

HEATED TOBACCO PRODUCTS: Common Regulatory and Drafting Issues

Governments have taken different approaches to regulating heated tobacco products (HTPs), including banning retail sales.

This resource concentrates on common regulatory and drafting issues that arise when HTPs are permitted onto a country's market.

Prior to allowing HTPs onto a country's market, governments should review their existing tobacco control lawsⁱ to ensure those laws properly address HTPs, including the tobacco inserts (sticks, pods) and heating devices. Laws should be fully in line with the WHO Framework Convention on Tobacco Control (WHO FCTC), the Guidelines for implementation of the WHO FCTC,¹ and decisions adopted by the Conference of the Parties to the WHO FCTC.²

Recommendations on how WHO FCTC measures should be applied to HTPs are contained in [HTPs: Global Regulation and Recommended Measures](#)

Common regulatory and drafting issues include:

1. **DEFINITIONS:** Whether the definitions of “tobacco products,” “tobacco advertising and promotion,” and “tobacco sponsorship” in existing legal measures are broad enough to apply to tobacco inserts and/or devices.
2. **COVERING HTPS IN SMOKE-FREE LAWS:** Whether HTP emissions or HTP use fall within the definition of tobacco “smoke” or “smoking” in existing laws.
3. **CATEGORIZING HTPS:** How HTPs should be categorized, where existing laws apply differently across categories of tobacco products.
4. **SPECIFIC ISSUES TO CONSIDER WHEN THE SALE OF HTPS IS BANNED:** Whether laws explicitly prohibit public use of HTPs and advertising, promotion, and sponsorship of tobacco inserts and devices where their retail sale is banned.

The Campaign for Tobacco-Free Kids' International Legal Consortium (ILC) has developed a [Template for Effective Tobacco Control Legislation](#), which includes one set of drafting solutions to ensure HTPs (both tobacco inserts and devices) are effectively covered by all relevant WHO FCTC measuresⁱⁱ and addresses these common regulatory issues. Other possible drafting solutions are shown by way of country examples in this resource.

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ⁱ In this document, the terms “laws,” “legislation,” and “legal measures” are used interchangeably and include legislation, regulations, decrees, resolutions, and any other enactments that have legal force and effect.

ⁱⁱ The Legislation Template does not include provisions relating to taxation or illicit trade.

TOBACCO COMPANIES ARE CIRCUMVENTING EXISTING LAWS



HTP systems generally have two main components:

- 1. Tobacco inserts: sticks or pods of processed tobacco; and**
- 2. A rechargeable electronic heating device which contains no tobacco.**

Tobacco companies almost always use different branding for these two components. For example, PMI's *HEETS* (tobacco inserts) are for use with the *IQOS* device, and BAT's *Neosticks* (tobacco inserts) are for use with the *glo* device. HTP systems are integrated, so the tobacco inserts for one system can only be used with the device for the same system.

In many countries, the devices are not within the legal definition of a "tobacco product" and, therefore, may fall outside existing tobacco control regulatory regimes. The tobacco companies' marketing strategies in most countries deliberately focus on the device brand (e.g., *IQOS* and *glo*) to circumvent existing tobacco advertising bans.

In addition, the attractive packaging used for the devices is often not required to contain tobacco health warnings.

Furthermore, tobacco companies have marketed HTPs as "reduced risk products," using terms such as "heat-not-burn," "smoke free," and "smokeless" to promote them. The companies have also sought to create uncertainty over whether consumption of HTPs involves combustion and have challenged their classification by governments as "tobacco products for smoking," instead arguing that they are "smokeless tobacco products," which are typically subject to less strict tobacco control measures. Therefore, it is important to adopt clear, robust definitions to eliminate ambiguity about the products being regulated.

1. DEFINITIONS

1.1 ISSUE

Whether tobacco *inserts* fall outside the definition of “tobacco products.”

