For discussion on
19 June 2018

LC Paper No. CB(2)1578/17-18(05)

Legislative Council Panel on Health Services

Legislative Proposal to Regulate Electronic Cigarettes and Other New Tobacco Products

PURPOSE

This paper briefs Members on the Government's legislative proposal to regulate electronic cigarettes ("e-cigarettes") and other new "tobacco" products, namely heat-not-burn ("HNB") products and herbal cigarettes.

BACKGROUND

2. The Government's tobacco control policy seeks to safeguard public health by discouraging smoking, containing the proliferation of tobacco use and minimising the impact of passive smoking on the public. Our multi-pronged approach, comprising legislation, enforcement, publicity, education, smoking cessation services and taxation, has gradually reduced the smoking prevalence rate of Hong Kong from 23.3% in early 1982 to 10.0% in 2017.

E-cigarettes

3. E-cigarettes, also known as electronic nicotine delivery systems ("ENDS") or electronic non-nicotine delivery systems ("ENNDS"), are battery-powered devices that heat a solution (called the "e-liquid") in a cartridge/tank with a metallic coil to deliver an aerosol that users inhale through a mouthpiece in a way that simulates the act of cigarette smoking. They may look like conventional tobacco products such as cigarettes or cigars, or they can take the form of other ordinary items. The e-liquid is a chemical mixture typically composed of propylene glycol, glycerin, flavourings, and other additives. E-cigarettes do not contain tobacco but ENDS (not ENNDS) contain nicotine.

4. Propylene glycol, a known irritant when inhaled, may induce airway disorders such as asthma and other inflammatory lung diseases. Propylene glycol and glycerin when heated form formaldehyde (Group 1 carcinogen), acetaldehyde (Group 2B carcinogen) and acrolein (eye and respiratory irritant)

in the aerosol. Nicotine-containing e-cigarettes are addictive, and increase cardiovascular risks. Fetal nicotine exposure adversely affects intra-uterine growth and brain development, and adolescent nicotine exposure may lead to learning and anxiety disorders.

5. Various research studies have also found fine and ultrafine particulate matter, heavy metals, volatile organic compounds like benzene and toluene, and other carcinogens and toxic chemicals in e-cigarette aerosol.

6. Direct health effects from use of e-cigarettes aside, the World Health Organization ("WHO") has expressed concern about their gateway[1] effect. Adolescents are particularly vulnerable to visual cues and social norms, and young adults are drawn to technological innovation. Even though e-cigarettes on the local market should be nicotine-free, the design of such products, which simulates the behavioural and sensory characteristics of conventional cigarette smoking, may familiarise young people with the act of smoking who eventually progress to smoking conventional cigarettes[2]. This concern has only strengthened with the publication of a number of researches showing that adolescent users of e-cigarettes had much greater risk of starting to smoke compared with their peers who had not used e-cigarettes[3,4,5,6]. The increasing ubiquity of e-cigarettes in the public arena may also renormalise the smoking imagery, increasing acceptance of smoking in general.

7. At present, e-cigarettes containing nicotine used for cessation purpose or with medicinal claim are arguably pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138) ("Cap. 138") which must be registered with the Pharmacy and Poisons Board before they can be sold in Hong Kong. In addition, nicotine is a listed Part 1 poison under Cap. 138 which can only be legally possessed or sold in accordance with Cap. 138 (e.g. by "authorised sellers of poisons")[7]. Illegal possession or sale of unregistered

[1] Gateway effect refers to the possibility that youth and young people getting used to e-cigarettes and ultimately turn to smoking cigarettes

[2] Primack BA, Soneji S, Stoolmiller M, Fine MJ, Sargent JD. Progression to traditional cigarette smoking after electronic cigarette use among US adolescents and young adults. JAMA Pediatrics. 2015;169(11):1018-1023.

[3] Leventhal AM, Strong DR, Kirkpatrick MG, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. JAMA 2015;314(7):700-707.

[4] Bold KW, Kong G, Camenga DR, et al. Trajectories of e-cigarette and conventional cigarette use among youth. Pediatrics. 2018;141(1):e20171832.

[5] Hammond D, Reid JL, Cole AG, Leatherdale ST. Electronic cigarette use and smoking initiation among youth: a longitudinal cohort study. CMAJ 2017;189(43):E1328-E1336.

[6] Soneji S, Barrington-Trimis JL, Wills TA et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis. JAMA Pediatrics 2017;171(8):788–797.

[7] Nicotine contained in tobacco not being a pharmaceutical product is exempted from the application of Cap. 138: see Regulation 8 of and Schedule 2 to the Pharmacy and Poisons Regulations, Cap. 138A.

pharmaceutical products or Part 1 poisons is a criminal offence attracting a fine of up to $100,000 and imprisonment for up to two years.

