

# **Information Note**

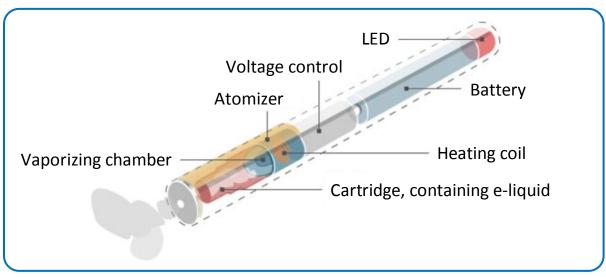
# Regulation of e-cigarettes and heated tobacco products in selected places

IN11/17-18

# 1. Introduction

1.1 The past decade or so has seen a rise in the use of novel cigarette and tobacco products worldwide, noticeably non-combustible electronic cigarettes ("e-cigarettes") and heated tobacco products ("HTPs"). E-cigarettes were invented in 2003 and entered the European and United States ("US") markets in 2006. Unlike conventional cigarettes, e-cigarettes do not burn or use tobacco. It works by heating "e-liquid" to create vapour for users to inhale (known as "vaping"). Typical e-liquid contains ingredients such as propylene glycol/vegetable glycerine, water, flavouring and nicotine. As shown in Figure 1, an e-cigarette usually comprises a mouthpiece, a battery-powered heating element, a cartridge or refillable tank containing e-liquid and an atomiser that vaporizes e-liquid when heated. 3

Figure 1 – Parts of e-cigarette



Source of picture: British Broadcasting Corporation.

See House of Commons (2017).

In 2016, the global market for e-cigarettes and HTPs grew by 34% year-on-year to reach US\$12.3 billion (HK\$95.5 billion). Within the total, e-cigarettes accounted for US\$10.2 billion (HK\$79.2 billion) and HTPs represented a further US\$2.1 billion (HK\$16.3 billion). See Euromonitor (2017).

See Consumer Advocates for Smoke-free Alternatives Association (2018).

1.2 HTPs, also known as "heat-not-burn" tobacco products, were first launched in Japan in 2014, and are growing popularity around the world. HTPs produce aerosol containing nicotine and other chemicals, which is inhaled by users through the mouth. In order to produce the nicotine-infused aerosol, HTPs use a battery-powered heating system to heat tobacco up to 350°C, compared with 600°C when a conventional cigarette burns. The heating system, which is enclosed in a device, can be (a) an external heat source to aerosolize nicotine from specially designed cigarettes or tobacco sticks (Figure 2); or (b) a heated sealed chamber to aerosolize nicotine directly from tobacco leaf.

Case (charger)

Holder inside the case

Heated blade

Tobacco stick

Tobacco plug

Figure 2 – Parts of heated tobacco product

Source of picture: Washington Post.

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<sup>&</sup>lt;sup>4</sup> According to the World Health Organization (2018a), HTPs were sold or planned to be marketed in 34 countries as at September 2017.

See World Health Organization (2018a).

- 1.3 E-cigarettes and HTPs, like conventional cigarettes, contain nicotine that could lead to addiction. Furthermore, irritants, carcinogens and other harmful substances may be released during the process of vaporization. The potential health effects of e-cigarettes and HTPs have provoked discussions about the regulation of these two novel products in recent years.
- 1.4 At its meeting on 21 May 2018, the Panel on Health Services requested the Research Office to study the regulation of e-cigarettes and HTPs in overseas places to facilitate discussion of the subject matter. This information note studies the US, the European Union ("EU") and South Korea in view of the salient features of their regulatory frameworks.
- 1.5 The US is an early adopter of e-cigarettes, with regulations currently in place governing the ingredient, packaging, sale, advertisement and sponsorship of e-cigarettes. The EU has set out a comprehensive regulatory framework for both e-cigarettes and HTPs, and South Korea has recently amended its legislation to regulate these two novel products. The paragraphs below first highlight the regulation of e-cigarettes and HTPs in Hong Kong, followed by a summary of the global regulatory approaches with special reference to the experience of the US, the EU and South Korea. Details of the regulatory frameworks adopted by the above three overseas places are set out in **Tables 1 and 2**.

# 2. Regulations of e-cigarettes and HTPs in Hong Kong

2.1 At present, there is no specific legislation governing e-cigarettes or HTPs in Hong Kong. Nevertheless, e-cigarettes and tobacco products containing more than 0.1% of nicotine are categorized as Part 1 poisons and are considered pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138).<sup>8</sup> As such, they must be registered with the Pharmacy and Poisons Board of Hong Kong<sup>9</sup> for sale or distribution, and can only be legally possessed or sold by licensed medicine dealers, including licensed

See World Health Organization (2015).

South Korea has one of the highest per capita cigarette consumption rates in the world. In 2016, the prevalence of tobacco smoking in South Korea, at 23.6%, was higher than that of Japan (22.5%), Singapore (16.8%) and Australia (14.8%). See World Health Organization (2018b).