The WHO FCTC definition of “tobacco products” refers to products containing tobacco which are manufactured to be used for “smoking, sucking, chewing or snuffing.”³ This definition is used in many countries’ tobacco control laws. Tobacco companies have claimed that HTPs do not emit “smoke” and that using them is not “smoking.” Therefore, they argue that HTPs do not fall under the definition of “tobacco products” contained in the WHO FCTC because the use of an HTP does not involve “smoking, sucking, chewing or snuffing.”

SOLUTION

HTP emissions are tobacco smoke and the definition of “tobacco products” should be expanded to remove any doubt.

Although the industry claims that HTPs are part of a “smoke-free future,”⁴ HTP emissions are tobacco smoke^{5,6} and are inhaled by users and drawn from the product through the process of sucking.⁷ To remove any doubt among regulators and enforcement authorities about whether HTPs are “smoked” or “sucked,” the definition of “tobacco products” should be expanded. The ILC’s [Template for Effective Tobacco Control Legislation](#) provides an example:

- “**Tobacco product**” means a product made entirely or partly from any part of a tobacco plant as raw material manufactured to be used for smoking, sucking, chewing, *inhaling*, or snuffing, *or consuming by any other means* (*emphasis added*).

COUNTRY EXAMPLE

■ Belarus

Decree No. 28 of 2002⁸ was amended in 2019 to expand the definition of “tobacco product”:

- “**Tobacco product**” means a product made entirely or partially of tobacco raw materials in such a way as to be used for smoking, sucking, chewing or sniffing, [or] *other consumption methods*, packaged in consumer packaging for retail (*emphasis added*). (Section 37).

1.2 ISSUE

Whether HTP **devices**, as electronic items, fall outside the definition of “tobacco products.”

This may mean that devices are not covered by:

- Restrictions on tobacco advertising, promotion, and sponsorship.
- Health warning requirements and other packaging rules.
- Sales restrictions, such as bans on internet and vending machine sales.

SOLUTION

Ensure devices are included in the legislation by either:

1. Amending the definition of “tobacco products” to specifically include devices; or
2. Defining devices separately and ensuring that each relevant policy measure (e.g., ban on advertising, promotion, and sponsorship, health warnings and other packaging requirements, etc.) is applied to both tobacco inserts and devices.

The ILC’s [Template for Effective Tobacco Control Legislation](#) provides an example of a definition for devices:

- **“Tobacco device”** means a device that is not a tobacco accessory manufactured for consuming a tobacco product by producing an emission for inhalation and includes, whether sold separately or not, any item or part, other than a tobacco product, manufactured for use with the device. A device manufactured to allow the consumption of both a tobacco product and a nicotine product shall be considered a tobacco device.
- **“Tobacco accessory”** means an item that is not a tobacco device manufactured to be used in the consumption of a tobacco product, including: a pipe, water pipe, rolling papers, filters, and tubes sold

separately from a tobacco product, and any other item designed to facilitate or enhance consumption of a tobacco product.

Note that these definitions are drafted to be read together. HTP devices fall under the definition of “tobacco devices” whereas “tobacco accessories” capture waterpipes, other pipes, filters, and tubes sold separately from a tobacco product, for example.

COUNTRY EXAMPLE

■ Canada

The Tobacco and Vaping Products Act (TVPA)⁹ was amended to include devices in the definition of “tobacco product.” This ensures that all restrictions applying to tobacco products also apply to devices unless the law explicitly states otherwise. The definition of “tobacco product” from the TVPA is:

- **“Tobacco product”** means a product made in whole or in part of tobacco, including tobacco leaves. It includes papers, tubes and filters intended for use with that product, **a device**, other than a water pipe, **that is necessary for the use of that product and the parts that may be used with the device** (*emphasis added*). (Section 3(1)).

Thus, the provisions of the TVPA and the Tobacco Products Appearance, Packaging and Labelling Regulations (as amended),¹⁰ which regulate policies such as tobacco advertising, promotion, and sponsorship, sales restrictions, health warnings and plain packaging also apply to devices.

1.3 ISSUE

Whether the definitions of “tobacco advertising and promotion” and “tobacco sponsorship” are sufficiently broad to cover devices.

Legal measures in some countries do not define these terms, while others have narrow definitions that list the specific types or means of promotion that are prohibited. Such laws may not cover devices.

