# HEATED TOBACCO PRODUCTS

## A BRIEF

World Health Organization
REGIONAL OFFICE FOR Europe

# Abstract

Heated tobacco products (HTPs) are tobacco products that produce an emission containing nicotine and other chemicals, which is then inhaled by users. HTPs are a re-emerging class of tobacco products marketed as so-called potentially reduced-exposure products, or even as modified-risk tobacco products. Currently there is insufficient evidence to conclude that HTPs are less harmful than conventional cigarettes. In fact, there are concerns that while they may expose users to lower levels of some toxicants than conventional cigarettes, they also expose users to higher levels of other toxicants. It is not clear how this toxicological profile translates into short- and long-term health effects. The Conference of the Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC) recognizes HTPs as tobacco products and therefore considers them to be subject to the provisions of the WHO FCTC.



# Keywords

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# Introduction

Processed tobacco in heated tobacco products (HTP)[1] is heated without reaching ignition to produce an emission containing nicotine and other chemicals, which is then inhaled by users. HTPs are a re-emerging class of tobacco products marketed as so-called potentially reduced-exposure products, or even as modified-risk tobacco products.

This class of products is defined as re-emerging because at the time of this brief, HTPs were conceptually and technologically an evolution of similar products tobacco companies marketed through the 1980s and 1990s. Back then, the precursors of these products were unsuccessful, and their sale discontinued. The emerging HTPs, however, are expected to capture a significant market share.

Total sales for HTPs in 2016 were US$ 2.1 billion, and they are expected to reach US$ 17.9 billion by 2021 *(1)*. They stand a better chance of profitable marketing today because the tobacco industry is riding partly on the popularity of electronic nicotine and non-nicotine delivery systems (EN&NNDS) in some countries. Although an entirely different class of product, EN&NNDS have changed social norms and perceptions about conventional cigarette-smoking and the use of devices to deliver nicotine in many countries.

Only a few HTPs have been marketed so far *(1)*. Japan Tobacco International (JTI) introduced the Ploom in 2013 jointly with a firm known as Pax Labs, which has continued independently to market the PAX brand. JTI relaunched the Ploom independently in 2016. Philip Morris International (PMI) launched IQOS (I Quit Ordinary Smoking) in 2014. British American Tobacco (BAT) first marketed iFuse in Romania in 2015. Later, BAT marketed Glo in Asia. The Korea Tobacco and Ginseng Corporation (KT&G) is the latest incomer to the HTP market with the lil HTP in 2017 *(2)*. Currently, HTPs are marketed in about 40 countries and IQOS is present in most of them.

There is not much information about the prevalence of HTP use and less about its trends. In Japan, 0.3% of the population aged 15–69 years reported using IQOS in the last 30 days (current use) in 2015 *(3)*. Two years later, this figure was 3.6%. In 2017, 1.2% were currently using Ploom and 0.8% Glo *(4)*. These figures are not mutually exclusive. In Italy, 1.4% of the population aged ≥ 15 years tried IQOS in 2017. Overall, 1.0% of never-smokers, 0.8% of ex-smokers and 3.1% of current cigarette smokers had tried IQOS *(5)*. In Germany, 0.3% of current smokers and recent ex-smokers aged 14 years or more currently used HTPs in 2017 *(6)*. In Great Britain, 1.7% of adults had tried or were using HTPs in 2017, but only 13% of them had been using it daily *(7)*. Three months after the introduction of IQOS in the Republic of Korea in 2017, 3.5% of young adults aged 19–24 years were current users, although all of them also used conventional cigarettes and EN&NNDS *(8)*.

Smoking, the traditional way of extracting nicotine by burning tobacco, results in smoke containing thousands of compounds, many of which are harmful to health. HTPs are based on the principle that burning tobacco is unnecessary to liberate nicotine. In smoking, aerosolizing nicotine is achieved by igniting tobacco, reaching temperatures of up to 900 °C in the burning cone, but a similar release is attained in HTPs by the volatilization and even pyrolysis *(9)* of tobacco at temperatures of around 350 °C, although in some products it may reach up to 550 ºC *(10)*. The lower temperature at which nicotine is volatilized is expected to expose the user to emissions that have fewer toxicants and in smaller amounts than in conventional cigarette smoking. The essential difference between HTPs and EN&NNDS is that the former uses tobacco leaf while the latter does not.

This brief provides a summary of existing evidence of the ingredients, emissions and health effects of HTPs, with a review of policy options for regulation.

[1] The tobacco industry calls HTPs "heat-not-burn" products.

