

# HEATED TOBACCO PRODUCTS INFORMATION SHEET

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## What are heated tobacco products?

Heated tobacco products (HTPs) produce aerosols containing nicotine and toxic chemicals when tobacco is heated or when a device containing tobacco is activated. These aerosols are inhaled by users during a process of sucking or smoking involving a device. They contain the highly addictive substance nicotine as well as non-tobacco additives, and are often flavoured. The tobacco may be in the form of specially designed cigarettes (e.g. “heat sticks” and “Neo sticks”) or pods or plugs.

Newer heated tobacco products include lower- and higher-temperature variants, hybrid electronic devices with both tobacco and liquid, carbon-tipped devices, devices using a metallic mesh punctured with tiny holes to heat a pre-filled, pre-sealed liquid cap, and others which allow users to customize the temperature and manage the aerosol and flavour output. Additionally, several products in this category are under development, some of which are based on new technology.

### HTPs:

- contain tobacco and are tobacco products;
- do not help smokers to end tobacco use;
- emit toxic emissions that are similar to those found in cigarette smoke, many of which can cause cancer;
- expose users to toxic emissions, some of which are specific to HTPs and which could also expose bystanders;
- contain toxicants – though generally lower than those found in conventional cigarettes, the levels of some toxicants are higher and there are new substances absent in tobacco smoke which could potentially harm human health;
- have reduced toxicant levels relative to conventional cigarettes, although this does not necessarily translate to a reduction in health risk;
- contain nicotine, which is highly addictive, at levels similar to conventional cigarettes and nicotine is linked to health harms, particularly in children and adolescents; and
- have an unknown long-term health impact in terms of their use and exposure to their emissions, and because there is currently insufficient independent evidence on the relative and absolute risk, independent studies are needed to determine the health risk they pose to users and bystanders.

## What are some examples?

Examples of HTPs include iQOS from Philip Morris International (PMI), Ploom from Japan Tobacco International, glo from British American Tobacco, and PAX products from PAX Labs.

## How do HTPs work?

In order to produce the nicotine-infused aerosol, HTPs heat tobacco, sometimes in conjunction with a liquid, up to temperatures lower than conventional cigarettes (generally less than 600 °C) using battery-powered heating-systems. The heating-system enclosed in a device can be an external heat source that aerosolizes nicotine from specially designed cigarettes (e.g. iQOS and glo), or a heated sealed chamber which aerosolizes nicotine directly from tobacco (e.g. Ploom and Pax). The heating device requires charging and the user draws on the mouthpiece at intervals to inhale volumes of the aerosol, which is then taken into the body.

## Where are HTPs marketed?

HTPs are marketed in more than 40 countries as of July 2019,<sup>i</sup> covering all six regions of WHO. These products are also present in markets where they are banned by law. Marketing channels include the internet, promotional events, flagship stores, supermarkets, shopping malls, social media etc., especially with an eye towards markets in low- and middle-income countries.<sup>1</sup>

<sup>i</sup> For instance, PMI's iQOS is available in: Andorra, Albania, Armenia, Bosnia and Herzegovina, Bulgaria, Canada, Colombia, Croatia, Cyprus, Czechia, Denmark, the Dominican Republic, France, Germany, Greece, Guatemala, Hungary, Italy, Israel, Japan, Kazakhstan, the Republic of Korea, Latvia, Lithuania, Malaysia, Moldova, Monaco, the Netherlands, New Zealand, Palestine, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, South Africa, Spain, Switzerland, Ukraine and the United Kingdom.

## Are HTPs electronic cigarettes or electronic nicotine delivery systems (ENDS)?

No, HTPs should not be confused with e-cigarettes/ENDS. HTPs heat tobacco to generate nicotine and are not “vape products” as often referred to by tobacco and related industries. E-cigarettes/ENDS heat a liquid containing nicotine and do not contain tobacco. Those that do not contain nicotine are called electronic non-nicotine delivery systems (ENNDS).

## Are HTPs safer than conventional tobacco?

Currently, there is no evidence to demonstrate that HTPs are less harmful than conventional tobacco products. HTPs contain chemicals not found in cigarette smoke and may have associated health effects. Independent assessment of industry data shows that more than 20 harmful and potentially harmful chemicals are significantly higher than in reference cigarette smoke.<sup>2</sup> Additionally, these products are highly variable and some of the toxicants found in the emissions of these products are carcinogens (i.e. they can cause cancer in humans).

In addition to tobacco industry-funded studies, there are some independent studies showing that there are significant reductions in the formation of and exposure to some harmful and potentially harmful constituents (HPHCs) relative to standard cigarettes<sup>3</sup> and independent reviews of industry data have concluded the same.<sup>4,5,6</sup> However, the relationship between exposure and health effect is complex and reduced exposure to these harmful chemicals does not mean that they are harmless, nor does it translate to reduced risk in humans. Based on submissions to some regulatory agencies, the industry has not been able to demonstrate that these products will reduce tobacco-related disease. HTPs also emit small particles that can easily access the lung and

potentially damage lung tissue.<sup>7</sup> Currently, there is insufficient evidence to support the claim of less harm relative to conventional cigarettes and additional independent studies will be required to substantiate any claims of reduced risk/harm.