The WHO FCTC definitions of “tobacco advertising and promotion” and “tobacco sponsorship” are phrased broadly to cover communications, recommendations, and actions (in the case of advertising and promotion) and contributions (in the case of sponsorship) with the **“aim, effect or likely effect”** of promoting a tobacco product or tobacco use either **directly or indirectly**¹¹ (*emphasis added*).

Promoting an HTP device has both the *aim* and *effect* of promoting the tobacco inserts themselves and the use of tobacco inserts because the device has no functional purpose other than to be used for consumption of the tobacco inserts.

If legislation uses the WHO FCTC definitions, regulators have good reason to treat advertising, promotion, and sponsorship of the device as promotion of a tobacco product under the law. In some countries, courts and tribunals have agreed with this interpretation (see the text box on Court Decisions Broadly Interpreting “Tobacco Advertising and Promotion” to Cover Advertising of HTP Devices),^{12,13} but there is no guarantee it will be applied in every country or every context. In legislation using definitions of “tobacco advertising and promotion” and “tobacco sponsorship” that are not as broad as the WHO FCTC definitions, it may be more likely that the law will not apply to HTP devices.

SOLUTION

Even where legislation defines “tobacco advertising and promotion” and “tobacco sponsorship” to include a phrase equivalent to “aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly,” legal measures should clearly apply the relevant tobacco advertising, promotion, and sponsorship provisions to both tobacco inserts and devices.

As discussed above, this can be accomplished either by defining “tobacco products” to specifically include devices (as done by Canada, see above), or defining devices separately and then incorporating devices into the provisions banning tobacco advertising, promotion, and sponsorship (as done by Moldova, see below).

COUNTRY EXAMPLE

■ Moldova

Law No. 278-XVI on Tobacco Control,¹⁴ as amended by **Law No. 142**,¹⁵ defines “devices and accessories for the use, recharging, or heating of tobacco products or related products”:

- “Devices and accessories for the use, recharging, or heating of tobacco products or related products” means a set of interconnected parts, which perform a specific function in a system that allows them to be brought to the optimum temperature or being recharged with a tobacco product and other compounds or liquid for a related product, for consumption. (Article 2).

The law then uses the term in the relevant provisions of Article 21. For example, among other digital and entertainment media marketing restrictions applied to both inserts and devices, the law states:

- (1) It shall be prohibited to advertise in any form for tobacco products, related

products, ***devices and accessories for their use, recharging or heating***, direct or indirect, including radio and television advertising, printed media, cinema and video outlets, Internet, using telephone, telegraph networks which includes, but is not limited to, advertising outside and inside enclosed or semi-enclosed public spaces, particularly advertising outside and inside wholesale and retail outlets that sell tobacco products, related products, ***devices and accessories for their use, recharging or heating***, advertising in service-oriented establishments, advertising on or inside public transportation means, and by post mail, as well as advertising on smoking accessories (*emphasis added*).

COURT DECISIONS BROADLY INTERPRETING “TOBACCO ADVERTISING AND PROMOTION” TO COVER ADVERTISING OF HTP DEVICES



In *Philip Morris Baltic v. Department of Drug, Tobacco and Alcohol Control, Ruling of 24 March 2021, Supreme Administrative Court of Lithuania (2021)*, the Philip Morris subsidiary appealed a government decision fining the company for promoting its IQOS devices on the internet and at points of sale. Philip Morris argued that the law does not apply to electronic devices and the promotions were not about tobacco products. The court upheld the original decision, finding that the advertising was unlawful because it had the ***indirect effect of promoting tobacco products and encouraging their consumption***.

The court specifically found that the IQOS device promoted a tobacco product because the only function of the device is to consume a tobacco product, stating in paragraph 19 that, “[W]hen purchasing the Device, an ordinary consumer must inevitably purchase the Tobacco Product distributed by the Appellant, otherwise the purchase of the Device would have no purpose and would not fulfil its sole function. Thus, by providing information on the Device solely intended for use with tobacco products distributed by the Appellant in an attractive manner, the Appellant surreptitiously promoted tobacco products...”¹³ (unofficial translation).