# Types of HTPs

There are four types of HTPs, depending on how tobacco is heated to deliver nicotine to the user's lungs *(11)*. The first is a cigarette-like device with an embedded heat source that can be used to aerosolize nicotine. The heat is provided by a pressed carbon-tip heat source located at the end of the product, which must be lighted like a conventional cigarette with a standard match or lighter (Fig. 1). Once lit, heat is transferred from the carbon tip to the tobacco, which is not in contact. The resulting temperature of about 350 °C generates an emission infused with nicotine that is inhaled through the mouthpiece. No electrical system is used. After use, the product needs to be extinguished and discarded *(12)*.

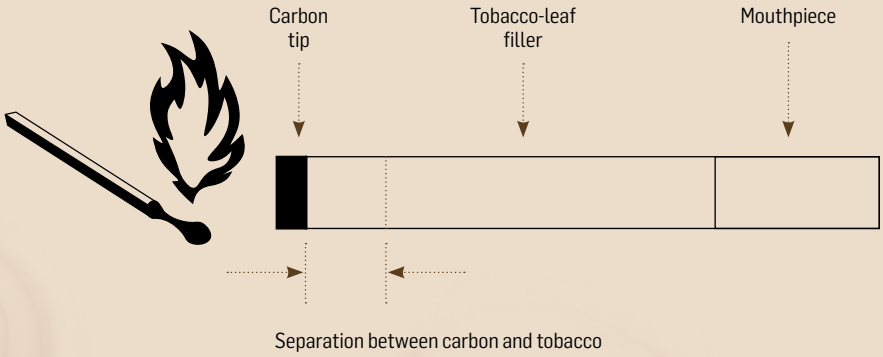
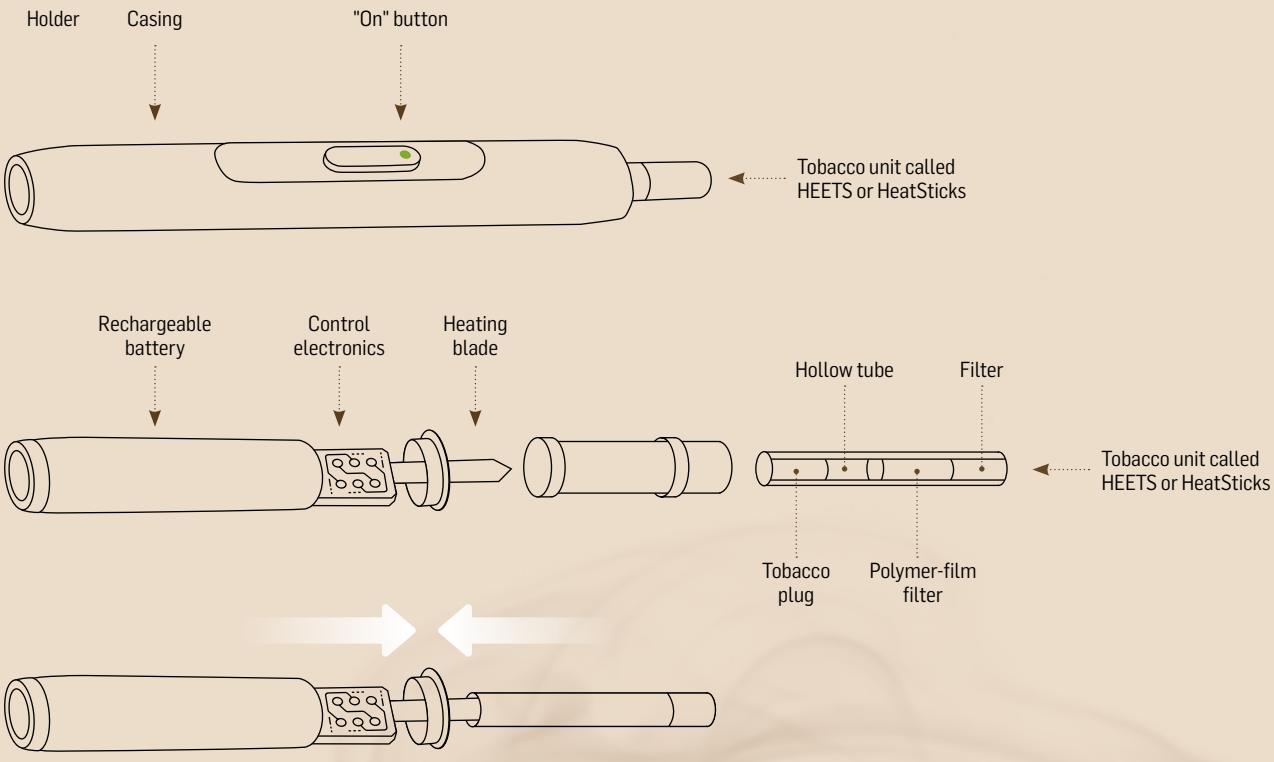



