relating to alleged 'gateway effects' and youth uptake. It should advocate for following the evidence.

The UK should also seek to establish firm relationships with other member states who share its scientific and harm reduction approach with a view to forming an international coalition to reduce the harm caused by combustible cigarettes. Similarly, the UK should encourage other member states to include tobacco harm reduction public health experts in their national FCTC COP delegations for this and future events. It should also propose the establishment of a COP Working Group on harm-reduction.

In summation the UK delegation to the FCTC COP9 should advocate for risk proportionate, evidence-based, regulation.

The overwhelming cause of death and disease associated with tobacco use comes from smoke inhalation from combustible tobacco. The UK should remain steadfast in its commitment to a smoke-free nation, but this should not be conflated with a 'nicotine free' or 'tobacco free' objective which would be counter-productive from a public health perspective.

Summary of recommendations

CORE PRINCIPLES – *Upholding our strong domestic position on tobacco harm reduction*

1) Article 1(d) of the FCTC clearly states: ""*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*".[13] There needs to be a fundamental shift in the mindset of the WHO, and at the COP9, to reacknowledge that one of the founding principles of the FCTC Treaty is 'harm reduction'. If they are opposed to adhering to this and continue to pursue an agenda-driven approach to ban reduced harm products, then the UK should consider dramatically scaling back our funding.

2) The UK has successfully incorporated vaping into its public health harm reduction strategy. It is a global leader in harm reduction in relation to smoking cessation and has embraced an evidence-based approach. The UK should look to advance this position at COP9 and encourage the WHO to be guided by the evidence. If the COP9 does not accept this approach and refuses to accept the role that less harmful alternatives can play, the UK delegation should make it clear that the UK will assert their national sovereignty – given the outcomes will not be binding – and continue to pursue our current domestic strategy.

UK POSITIONING – *Aligning our strategy for COP9 with our position at home & ensuring the UK's voice is heard*

3) The FCTC should be updated to reflect the positive public health opportunity from low-risk nicotine products that have been introduced since the text was finalised in 2003.

4) The UK should reject any decision by the FCTC that would restrict adult use of vaping and reduced risk nicotine delivery systems. Moreover, the UK is in a unique position to present the evidence that such products have helped its own citizens quit smoking and present its findings to the Parties of the FCTC, urging COP9 to focus the debate back to cigarettes and smoke as the source of harm.

5) The UK should send a balanced delegation of officials and experts that includes proponents of evidence-based policy and harm reduction to COP9. The delegation should include experts who have first-hand experience of seeing the impact and benefit of reduced risk products as they are best placed to advocate for risk proportionate regulation. The UK should specifically push for a delegation which involves consumers and those with first-hand experience of vaping and reduced risk nicotine delivery systems. The UK should consider withdrawing funding from the FCTC if the WHO continues to discourage this form of smoking cessation.

6) The UK should remain committed to a smoke-free goal – not nicotine-free or tobacco-free. The overwhelming cause of death and disease associated with tobacco use comes from smoke inhalation from combustible tobacco.

7) The UK delegation to COP9 should highlight the work that has been done in the UK to successfully bring down smoking rates as well as the consensus of opinions from UK public health bodies and NGOs on the safety and real-world efficacy of vaping and other reduced harm products in smoking cessation and harm reduction efforts.

8) The UK delegation should refer to our strong commitment to ensure that harm reduction products do not face issues relating to alleged 'gateway effects' and youth uptake and should highlight the clear results we have on this.

9) The UK approach should also be promoted in upcoming papers, such as the expected WHO regulatory framework for novel tobacco products and the expected FCTC/WHO reports on vaping.

[13] https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf

10) If necessary, the UK delegation should raise objections with the FCTC Secretariat to any inclusion of vaping products in the report on novel and emerging products as beyond the scope of its mandate, as per FCTC/COP8(22)[14]. It should oppose any decision proposed by the FCTC Secretariat or by a Party that would include vaping products within the scope of policy recommendations on novel and emerging products, or one that would equate vaping products with combustible tobacco products.

11) The UK delegation to COP9 should propose the establishment a COP Working Group on harm-reduction.

12) The UK should challenge the unduly restrictive and selective policy towards civil society observers and media allowed into COP meetings. The present arrangements create an unhealthy and unrepresentative echo chamber.