In *Altadis, S.A. v. Philip Morris Spain, SL, SJM M 1157/2019, Commercial Court No. 03 of Madrid (2019)*, Altadis (a subsidiary of Imperial Brands) filed a complaint against the Philip Morris subsidiary for violating the advertising prohibition in the tobacco control law (Law No. 28/2005). The complaint alleged that Philip Morris violated the law by conducting a communication campaign for its IQOS device and the accompanying HEETS tobacco inserts. The campaign included details on the product’s characteristics (i.e., how it differs from conventional cigarettes and technology) and purchase options (i.e., where to purchase the device and HEETS and pricing for both). Philip Morris argued that the tobacco control law does not apply to the device because it is not a tobacco product, and the campaign was not advertising but intended for the public interest.

The court held that Philip Morris violated the advertising ban and ordered it to cease the campaign because the published information was a ***form of communication*** that had a ***direct or indirect purpose or effect of promoting a tobacco product***. Furthermore, similar to the Lithuanian court, the Spanish court emphasized that although the IQOS device is not a tobacco product, it has no other purpose but to be used with a tobacco product. Therefore, promoting the sale of the device is equivalent to promoting tobacco use.¹⁴

2. COVERING HTPS IN SMOKE-FREE LAWS

2.1 ISSUE

Public use of HTPs could fall outside the existing definition of “smoking.”

Legislation using the definition of “smoking” contained in the Guidelines for implementation of Article 8 of the WHO FCTC refers to being in possession or control of a “lit tobacco product.”¹⁶ The term “lit” normally implies combustion, and there is uncertainty as to the exact nature of thermochemical reactions within all HTP systems.¹⁷ While some regulators or courts may broadly interpret the term “lit” to encompass the activation of HTPs, others may not.

SOLUTION

Ensure legislation regulating smoking in indoor public places, workplaces, and public transport either:

1. Includes HTP emissions as “smoke” and the use of HTPs as “smoking”; and prohibits “smoke” and “smoking” in these places; or
2. Prohibits the use, possession, and control of HTPs in these places.

An example of the first approach is contained in the ILC’s [Template for Effective Tobacco Control Legislation](#):

- “Smoke” means the emissions from a lit tobacco product or the emissions produced for inhalation from a tobacco or related product.
- “Smoking” means being in possession or control of a tobacco or related product producing smoke, regardless of whether the smoke is being actively inhaled or exhaled.

Note that the Legislation Template applies many provisions to tobacco products, tobacco devices, nicotine products, and nicotine devices. Using all these terms together is cumbersome and can make reading the text

more difficult. Therefore, the phrase “tobacco and related product” is used to cover all four terms. Accordingly, in the definitions above, “related product” specifically includes HTP devices and tobacco inserts fall under the definition of “tobacco product.”

COUNTRY EXAMPLES

■ Moldova

Law No. 278-XVI on Tobacco Control,¹⁵ as amended through Law No. 125,¹⁸ defines “smoking” in a manner that explicitly includes possession, control, and use of HTPs (among other tobacco and nicotine products):

- “Smoking” means being in possession or in control of a lit tobacco product ... or a related product, regardless of whether the smoke is being actively inhaled or exhaled. For the purposes of this Law, possession or control of an activated device for heating a heated tobacco product..., regardless of whether the aerosol is being actively inhaled or exhaled,... is considered smoking. (Article 2).

Moldova has a comprehensive smoking ban which includes not only all indoor public places, workplaces, and public transport but also certain outdoor places and private vehicles when minors are present (Article 26).

■ Colombia

Law No. 1335 of 2009,¹⁹ as amended by Law No. 2354 of 2024,²⁰ specifies that all tobacco control measures apply to HTPs and provides that the smoke-free provisions also prohibit the consumption of HTPs:

- “[T]obacco products”...shall be understood as “cigarettes, tobacco products, its derivatives, substitutes or imitators and the devices necessary for their operation; among which are...Heated Tobacco Products...”(*emphasis added*). (Article 1).

