WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

CONFERENCE OF THE PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

FCTC/COP/10/10
7 July 2023

Tenth session
Panama City, Panama, 20–25 November 2023
Provisional agenda item 6.3

Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, in response to paragraphs 2(a)–(d) of decision FCTC/COP8(22)

Report by the World Health Organization

Purpose of the document

In accordance with decision FCTC/COP9(2), the present report is an updated version of document FCTC/COP/9/9 submitted to the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC). This report summarizes *Technical Report Series 1029*, the eighth report of the WHO Study Group on Tobacco Product Regulation, and the outcomes of the Heated Tobacco Product (HTP) Expert meeting held in February 2020, both of which respond to paragraphs 2(a)–(d) of decision FCTC/COP8(22). It also reports on changes to the 2022 World Customs Organization Harmonized System Codes for nicotine and tobacco products. The report also includes updated evidence, market developments and some recent updates related to HTPs, including policy measures adopted up to 31 December 2022.

Action by the Conference of the Parties

The COP is invited to note the present report and provide further guidance.

Contribution to the Sustainable Development Goals (SDGs): All SDGs; in particular, SDG 3 and Target 3.a.

Link to Workplan and Budget item: 1.1.1.3, 1.1.2.1, 1.1.3.1, 1.1.3.2.

Additional financial implications if not included in the Workplan and Budget: None.

Related document(s): FCTC/COP/10/7; FCTC/COP/10/9; previous COP decisions concerning novel and emerging tobacco products.

INTRODUCTION

1. The Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), at its Eighth session (COP8), requested the Convention Secretariat "to invite the World Health Organization (WHO) and, as appropriate, the WHO Tobacco Laboratory Network (TobLabNet):

> (a) to prepare a comprehensive report, with scientists and experts, independent of the tobacco industry, and competent national authorities, to be submitted to the Ninth session of the COP on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, regarding their health impacts, including on non-users; their addictive potential, perception and use, attractiveness, potential role in initiating and quitting smoking, marketing including promotional strategies and impacts, claims of reduced harm, variability of products, regulatory experience and monitoring of Parties; impact on tobacco control efforts and research gaps, and to subsequently propose policy options to achieve the objectives and measures outlined in paragraph 5 of the present decision;
>
> (b) to examine the chemical and physical processes these products are undergoing during use, including the characterization of emissions;
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> (c) to assess whether the available standard operating procedures for contents and emissions are applicable or adaptable to heated tobacco products;
>
> (d) to advise, as appropriate, on suitable methods to measure the contents and emissions of these products".

2. WHO, in line with decision FCTC/COP8(22) on novel and emerging tobacco products, developed the terms of reference for 11 commissioned papers based on the specific areas highlighted in the request. These formed the basis for the development of the content of the papers by the commissioned experts, who conducted extensive searches of published literature in order to synthesize available evidence. These papers constituted the background papers for the 10th meeting of the WHO Study Group on Tobacco Product Regulation (TobReg), which was held virtually from 28 September to 2 October 2020[1] and coordinated from WHO headquarters in Geneva.

3. Working through TobReg, a rigorous process was followed in terms of the development, review and finalization of the papers. More than 50 independent experts provided the most recent empirical scientific evidence and related regulations – up to the second quarter of 2020 – on nicotine and tobacco products in their background papers, which contributed to their discussions. This report, which summarizes the TobReg papers focused on heated tobacco products (HTPs), addresses paragraph 2 of decision FCTC/COP8(22). Further details on these papers are provided in the full TobReg report published in May 2021 and available at https://www.who.int/publications/i/item/9789240022720 and its accompanying brief, which is available on the WHO website.[2] These documents provide the bibliographic references to the evidence contained in this report.

4. WHO also held a meeting of experts active in HTP research, including laboratory experts, in February 2020 that considered four background papers to address paragraphs 2(b)–(d) of

[1] The 10th Meeting of the WHO Study Group on Tobacco Product Regulation. 2020. https://www.who.int/news-room/events/detail/2020/09/29/default-calendar/the-tenth-meeting-of-the-who-study-group-on-tobacco-product-regulation.