**FIG. 1. HTP type 1**

The second type uses an external heat source to aerosolize nicotine from specially designed cigarettes. This is the basic design of IQOS *(13)* (Fig. 2) and Glo *(14)*. The tobacco used in PMI's HTP is apparently not typical tobacco cut-filler but rather a reinforced web of cast-leaf tobacco (a type of reconstituted tobacco) that includes 5–30% by weight of compounds that form emissions, such as polyols, glycol esters and fatty acids. In IQOS, the tobacco is heated by a blade in the heater device inserted into the end of the heat stick (or tobacco-containing element) so that the heat dissipates through the tobacco plug on a puff. The emission then passes through a hollow acetate tube and a polymer film filter on the way to the mouth. BAT describes its Glo product as a heating tube consisting of two separately controlled chambers that are activated by a button on the device to reach the operating temperature (240 °C) within 30–40 seconds.

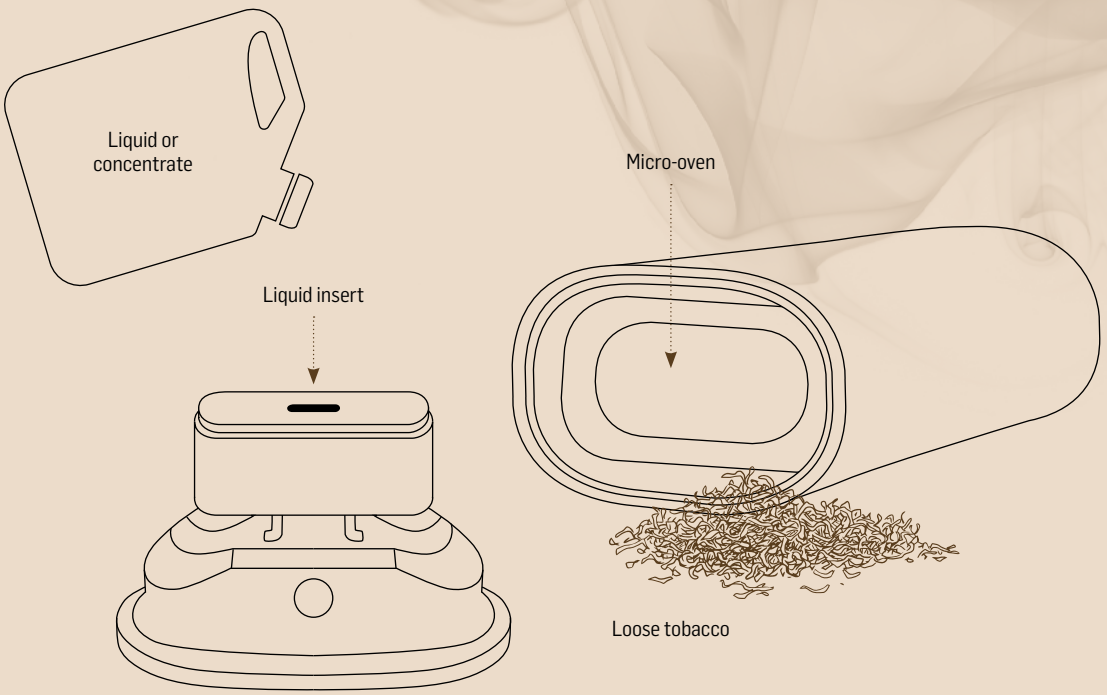
**FIG. 2. HTP type 2**



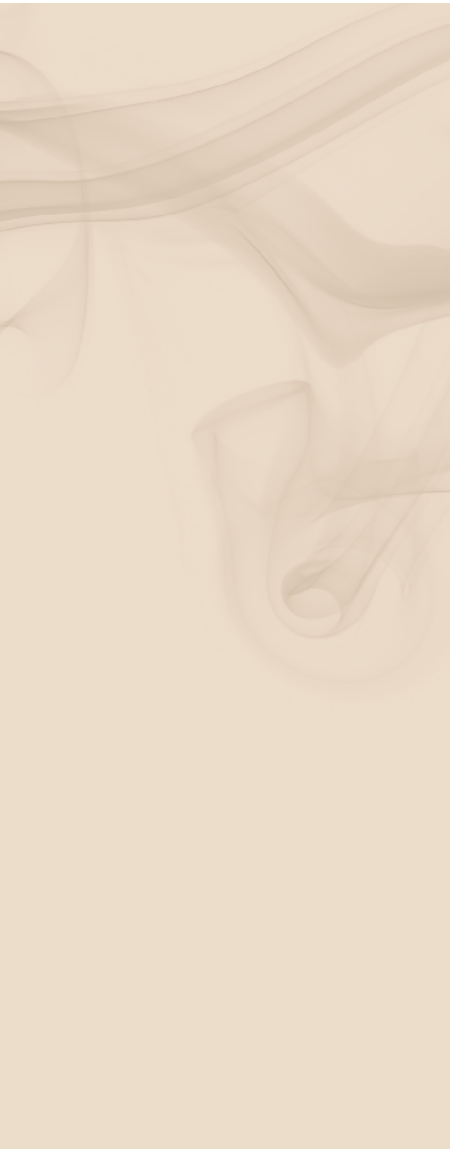
A third type uses a heated sealed chamber like a micro-oven (Fig. 3). A battery supplies the power to heat the chamber that transfers the heat through physical contact to any material the user places inside. The user must fill the micro-oven with the grounded tobacco leaf to aerosolize nicotine. The emission is then inhaled by the user through the mouthpiece. This is how dry-herb or loose-leaf vaporizers, such as Pax, work *(15)*. Unlike the other HTPs, the manufacturer does not provide or recommend any of the materials to fill the chamber of the liquid insert.

A fourth type uses a technology similar to EN&NNDS to derive flavour elements from small amounts of tobacco. BAT's iFuse product *(16)* appears to be a hybrid ENDS–tobacco product in which the emission is passed over tobacco to heat it and pick up the flavour and is then inhaled by the user. The JTI Ploom TECH operates in a similar manner *(17)*.

**FIG. 3. HTP type 3**



# HTP emission content



## Nicotine delivery

The mainstream emission from IQOS seems to deliver less nicotine per stick than a conventional cigarette. In studies, nicotine in mainstream emission ranged from 57–83% of that of a reference cigarette. Glo and iFuse deliver less nicotine than IQOS (19–23% of that of a conventional cigarette). HTPs deliver more nicotine than early generations of ENDS *(18)*. No comparison is available for third-generation ENDS. Nicotine delivery measurements were similar in the tobacco industry and independently funded studies *(18)*.