See GovHK (2014) and GovHK (2017).

Pharmacy and Poisons Board of Hong Kong is established under section 3 of the Pharmacy and Poisons Ordinance) to license various medicine dealers, register pharmaceutical products and approve clinical trials of drugs. See Food and Health Bureau (2009).

wholesale dealers and authorized sellers of poisons. Illegal possession or sale of Part 1 poisons or unregistered pharmaceutical products is an offence and may be liable to a maximum fine of HK\$100,000 and imprisonment for up to two years. Furthermore, the Smoking (Public Health) Ordinance (Cap. 371) restricts people from smoking, including vaping of e-cigarettes and HTPs, in the statutory no smoking areas.<sup>10</sup>

- 2.2 Regulation of e-cigarettes has been discussed in the Legislative Council on several occasions since 2014.<sup>11</sup> Members have voiced concerns that relevant regulations on sales of e-cigarettes were so lax that the underage persons could purchase e-cigarettes easily.<sup>12</sup> In addition, Members have expressed concerns over the e-liquid for e-cigarettes, even claimed to be nicotine-free, possibly containing heavy metals and nano particles that were harmful to the human body.<sup>13</sup> As such, Members have called on the Government to introduce comprehensive regulation of e-cigarettes to address the above concerns.
- 2.3 In 2016, the Government responded that an amendment bill to the Smoking (Public Health) Ordinance would be introduced into the Legislative Council in 2016-2017, in order to "completely prohibit the import, manufacture, sale, distribution and advertising of e-cigarettes". <sup>14</sup> The amendment bill also includes provisions setting out restrictions on all sale activities of e-cigarettes, regardless of whether the purchase is in-store or online. However, the proposed amendment bill has yet to be tabled before the Legislative Council.

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Section 2 of the Smoking (Public Health) Ordinance defines "smoke" as "inhaling and expelling the smoke of tobacco or other substance". As such, smoking, including consuming e-cigarettes and HTPs, in a statutory no smoking area commits an offence and is subject to a fixed penalty of HK\$1,500. See GovHK (2016) and GovHK (2017).

The subject matter of novel cigarette and tobacco products was raised in the Council meetings on 22 October 2014, 15 June 2016 and 11 January 2017, and the meetings of the Panel on Health Services on 18 May 2015, 6 July 2015 and 21 May 2018. The discussions have hitherto evolved the regulation of e-cigarettes.

<sup>&</sup>lt;sup>12</sup> See GovHK (2014).

See Official Report of Proceedings of the Legislative Council (2014).

See GovHK (2016).

# 3. Global regulatory approaches for e-cigarettes and HTPs

- In 2014, the World Health Organization ("WHO") issued a report with suggestions<sup>15</sup> for bringing e-cigarettes and related products under regulation covering areas such as (a) health claims; (b) use of electronic nicotine delivery systems in public places; (c) advertising, promotion and sponsorship; (d) protection from vested commercial interests; (e) product design and information; (f) health warnings; and (g) sale to minors. A number of countries have subsequently based on the WHO report to enact legislation regulating e-cigarettes.<sup>16</sup> On the other hand, HTPs are new to the market and policymakers need time to consider what specific regulations should apply to this novel product. As such, the regulatory framework for HTPs is still developing in many countries.
- 3.2 According to a study conducted by a leading international authority on public health in 2018<sup>17</sup> ("the 2018 study"), a total of 83 countries have put in place specific regulations for e-cigarettes as at October 2017. Among them, 27 prohibit sales of all types of e-cigarettes, and 56 allow the sale of e-cigarettes with regulations pertaining to product requirement, sale and age restriction of e-cigarettes as described below.<sup>18</sup>

### Product requirements

3.3 E-cigarettes typically consume nicotine-containing e-liquid. In the 2018 study, 28 countries regulate the amount and concentration of nicotine in e-liquid. For example, the maximum nicotine level is 20 mg/ml in the European countries. Furthermore, non-nicotine ingredients that pose a risk to human health are not permitted in 28 countries, mostly European countries.

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<sup>&</sup>lt;sup>15</sup> See GovHK (2014).

There are also places developing regulations on e-cigarettes. For example, Taiwan is proceeding to amend its Tobacco Hazards Prevention Act to prohibit the manufacturing, importation and sale of e-cigarettes.

Since 2016, Johns Hopkins Bloomberg School of Public Health has been conducting a study to review the national policies and legislation on regulating e-cigarettes among 123 countries. The School is the first and the largest institution of public health globally. See Cohen (2016), Johns Hopkins Bloomberg School of Public Health (2018), and World Health Summit Foundation (2018).