13) The UK should work with other member states who share its scientific and harm reduction approach to establish an international coalition with the aim of reducing the harm caused by combustible cigarettes. The UK should encourage other member states to also include tobacco harm reduction public health experts in their national COP delegations for this and future events. In taking a science-based approach the UK should work with our coalition partners to encourage regulation that ensures that all reduced risk products are of a high level of (i) quality, (ii) safety and, (iii) performance, in terms of nicotine delivery and improved vapor chemistry.

[14] https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf

CORE PRINCIPLES – *Upholding our strong domestic position on tobacco harm reduction*

The present interpretation of the Framework Convention on Tobacco Control objectives is not compatible with UK policy; the UK must continue to be guided by the evidence

The overall purpose of the Framework Convention on Tobacco Control (FCTC) is to alleviate the worldwide burden of disease and death caused by smoking cigarettes. Given half of all regular smokers will die prematurely as a result of their smoking and many more will live with smoking related disease or disability, this is an incontestable goal.[15] Over recent years a key issue has been what role vaping and reduced risk products will play in the fight to end tobacco smoking.

With the emergence of vaping/e-cigarettes and other reduced risk nicotine or tobacco products, the World Health Organisation (WHO) appears to be moving away from a focus on reducing smoking related harms, to focus instead on reducing tobacco and nicotine use.

When the UK signed up to the FCTC, a key pillar of that was the acknowledgement of harm reduction in Article 1(d) of the FCTC itself. It is imperative that the WHO reasserts the founding pillar of the Treaty – which hitherto seems to have been forgotten – and ensures that vaping and other reduced risk products are accepted for the role they are playing in the fight to end tobacco smoking.
The major issue between the WHO and UK position seems to be that the WHO sees reduced risk nicotine products such as vapes/e-cigarettes as part of the problem (and treats these products like tobacco smoking).

By contrast, in the UK, the potential of vaping to promote smoking cessation, thereby contributing in reducing the harms associated with smoking, is seen as part of the solution. As such, these products are accepted as very different to smoking.

As Professor Dawkins submitted during both oral and written evidence to the APPG[16]:

1. E-cigarettes (ECs) **DO** help smokers to quit

    a. Evidence from Randomised Controlled Trials (RCTs) as recently reviewed in the esteemed Cochrane review demonstrate that ECs are **at least** as effective as Nicotine Replacement Therapy (NRT) and the largest RCT in England showed ECs are almost twice as effective as NRT.

    b. Observational studies of ECs used in real-world conditions (e.g. from the Smoking Toolkit Survey [STS], an ongoing monthly survey in England) support this evidence that ECs can help people to quit.

    c. Population trends (in UK and US) show as the prevalence of e-cigarette use increases, the prevalence of smoking cessation activity also increases.

[15] Professor Lynne Dawkins & Dr Catherine Kimber, Centre for Addictive Behaviours Research, London South Bank University, Written submission to the APPG for Vaping inquiry into the FCTC COP9.
[16] Professor Lynne Dawkins & Dr Catherine Kimber, Centre for Addictive Behaviours Research, London South Bank University, Written submission to the APPG for Vaping inquiry into the FCTC COP9.

d. Testimonials from smokers who have quit using EC adds to the growing body of evidence that they help promote cessation - as found here for example:

   https://casaa.org/_testimonials/

2. E-cigarettes (EC) **ARE** much less harmful than smoking.

   a. Almost all the harms from tobacco come burning and inhaling smoke. EC do not burn and do not contain tobacco.

   b. Switching studies show health improvements (e.g. improved breathing, reduced cough etc) where vaping has completely displaced smoking
   c. Toxicology studies which have analysed the contents of EC vapour show far lower levels of harmful & potentially harmful chemicals compared to tobacco smoke.

   d. Biomarker studies (which look at toxicants/harmful chemicals in urine, saliva or blood) show greatly reduced exposure in EC users compared to smokers – in many cases at levels comparable to ex-smokers or LT NRT users.

   e. Although we cannot be certain about the long-term effects, we know enough from these types of studies that vaping is far less harmful than smoking.

   f. Other studies showing an association between vaping and heart attacks have been heavily criticised and discredited. One study (still often cited) was retracted by the journal for failing to take into account when the heart attacks occurred – when data were re-analysed, it was revealed that many occurred before vaping and no evidence to support the link when these were removed.

Conclusion

The WHO continues to undermine a policy which has been proven to help people stop smoking.