Studies with humans that measured plasma nicotine levels after use of HTPs indicate that nicotine delivery of HTPs varies by brand but is always lower than that supplied by a conventional cigarette, except for IQOS. Nicotine delivered by HTPs attained peak concentration in plasma as quickly as with conventional cigarettes *(18)*.

## Potentially toxic substances in mainstream emission

HTPs' emission contains almost the same number of harmful and potentially harmful compounds (HPHCs) than conventional cigarette smoke, although in some cases at a lower level. A systematic review of published peer-reviewed papers shows that the levels of analysed toxicants were at least 62% lower than in cigarette smoke and particulate matter (PM) was 75% lower than in conventional cigarette smoke *(18)*. Both tobacco-industry and independently funded studies, including some government institutions in Germany *(19)*, the Netherlands *(20)* and the United Kingdom *(21)*, found lower levels of toxicants in HTP emission than in cigarette smoke. The independent studies nevertheless reported less tar but more tobacco-specific nitrosamines and, apparently, acetaldehyde, acrolein and formaldehyde than industry-affiliated studies *(18)*.

The finding of a lower level of toxicants in HTP emission must be qualified by the following caveats.

- The number of toxicants measured so far in peer-review articles does not cover the full range of HPHCs of interest. For example, PMI reported in its submission to the United States Food and Drug Administration (FDA) on 40 of the 93 HPHCs in IQOS mainstream emission recommended by the agency. The levels of the missing 53 HPHCs, of which 50 are carcinogenic, are unknown *(22)*.

- The reports submitted by PMI to the FDA include levels of 57 other constituents that are not included in the FDA's list of HPHCs. The level of 56 of them was higher in IQOS emissions than in conventional cigarettes. Their levels were double those in the reference conventional cigarettes for 22 compounds and more than 10 times higher for seven. It appears that IQOS reduces exposure to some toxicants but elevates exposure to other substances. A number of these substances belong to chemical classes that are known to have significant toxicity, but in general, there is limited information on the toxicity of many of them *(22)*.