These include developed economies like Australia where sale of nicotine-containing e-cigarettes is prohibited unless approved as an aid to help people quit smoking. However, no e-cigarette has been approved for this purpose as at March 2018. Indeed, regulation of e-cigarettes is common in developed economies like the US, Canada, the EU member states, New Zealand and South Korea. See Parliament of Australia (2018) and Johns Hopkins Bloomberg School of Public Health (2018).

3.4 In addition, 29 countries require child safety packaging on the containers for the liquid nicotine that is used in e-cigarettes to remind keeping the products out of reach of children. Health warnings are also required to be placed on the e-cigarette packages in 31 countries, including the US, Canada, South Korea and most European countries.

# Sale requirement

3.5 In the 2018 survey, 36 countries require the registration of e-cigarettes by their respective manufacturers before they can be legally sold. Some of them also restrict cross-border sales to control postal and online sales activities. Advertising, promotion and sponsorship of e-cigarette by the trade are either prohibited or regulated in 62 countries, mostly in North America, Europe and Asia.

### Age restrictions

3.6 There are age restrictions on purchase of e-cigarettes in 32 countries, mostly the US, Canada and European countries. Most of them set the age limit at 18.

# 4. Regulations of e-cigarettes and HTPs in selected places

4.1 As mentioned above, WHO published a report in 2014 with a list of regulatory options proposed to help countries around the world develop regulation of e-cigarettes. <sup>19</sup> The EU revised its Tobacco Products Directive accordingly in 2014 to bring e-cigarettes under regulation. <sup>20</sup> Likewise, the Food and Drug Administration ("FDA<sup>21</sup>") of the US enacted a rule in 2016 to regulate all tobacco products, including e-cigarettes, under the Federal Food,

<sup>19</sup> See World Health Organization (2014).

The Directive only covers e-cigarettes which contain nicotine. The EU has left the decision of whether to regulate nicotine-free e-cigarettes to individual member states. See European Commission (2016).

FDA is a federal agency established by the US Department of Health and Human Services to protect public health through the control and supervision of tobacco, food products, human and veterinary drugs, biological products, medical devices, cosmetics and radiation emitting products.

Drug, and Cosmetic Act.<sup>22</sup> In South Korea, e-cigarettes are regulated under the National Health Promotion Act and the Tobacco Business Act.<sup>23</sup>

- 4.2 As to HTPs, they are regulated under the Tobacco Products Directive in the EU.<sup>24</sup> In South Korea, HTPs are regarded as a type of e-cigarettes, which are subject to the same regulations governing the nicotine-containing e-cigarettes.<sup>25</sup> In the US, FDA has yet to make a decision on whether to allow HTPs on the market, and if so, the way they could be marketed to consumers.
- 4.3 Broadly speaking, the regulatory frameworks adopted by the EU, the US and South Korea for e-cigarettes and/or HTPs cover (a) product requirements such as restrictions of ingredients, labelling and warning messages; (b) obligations of the trade in respect of manufacturing, importation, sales, advertising and promotion; and (c) user restrictions such as age limit and use of e-cigarettes in public places.

### **Product requirements**

4.4 The EU and South Korea have imposed restriction on **nicotine strength** of e-cigarettes and/or HTPs under their respective tobacco laws. The EU further restricts e-cigarette tanks to a capacity of no more than 2 ml and the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10 ml. It also bans certain ingredients including vitamins, colouring and caffeine.<sup>26</sup> In contrast with the EU and South Korea, the US has

Non-nicotine e-cigarettes also fall within the purview of FDA and the regulation of which is subject to a case-by-case approach. It is because even though some e-cigarettes and e-liquid are marketed as nicotine free, studies have found that they encompass a broad, heterogeneous, and evolving category of products, and that the labels may not accurately reflect the amount of nicotine in the e-liquid. See Federal Register (2016).

In South Korea, the Ministry of Finance regulates tobacco and other products containing nicotine (including nicotine-containing e-cigarettes). Nicotine-free e-cigarettes are regarded as consumer products and regulated by the Korean Food and Drug Administration. See Johns Hopkins Bloomberg School of Public Health (2018) and Goniewicz (2015).

Under article 2(4) of the Tobacco Products Directive, "tobacco products means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not". HTPs heat up tobacco to generate aerosol and they are, therefore, regulated under the Directive.

Under article 27-2(2) of the Enforcement Decree of the National Health Promotion Act, e-cigarettes are defined as "[t]obacco made to cause the same effect as the smoking by inhaling nicotine-contained solution or shredded tobacco into the body through respiratory organ with an electronic device". See National Law Information Center (2018).

Pursuant to articles 7(6)(a)-(b) and 20(3)(c) of the Tobacco Products Directive, the EU member states are required to prohibit the placing on the market of tobacco products containing (a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks; and (b) caffeine, taurine or other additives and stimulant compounds that are associated with energy and vitality. See European Commission (2014).

not set out similar product requirements for e-cigarettes. Whether a particular brand of e-cigarette is approved for sale in the US is decided by FDA, which bases its decisions on the assessment of its ingredients and other relevant product information submitted by the manufacturers and/or importers.