[2] Heated tobacco products: summary of research and evidence of health impacts. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240042490.

decision FCTC/COP8(22). The meeting was attended by more than 20 experts who deliberated on the papers and provided expertise to address specific requests on the examination of the chemical and physical processes these products undergo during use, including the characterization of emissions, an assessment of whether the standard operating procedures (SOPs) for the contents and emissions of cigarettes are applicable or adaptable to HTPs, and the appropriateness of these methods as suitable to measure the contents and emissions of HTPs.

5. Given that full consideration of this report was deferred from the Ninth session of the COP (COP9) and the time elapsed since the 10th TobReg meeting that formed the basis for the evidence of the report delivered to COP9, a few updates that were not part of the original papers submitted to TobReg are included in the present report.

HTPs: DEFINITION, BASIC CHARACTERISTICS AND DESIGN FEATURES

6. HTPs are a re-emerging class of products promoted by manufacturers as "reduced risk", "reduced harm", "cleaner alternatives", "smoke free" or "non-combustible" products.

7. The concept of heating rather than burning tobacco emerged in the 1980s. These earlier products have continued to evolve and are re-emerging now. This paper focuses on HTPs, the newer generation of the products, re-emerging since about 2013 and currently on the market in over 70 countries.

8. HTPs, as a product category, are exceptionally heterogeneous, differing in materials, configuration, the content of their tobacco inserts and the temperature to which the heating element can rise. Nevertheless, HTPs are an integrated tobacco product that usually consists of two standard components that cannot be used, one without the other: a consumable part (an insert containing processed tobacco) and a means for heating the tobacco.

9. HTPs heat tobacco at lower temperatures than conventional cigarettes (CCs). While CCs heat tobacco to at least 800°C, HTPs generally heat tobacco at less than 350°C – but there are some which heat tobacco at higher temperatures. The heat aerosolizes the tobacco constituents into an inhalable nicotine-containing aerosol. This paper does not address the question of whether HTPs generate smoke or whether their use should be considered smoking. This is addressed in document FCTC/COP9/10, recalling paragraph 3 of decision FCTC/COP8(22), which has been updated for the Tenth session of the COP (COP10) and is now before COP10 as document FCTC/COP/10/9.

10. HTPs are the first tobacco product that can harvest personal data on users' tobacco habits. Some HTPs can store user information and potentially transmit it to the producer for marketing purposes.

USE OF HTP AT THE POPULATION LEVEL

11. A systematic review and meta-analysis of the global prevalence of HTP use from 2015 through 2022 indicate that the estimated prevalence for lifetime, current and daily HTP use was 4.9%, 1.5% and 0.8%, respectively, for the entire period. The review covers 45 studies reported on in 38 national surveys, covering 42 countries and areas from four WHO regions.[1] The existing data allow the authors to detect a statistically significant increase in the prevalence of current use in the European Region and the

[1] Sun T, Anandan A, Lim CC, et al. Global prevalence of heated tobacco product use, 2015–22: A systematic review and meta-analysis. Addiction Published Online First: 2023. doi:10.1111/add.16199.

Western Pacific Region. In the Western Pacific Region, the prevalence of current HTP use grew from 0.12% in 2015 to 10.6% in 2020. In the European Region, the prevalence of current HTP use increased from 0% in 2016 to 1.2% in 2020.

12. Independent studies indicate that simultaneous use of CCs and HTPs or other smoking products (also known as "dual use" or "poly use") is more common than implied by industry-sponsored studies. However, the existing studies do not provide a sound estimate of the frequency of dual use.

ATTRACTIVENESS OF HTPs

13. The attractiveness of a product refers to the overall experience of users with it, based on the product itself and the expectations created by its marketing. The attractiveness elements of HTPs as an integrated tobacco product include:

(a) **HTPs reduced-risk expectation**. The tobacco industry claims that HTPs have the potential to benefit the health of users, such as through reduced exposure to toxicants, reduced harm compared to CCs, a claim that is reviewed in paragraphs 19–26 below, and have the potential capacity to help smokers switch away from their use of other smoked tobacco products, a claim which is examined in paragraphs 30–32 below.