As the UK Vaping Industry Association (UKVIA) stated in its submission to the APPG for this inquiry: *"There is clear evidence that embedding the use of vaping in the UK as part of its tobacco harm reduction and cessation efforts has achieved extremely positive results, with smoking rates reduced by almost 5% in the last 5 years to 14.1%. Yet the WHO continues to attempt to discredit the UK's science, it's approach and progress made."*

Recommendation

1) Article 1(d) of the FCTC clearly states: ""*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*".[17] There needs to be a fundamental shift in the mindset of the WHO, and at the COP9, to reacknowledge that one of the founding principles of the FCTC Treaty is 'harm reduction'. If they are opposed to adhering to this and continue to pursue an agenda-driven approach to ban reduced harm products, then the UK should consider dramatically scaling back our funding.

[17] https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf

2) The UK has successfully incorporated vaping into its public health harm reduction strategy. It is a global leader in harm reduction in relation to smoking cessation and has embraced an evidence-based approach. The UK should look to advance this position at COP9 and encourage the WHO to be guided by the evidence. If the COP9 does not accept this approach and refuses to accept the role that less harmful alternatives can play, the UK delegation should make it clear that the UK will assert their national sovereignty – given the outcomes will not be binding – and continue to pursue our current domestic strategy.

UK POSITIONING – *Aligning our strategy for COP9 with our position at home & ensuring the UK's voice is heard*

The Framework Convention on Tobacco Control is no longer fit for purpose

Current state of play

Article 3 of the Framework Convention on Tobacco Control (FCTC) states:

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.[18]

In its current form it allows little room for the concept that some tobacco products are less harmful than others, or that lower-risk products could act as an effective alternative for the higher-risk products.

Despite this, the FCTC provides explicit support for the possibility that harm reduction could provide a potential solution, stating: "'*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."*

The FCTC in effect contradicts itself by allowing for harm reduction as a potential option for enabling 'tobacco control', but it does not accept that it actually exists as a concept let alone a realistic option which is now available on the market in 2021.

This really is not consistent with the founding pillar of the Treaty and is based on a narrow review of self-supporting evidence. This has forced the World Health Organisation (WHO) to make a choice which has, in turn, led to it taking an increasingly draconian approach to tobacco control; one which is not founded in the evidence.

As a consequence of this choice, the WHO's efforts to reduce smoking rates has focused solely on regulations, sin taxes, and public education campaigns, rather than changing behaviours or enabling a move away from the most harmful options. This stance has contributed to policy which is ineffective at significantly reducing cigarette consumption due to the side-lining of harm reduction strategy, and instead only providing consumers with one option: a "quit or die" strategy which does not resonate with all smokers.

The emergence and subsequent proliferation of reduced risk products, such as vapes, e-cigarettes, and heated tobacco products, which have emerged onto the market since the FCTC's inception in 2003, and especially over the last decade, shows the short-sighted nature of the WHO'S approach.

During oral evidence Liam Humbertsone, Board member at the Independent British Vape Trade Association, declared that whilst the FCTC does have harm-reduction contained in its definition of tobacco control, the WHO change of direction regarding reduced risk products appeared to be a consequence of the EVALI (Vaping Use-Associated Lung Injury) crisis in the USA. This was quickly followed by what the WHO perceived to be a youth vaping epidemic in the USA, something not backed up by the evidence. It is also worth noting that the USA is not a signatory to the FCTC and the issues in the USA were a result of poor regulation and

[18] https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf

enforcement, so that the situation in the USA was far different to that in the UK at the time of the EVALI crisis. This was attested to by both Martin Cullip, Chair of the New Nicotine Alliance, and Professor Lynne Dawkins, during oral evidence to the APPG. Both witnesses highlighted that the EVALI outbreak was used by the FCTC to its advantage to justify its policies towards vaping and reduced-risk products.

However, there was a knock-on effect in the UK as the number of vapers in the UK at the time reduced from 2.9 to 2.5m. This was a consequence of negative media reporting and negative reports in WHO publications.

However, there was a knock-on effect in the UK as the number of vapers in the UK at the time reduced from 2.9 to 2.5m. This was a consequence of negative media reporting and negative reports in WHO publications. However, even where a country is not a signatory of the FCTC, a domestic problem is allowed to have an international impact with the WHO adopting a hard-line approach wherever possible, with the knock-on, negative impact upon the harm reduction agenda evident to see.