- All the overseas places studied have put in place requirements for **labelling** and **display of information** on the packaging of e-cigarettes and/or HTPs. While manufacturers are required to display essential facts such as the ingredients and contents of the products, they are prohibited in the EU from displaying information that may create an erroneous impression of health effect. In the US and South Korea, misleading words or phrases such as "less harmful", "safer", "light" and "mild" are prohibited.
- 4.6 Similar to the regulation of conventional cigarettes, a **warning message** is mandatory for all e-cigarettes and/or HTPs in all the overseas places studied. The EU and South Korea go further than the US in also requiring all cigarette packs to be covered with **warning photos** like diseased lungs. The size of the warning message and/or warning photo is also regulated. For example, the US requires the warning message to cover 30% of the front and back surfaces of the packet. In the EU and South Korea, the warning message and photo altogether must cover 65% and 50% of the front and back surfaces of the e-cigarette packet respectively.

# <u>Trade requirements</u>

- 4.7 In all the overseas places studied, it is mandatory for manufacturers and/or importers of e-cigarettes and HTPs to register with the relevant government authorities and **submit relevant product information** for registration before the product can be sold legally. In the US, manufacturers and importers are further required to notify FDA of the labelling and advertisements of the product.
- 4.8 E-cigarettes and/or HTPs can only be sold by **registered retail outlets** to those who meet the minimum age requirement in all the overseas places studied. In the US and South Korea, vending machines for e-cigarettes and/or HTPs are only permitted to locate at the places not accessible to minors. The US and South Korea also impose a general ban on distributing free samples of e-cigarettes and/or HTPs. Furthermore, cross-border and online sales are

prohibited in South Korea, but they are allowed in the US as long as the product is approved by FDA. Unlike the US and South Korea, the EU has not set out in its Tobacco Products Directive any restrictions for e-cigarettes and/or HTPs in terms of the locations of vending machines and distribution of free product samples.

- 4.9 In addition to the above, all the overseas places studied have prohibited **advertising** of e-cigarettes and/or HTPs on television and radio. The EU also prohibits advertising on press or printed publications, whereas the US and South Korea allow printed advertisements if they have fulfilled certain requirements and restrictions such as incorporating warning statements and limited frequency of advertising on magazines.
- 4.10 **Promotion** of e-cigarettes and/or HTPs is also regulated in all the overseas places studied. The EU prohibits sponsorship by any e-cigarette/HTP companies or brands in support of private or public sector activities. Likewise in the US, sponsorship of sports, social or culture activities in the product brand name or showing the characteristics<sup>27</sup> similar to those used for e-cigarettes are prohibited. In contrast, South Korea allows the sponsorship of social, cultural, musical and sports events (a) which women and children are not their target audiences; and (b) on the condition that only the sponsor's name can be shown.

### User restrictions

4.11 The US allows the selling of e-cigarettes only to persons aged 18 or above, and South Korea sets the minimum age at 19. The EU's Directive has not laid down any age requirement for purchasing e-cigarettes and HTPs. It allows individual EU member states to decide on their own the age limit for purchasing e-cigarettes and HTPs, and most of them have set 18 as the age threshold. In addition to the age limit, e-cigarettes and/or HTPs are usually not allowed in most public places, restaurants, schools and public transport.

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These characteristics include the logo, symbol, motto, selling message, recognizable colour and pattern of colours identical or similar to those used for the e-cigarette under the sponsor's business.

Table 1 – Product requirements of e-cigarettes and/or HTPs in the places studied

	The European Union		The United States		South Korea	
	E-cigarettes	HTPs		E-cigarettes	E	-cigarettes and HTPs*
Key legislation	Tobacco Products Directive 2014/40/EU ("the EU's Directive")			Federal Food, Drug, and Cosmetic Act ("the Act")		onal Health Promotion Act d Tobacco Business Act ("the Acts")
Restrictions on ingredients/emission	<ul> <li>Permissible nicotine strength:         ≤ 20mg/ml.</li> <li>Permissible e-liquid volume:         (a) Refill tank: ≤ 10 ml; or         (b) Single-use tank: ≤ 2 ml.</li> <li>Whether flavouring is allowed or not is decided by individual EU member states.</li> <li>Vitamins, as well as those ingreding health in heated or unheated for colourings), are prohibited.</li> </ul>	<u> </u>	•	Restrictions on nicotine strength, e-liquid volume and prohibited ingredients are not set out in the Act. Upon product registration, FDA will consider:  (a) whether the nicotine produces dependence on the product; and  (b) safety and health issues involved.	(a) (b)  • Resileve	re-cigarettes: permissible nicotine strength: ≤ 10mg/ml; and permissible e-liquid volume: no restrictions, but the amount of liquid nicotine must be indicated on the tank. strictions on permissible el of nicotine and other redients are not set out in e Acts.
Requirement for displaying warning message/photo on the product's packet	A warning photo and a warning message stating:     (a) "This product contains nicotine which is a highly addictive substance. It is not recommended for use by nonsmokers"; or     (b) "This product contains nicotine which is a highly addictive substance".	A warning photo and a warning message stating:     (a) "Smoking kills – quit now"; or     (b) "Smoking kills".	C	A warning message stating: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."	wa (a)	varning photo and a rning message stating: smoking may cause diseases; and carcinogens contained in tobacco.
Size of warning message/photo	• ≥ 65% of the front and back surfaces of packet.	• ≥ 65% of the front and back surfaces of packet.		≥ 30% of the front and back surfaces of packet.		0% of the front and back faces of packet.