## Are HTPs safe for second-hand exposure?

At the moment, there is insufficient evidence on the effects of second-hand emissions produced by HTPs, though the emissions do contain HPHCs.<sup>8</sup> Independent studies are needed to assess the risk posed to bystanders.

## What are the gaps in current research findings on HTPs?

There is a large knowledge gap, as this generation of HTPs has not been on the market long enough for the potential effects to be studied. Conclusions cannot yet be drawn about their potential to attract new, young tobacco users (gateway effect), or the interaction in dual use with other conventional tobacco products and e-cigarettes. Future independent studies should address these effects, as well as the safety and risk of HTPs.

## How are HTPs regulated or classified for regulatory purposes?

HTPs are banned in a few countries; elsewhere they are classified as novel tobacco products, tobacco products, smokeless tobacco products, or electronic cigarettes. In the United States, they are regulated as non-combustible cigarettes. Some countries also utilize multiple categories (for example some categorize the heating device and HTP consumables separately).

## How should HTPs be regulated?

HTPs should be regulated as tobacco products in line with WHO's guidance<sup>9</sup> and with the relevant decision of the eighth session of the Conference of the Parties (COP8) to the WHO Framework Convention on Tobacco Control (WHO FCTC) on novel and emerging tobacco products.<sup>10</sup> Regulators are urged to take action based on the available evidence.

WHO's guidance states that all forms of tobacco use are harmful, including HTPs. Tobacco is inherently toxic and contains carcinogens, even in its natural form. Therefore, HTPs should be subject to policy and regulatory measures applied to all other tobacco products, in line with the WHO FCTC and national law. This is reinforced by the WHO FCTC COP8 decision and countries are encouraged to fully apply the WHO FCTC to HTPs, to the extent possible. Countries may also wish to prioritize tobacco demand-reduction measures, such as those of MPOWER.<sup>11</sup>

## What are the next steps?

WHO continues to monitor research and build evidence, including through its tobacco product regulation collaborating centres and its technical groups, the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet) and its various resources. WHO also continues to monitor market developments and industry activities. Further, it will update relevant global surveillance mechanisms to ensure effective monitoring and evaluation of HTPs. These activities will contribute to WHO's efforts to assist Member States in formulating effective strategies to regulate these products.

## References

<sup>1</sup> World Health Organization. Heated tobacco products (HTPs) market monitoring information sheet. Geneva. [Online]. ([https://www.who.int/tobacco/publications/prod\\_regulation/https-marketing-monitoring/en/](https://www.who.int/tobacco/publications/prod_regulation/https-marketing-monitoring/en/))

<sup>2</sup> St. Helen G, Jacob P III, Nardone N, Benowicz NL. IQOS: examination of Philip Morris International's claim of reduced exposure. *Tobacco Control*. 2018;27:s30-s36. <http://dx.doi.org/10.1136/tobaccocontrol-2018-054321>.

<sup>3</sup> Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R and Gallus S. Heat-not-burn tobacco products: concerns from the Italian experience. *Tobacco Control*. 2019;28:113-114. doi 10.1136/tobaccocontrol-2017-054054.

<sup>4</sup> U.S. Food and Drug Administration. Meeting of the Tobacco Products Scientific Advisory Committee, January 24-25, 2018. [Online] (<https://www.fda.gov/media/111455/download>).

<sup>5</sup> U.K. Committee on Toxicity. Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary. [Online] ([https://cot.food.gov.uk/sites/default/files/heat\\_not\\_burn\\_tobacco\\_summary.pdf](https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf), accessed 28 October 2019).

<sup>6</sup> U.K. Committee on Toxicity. Statement on the toxicological evaluation of novel heat-not-burn tobacco products. [Online] ([https://cot.food.gov.uk/sites/default/files/heat\\_not\\_burn\\_tobacco\\_statement.pdf](https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf), accessed 28 October 2019).

<sup>7</sup> Singh SS, Eapen MS, Naidu EGM, Sharma P. IQOS exposure impairs human airway cell homeostasis: direct comparison with traditional cigarette and e-cigarette. *ERJ Open Research* Feb 2019, 5 (1) 00159-2018. doi: 10.1183/23120541.00159-2018.

<sup>8</sup> Davis B, Williams M, Talbot P. iQOS: evidence of pyrolysis and release of a toxicant from plastic. *Tobacco Control* 2019;28:34-41. <http://dx.doi.org/10.1136/tobaccocontrol-2017-054104>

<sup>9</sup> World Health Organization. Heated tobacco products (HTPs) information sheet. [Online] ([https://www.who.int/tobacco/publications/prod\\_regulation/heated-tobacco-products/en/](https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/), accessed 28 October 2019).

<sup>10</sup> Conference of the Parties WHO Framework Convention on Tobacco Control Decision, eighth session, Decision FCTC/COP8(22) Novel and emerging tobacco products.

<sup>11</sup> World Health Organization. MPOWER. Geneva. [Online] (<https://www.who.int/tobacco/mpower/publications/en/>, accessed 28 October 2019).

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