With the increased availability of reduced harm alternatives there is a clearly pressing need for a re-examination of the FCTC, and the WHO's policy priorities strategies with regards to tobacco control overall.

Stumbling Blocks

Since 2003 no amendments have been made to the text of the FCTC. Therefore, the FCTC reflects a view of tobacco control formed at the turn of the century and is consequently out of date.

The FCTC Secretariat in theory serves the FCTC parties and members of the World Health Assembly. However, far from being passive policy-takers, they also have an influencing role. The FCTC COPs would arguably be more productive if the WHO and the FCTC Secretariat had a more constructive and pragmatic perspective on tobacco harm reduction.

During oral evidence and in his written submission as part of the inquiry, Clive Bates, Director of Counterfactual & former Director of Action on Smoking and Health (ASH), attested that the WHO and the FCTC Secretariat have been overwhelmingly negative on the subject of vaping products and, by extension, the harm reduction agenda. This suggests the FCTC community focus upon seeking the evidence to justify the policy they want, rather than assessing the evidence to determine the policies that would best achieve harm reduction.[19] Similarly, during the first evidence session similar sentiments were expressed by Martin Cullip, Chair of the New Nicotine Alliance.

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. Then, as now, many tobacco control advocates simply did not wish to acknowledge that it was possible to use tobacco or nicotine with very low risks.

Evidence of this can be seen in the statement made by Dr Adriana Blanco Marquizo, Head of the Convention Secretariat to the FCTC, in which she stated "individuals should be encouraged and assisted in taking the opportunity to quit and refrain from the use of any form of tobacco and nicotine products".[20] This demonstrates that the Secretariat is grouping nicotine products in with tobacco products and treating them as synonymous, rather than distinguishing the health risks associated with tobacco and nicotine individually.

As a result, there is no structure in the FCTC that allows for differential measures according to radically different levels of risk (or recognition that a real continuum of risk exists) and no appetite to establish such a structure due to choices made right at the outset of the FCTC, and the direction of travel ever since.

[19] https://www.clivebates.com/documents/APPGVapingFeb2021.pdf
[20] https://www.who.int/fctc/secretariat/head/statements/2020/joint-emro-director/en/

There is no established precedent for changing the content of the FCTC and no realistic mechanism for it either due to the intransigence of the Secretariat who do not simply act as a civil service but as active participants and influencers, creating a clear stumbling block to making the FCTC fit for purpose again.[21]

The voice of the consumer

The gold standard in research on health matters is commonly accepted to include Patient and Public Involvement (PPI). It is argued that PPI will lead to higher quality health research, which considers real-life experience, has been validated by patients or members of the public, is more relatable to and recognises that the public has a legitimate interest in the field. It is defined as 'research being carried out 'with' or 'by' members of the public, rather than 'to', 'about' or 'for' them'.[22] The WHO accepted this principle in a Declaration as far back as 1978[23]. This principle needs to be brought to the fore front of policy making by Parties to the FCTC (the COP) at its next meeting in November this year (COP9).

In documents prior to COP6 held in 2014, the WHO had suggested designating e-cigarettes/vaping devices as a tobacco product, and therefore subject to significant taxes, as well as restrictions on marketing, packaging, and use. The APPG was informed via submissions that the then fledgling UK consumer association – the New Nicotine Alliance (NNA) – wrote to then Director General of the WHO, Margaret Chan, asking for its stance to be reconsidered and suggesting a meeting to discuss it. The WHO did not reply and there was no change in emphasis in any documents presented to COP6 by the FCTC Secretariat. For the temerity of attempting to engage with the WHO, the NNA was subsequently excluded from other WHO consultations and a campaign of intimidation continues to this day.

The NNA also informed the APPG that in 2018, prior to COP8 held in Geneva, the International Network of Nicotine Consumer Organisations (INNCO) – staffed entirely by unpaid consumers - applied for observer status to the FCTC COP. They were not only denied this but were actively defamed for their attempt to engage.

The approach by allies to the FCTC COP Secretariat has increasingly been to conflate consumer engagement with that of the tobacco industry. A recent research paper on tobacco industry lobbying defined it as including "influential vaping groups that are financially independent, but whose messaging is consistent with the tobacco industry". This seems designed to extinguish all potential engagement from any member of the public who has a different view to that of the FCTC COP Secretariat and those that influence it such as Bloomberg Philanthropies.