Note: (\*) South Korea regulates tobacco and other products containing nicotine, and e-cigarettes and HTPs are brought under regulation as other nicotine-containing products.

Table 1 – Product requirements of e-cigarettes and HTPs in the places studied (cont'd)

	The European Union		The United States	South Korea
	E-cigarettes	HTPs	E-cigarettes	E-cigarettes and HTPs
Requirements for labelling and display of information on the product's packet	<ul> <li>The following information must be displayed on the packet:         <ul> <li>(a) list of all ingredients;</li> <li>(b) nicotine content and delivery per dose;</li> <li>(c) possible adverse effect;</li> <li>(d) addictiveness and toxicity;</li> <li>(e) a message of not recommending for use by young people and non-smokers; and</li> <li>(f) a message to remind keeping the product out of reach of children.</li> </ul> </li> </ul>	<ul> <li>The information displayed on the packet must not contain any elements that         <ul> <li>(a) create an erroneous impression about its health effects, risks or emissions; or</li> <li>(b) refer to taste, smell, or any flavouring.</li> </ul> </li> <li>The following descriptions about HTPs are also prohibited:         <ul> <li>(a) resembling a food or a cosmetic product;</li> <li>(b) being less harmful than other products;</li> <li>(c) reducing the effect of harmful components in tobacco smoke;</li> <li>(d) having vitalising, energetic, healing, rejuvenating, natural, or organic properties; or</li> <li>(e) possessing other health or lifestyle benefits.</li> </ul> </li> </ul>	<ul> <li>the accurate description of quantity of contents (weight or amount) of the product.</li> <li>The packet must not claim the product as being healthier, safer or less risky to use.</li> </ul>	<ul> <li>For e-cigarettes and e-liquid, the packet must indicate the major ingredients and contents.</li> <li>For HTPs, the packet must indicate the ingredients of tar and nicotine.</li> <li>The packets of e-cigarettes and HTPs must not use misleading words, phrases, or trademarks, such as "light", "mild", "low tar", "genuine", or other indications that are likely to cause misconceptions by treating lightly the effects of tobacco on human health.</li> </ul>

Table 2 – Trade and user requirements of e-cigarettes and HTPs in the places studied

	The European Union	The United States	South Korea
	E-cigarettes and HTPs	E-cigarettes	E-cigarettes and HTPs
Trade requirements			
Product registration	Manufacturers and importers of e-cigarettes, e-liquid and HTPs are required to register their products with the relevant government authorities before they can sell the products legally.	<ul> <li>Manufacturers and importers are required to register with FDA and provide information about:         <ul> <li>(a) key ingredient information;</li> <li>(b) quantities of harmful and potentially harmful constituents;</li> <li>(c) labelling of the product; and</li> <li>(d) advertisements of the product.</li> </ul> </li> </ul>	Manufacturers and importers are required to register their products with the relevant government authorities and submit relevant product information for applications of registration.
Retail sales and distribution	<ul> <li>E-cigarettes and HTPs can be sold at the retail outlets which have been registered with the relevant government authorities.</li> <li>The EU's Directive does not stipulate whether it is allowed to:         <ul> <li>(a) install e-cigarettes and HTPs vending machines; and</li> <li>(b) offer free samples of e-cigarettes and HTPs.</li> </ul> </li> </ul>	<ul> <li>E-cigarettes can be sold at the retail outlets which have been registered with the relevant government authorities.</li> <li>As e-cigarettes can only be sold to persons aged 18 or above, retailers are required to check the photo ID of those intending to buy the e-cigarettes.</li> <li>It is not allowed to:         <ul> <li>(a) sell e-cigarettes or e-liquid in vending machines unless in adult-only facilities;</li> <li>(b) offer free samples of e-cigarettes or e-liquid; and</li> <li>(c) sell e-cigarettes or e-liquid without health warning.</li> </ul> </li> </ul>	<ul> <li>E-cigarettes and HTPs can only be sold by registered tobacco retailers, who are also allowed to sell conventional cigarettes as well.</li> <li>E-cigarettes and HTPs vending machines can only be installed in:         <ul> <li>(a) places not accessible to persons under the age of 19;</li> <li>(b) registered tobacco retail outlets; and</li> <li>(c) designated smoking areas.</li> </ul> </li> <li>It is not allowed to offer free samples of e-cigarettes and HTPs.</li> </ul>
Cross-border sales and online sales	Approval or otherwise is decided by individual EU member states.	Not prohibited.	• Prohibited.