(b) **Sensory attributes of both the tobacco insert and the device leading to the overall experience of the product**. Available studies indicate that users consider HTPs less satisfying, not tasting as good and not as calming as CCs, but with less throat discomfort. Some HTPs provide a smaller, but still significant, decrease of nicotine craving than CCs. HTPs are available in a variety of flavours, which appeal to users and bystanders who may be exposed to second-hand aerosols, particularly the youngest ones.

(c) **Ease of use of insert and device**. Users report that HTPs are easy to use, particularly given the existing experience with Electronic Nicotine Delivery System (ENDS) technology. Users sometimes find HTPs more convenient to use than CCs when there are prohibitions on the use of CCs, such as smoke-free places or "because it creates no ash".

(d) **Cost of insert and device**. The price of devices can far exceed the price of the consumables (the insert containing processed tobacco). However, the unit price of consumables is generally close to conventional cigarettes, and the excise tax on HTP consumables is generally lower than those on CCs. Although the device's price could be a potential barrier, it may contribute to the cachet of the product as luxurious and prestigious.

(e) **Reputation and image of the product**. The product name, sleek appearance and packaging, and futuristic flagship shops resemble those of popular cell phones that attract children and adolescents. In combination with the purchasing process, this is an attempt to position HTPs as a high-demand status symbol and upscale product for tech-savvy users.

MARKETING OF HTPs

14. As of July 2023, HTPs were available in over 70 countries. However, in terms of predicted sales, the level is increasing rapidly to a predicted value of US$ 61.5 billion by 2026, from US$ 1.4 billion in 2016. The leading manufacturers that currently dominate the HTP market are Philip Morris International (PMI), with an estimated 71.4% of retail volume in 2021, followed by British American Tobacco (BAT),

with 15.5% of retail volume in 2021, and Japan Tobacco International (JTI), with 4.3% of retail volume in 2021 (Euromonitor).

15. Claims of reduced risk or reduced harm relative to CC use through advanced technology is the basis for the marketing narrative of HTPs. In the process, some manufacturers of these products may hope to improve their corporate image.

16. Tobacco companies use a split marketing approach, using both the device and the tobacco inserts to channel the appeal to potential customers:

(a) through ever-evolving device designs and functions that companies use to appeal to a sense of novelty and to tap into the passion for cutting-edge technology of primarily young people; and

(b) through new sensory experiences, by providing additional flavours of the tobacco inserts, some of which bear close resemblance with CCs.

17. The split marketing strategy hopes to overcome the existing regulatory limits on the advertising, promotion and sponsorship of tobacco products, claiming that the devices are not tobacco products and, therefore, such limits do not apply to them.

STRENGTH OF THE EVIDENCE ON HTPs

18. Before examining the scientific evidence on HTPs, the COP may wish to note that the evidence to date is limited and mostly produced by the industry. A systematic review of the scientific literature on interventional clinical trials of any design published up to April 2022 identified 40 trials, 29 of which were tobacco-industry affiliated. The authors concluded that "the conduct and reporting of HTP interventional clinical trials were poor in many respects and limited to investigating effects of short-term exposure".[1] Therefore, these trials do not provide a good basis for tobacco control policy decisions.

TOXICANTS IN HTP EMISSIONS

19. Standardized laboratory methods for measuring toxicants are lacking, making comparable toxicant measurements difficult. Accurate comparisons of HTPs with other tobacco products cannot yet be made, and generic statements of relative risk for HTP users are still preliminary.

20. The effect of temperature on the formation of harmful constituents in emissions of tobacco products and ENDS is well documented. In the case of HTPs, the emission of toxicants is also related to the temperature at which they operate. The levels of toxicants in emissions are expected to vary depending on how the tobacco is heated and the temperatures reached.

21. Nicotine in the aerosol. Most publications, including non-industry studies, show that the levels of nicotine in HTPs (on a per-stick basis) are about 70% of that of CCs for one HTP brand, while lower for other brands of HTPs.

[1] Braznell S, Van Den Akker A, Metcalfe C, et al. Critical appraisal of interventional clinical trials assessing heated tobacco products: A systematic review. Tobacco Control Published Online First: 2022. doi:10.1136/tc-2022-057522.

HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS (HPHCs)

22. Independent and manufacturer-funded studies show that, even if the temperatures reached by HTPs are not sufficient for combustion, they are still sufficient for the formation of harmful chemicals from pyrolysis and thermogenic degradation, which may include forms of incomplete combustion. The evidence shows that:

- HTPs generate fewer chemical compounds than CCs.
- Many toxicants found in tobacco smoke are at significantly lower levels in HTP aerosol but higher than in ENDS. This includes carbon monoxide, poly aromatic hydrocarbon, some carbonyl compounds and other volatile toxicants. However, HTP aerosol contains other toxicants found sometimes at higher levels than in tobacco smoke, such as glycidol, pyridine, dimethyl trisulfide, acetoin and methylglyoxal.
- Some toxicants found in HTP aerosol are not found in CC smoke. In at least one well-selling brand, four chemicals that are possibly cancer-causing and 15 potentially damaging to the genetic structure were found.

BIOLOGICAL AND HEALTH EFFECTS ON HTP USERS[1]

23. Industry-published studies generally show reduced toxicity for cells and genetic material and lower levels of a range of toxicological and inflammatory biomarkers after exposure in vitro to HTP aerosols, compared with CC smoke. Increasing HTP use intensity, however, results in substantial increases in these effects. Nevertheless, damage to cells and genetic material is more significant after exposure to HTP aerosol than after exposure to air.

24. Industry studies report that animals exposed to HTP aerosol had lower tumour incidence, fewer inflammatory and cellular stress responses, and fewer histological changes than animals exposed to CC smoke. However, the greater the exposure, the greater the harm. Also, harmful effects were more significant in animals treated with HTPs than in air controls.

25. Industry publications report reductions in human tumour biomarkers of exposure to some toxicants in smokers who switch to HTPs. These levels, however, are substantially higher than in groups assigned to stop smoking and not use any product. Nevertheless, the levels of biomarkers of many cardiovascular and other diseases did not decrease over baseline levels after a switch to HTPs, suggesting that HTPs have similar cardiovascular toxicity to CCs.

EXPOSURE AND HEALTH EFFECTS ON BYSTANDERS

26. Research on passive exposure to HTP aerosol is limited. The results to date suggest that the use of HTPs may expose bystanders to certain constituents at higher levels than exposure to clean air or e-cigarette aerosol, although at levels lower than with second-hand smoke from CC smoke.

[1] It should be noted that mainly tobacco industry references are available on these matters.

REDUCED RISK OR HARM CLAIMS

27. Evidence should be examined in relation to two claims that are made about HTPs. A claim that HTPs "reduce risk" should be supported by evidence that switching completely from CCs to HTPs presents less risk of harm from tobacco-related diseases than continuing to smoke CCs, whereas a "reduced exposure" claim should be supported by evidence of a significant reduction in the smoker's exposure to harmful and potentially harmful constituents (HPHCs) by switching completely from CCs to HTPs.

28. As summarized in paragraphs 18–22, the existing evidence is insufficient to support the reduced exposure claims for HTPs. While it is true that the level of some HPHCs in the aerosols from HTPs is lower than in CC smoke, the level of others has not been reported or is actually higher.

29. As summarized in paragraphs 23–26, the existing evidence is insufficient to support either the reduced risk or reduced harm claims for HTPs. The data indicate no improvement in several pulmonary and cardiovascular indicators and a high prevalence of dual use (with smoking) in participants in switching studies. Therefore, uptake of HTPs by smokers may not significantly reduce the prevalence of smoking-associated chronic diseases.

ADDICTIVENESS AND POTENTIAL TO SUBSTITUTE FOR CONVENTIONAL CIGARETTES

30. A few existing studies show that only one HTP brand delivers about 70% of the nicotine in the smoke of CC at a dose, speed and duration comparable to that of cigarettes. At the time of the writing of the commissioned papers for the TobReg report, which was published in May 2021, there were no published efficacy and effectiveness studies of HTPs as aids to switch from CCs to these products completely. Later a systematic review of the scientific literature published up to January 2021 also found no studies reporting on switching from cigarette to HTP smoking. Therefore, no claims can be made of HTPs as aids to switch away from CCs.[1] After the publication of this systematic review, new studies suggest that either HTP users are less likely to transition away from smoking CCs than exclusive cigarette smokers, or that former smokers that use HTPs are more likely to relapse.[2,3,4]

31. In addition to the delivery of nicotine, product attractiveness is important in substitution behaviour. As indicated in paragraph 13(b) of the present document, HTPs, particularly one brand, appear to reduce subjective smoking craving, although not as significantly as CCs.