The WHO's Ottawa Charter[24] describes health promotion as the process of enabling people to increase control over, and to improve, their health. It states that that "People cannot achieve their fullest potential unless they are able to take control of those things which determine their health". This is reiterated in the WHO's Jakarta Declaration on Leading Health Promotion into the 21st Century[25], which described health promotion as "a process of enabling people to increase control over and to improve their health" and that

[21] https://www.clivebates.com/documents/APPGVapingFeb2021.pdf
[22] INVOLVE. Frequently asked questions. 2018 https://www.invo.org.uk/frequently-asked-questions/
[23] World Health Organisation. Declaration of Alma Ata: report of the International Conference on Primary Health Care. Geneva, 1978.https://scholar.google.com/scholar?q=World+Health+Organisation.+Declaration+of+Alma+Ata%3A+report+of+the+International+Conference+on+Primary+Health+Care.+Geneva%2C+1978.

[24] World Health Organisation, Ottowa Charter: https://www.who.int/teams/health-promotion/enhanced-wellbeing/first-global-conference
[25] World Health Organisation, Jakarta Declaration: https://www.who.int/healthpromotion/conferences/previous/jakarta/declaration/en/

"participation is essential to sustain efforts. People have to be at the centre of health promotion action and decision-making processes for them to be effective". The same principle appears in the WHO Constitution and the FCTC Preamble that the FCTC is built on.

Not only are these previously stated commitments to transparency and consumer engagement wilfully ignored by the FCTC COP Secretariat, but its COP meetings are well-known for the routine ejection of the public from proceedings, sometimes physically, in places where there should be and usually is, a designated place for members of the public to observe. There is no expectation that this will be any different for COP9. It is almost certain that, even with the conference taking place virtually, consumers will not be permitted to watch, let alone participate. An anti-vaping webinar in June 2020 , funded by Bloomberg Philanthropies, barred registrations from anyone with "links to the tobacco industry", including "professional or public interests, family's or spouse's/partner's interests, relationships up to the fourth degree of consanguinity and affinity, and frequent or regular social relationships" and referred to an "annexed chart of relatives for clarity".

This is a stark difference from other UN institutions which value inclusion, openness and debate towards constructive regulation and policymaking. As an example, the UN Framework Convention on Climate Change (FCCC) COP Secretariat welcomes contributions from the public, special interest groups, unions, academic institutions, and industry, whether sharing the aims of the FCCC or not. By contrast, the WHO and FCTC COP Secretariat refuses to engage with any individual, NGO or other organisation which are not unreservedly "in conformity" with the "spirit, purpose and principles" of the FCTC, effectively excluding all critics and eliminating debate. This is peculiar given that the FCTC embraces harm reduction, and the organisations barred from the meetings are in support of tobacco harm reduction and the objective of the FCTC treaty which is to protect people from exposure to tobacco smoke. Engagement with industry – or with any organisation which is perceived to have even met someone working in the tobacco industry - is prohibited, to such an extent that Interpol was denied observer status at COP5 for having previously been supported by the tobacco industry for a global initiative to combat trans-border crime and the elimination of all forms of illicit trade in tobacco products, which international organised crime has a significant role in.

UK taxpayers provide the WHO FCTC Secretariat with over 70% of its funding yet consumers are excluded from any chance of having their say. The Department of Health & Social Care does not consult on policy before it sends its delegation to an FCTC COP and has not objected to the public being excluded from the event in its entirety when that question has been put to the government participants (the Parties), although many organisations hope that his year will be different now that UK is outside of the EU and thus has more freedom to deviate from the block's collective stance.

In submissions to the APPG as part of this inquiry, and in oral evidence, it was clear that many believe that the FCTC COP Secretariat 'cherry-picks' its research to present to Parties to COP without any avenue by which those who could be affected by their decisions are able to object or provide alternative research. The only way to object is via a government Party doing so. It would be unconscionable to UK regulators and policymakers to exclude the public from decisions made on important aspects of their lives, yet the FCTC COP Secretariat does this routinely and without adherence to the WHO's longstanding stated declarations.

Conclusion

The FCTC has an in-built contradiction which a) fatally undermines its ability to adapt, and b) has forced the WHO to make a choice, leading to a draconian approach to tobacco control; an approach which has limited success around the globe.

With the increased availability of reduced harm alternatives, including vaping devices, heated tobacco products and pouches, the market has developed in a different direction from the WHO. However, this direction is not contradictory to the FCTC itself, only the policies the WHO has chosen to pursue in the interim.