## Potentially toxic substances in side-stream and second-hand emission

Like conventional cigarettes, but unlike EN&NNDS, analysed HTPs generate a side-stream emission. Three studies (one independently funded and two affiliated to the tobacco industry) reported the levels of some HPHCs in IQOS and Glo. All of them found that formaldehyde and acetaldehyde were present in the second-hand emission, although at a level about 10–20 times lower than in cigarette smoke, respectively. Only the independent study found PM and acrolein in the second-hand emission; in this study, PM was about four times lower than in cigarette smoke and acrolein about 50 times lower *(18)*. Consequently, the evidence suggests that second-hand emission from HTPs expose bystanders to quantifiable levels of PM and key toxicants but at a lower level than from second-hand smoke of combustible tobacco products.

# Effects of HTP use on health

## Nicotine delivery

The nicotine delivery profile of some (but not all) HTPs, particularly IQOS, approximates to that of conventional cigarettes. Some HTPs therefore might be adequate substitutes for cigarettes in the delivery of nicotine, although user satisfaction is reported to be lower than for conventional tobacco products.

## Health risks to HTP users from exposure to mainstream emission

There is no available evidence to conclude whether HTP use is associated with any long-term clinical outcome, positive or negative, from exposure to the mainstream emission. One PMI study claimed that IQOS, compared to smoking a conventional cigarette, reduced biomarkers associated with endothelial dysfunction, oxidative stress, inflammation and high-density lipoprotein and cholesterol counts *(23)*. PMI also claimed in the submission to the United States FDA that "human clinical studies have confirmed that clinical markers of … inflammation show positive changes, similar to those seen following smoking abstinence." A critical review of PMI's data concluded, however, that PMI presented no human clinical data directly from the lung. It also concluded that in human users, there was no evidence of improvement in pulmonary inflammation or pulmonary function in cigarette smokers who switched to IQOS. PMI's claim that smokers who switch to IQOS reduce inflammation and the risk of chronic obstructive pulmonary disease therefore is not supported even by their own data. There are very few independent studies reporting on the short-term effects of HTP use. They indicate some short-term physiopathological effect *(24–26)*.

## Health risks from exposure to HTP second-hand emission

There is no available evidence to indicate whether HTP use is associated with any long-term clinical outcomes from exposure to the second-hand emission. HTPs nevertheless generate side-stream emission with ultrafine particles and a number of harmful toxicants, although at a lower level than in conventional cigarettes. A recent study found that a proportion of people exposed to second-hand IQOS emissions experienced short-term symptoms such as sore throat, eye pain and feeling ill *(4)*.

Given that a number of public health organizations, including WHO *(27,28)*, have deemed that no level of side-stream exposure is safe or acceptable, these findings are clearly concerning and merit further study.

# Key messages

- HTPs contain tobacco and emit nicotine and other toxicants.

- HTPs generate a mainstream emission and a side-stream emission. Inhaling the mainstream emission exposes HTP users to the toxicants contained in the emission. Bystanders may inhale the side-stream or second-hand emissions.

- Currently there is insufficient evidence to conclude that HTPs are less harmful than conventional cigarettes. In fact, there are concerns that while they may expose users to lower levels of some toxicants than conventional cigarettes, they also expose users to higher levels of other toxicants. It is not clear how this toxicological profile translates into short- and long-term health effects.

# Conclusions

Governments should introduce a system for the pre-market assessment of novel tobacco products, including HTPs. Marketing of HTPs should not be permitted unless there is conclusive evidence that compared to conventional cigarettes, the product reduces exposure to harmful and potentially harmful components and reduces health risks.

Governments that cannot prevent the introduction of HTPs in their markets or decide to allow the marketing of HTPs in the absence of such evidence should ensure the tobacco industry cannot claim government authorization of the product as its endorsement.

In addition, HTPs should be taxed similarly to other tobacco products, following the recommendations of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC) in its decision FCTC/COP8(22) *(29)*. The decision recognized HTPs as tobacco products and therefore considers them to be subject to the provisions of the WHO FCTC. The decision also reminded Parties to prioritize the following measures in accordance with the WHO FCTC and national law:

- prevent the initiation of HTP use;
- protect people from exposure to HTP emissions and explicitly extend the scope of smoke-free legislation to these products in accordance with Article 8 of the WHO FCTC;
- prevent health claims being made about HTPs;
- apply measures regarding advertising, promotion and sponsorship of HTPs in accordance with Article 13 of the WHO FCTC;
- regulate the contents and disclosure of contents of HTPs in accordance with articles 9 and 10 of the WHO FCTC;
- protect tobacco-control policies and activities from all commercial and other vested interests related to HTPs, including interests of the tobacco industry, in accordance with Article 5.3 of the WHO FCTC; and
- regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of HTPs as appropriate to national laws, taking into account a high level of protection for human health.

Finally, it is important to monitor comprehensively not only market developments, but also the use of HTPs through inclusion of relevant questions in all appropriate surveys.

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