Table 2 – Trade and user requirements of e-cigarettes and HTPs in the placed studied (cont'd)

	The European Union	The United States	South Korea	
	E-cigarettes and HTPs	E-cigarettes	E-cigarettes and HTPs	
Trade requirements (cont'd)				
Advertising	Advertising on the following media is prohibited:     (a) press and printed publications;     (b) radio programmes; and     (c) audio-visual commercial communication, including television, online shopping and product placement.	<ul> <li>Advertising on television and radio are prohibited.</li> <li>Print advertisements and other advertisements with visual components (e.g. on signs, web and email) are allowed.         Nevertheless, they are required to show warning statements that:         (a) appear on the upper portion of the advertisement;         (b) occupy at least 20% of the area of the advertisement; and         (c) are printed conspicuously and legibly.     </li> </ul>	place.	
Sponsorship	Sponsorship of any public or private sector activities or making contribution to individual persons with the aim of promoting the products is prohibited.	Sponsorship of any athletic, musical, artistic or other social or cultural events (a) in the product brand name; or (b) showing the characteristics (e.g. logo, symbol, motto, selling message, recognizable colour or pattern of colours) identical or similar to those used for e-cigarettes is prohibited.	Sponsorship of social, cultural, musical and sports events, which women and children are not their target audiences, is allowed. However, only the sponsor's name is allowed to be shown.	

Table 2 – Trade and user requirements of e-cigarettes and HTPs in the places studied (cont'd)

	The European Union	The United States	South Korea
	E-cigarettes and HTPs	E-cigarettes	E-cigarettes and HTPs
User requirements			
Age limit for purchasing e-cigarettes and/or HTPs	<ul> <li>The EU's Directive does not set out any age limit, which is subject to the national law of individual EU member states.</li> <li>Most EU member states allow retailers to sell e-cigarettes and HTPs to those aged 18 or above, except in Belgium where the minimum age is 16 years old.</li> </ul>	E-cigarettes can only be sold to persons aged 18 or above.	E-cigarettes and HTPs can only be sold to persons aged 19 or above.
Use of e-cigarettes and/or HTPs in public places	The EU's Directive does not set out any restriction on the use of e-cigarettes and/or HTPs in the public places, which is subject to the national law of individual EU member states.	<ul> <li>The restriction on the use of e-cigarettes in public places is determined by individual states.</li> <li>As at March 2018, 11 states have established the rules to restrict the use of e-cigarettes in public places. In those states, e-cigarettes are prohibited in indoor public places, school campuses, restaurants, libraries, playgrounds, sports facilities, on public transport, etc.</li> </ul>	Vaping of e-cigarettes and HTPs are not allowed in public places covered by the smoke-free policy. These places include most indoor workplaces, government buildings, restaurants, parks, theatres, hospitals, schools, and public transport facilities and designated cultural heritage.

### References

# **Hong Kong**

- 1. Census and Statistics Department. (2016) *Thematic Household Survey Report No. 59 Pattern of smoking*. Available from: http://www.statistics.gov.hk/pub/B11302592016XXXXB01 00.pdf [Accessed June 2018].
- 2. Census and Statistics Department. (2018) *Thematic Household Survey Report No. 64 Pattern of smoking*. Available from: http://www.statistics.gov.hk/pub/B11302642018XXXXB01 00.pdf [Accessed June 2018].
- 3. Food and Health Bureau. (2009) Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong. Available from: http://www.fhb.gov.hk/download/press\_and\_publications/otherinfo/1001 05\_pharm\_review/en\_full\_report.pdf [Accessed June 2018].
- 4. Food and Health Bureau. (2015) *Progress of Tobacco Control Measures*. Available from: http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150518cb2-1456-7-e.pdf [Accessed June 2018].
- 5. GovHK. (2014) *LCQ5:* Regulation of electronic cigarette. Available from: http://www.info.gov.hk/gia/general/201410/22/P2014102 20539.htm [Accessed June 2018].
- 6. GovHK. (2016) *LCQ20: Regulation of e-cigarettes*. Available from: http://www.info.gov.hk/gia/general/201606/15/P2016061 50618.htm [Accessed June 2018].
- 7. GovHK. (2017) *LCQ18: Stepping up regulation of e-cigarettes*. Available from: http://www.info.gov.hk/gia/general/201701/11/P2017011 100268.htm [Accessed June 2018].
- 8. HKU. (2016) Electronic cigarette use among adolescents: a cross-sectional study in Hong Kong. Available from: http://hub.hku.hk/bitstream/10722/2 23974/1/content.pdf [Accessed June 2018].