8. The Government tested e-cigarettes purchased from the market for the presence of selected harmful chemicals. The samples were purchased from consignment stores, e-cigarette specialty shops as well as the Internet. The tests detected the presence of formaldehyde, a carcinogen, in many of the samples (see results set out at **Annex A)**. The Hong Kong Baptist University also conducted tests in 2015 on the aerosol of e-cigarettes and detected formaldehyde and heavy metals[8]. These test results show that **e-cigarettes are harmful to health** and echo the view of WHO, that e-cigarette aerosol is not merely "water vapour" as is often claimed in the marketing of these products. WHO reiterates that e-cigarettes are **unlikely to be harmless**, and long-term use is expected to increase the risk of respiratory diseases, cardiovascular diseases, cancer, as well as some other diseases associated with smoking. Besides, simple comparison of toxicant levels in e-cigarette aerosol and tobacco smoke, as advocated by the industry, may be of little value given the absence of science on safe tolerance limits for smoke constituents or their specific effects on the multiple diseases caused by smoking.

<u>WHO recommendations and overseas practices</u>

9. The sixth Conference of the Parties ("COP") to the **WHO Framework Convention on Tobacco Control ("FCTC")** invited Parties to consider taking measures in accordance with national law to achieve at least the following objectives:

(a) **prevent** the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;
(b) **minimise** as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;
(c) **prevent** unproven health claims from being made about ENDS/ENNDS; and
(d) **protect** tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.

10. The seventh session of the COP to WHO FCTC held in November 2016 further proposed to its member countries to **apply regulatory measures** either to prohibit or restrict the manufacture, importation, distribution,

[8] http://smokefree.hk/UserFiles/resources/about_us/cosh_reports/COSHRN_C20.pdf

presentation, sale and use of e-cigarettes, as appropriate to their national laws and public health objectives.

11. There are 83 countries that have national/federal laws regulating e-cigarettes including laws related to the use, sale (such as minimum age), advertisement, promotion, sponsorship, packaging (such as health warning labelling and trademark), product regulation (such as ingredients/flavors), reporting/notification and taxation of e-cigarettes.[9] Examples of the regulation of e-cigarettes in overseas countries are set out in **Annex B**.

Heat-not-burn ("HNB") Products

12. Major tobacco companies have recently developed specifically designed tobacco sticks for consumption of **real tobacco** in the same manner as conventional cigarettes using a special electronic heating device[10]. The presence of real tobacco in these HNB products should be more appealing to smokers than existing e-cigarettes, while **retaining** the **addictive effect of nicotine**.

13. Since HNB products are new to the market, research on their health effects has been scarce. Industry-funded studies have claimed that there are significant reductions in the formation of harmful smoke constituents[11,12] and exposure to environmental tobacco smoke constituents[13] relative to conventional cigarettes. Other studies, however, have found that HNB products emit many harmful substances such as carbon monoxide, tar, carcinogenic tobacco-specific nitrosamines, carbonyl compounds, and volatile organic compounds[14,15,16,17].

---

[9] https://www.globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes

[10] http://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/

[11] Lüdicke F, Baker G, Magnette J, Picavet P, Weitkunat R. Reduced exposure to harmful and potentially harmful smoke constituents with the tobacco heating system 2.1. Nicotine & Tobacco Research. 2016:ntw164.

[12] Haziza C, de La Bourdonnaye G, Merlet S, et al. Assessment of the reduction in levels of exposure to harmful and potentially harmful constituents in Japanese subjects using a novel tobacco heating system compared with conventional cigarettes and smoking abstinence: A randomized controlled study in confinement. Regul Toxicol Pharmacol. 2016;81:489-499.

[13] Tricker AR, Schorp MK, Urban HJ, et al. Comparison of environmental tobacco smoke (ETS) concentrations generated by an electrically heated cigarette smoking system and a conventional cigarette. Inhal Toxicol. 2009;21(1):62-77.

[14] Forster M, Liu C, Duke MG, McAdam KG, Proctor CJ. An experimental method to study emissions from heated tobacco between 100-200 C. Chemistry Central Journal. 2015;9(1):1.

[15] Mallock N, Böss L, Burk R, Danziger M, Welsch T, Hahn H, et al. Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks. Archives of Toxicology. 2018;10.1007/s00204-018-2215-y

[16] Li X, Luo Y, Jiang X, Zhang H, Zhu F, Hu S, et al. Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes. Nicotine & Tobacco Research. 2018:nty005-nty.

[17] Bekki K, Inaba Y, Uchiyama S, Kunugita N. Comparison of chemicals in mainstream smoke in heat-not-burn tobacco and combustion cigarettes. Journal of UOEH. 2017;39(3):201-7.