32. At this point, the existing indirect evidence shows that the nicotine delivered by HTPs approximates the addiction potential of nicotine delivered by CCs. The evidence is still inconclusive as to whether this potential is enough to facilitate the total substitution for the use of CCs.

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[1] Tattan-Birch H, Hartmann-Boyce J, Kock L, et al. Heated tobacco products for smoking cessation and reducing smoking prevalence. Cochrane Database of Systematic Reviews 2022;2022. doi:10.1002/14651858.cd013790.pub2.

[2] Kanai M, Kanai O, Tabuchi T, et al. Association of heated tobacco product use with tobacco use cessation in a Japanese workplace: A prospective study. Thorax 2021;76:615–7. doi:10.1136/thoraxjnl-2020-216253.

[3] Luk TT, Weng X, Wu YS, et al. Association of heated tobacco product use with smoking cessation in Chinese cigarette smokers in Hong Kong: A prospective study. Tobacco Control 2020;30:653–9. doi:10.1136/tobaccocontrol-2020-055857.

[4] Odani S, Tsuno K, Agaku IT, et al. Heated tobacco products do not help smokers quit or prevent relapse: A longitudinal study in Japan. Tobacco Control Published Online First: 2023. doi:10.1136/tc-2022-057613.

CHEMICAL/PHYSICAL PROCESSES OF HTPs AND SUITABILITY OF AVAILABLE METHODS FOR TESTING HTPS

33. Following assessment of the available SOPs for testing the contents and emissions of cigarettes and their applicability or adaptability to HTPs, the existing SOPs are considered by WHO to be applicable and adaptable to HTPs. However, preliminary analysis will be required to make some modifications to the methods by TobLabNet and to validate the methods for the determination of priority toxicants in HTPs. For contents, the validation of the methods for nicotine and aerosolizing agents (propylene glycol and glycerol) was prioritized, which led to the publication of the *Standard operating procedure for determination of nicotine, glycerol and propylene glycol content in the tobacco of heated tobacco products* (WHO TobLabNet Method SOP15).[1] For emissions, the validation of methods for nicotine, carbon dioxide and aldehyde should be prioritized, and work is currently underway by WHO to organize a collaborative study for the determination of these analytes in the emissions of HTPs. The *Information sheet on measuring priority emissions in heated tobacco products – importance for regulators and significance for public health* provides further information on emissions testing in HTPs.[2]

REGULATORY STATUS

34. According to the data collected by WHO as of 31 December 2022 for 195 countries and territories, 19 countries had banned the sale of HTPs, while 69 specifically regulated HTPs in one form or another: 16 as conventional tobacco products, 29 as novel products, five as ENDS, 10 as smokeless tobacco and the rest as other products. Another 86 countries seem to implicitly regulate HTPs (tobacco sticks) under conventional tobacco product regulations. Of the 175 countries and one territory that do not ban the sale of HTPs,

- three ban all flavours and 11 have flavour restrictions
- 57 ban the use of HTPs where smoking is not permitted
- 46 have some labelling requirements for HTP tobacco sticks
- 67 apply the same advertising, promotion and sponsorship requirements as for CCs.

With regard to HTP taxation, most countries tax HTPs at much lower rates than CCs. However, HTP prices are similar or higher than for CCs in most countries.[3,4,5]

[1] Standard Operating Procedure for determination of nicotine, glycerol and propylene glycol content in the tobacco of heated tobacco products. WHO TobLabNet Official Method SOP15. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240079304.

[2] Available at https://www.who.int/publications/i/item/WHO-HEP-HPR-TFI-2021.1.

[3] Filippidis F. Cost, affordability and market share of heated tobacco products. Tobacco Prevention & Cessation 2019;5. doi:10.18332/tpc/105160.