- 9. HKU. (2017) Research Plan of the School-based Survey on Smoking Among Students 2016/17. Available from: http://sph.hku.hk/yss/index.php/research\_plan [Accessed June 2018].
- 10. Hong Kong Council on Smoking and Health. (2016a) Fact Sheet on Electronic Cigarettes. Available from: http://smokefree.hk/en/content/we b.do?page=ecigarette [Accessed June 2018]
- 11. Hong Kong Council on Smoking and Health. (2016b) *Heat-Not-burn tobacco products*. Available from: http://www.smokefree.hk/en/content/web.do?page=hnbtp [Accessed June 2018].
- 12. Legislative Council Secretariat. (2015) *Minutes of special meeting of Penal on Health Services*. Available from: http://www.legco.gov.hk/yr14-15/english/panels/hs/minutes/hs20150706.pdf [Accessed June 2018].
- 13. Official Report of Proceedings of the Legislative Council. (2014) 22 October.
- 14. Tobacco Control Office. (2018) *Prevention of the Use on Heat-not-Burn (HnB) Tobacco Products*. Available from: http://www.tco.gov.hk/english/downloads/files/Hnb eng.pdf [Accessed June 2018].

# **European Union**

- 15. European Commission. (2014) Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. Available from: http://ec.europa.eu/health//sites/health/files/tobacco/docs/dir 201440 en.pdf [Accessed June 2018].
- 16. European Commission. (2016) *E-cigarettes Myth Buster*. Available from: http://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco\_myth buster\_en.pdf [Accessed June 2018].
- 17. European Parliament. (2017) Answer given by Mr Andriukaitis on behalf of the Commission. Available from: http://www.europarl.europa.eu/sides/get AllAnswers.do?reference=E-2016-009704&language=EN#def1 [Accessed June 2018].

- 18. House of Commons. (2017) *The regulation of e-cigarettes*. Available from: http://researchbriefings.files.parliament.uk/documents/CB P-8114/CBP-8114.pdf [Accessed June 2018].
- 19. Public Health England. (2018) Evidence review of e-cigarettes and heated tobacco products 2018: executive summary. Available from: http://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary#heated-tobacco-products [Accessed June 2018].

# South Korea

- 20. Goniewicz, M. et al. (2015) Nicotine levels in electronic cigarette refill solutions: A comparative analysis of products from the US, Korea, and Poland. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC44 57636/ [Accessed June 2018].
- 21. Lee, S.K. et al. (2011) *Public Health Challenges of Electronic Cigarettes in South Korea*. Available from: http://www.researchgate.net/publication/51 854286\_Public\_Health\_Challenges\_of\_Electronic\_Cigarettes\_in\_South\_Korea [Accessed June 2018].
- 22. *National Law Information Center.* (2018) Available from: http://www.law.go.kr/LSW/eng/engMain.do [Accessed June 2018].
- 23. University of Waterloo. (2012) *ITC National Report: Korea 2005-2010*. Available from: http://www.itcproject.org/files/ITC\_KoreaNR-ENG-Nov9-web-FINAL.pdf [Accessed June 2018].

### **United States**

24. FDA. (2016) FDA's Deeming Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products. Available from: http://www.fda.gov/tobaccoproducts/labeling/rulesregulationsguidance/ucm394909.htm [Accessed June 2018].

- 25. FDA. (2017a) Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products. Available from: http://www.fda.gov/downloads/TobaccoProduct s/GuidanceComplianceRegulatoryInformation/UCM501016.pdf [Accessed June 2018].
- 26. FDA. (2017b) Guidance for Industry Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. Available from: http://www.fda.gov/downloads/TobaccoProducts/Labeling /RulesRegulationsGuidance/UCM191940.pdf [Accessed June 2018].
- 27. FDA. (2018a) *Advertising and Promotion*. Available from: http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/default.htm [Accessed June 2018].
- 28. FDA. (2018b) *Pipe, Cigar, and Vape Shops that Are Regulated as Both Retailers and Manufacturers*. Available from: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInf ormation/ucm514606.htm [Accessed June 2018].
- 29. FDA. (2018c) *Summary of Federal Rules for Tobacco Retailers*. Available from: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm [Accessed June 2018].
- 30. Federal Register. (2016) Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Available from: http://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the [Accessed June 2018].
- 31. Federal Register. (2018) A Proposed Rule by the Food and Drug Administration on 03/16/2018 "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes". Available from: http://www.federalregister.gov/documents/2018/03/16/2 018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes [Accessed June 2018].

- 32. Public Health Law Centre. (2018) *U.S. E-Cigarette Regulation: A 50-State Review*. Available from: http://www.publichealthlawcenter.org/sites/defa ult/files/E-Cigarette-Legal-Landscape-50-State-Review-March-2018.pdf [Accessed June 2018].
- 33. U.S. Government Publishing Office. (2009) Family Smoking Prevention and Tobacco Control and Federal Retirement Reform.