Colombia has a comprehensive smoking ban which includes all indoor public places, workplaces and means of public transport and specified outdoor spaces, including parks (Article 19).

■ Ukraine

Law No. 2899-IV,²¹ as amended by Law No. 1978-IX,²² includes the use and consumption of HTPs in the provisions banning smoking in public places:

- Smoking, consumption and use of tobacco products, items related to their use, herbal products for smoking, electronic cigarettes, heat-not-burn tobacco products, [and] hookahs are prohibited [in the specified places]. (Law No. 2899-IX, Article 13; Law No. 1978-IX, Section I.3(9)).

This includes public transport and virtually all indoor public places and workplaces, with the exception of designated smoking areas in airports.

3. CATEGORIZING HTPS

3.1 ISSUE

Some countries categorize tobacco inserts as “smokeless” or “smoke-free” tobacco products and regulate them less strictly than conventional cigarettes.

Less stringent regulations may include applying smaller, text-only health warnings or lower taxes. Note that this is only an issue where existing laws apply differently to different categories of tobacco products.

Although tobacco companies’ claim that HTPs do not emit smoke,^{23,24} HTP emissions are unambiguously tobacco smoke.^{5,6,18} Even so, there is a risk that governments or enforcement authorities accept the tobacco industry’s misinformation. Legislative or regulatory text should strictly apply the full suite of WHO FCTC-based measures to tobacco inserts and devices and all tobacco products.

SOLUTION

Where existing legal measures apply differently to different categories of tobacco and nicotine products, legislation or regulations should classify HTPs as smoked tobacco products. This is because HTPs contain tobacco and emit smoke that is inhaled by the user.^{2,18}

While different terms may be selected to define tobacco inserts, legal measures should be drafted to **ensure that policies regulating tobacco inserts are equivalent to and as strong as those regulating conventional tobacco products.** Under the WHO FCTC, there are no provisions that recommend or imply that certain categories of tobacco products can be regulated less strictly than others. HTPs are addictive tobacco products that pose serious health risks to people who smoke

them and there is no public health justification for applying less strict rules to HTPs than for conventional tobacco products, including cigarettes.

COUNTRY EXAMPLE

■ New Zealand

Packaging and labeling requirements for “smokeless tobacco products” are less strict than for conventional cigarettes. The Smokefree Environments and Regulated Products Act 1990²⁵ provides for a separate category of “smokeless tobacco products.” In a 2020 amendment to the law, “heated tobacco products” were defined so that both tobacco inserts and devices are categorized as “smokeless tobacco products” (Section 2). Many provisions (including HTP use in public places, advertising and promotion restrictions, including display at points of sale, sales restrictions, and flavor restrictions) in the Act apply in the same way to all regulated products.

However, the packaging and labeling requirements for smokeless tobacco products are less strict than for conventional cigarettes (Smokefree Environments and Regulated Products Regulations 2021, Sections 3, 64–65).²⁶ Smoked tobacco products are required to have pictorial health warnings covering 75% of the front and 100% of the back surface of the packaging and standardized plain packaging rules apply. Smokeless tobacco products, including HTP inserts and devices, are required to have text-only health warnings covering 32% of the front and back surfaces and plain packaging requirements do not apply.

COURT DECISIONS INVOLVING CHALLENGES TO THE CLASSIFICATION OF HTPs AS A CERTAIN TYPE OF TOBACCO PRODUCT AND THE IMPACT ON TOBACCO CONTROL MEASURES



In [Philip Morris GmbH v. Federal Republic of Germany, 4A 23/19, Administrative Court of Braunschweig \(2021\)](#),²⁷ the Philip Morris subsidiary brought an action alleging that the German government had misclassified its heated tobacco product insert (“HEETS”) as a “tobacco product for smoking.” The main ground for Philip Morris’ argument was that combustion did not occur during consumption, and, because of this, the products should be classified as “smokeless tobacco products.” However, the government argued that HTPs emit “smoke” and therefore, it would be contradictory to classify them as “smokeless tobacco products.”