[4] Kyriakos C, Ahmad A, Chang K, et al. Price differentials of tobacco products: A cross-sectional analysis of 79 countries from the six who regions. Tobacco Induced Diseases 2021;19:1–9. doi:10.18332/tid/142550.

[5] Dauchy E, Shang C. The pass-through of excise taxes to market prices of heated tobacco products (HTPs) and Cigarettes: A cross-country analysis. The European Journal of Health Economics 2022;24:591–607. doi:10.1007/s10198-022-01499-x.

35. The World Customs Organization has a Harmonized System Code (HS Code) that harmonizes domestic customs codes applied to the entry and exit of goods at borders, and the HS Code is often used classify good for the purposes of levying excise taxes. Until 2022, HTPs did not have a specific customs code and fell under the subheading of "other" (2403.99) in the chapter devoted to tobacco and manufactured tobacco substitutes. Amendments to the HS Code took effect on 1 January 2022, creating a new heading (2404) for "products intended for inhalation without combustion", including subheadings for products "containing tobacco or reconstituted tobacco" (2404.11), which would include HTPs.

36. National customs codes, used for purposes of imposing customs duties and often for purposes of levying excise taxes, should now have been updated. Customs duties previously applicable to HTPs under 2403.99 should now apply to the new category of products under 2404.11. Given these changes, corresponding changes should be made to excise tax laws where they refer to national customs codes to distinguish between product categories. In this respect, WHO recommends that HTPs be taxed at an equivalent rate to CCs. To ensure this, where excise tax laws refer to customs codes in this way, it is recommended that any product falling within the new 2404.11 subheading should be taxed at an equivalent rate to CCs under 2402.90.

KEY FINDINGS

37. As is the case for ENDS and Electronic Non-nicotine Delivery System (ENNDS), the administration of nicotine with HTPs requires the combination of a source of nicotine with a device. The apparatus may be sold separately from the nicotine liquid or tobacco insert, but it is necessary to the user's experience since they are an integrated product.

38. Harm reduction or risk reduction claims are the basis for the marketing narrative of HTPs, combined with tapping into the passion for technology, primarily of young people. Tobacco companies often split their marketing between the device and the tobacco insert, claiming that the devices are not tobacco products and should not be subject to health warning requirements and bans on advertising, promotion and sponsorship, or other marketing restrictions that are in place for tobacco products.

39. The existing evidence indicates that HTPs are harmful and that while smokers switching completely from CCs to HTPs may reduce their exposure to some HPHCs, they do not reduce their exposure to all of them.

40. The evidence is inconclusive as to whether smokers switching completely from CCs to HTPs decrease the harm from tobacco-related diseases compared to continuing smokers.

41. The existing evidence is inconclusive about whether HTPs overall help to transition smokers from CCs, either partially or entirely.

LEGAL OBLIGATIONS AND POLICY OPTIONS

42. In decision FCTC/COP8(22), Parties recognized HTPs as tobacco products and were reminded about their commitments under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products, such as HTPs and devices designed for consuming such products.

43. Covering some items already included in decisions FCTC/COP7(9) and FCTC/COP8(22), and in dealing with the regulation of novel and emerging tobacco products like HTPs, a focus must be maintained on wider tobacco control. Parties should consider the following regulatory objectives:

- prevent the initiation of use by non-smokers and youth, with special attention to vulnerable groups;
- minimize as far as possible potential health risks to users and protect non-users from exposure to their emissions;
- prevent unproven claims from being made about these products, including health claims, comparative claims, smoking cessation claims, ingredient/emission claims and reduction of disease risk claims; and
- protect tobacco-control activities from all commercial and other vested interests related to the tobacco and related industries.

44. Further to these decisions, and in light of the design and marketing strategies for HTPs, both the device and the tobacco insert should be addressed as tobacco products for the purposes of domestic tobacco control laws. Where sold together, or otherwise bundled, tobacco inserts and devices are one integrated tobacco product. The HTP device and the tobacco inserts are designed to be used together, since one without the other is useless. Devices and tobacco inserts are also always used together, meaning that they should be treated as integrated products even where sold or marketed separately.

