

Japan Tobacco International submission to the APPG for Vaping Inquiry into FCTC COP9

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About Japan Tobacco International

JTI is a leading international tobacco and vaping company with operations in more than 130 countries. It is the global owner of both Winston, the number two cigarette brand in the world, and Camel, outside the USA and has the largest share in sales for both brands. Other global brands include Mevius and LD. In the UK, JTI's brands include Benson & Hedges, Silk Cut, Mayfair, Sovereign and Sterling, as well as a number of other tobacco products including hand-rolling tobacco (Amber Leaf), cigars (Hamlet), pipe tobacco (Condor). JTI is also a major player in the international vaping market with its brand, Logic and tobacco vapor brand, Ploom. Headquartered in Geneva, Switzerland, JTI employs over 44,000 people and in 2021 was certified Global Top Employer for a seventh consecutive year. JTI is a member of the Japan Tobacco Group of Companies. For more information, visit www.jti.com.

Introduction

Reduced-Risk Products (RRPs) are those with potential to reduce the risks associated with smoking. RRP include different nicotine and novel tobacco products such as electronic cigarettes and heated tobacco products (HTPs). Consumers should be free to choose RRP based on accurate information, which requires a thoughtfully designed regulatory environment.

HTPs are tobacco products and therefore fall under the scope of the World Health Organisation's (WHO) Framework Convention on Tobacco Control (FCTC). HTPs are products in which tobacco is heated without combustion to create an inhalable vapor. Due to the absence of combustion, HTPs have the potential to reduce the health risks from smoking.

If regulation ensures HTPs are of a high level of (i) quality, (ii) safety, and (iii) performance, in terms of nicotine delivery and improved vapor chemistry, they (HTPs) can be a satisfying alternative to smoking for existing adult smokers.

Tobacco Harm Reduction (THR) and the FCTC

According to Article 1 (d) of FCTC Treaty¹ 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*'.

Although public bodies² in some countries, including the UK, have acknowledged the role that RRP can play in THR, the FCTC has never properly considered this.

¹ http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf?ua=1

² <https://www.fda.gov/NewsEvents/Speeches/ucm588661.htm>



For THR to work, there must be products with potential to reduce the harm associated with smoking (e.g. HTPs), and these products must be a satisfactory alternative to combustible tobacco products in order for smokers to make the choice to switch. Only in this way can population level harm reduction be achieved.

Even though THR strategies are embedded in the Treaty itself, and in the definition of tobacco control, HTPs are not perceived by the FCTC as a tool in achieving these strategies.

HTPs in previous Conferences of the Parties (COPs)

RRPs have been a subject of discussion in previous COPs. The outcome of these discussions was the non-binding Decision³ adopted during last COP (COP8).

It was also concluded in the report⁴ on further development of the partial guidelines for implementation of Articles 9 and 10 of the FCTC that HTPs should be regulated in the same manner as combustible tobacco products, and that additional independent studies are required. This was reiterated in a WHO information sheet⁵ about HTPs.

The aforementioned COP8 Decision:

- Recognised *‘that the properties of certain novel and emerging tobacco products such as heated tobacco products may pose regulatory challenges regarding their definition and classification, e.g. in relation to the emissions they produce, and that these may pose challenges for the comprehensive application of the WHO FCTC’*
- Acknowledged *‘the new generation of heated tobacco products have not been on the market for long, which results in very few Parties having experience regulating them’*
- Urged the Parties (among other measures):
 - *‘to regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products’*
 - *‘to prevent health claims from being made about novel and emerging tobacco products’*
 - *‘to regulate the contents and the disclosure of the contents of novel and emerging tobacco products’*
 - *‘to explicitly extend the scope of smoke-free legislation to these products’*

The above decision was reflected in a report⁶ to the WHO’s Executive Board on the tenth meeting of the Study Group on Tobacco Product Regulation, published in December 2020.

