

# HEATED TOBACCO PRODUCTS

## Global Regulation

Heated tobacco products (HTPs) are a relatively new category of tobacco products, and the tobacco control laws in many of the countries where these products are sold were adopted before HTPs were first introduced. These laws, and the definitions used in them, are often not well suited to regulating HTPs, in particular because HTPs do not fit within existing categories of tobacco products, and because a key component of the systems are the electronic heating devices, which the tobacco companies often promote separately from the cigarettes and tobacco pods.

The WHO Framework Convention on Tobacco Control (FCTC)'s 8th Conference of the Parties adopted a Decision in 2018 reminding Parties to “*regulate, including restrict, or prohibit*” novel tobacco products such as HTPs, including “*the devices designed for consuming the products.*” Therefore, Parties should either ban HTPs entirely or ensure their laws:

- Prohibit all advertising, promotion and sponsorship of HTPs including the devices;
- Apply all packaging requirements to HTPs, including the devices, such as prohibiting any misleading packaging and labeling, requiring picture health warnings of 50% or greater, and considering plain packaging;
- Restrict the use of HTPs in all indoor public places and any other smoke-free areas;
- Prohibit characterizing flavors including the addition of flavors by the consumer; and
- Tax the HTP cigarettes or pods at the same rate as conventional cigarettes.

### How countries have regulated HTPs

Few countries have adopted laws or regulations to specifically address HTPs in their tobacco control laws, meaning that existing laws have to be applied to HTPs. The regulatory situation across countries where HTPs are sold is varied and complex.

#### Countries with bans on HTPs

- **Panama**<sup>2</sup>, **Ethiopia**<sup>3</sup> and **India**<sup>4</sup> have legislated to ban the sale of HTPs. **Mexico**<sup>5</sup> and **Turkey**<sup>6</sup> have legislated to ban the import of HTPs.
- In at least 12 countries, HTPs are banned under existing laws either because those countries prohibit all new nicotine products (**Australia, Brazil, Norway** and **Singapore**) or because HTPs are covered by laws that ban ‘smokeless’ tobacco (**Finland, Malta** and **Sri Lanka**) or e-cigarettes (**Brunei, Cambodia, Qatar, Thailand** and **Uganda**).

#### Countries taking specific regulatory action on HTPs

At least eight countries have adopted new laws to specifically regulate HTPs.

- **Canada**<sup>7</sup>, **Belarus**<sup>8</sup>, **Moldova**<sup>9</sup> and **Georgia**<sup>10</sup> have legislated to include HTPs within their tobacco control laws so that both the cigarettes/pods and heating devices are covered by advertising bans, smoke-free laws and, for Canada, the plain packaging law.

- **Israel's** tobacco control law applies advertising restrictions, a display ban, text health warnings and plain packaging to the packaging of cigarettes/pods and heating devices.<sup>11</sup>
- **Republic of Korea** devised new health warnings for the packs of cigarettes/pods.<sup>12</sup>
- **Portugal** includes the use of HTPs under its smoke-free law and has extended its tobacco advertising ban to include heating devices.<sup>13</sup>
- **Sweden** specifically includes the use of HTPs in its smoke-free laws.<sup>14</sup>

### Countries where HTPs fall under existing tobacco control laws

Many countries have not specifically regulated HTPs and while some of the existing tobacco control laws apply, regulation is often not comprehensive. For instance, in many European countries, the HTP cigarettes and pods are often classified as 'smokeless' tobacco products and this impacts how tobacco control policy measures are applied to HTPs.

- HTP packs carry a 30% text-only health warning instead of the 65% picture health warning required on conventional cigarette packs.
- HTP packs are not required to be in plain packaging in France, UK or Slovenia, as these countries only apply plain packaging to cigarettes and roll-your-own tobacco.
- In some countries smoke-free laws are not applied to the use of HTPs.
- HTPs are subject to lower tobacco excise tax rates.
- Advertising of HTPs varies across different European countries, most likely due to tobacco companies marketing the heating devices rather than the cigarettes and pods.



## Tobacco companies are circumventing existing laws

HTP systems have two main components:

1. sticks (by definition, a cigarette) or pods of processed tobacco; and
2. rechargeable electronic heating device which contains no tobacco.