45. Consequently, policymakers should apply the existing national tobacco products regulations to HTPs, including the device. In some instances, this may already be possible. For example, device advertising or promotion also promotes consumption of the tobacco inserts, meaning that existing laws may address the issue. However, in other instances existing tobacco regulations may need to be strengthened to close loopholes and provide the highest standards for the protection of the public's health, even in countries where HTPs are currently not legally available.

46. Regulators should not allow themselves to be distracted by tobacco and related industry tactics or the aggressive promotion of these products. To this end, it is evident that tobacco control policies must be forcefully protected from the influence of the nicotine and tobacco industries in line with Article 5.3 of the WHO FCTC and its Guidelines for implementation. In this regard, policymakers must base decisions on sound science, promote independent research, clarify the source of research funding to identify undue influence and verify the industry's research. Furthermore, they should seek full disclosure of product information to regulators.

47. As requested in paragraph 2(a) of decision FCTC/COP8(22), the following policy options may be considered by Parties in order to achieve the objectives and measures outlined in paragraph 5 of that decision:

(a) **Article 6:** Until more clarity is provided about the harms and relative risks of HTPs and given the relative homogeneity of tobacco inserts used in HTPs, these products should be taxed at the same rate as CCs, in order to achieve parity with the average CC tax rates within a country. In the case of a specific tax, the base should be per unit.

(b) **Article 8:** Taking into account paragraph 26 of this report, ban the use of HTPs where smoking is prohibited, making sure that legislation for smoke-free environments complies with all recommendations of Article 8 Guidelines for implementation and treats HTP use as smoking.

(c) **Articles 9 and 10:**

(i) Monitor priority harmful compounds in HTP emissions such as nicotine, aldehydes and carbon monoxide, and reduce as appropriate, based on WHO recommendations and the national context.

(ii) Consider using the methods developed by TobLabNet (see annex to document FCTC/COP/10/7) to measure priority toxicants in HTP contents and emissions.

(iii) Regulate the contents, emissions and design features of HTPs and require disclosure of the contents of HTPs in accordance with Articles 9 and 10 of the WHO FCTC, including restriction of the use of flavours that appeal to minors and prohibit the addition of pharmacologically active substances, in jurisdictions where they are legal.

(d) **Article 11:** Require large graphic health warnings and plain packaging on HTP inserts and device packages as for any other smoked tobacco products.

(e) **Article 12**: Ensure that the public is well informed about the risks associated with use of HTPs, including the risks of dual use with CCs and other tobacco products, and stress that reduced exposure does not necessarily mean reduced harm.

(f) **Article 13**: Apply existing bans on tobacco advertising, promotion and sponsorship to tobacco inserts and devices, and where this is not currently possible (as indicated in paragraphs 3 and 4 of Article 13 of the WHO FCTC) strengthen the law to ban all forms of advertising, promotion and sponsorship of HTP inserts and devices, in accordance with Article 13 and its Guidelines for implementation. In order to address the newer forms of advertising, promotion and sponsorship, Parties are urged to consider the following recommendations by TobReg in its Ninth Report[1]:

- ensure that laws on tobacco advertising, promotion and sponsorship are comprehensive and in line with the WHO FCTC at a minimum, if they are not already, and that they encompass online digital media platforms, including social media and any other forms of direct or indirect marketing;

- strengthen monitoring and enforcement and cooperate internationally to address cross-border practices of the tobacco and related industries, including online digital tobacco advertising, promotion and sponsorship; and

- require the tobacco and related industries to disclose to government authorities all advertising, promotion and sponsorship activities, including those on online digital media platforms.

[1] WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1047). Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240079410.

(g) **Article 14:** In taking effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence, HTPs are tobacco products and should be treated as such, with the measures applicable to all tobacco use applied to HTPs.

(h) **Article 16:** Ban sale of HTPs to and by minors.

(i) **Article 20:** Strengthen national and international monitoring and surveillance of trends in HTP use, sales and marketing strategies, with particular attention to social media.

ACTION BY THE CONFERENCE OF THE PARTIES

48. The COP is invited to note this report and to provide further guidance.

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