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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

This World Health Organization 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 Expert meeting held in February 2020, both of which respond to paragraphs 2(a)–(d) of decision FCTC/COP8(22), as well as recent outcomes of the World Customs Organization on harmonized codes for nicotine and tobacco products.

Action by the Conference of the Parties

The Conference of the Parties is invited to note the report and provide further guidance.

Contribute to the Sustainable Development Goals (SDGs), if applicable: Target 3.a and Goal 3.

Link to the 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/9/8; FCTC/COP/9/10; 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;
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> (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;
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> (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 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.[1] 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 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

[1] Policy Brief on heated tobacco products (2021). https://www.who.int/health-topics/tobacco#tab=tab_1.

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.

HTPs: DEFINITION, BASIC CHARACTERISTICS AND DESIGN FEATURES

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

6. 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 more than 50 countries.

7. 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.

8. 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).

9. 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

10. Data on the proportion of the population using HTPs globally are scant and involve studies from 2015 to 2019. About 3% of the young adult population in Japan and the Republic of Korea were currently using HTPs during that period. In the remaining countries with available data, all of which are in Europe, current use during that period was under 0.5% of the adult population.

11. 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 any real sense of the frequency of dual use.

ATTRACTIVENESS OF HTPs

12. 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 17–24 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 28–31 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 are generally close to conventional cigarettes, and the excise tax on HTP consumables are 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

13. HTPs are currently available in over 50 markets. However, in terms of predicted sales, the level is increasing rapidly to a predicted value of US$ 22 billion by 2024, from US$ 6.3 billion in 2018. Three leading manufacturers currently dominate the HTP market: Philip Morris International (PMI); Japan Tobacco International (JTI); and British American Tobacco (BAT).

14. 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.

15. 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 of 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.

16. 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.

TOXICANTS IN HTP EMISSIONS

17. 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.

18. 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.

19. 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.

HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS (HPHCs)

20. 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]

21. 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.

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

22. 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.

23. 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

24. 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.

REDUCED RISK OR HARM CLAIMS

25. 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.

26. As summarized in paragraphs 17–20, 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.

27. As summarized in paragraphs 21–24, 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

28. 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 completely switch from CCs to these products. In the absence of direct empirical evidence of the potential efficacy and effectiveness of HTPs in aiding a switch away from CCs, the 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.

29. In addition to the delivery of nicotine, product attractiveness is important in substitution behaviour. As indicated in paragraph 12b of the present document, HTPs, particularly one brand, appear to reduce subjective smoking craving, although not as significantly as CCs.

30. 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.

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

31. 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) should be prioritized, and for emissions the validation of methods for nicotine, carbon dioxide and aldehyde should be prioritized. 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.[1]

REGULATORY STATUS

32. According to the 2021 WHO report on the *Global Tobacco Epidemic*, which covered the year ending 31 December 2020, 11 countries had banned the sale of HTPs, while 48 specifically regulated HTPs in one form or another. A handful of countries neither regulate nor ban these products, and all the remaining countries implicitly regulate HTPs as tobacco products. The data available, however, show that these products are often subject to more lenient regulations than conventional tobacco products. Some countries regulate labelling of both the device and the tobacco insert, while others regulate only the insert. Some countries regulate the advertising, promotion and sponsorship (APS) of HTP devices and inserts, while others regulate only the APS of the inserts. According to a policy scan, 23 of 70 countries reviewed applied taxes to HTPs as of December 2020. Some countries are taxing HTPs at the same rate per stick as CCs (Azerbaijan, Colombia, Georgia, Israel, Japan and Ukraine, as well as in the occupied Palestinian territory, including east Jerusalem). Saudi Arabia and the United Arab Emirates, which have recently introduced an excise tax on tobacco products as part of a Gulf Cooperation Council initiative, are now applying the same import duty rate and excise tax structure for CCs and HTPs.

33. 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 for the purposes of levying excise taxes. Until now, 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. Beginning in 2022, amendments to the HS Code will take effect, creating a new heading (2404) for "products intended for inhalation without combustion", including subheadings for products "containing tobacco or reconstituted tobacco" (2404.11). National customs codes, used for purposes of imposing customs duties and often for purposes of levying excise taxes, will also be updated. Customs

[1] Available at https://www.who.int/publications/i/item/WHO-HEP-HPR-2020.1

duties previously applicable to these products under 2403.99 will ordinarily apply to the new category of products under 2404.11. But excise tax laws will need to be updated 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, and without prejudice to the question of which products might fall under 2404.11, 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

34. 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.

35. 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 APS bans, or other marketing restrictions that are in place for tobacco products.

36. The existing evidence indicates that HTPs are likely not harmless 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.

37. 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.

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

LEGAL OBLIGATIONS AND POLICY OPTIONS

39. 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.

40. 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.

41. 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 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.

42. Consequently, policy-makers should apply the existing national tobacco products regulations to heated tobacco products, 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.

43. 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, policy-makers 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.

44. 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 24 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 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 sponsorships of HTP inserts and devices, in accordance with Article 13 and its Guidelines for Implementation.

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

(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

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

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