Tobacco companies use different branding for these two components. For example, Marlboro 'HEETS' (the cigarettes) are for use with the 'IQOS' device, and BAT's 'Neosticks' are for use with the 'glo' device. In many countries, the heating devices are not within the legal definition of a 'tobacco product' and, therefore, fall outside some tobacco control regulatory regimes.

The tobacco companies' marketing strategies in most countries focus on the heating device brand (for example, 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. For instance, in Canada prior to 2018, specialty IQOS stores displayed the device and used only IQOS branding and signage (as opposed to HEETS branding and signage), enabling PMI to evade the existing ban on tobacco product advertising.

After Canada amended its law to include the heating device within the definition of "tobacco product"<sup>7</sup>, PMI was forced to remove IQOS advertising, including signage from IQOS stores.<sup>15</sup>

### Applying smoke-free laws to HTPs

Many countries employ the definition of “smoking” advised in the WHO Framework Convention on Tobacco Control, which refers to being in possession or control of a “lit tobacco product.”<sup>22</sup> Because HTPs are not “lit” when used, their use may not be covered by the existing smoke-free laws. Countries should carefully review their definitions of “smoke” and consider whether revisions are needed in order to cover the use of HTPs.

### Enforcement actions

There have been a number of successful enforcement actions against PMI’s advertising of IQOS, including against posters in the UK<sup>23</sup>; sponsored newspaper and magazine articles in Italy<sup>24</sup> and Panama<sup>25</sup>; the use of IQOS signs on specialist stores in Canada<sup>15</sup>; and for general advertising of the IQOS device in Lithuania on the basis that it amounted to indirect advertising of tobacco products.<sup>26</sup>

### Recent decisions on HTPs by government authorities

**In April 2019, the US Food and Drug Administration (FDA) authorized the marketing and sale of IQOS.**<sup>16</sup> In August 2020, the FDA granted Philip Morris authorization to make a ‘reduced exposure’ marketing claim that switching completely from cigarettes to IQOS reduces exposure to harmful chemicals. However, the FDA denied Philip Morris’ authorization to claim that switching from cigarettes to IQOS reduces the user’s risk of disease – finding that a claim of reduced risk was not supported by the evidence presented by Philip Morris.<sup>17</sup>

**In June 2020, the Italian Ministry of Health denied an application by Philip Morris International for a certification that IQOS and HEET sticks are reduced-risk products.**<sup>18</sup> The decision was accompanied by a report that considered the evidence submitted by PMI, and which stated that the new HTP technology represented “a matter of concern for public health” and highlighted the need for more independent studies.<sup>19</sup>

**In August 2020, the Australian Department of Health’s Therapeutic Goods Administration (TGA) declined to amend its Poisons Standard to make an exception allowing the sale of HTPs.**<sup>20</sup> Under the Poisons Standard, new nicotine products are prohibited because nicotine is classified as a ‘dangerous poison.’<sup>21</sup> In its decision, the TGA noted “significant safety concerns” and cited the lack of “compelling evidence to establish a public health benefit from greater access to nicotine in HTPs.”

### Key Messages

- In many countries, tobacco control laws were adopted before heated tobacco products arrived on their markets, meaning these new products are not effectively regulated.
- Governments should consider banning heated tobacco products, particularly if they are not already on their market, or ensuring their existing tobacco control provisions apply to both the cigarettes and the devices.
- Governments should review their laws on tobacco product advertising, packaging and labeling, taxation, and exposure to secondhand smoke to ensure the laws properly address heated tobacco products, including the heating devices, and are fully compliant with the WHO Framework Convention on Tobacco Control.

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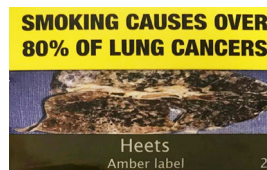
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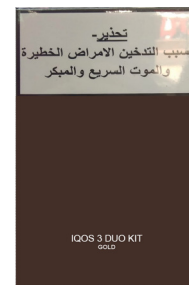
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EUROPEAN UNION (GERMANY)



NEW ZEALAND



ISRAEL HEATING DEVICE PACKAGING



ISRAEL HEATED CIGARETTES