  Available from: http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf [Accessed June 2018].
- 34. U.S. Government Publishing Office. (2012) *Federal Food, Drug, and Cosmetic Act*. Available from: http://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapIX.pdf [Accessed June 2018].

# **Others**

- 35. BIS Research. (2018) Global E-cigarette and T-Vapor Market, Analysis and Forecast (2017-2025). Available from: http://bisresearch.com/industry-report/global-e-cigarette-t-vapor-market-2025.html [Accessed June 2018].
- 36. British Broadcasting Corporation. (2014) *E-cigs banned from Isle of Man health buildings*. Available from: http://www.bbc.com/news/world-europe-isle-of-man-29595671 [Accessed June 2018].
- 37. Cohen, J. (2016) *Global Approaches to E-cigarette Regulation*. Available from: http://www.globaltobaccocontrolpartners.org/sites/default/files/Joanna%20Cohen%20ECig%20Policies%20Part%201.pdf [Accessed June 2018].
- 38. Consumer Advocates for Smoke-free Alternatives Association. (2018) A Historical Timeline of Electronic Cigarettes. Available from: http://www.casaa.org/historical-timeline-of-electronic-cigarettes/ [Accessed June 2018].
- 39. Euromonitor. (2017) *Latest Research: What the 2017 Edition Tobacco Data is Telling Us*. Available from: http://blog.euromonitor.com/2017/06/latest-research-tobacco-2017-edition-data.html [Accessed June 2018].

- 40. Grana, R. et al. (2013) *Background Paper on E-cigarettes* (*Electronic Nicotine Delivery Systems*). Available from: http://escholarship.org/uc/item/13p2b72n [Accessed June 2018].
- 41. Johns Hopkins Bloomberg School of Public Health. (2018) Country Laws Regulating E-cigarettes. Available from: http://www.globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes [Accessed June 2018].
- 42. Parliament of Australia. (2018) Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia. Available from: http://parlinfo.aph.gov.au/parlInfo/download/committees /reportrep/024115/toc\_pdf/ReportontheInquiryintotheUseandMarketingo fElectronicCigarettesandPersonalVaporisersinAustralia.pdf [Accessed June 2018].
- 43. Parliament of Canada. (2017) Legislative Summary of Bill S-5: An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts. Available from: http://lop.parl.ca/About/Parliament/LegislativeSummaries/bills\_ls.asp?so urce=library\_prb&ls=S5&Parl=42&Ses=1&Language=E [Accessed June 2018].
- 44. Washington Post. (2017) *Big Tobacco's new cigarette is sleek, smokeless but is it any better for you?* Available from: http://www.washingtonpost.com/national/health-science/big-tobaccos-new-cigarette-is-sleek-smokeless--but-is-it-actually-healthier/2017/08/11/60e9fe5a-763e-11e7-8839-ec48ec4cae25\_story.html?utm\_term=.81cf80400b43 [Accessed June 2018].
- 45. World Health Organization. (2014) *Electronic nicotine delivery systems*. Available from: http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev 1-en.pdf [Accessed June 2018].
- 46. World Health Organization. (2015) *Advisory note: Global Nicotine Reduction Strategy*. Available from: http://apps.who.int/iris/bitstream/handle/10665/189651/9789241509329 eng.pdf [Accessed June 2018].

- 47. World Health Organization. (2016) Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Available from: http://www.who.int/fctc/cop/cop7/FCTC COP 7 11 EN.pdf [Accessed June 2018].
- 48. World Health Organization. (2018a) Heated tobacco products information sheet. Available from: http://www.who.int/tobacco/publications/prod\_reg ulation/heated-tobacco-products/en/ [Accessed June 2018].
- 49. World Health Organization. (2018b) WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025, 2<sup>nd</sup> ed. Available from: http://apps.who.int/iris/bitstream/handle/10665/272694/9789241514170 -eng.pdf?ua=1 [Accessed June 2018].
- 50. World Health Summit Foundation. (2018) Johns Hopkins Bloomberg School of Public Health. Available from: http://www.worldhealthsummit.org/m8alliance/members/johns-hopkins-bloomberg-school-of-public-health.html [Accessed June 2018].
- 51. 立法院:《行政院函請審議「菸害防制法修正草案」案》, 2017 年,網址:http://lis.ly.gov.tw/lylgmeetc/dispprog?126:007E5851 00060101000000000000C800100003D00000000:0030369:lgmeetkm [於 2018 年 6 月登入]。
- 52. 行政院:《行政院會通過「菸害防制法」修正草案》 2017 年,網址:http://www.ey.gov.tw/Page/9277F759E41CCD91/ca5 d14d5-e484-4b35-b37f-38970354d487 [於 2018 年 6 月 登 入 ]。

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