Therefore, there is a clearly pressing need for a re-examination of the FCTC, and the WHO's policy priorities strategies with regards to tobacco control, which are no longer fit for purpose and do not reflect either the original intentions of the FCTC itself or what is now available on the market, which was not the case when the FCTC was first drafted.

However, while this inquiry accepts that the FCTC is no longer fit for purpose, it is worth noting that the WHO and the FCTC Secretariat are likely to be a significant block in any attempt to make the FCTC fit for purpose again both now and in the future.

Recommendations

1)The FCTC should be updated to reflect the positive public health opportunity from low-risk nicotine products that have been introduced since the text was finalised in 2003.

2) The UK should reject any decision by the FCTC that would restrict adult use of vaping and reduced risk nicotine delivery systems. Moreover, the UK is in a unique position to present the evidence that such products have helped its own citizens quit smoking and present its findings to the Parties of the FCTC, urging COP9 to focus the debate back to cigarettes and smoke as the source of harm.

3) The UK should send a balanced delegation of officials and experts that includes proponents of evidence-based policy and harm reduction to COP9. The delegation should include experts who have first-hand experience of seeing the impact and benefit of reduced risk products as they are best placed to advocate for risk proportionate regulation. The UK should specifically push for a delegation which involves consumers and those with first-hand experience of vaping and reduced risk nicotine delivery systems. The UK should consider withdrawing funding from the FCTC if the WHO continues to discourage this form of smoking cessation.

4) The UK should remain committed to a smoke-free goal – not nicotine-free or tobacco-free. The overwhelming cause of death and disease associated with tobacco use comes from smoke inhalation from combustible tobacco.

How the UK Government should approach the Framework Convention on Tobacco Control Conference of the Parties 9

Process and Procedure

A Conference of the Parties (COP) is the domain of diplomats, government advisors and subject matter experts, where the accepted practice is to diplomatically agree by consensus to proposals rather than to vote. Consequently, it is important that the UK delegation ensures that the points of view of all relevant stakeholders are taken into account in the formulation of the government's official position well in advance of the actual COP, and certainly before the UK delegation departs or participates.

Vaping of nicotine is potentially one of the most important health advances in the history of public health because cigarette smoking is the largest preventable cause of premature death worldwide. By adopting a policy in line with that position, the UK has been world leading in using vaping to help smokers quit and to help minimise young people becoming hooked on cigarettes. By contrast, most of the rest of the world, and of course the WHO, take the opposite view.

Therefore, given the success of tobacco harm reduction in the UK, it is essential that the UK delegation bring this national experience to the forthcoming COP and resist any policy recommendations that would conflict with its risk-proportionate approach to regulation. It is therefore imperative that the UK continues to lead the world on this issue and be the party which brings this policy to the table.

The UK boasts a world-leading number of public health experts in harm reduction whose knowledge and expertise could be invaluable resources in the crafting of the UK position. Moreover, the UK should also seek to exercise its right to bring one or more of these subject matter experts to support its negotiating team at the COP. This was a view expressed by a number of the witnesses providing oral evidence to the APPG including Professor Gerry Stimson, Director of Knowledge-Action-Change, Mark Oates, Director at We Vape, John Dunne, Director-General of the UK Vaping Industry Association, and Daniel Pryor, Head of Programmes at the Adam Smith Institute .

The UK's regulatory and taxation model regarding reduced-risk products has not received significant attention in previous WHO discussion. COP9 discussions would therefore significantly benefit from the UK's considerable body of evidence demonstrating that accurate public health communications, risk proportionate taxation, and the absence of wide-ranging product prohibitions can reduce smoking rates without unintended consequences. The benefits of replicating such an approach in other jurisdictions, whether they are full parties to the FCTC or not would be substantial.

The UK is world leading on the issue of harm reduction and the use of reduced risk products to reduce the smoking rates.

If tobacco harm reduction measures are not being advocated for at the COP, it is because they are not being brought to the table. It is therefore imperative that the UK continue to lead the world on this issue, with policies that promote the use of tobacco harm reduction products, including electronic cigarettes and heat-not-burn technologies.

The UK should therefore reject any decision by the FCTC that would restrict adult use of such products. Moreover, the UK is in a unique position to present the evidence that such products have helped its own citizens quit smoking and present its findings to the Parties of the FCTC.