On Health

Outcomes and recommendations on RRP from previous COPs contradict findings of some of the most reputable public health bodies. There is now a rapidly emerging scientific consensus, reflected in reports⁷ published by UK authorities, that the absence of a combustion process in HTPs makes them a potentially less harmful choice for existing adult smokers:

³ Please see the Decision at: [https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8\(22\).pdf?ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf?ua=1)

⁴ See the report at http://www.who.int/fctc/cop/cop7/FCTC_COP_7_9_EN.pdf?ua=1&ua=1

⁵ See the information sheet at http://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/

⁶ Please see the report at https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_47-en.pdf

⁷ See Public Health England (PHE) [report](#)

See [evaluation](#) and [statement](#) of UK Government’s independent advisory Committees on Toxicity, Carcinogenicity, and Mutagenicity in Food, Consumer Products and the Environment regarding heated tobacco products at [CDC information on HTP](#)

- *‘The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes’*
- *‘Heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC)’*
- *‘Compared with the known risks from conventional cigarettes, they are probably less harmful’*
- *‘The exposure to compounds of concern in using heat-not-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products’*
- *‘A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products’*
- *‘The emissions created from heated tobacco products generally contain lower levels of harmful ingredients than the smoke from regular cigarettes. However, that does not mean heated tobacco products are safe’*

Taking into consideration these developments and the stance of scientific community, it is clear that the discussions in the FCTC arena ignore the reduced-risk potential of these products, and run counter to the advice of THR advocates. This is not in spirit of the text of FCTC Treaty itself.

On Regulation

Recognising HTPs as a separate category

Having in mind the absence of combustion and related reduced-risk potential, it is clear that HTPs are different from combustible tobacco products. This differentiation should be reflected in the regulatory regime.

- One example is the revised EU Tobacco Products Directive (2014/40/EU)⁸ – a comprehensive and credible regulatory framework in which HTPs are regulated separately from tobacco products for smoking.
- Some of the HTP requirements in the Directive include disclosure of ingredients to the authorities, and pre-market submission of available scientific studies on toxicity and data on emissions.
- Such credible yet achievable scientific requirements allowed for a variety of HTPs to be commercialized in most of the member states, capturing substantial market share from combustible tobacco products.
- On the other hand, in the US, where pre-market requirements are excessive and include long term studies, only one HTP has been approved for placement on the market since 2016 (i.e., the implementation of the new regulation).

Acknowledging HTPs’ reduced-risk potential

- Some of the EU member states (e.g. Cyprus, Bulgaria⁹ and Italy¹⁰) went further in separating HTPs from combustibles and have acknowledged the reduced-risk potential of RRP in their national legislation by allowing HTP manufacturers to make limited health claims in comparison with combustible tobacco products. However, no HTPs have been granted the relevant Government approvals to date.
- In the US, any tobacco product (including HTPs) can be a ‘candidate’ for obtaining a reduced-risk or reduced-exposure claim. However, in order to obtain such authorization from the relevant authority, the product’s manufacturer must comply with excessive requirements prescribed by the

⁸ See EU Tobacco Products [Directive](#) (2014/40/EU)

⁹ <https://www.mi.government.bg/bg/library/pravilnik-za-prilagane-na-zakona-za-tyutyuna-tyutyunevite-i-svarzanite-s-tyah-izdeliya-665-c79-m261-1.html>

¹⁰ <https://www.gazzettaufficiale.it/eli/id/2017/08/12/17A05676/sg%22>

regulation and conduct long term studies, clinical and non-clinical investigations, epidemiological studies, etc. Only one HTP has received the authorization from the FDA for a reduced-exposure claim that is exclusively valid for communication purposes in the US.

Conclusions

At COP9 the Parties should promote regulation based on science and seek credible yet achievable scientific evidence from HTP manufacturers to ensure proper supervision of the market:

- Encourage regulation that ensures HTP are of high level of (i) quality, (ii) safety and, (iii) performance, in terms of nicotine delivery and improved vapor chemistry, confirming that they (HTPs) are a satisfying alternative to smoking.
- Acknowledge the reduced-risk potential of RRP and the impact it could have on THR.
- Require a balanced level of scientific assessment – HTPs are not a medicinal drug, nor a no-risk product. They have the potential of being less harmful products for smokers who want to use them as an alternative to combustible tobacco products.

The UK should use COP9 to call for these measures at the FCTC. It would send a strong message to all the Parties (and non-Parties) to consider carefully their regulatory treatment of the category. This would benefit consumers and public health in general.