The Court ruled in favor of Philip Morris, relying on evidence presented by the company, which argued that HEETS are consumed by heating the tobacco and that no combustion occurs during this process* (see the Note below: combustion is an element of the definition of “smokeless tobacco product” under the EU Tobacco Products Directive (EU TPD), which was transposed into national law). This classification meant that the HTP inserts would be subject to less stringent regulations, including packaging and labeling requirements.

A similar outcome was reached in [Philip Morris Products S.A. v. Public Health Agency of Sweden, Case no. 3803-22, Administrative Court of Stockholm \(2022\)](#),²⁸ where the Philip Morris subsidiary appealed a classification by Sweden’s Public Health Agency that HEETS were “tobacco products for smoking.” Again, Philip Morris argued that the tobacco inserts should be classified as a “smokeless tobacco product,” alleging that combustion did not occur when consuming the product. The government argued that some level of combustion occurred when HEETS were consumed and that they should not be classified as “smokeless tobacco products” because this could possibly signal to consumers that the products were less harmful than tobacco products for smoking, which research has shown to be untrue.

The Administrative Court agreed with Philip Morris and concluded that HEETS should be classified as “smokeless tobacco products.” The Court held that a determining factor in classifying a product as a smokeless tobacco product is whether the product is consumed by combustion and that HEETS were not consumed in that manner.

Conversely, in [New Zealand MOH v. Phillip Morris \(New Zealand\) Ltd., CRI-2017-085-001107 \(2018\)](#),²⁹ the Philip Morris subsidiary argued that HEETS *should not* be classified as smokeless tobacco products. In this case, the New Zealand Ministry of Health charged Philip Morris with violating a section of the law that prohibited the sale of tobacco products “labelled or otherwise described as suitable for chewing, or for any other oral use (other than smoking),” by selling the HEETS sticks. Here, Philip Morris argued that HEETS did not fall into the category of smokeless tobacco products because HEETS are inhaled and not consumed orally. The Court agreed. The law in New Zealand was subsequently amended, and HTPs are now classified as “smokeless tobacco products” (as shown above), subject to less strict regulations than conventional smoked tobacco products, including cigarettes.

The above cases demonstrate that definitions should be closely examined and amended as necessary to ensure comprehensive regulation of HTPs.

***Important note regarding the above EU decisions:** Under the EU TPD, “tobacco product for smoking” means tobacco products other than a smokeless tobacco product and “smokeless tobacco product” means a tobacco product **not involving a combustion process**, including chewing tobacco, nasal tobacco and tobacco for oral use (*emphasis added*).

4. SPECIFIC ISSUES TO CONSIDER WHEN THE SALE OF HTPS IS BANNED

4.1 ISSUE

Whether laws explicitly prohibit public use of HTPs and advertising, promotion, and sponsorship of tobacco inserts and devices where their retail sale is banned.

SOLUTION

Countries that prohibit the sale of HTPs should also take measures to ensure that there is a comprehensive ban on:

1. HTP use in indoor public places, indoor workplaces, and on public transport; and
2. Domestic and cross-border HTP advertising, promotion, and sponsorship.

Even in countries where the sale of HTPs is banned, products may be available under exceptions allowing import for personal use and/or may be accessible illegally. Thus, it is important that provisions banning their use in public and domestic and cross-border advertising, promotion, and sponsorship are included in the law to protect against potential health risks from HTP emissions, prevent uptake by non-smokers, and provide clarity to enforcement authorities.

COUNTRY EXAMPLE

■ Mauritius

In addition to prohibiting the manufacture, import, and sale of HTPs (Article 4(4)(h)), the Public Health (Restrictions on Tobacco Products) Regulations 2022 (as amended)³⁰ comprehensively ban the use of HTPs in indoor public places, indoor workplaces, and on public transport (Articles 2, 3(1), First Schedule) and advertising, promotion, and sponsorship of HTPs (Articles 2, 6).

FURTHER DETAILS ON COUNTRIES' EXISTING LAWS REGULATING HTPS ARE AVAILABLE AT

WWW.TOBACCOCONTROLLAWS.ORG

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