The UK approach should also be promoted in upcoming papers, such as the expected WHO regulatory framework for novel tobacco products and the expected FCTC/WHO reports on vaping.

International Standing

For the first time since the FCTC came into force in 2005, the UK government will participate in the FCTC COP not as a member of the European Union delegation, bound by a common EU position, but as an independent, sovereign nation, free to advance the interests of UK citizens through the promotion of science and evidence-based tobacco control policies.

Proactively promoting and mirroring its pragmatic domestic policy approach to vaping in the international COP process could form a key part of Global Britain's re-emergence on the world stage in this key area of public health.

In a post-Brexit UK, it is imperative that the government leverages its newly established independence as well as its strengths and expertise in tobacco control and harm reduction to influence COP decisions on vaping. This will require the UK government and its COP delegation to not just play a leading and active role during the COP meeting itself in November, but crucially also in the months leading up to the meeting as various reports and decisions are formulated and tabled.

Smoking related deaths are reaching 8 million per annum worldwide and over this century are set to lead to a total of a billion lives being shortened from combustible cigarettes. If the world were to fully embrace harm reduction strategies, then a vast number of lives could be extended, and health improved. Britain should not shy away from representing the c.3 million UK vapers who rely on access to well-regulated vaping products to consume a safer alternative to smoking, promoting internationally the policies that have been successful in the UK at helping millions of people quit smoking.

The UK is a major contributor to the WHO (77% of its budget in 2018[26]), therefore the world-leading policies we employ in this country towards reduced risk products – and the personnel behind them - should be backed up by our COP delegation in The Hague in November and that the UK has every right to do so. It would be entirely in keeping with previously stated aspirations from the WHO towards harm reduction; fits with the articles of the FCTC; is consistent with the scientific evidence; endorses the UK's leadership in this policy area and would advance public health on a global scale.

Finally, it is also imperative that as well as asserting the UK's domestic position, the UK government's preparatory assessments and positions to be submitted to the FCTC take into account the impact on the government revenue, trade, agriculture, and employment. Any proposal on the regulation of these products must not only be led by science and evidence-based, but they must also be fair, practical, and aligned with the particular conditions and circumstances of the local industry.

The approach of the WHO/FCTC/COP towards e-cigarettes is almost diametrically opposed to that of the UK. As one of the most significant financial contributors to the WHO, with extensive experience in international development and tobacco harm reduction, COP9 provides the UK with a significant opportunity to advance global health and development goals by sharing best practices from its successful implementation of smoking cessation strategies.

The UK should send a delegation of committed proponents of evidence-based policy and harm reduction to COP9 and should potentially consider withdrawing funding from the FCTC if the WHO continues to discourage this form of smoking cessation.

[26] https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_INF5-en.pdf

Hostility

The majority of NGOs listed as 'Observers' are hostile to the concept of tobacco harm reduction and thus the UK's policy approach. For instance, 'The Union' has advocated a complete ban on e-cigarettes and heated tobacco products in low and middle-income countries, which are home to 80 percent of the world's smokers. The same report does not, however, call for a ban on combustible cigarettes. While such a policy represents one of harm maximization rather than harm reduction, it also shows the stated position of the WHO and therefore, the resistance any alternative stance may face.

The 'civil society' observers are effectively hand-picked by the Secretariat to hold specific views about the FCTC and tobacco control policy. Dissenting views favouring alternative approaches are deliberately excluded. All this is done on the pretext of excluding the tobacco industry, but the industry may be represented on official delegations. This is true especially where there are state-owned tobacco companies or large populations of tobacco farmers. It is up to each Party to decide whom it wants on its delegation, but the tobacco industry should not be used as a pretext to exclude legitimate dissenting or challenging views.

The FCTC Conference of the Party meetings are also notoriously secretive and non-transparent. The public and the press are routinely excluded from the conference at an early stage without a vote being taken from delegates as attested to in oral evidence received by the APPG during its inquiry.

Furthermore, there is a danger that the FCTC Secretariat will propose language or definitions that will aim to treat all tobacco products the same despite extremely large difference in risk and the likelihood that low-risk products can displace high-risk products for many users. The UK should resist any efforts to use terminology, definitions, or classification to apply measures that may be appropriate for cigarettes to low-risk alternatives to cigarettes. If the Parties want to expand the scope of the FCTC they should modify the FCTC to reflect the great differences in risk between different categories of products and the opportunity to adopt a harm reduction strategy.

Finally, if the FCTC brings Electronic Nicotine Delivery Systems (ENDS) within its framework and is more aggressive against these devices and other reduced risk products, then the UK would be in a difficult position as the FCTC would incorporate policy far more restrictive than UK domestic policy. As such if the UK wished to remain ratified then it would be forced to adopt the new restrictive policies. In this scenario the UK would either have to implement polices contrary to its own stance on vaping or withdraw from the FCTC.

There will be widespread hostility from the WHO itself to the observers who attend the conference, to the domestic policy of the UK, and therefore to any position the UK may take which maintains its position.

It is therefore incumbent upon the UK delegation to raise objections, if necessary, with the FCTC Secretariat to any inclusion of vaping products in the report on novel and emerging products as beyond the scope of its mandate, as per FCTC/COP8(22), and oppose any decision proposed by the FCTC Secretariat or by a Party that would include vaping products within the scope of policy recommendations on novel and emerging products or would equate vaping products with combustible tobacco products.

UK Transparency

During oral evidence, APPG members were told by witnesses that the process for choosing the UK's FCTC COP delegates was not transparent. The delegations are published, and names of those attending is disclosed, but the process should be more open and transparent to ensure confidence, particularly the process by which delegates are selected.

Conclusion

The UK is a global leader in tobacco harm reduction and the use of vaping reduced risk nicotine delivery systems to reduce the smoking rates. It is therefore imperative that the UK continue to lead the world on this issue, with policies that promote the use of tobacco harm reduction products.

Although it should be noted that the WHO stance on vaping and reduced risk products may be due to risk aversion i.e. the concern that in the future vaping may be found to be more harmful than presently thought, the approach of the WHO/FCTC/COP towards vaping and reduced risk products is opposed to UK policy (which has adopted a more pragmatic and progressive approach based on the conclusion that vaping is certainly significantly less harmful than combustible tobacco). As one of the most significant financial contributors to the WHO, with extensive experience in international development and tobacco harm reduction, COP9 provides the UK with an opportunity to advance global health and development goals by sharing best practices from its successful implementation of smoking cessation strategies.

While no change has been made to the FCTC itself, there is sufficient precedent that the UK's domestic position has a degree of acceptability within the context of the WHO and the FCTC.

It is expected there will be widespread hostility to the domestic policy of the UK, and therefore to any stance the UK may take which maintains that position.

The UK currently maintains a highly secretive approach to the FCTC COPs, devoid of transparency, which leaves a number of question marks over the decision-making process it adopts ahead of the COP.

Recommendations

1) The UK delegation to COP9 should highlight the work that has been done in the UK to successfully bring down smoking rates as well as the consensus of opinions from UK public health bodies and NGOs on the safety and real-world efficacy of vaping and other reduced harm products in smoking cessation and harm reduction efforts.

2) The UK delegation should refer to our strong commitment to ensure that harm reduction products do not face issues relating to alleged 'gateway effects' and youth uptake and should highlight the clear results we have on this.

3) The UK approach should also be promoted in upcoming papers, such as the expected WHO regulatory framework for novel tobacco products and the expected FCTC/WHO reports on vaping.

4) If necessary, the UK delegation should raise objections with the FCTC Secretariat to any inclusion of vaping products in the report on novel and emerging products as beyond the scope of its mandate, as per FCTC/COP8(22)[27]. It should oppose any decision proposed by the FCTC Secretariat or by a Party that would include vaping products within the scope of policy recommendations on novel and emerging products, or one that would equate vaping products with combustible tobacco products.

5) The UK delegation to COP9 should propose the establishment a COP Working Group on harm-reduction.

6) The UK should challenge the unduly restrictive and selective policy towards civil society observers and media allowed into COP meetings. The present arrangements create an unhealthy and unrepresentative echo chamber.

7) The UK should work with other member states who share its scientific and harm reduction approach to establish an international coalition with the aim of reducing the harm caused by combustible cigarettes. The UK should

[27] https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf

encourage other member states to also include tobacco harm reduction public health experts in their national COP delegations for this and future events. In taking a science-based approach the UK should work with our coalition partners to encourage regulation that ensures that all reduced risk products are of a high level of (i) quality, (ii) safety and, (iii) performance, in terms of nicotine delivery and improved vapor chemistry.

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