14. In 2017, seven samples of HNB product were sent to the Government Laboratory for testing of nicotine and tar yields. **All the aerosol samples were confirmed to contain nicotine and tar**. Nicotine can cause addiction and narrowing of blood vessels. Tar is carcinogenic and can irritate airways. The test results show that **HNB products are harmful to health.** Comparison of the levels of harmful constituents between HNB aerosol and tobacco smoke is of little value, as the safe tolerance limits for smoke constituents are unknown. There is currently no evidence to suggest that reduced exposure to these toxic chemicals translates to reduced disease or death risk in human. These products also expose bystanders to side-stream emissions and passive smoking[18,19], and WHO has stated that **there is no safe level of exposure to second-hand tobacco smoke**[20]. The actual long-term health effects of HNB products to users and bystanders need to be assessed by epidemiological studies, the results of which would not be available for decades. While awaiting the scientific evidence to emerge and accumulate, HNB products may give smokers the false expectation that switching to these products means reduction in harm, thus preventing smokers who might otherwise have attempted to quit smoking completely from doing so, or even tempt those who might otherwise not have taken up smoking at all.

15. HNB products and accessories are produced with contemporary design and outlook, which may lure non-smoking youth and young adults into trying such products. **The presence of nicotine from the heating of real tobacco in HNB products would likely cause addiction,** bringing about gateway and renormalisation effects.

<u>WHO recommendation and overseas practices</u>

16. WHO considers that **all forms of tobacco use, including the use of HNB products, are harmful** and advises that HNB products should be "subject to policy and regulatory measures applied to all other tobacco products, in line with the WHO FCTC"[21].

[18] O'Connell G, Wilkinson P, Burseg K, Stotesbury S, Pritchard J. Heated tobacco products create side-stream emissions: Implications for regulation. J Environ Anal Chem. 2015;2(163):2380-2391.10001.

[19] Protano C, Manigrasso M, Avino P, Sernia S, Vitali M. Second-hand smoke exposure generated by new electronic devices (IQOS® and e-cigs) and traditional cigarettes: submicron particle behaviour in human respiratory system. Annali di igiene: medicina preventiva e di comunità. 2016;28(2):109.

[20] http://www.who.int/mediacentre/news/releases/2007/pr26/en/

[21] http://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/

17. As of September 2017, HNB products are marketed or planned to be marketed in close to 40 countries[22] according to information from WHO. Certain overseas practices in regulating HNB products are at **Annex C**.

Herbal cigarettes

18. Other than e-cigarettes and HNB products, in recent years, herbal cigarettes have also become available. Herbal cigarette is made with plants, herbs or fruits with no tobacco but looks exactly like a conventional cigarette. Similar to other conventional tobacco products, herbal cigarette is consumed via a combustion process. The product is often erroneously promoted as a healthier alternative to smoking, or a cessation aid by manufacturers.

19. There is evidence showing that **herbal cigarettes that do not contain tobacco or nicotine may still produce toxic substances and carcinogens**. For example, a research[23] has examined DNA damage response arising from exposure of human lung cells to smoke from tobacco- and nicotine-free cigarettes. This exposure led to DNA damages that are potentially carcinogenic[24]. The study concluded that smoking tobacco- and nicotine-free cigarettes was at least as hazardous as smoking conventional cigarettes. Similarly, another study revealed that the mainstream smoke of herbal cigarettes contained various harmful substances such as tar, carbon monoxide and aromatic amines[25]. As such, not only smokers but also bystanders will be exposed to various harmful substances from the smoke of herbal cigarettes.

20. Examples of overseas regulation of herbal cigarettes are at **Annex D**.

LEGISLATIVE PROPOSAL

21. According to the Thematic Household Survey Report No. 64 issued in April 2018, some 5 700 persons aged 15 or over were daily smokers of

[22] According to WHO, provisional list of countries where HNB tobacco products are either marketed or planned to be marketed as of September 2017: Australia, Austria, Belgium, Canada, Colombia, Czechia, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Japan, Kazakhstan, Lithuania, Luxembourg, Monaco, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Serbia, South Africa, Spain, Sweden, Switzerland, Ukraine, the United Kingdom and the United States of America.

[23] Jorgensen ED, Zhao H, Traganos F, Albino AP and Darzynkiewicz Z. DNA damage response induced by exposure of human lung adenocarcinoma cells to smoke from tobacco- and nicotine-free cigarettes. Cell Cycle 2010;9(11):2170-6.

[24] The pattern of DNA damage response induced by the tested herbal cigarette was similar to that of conventional cigarettes. The data imply that similar to conventional cigarette, exposure of body cells to herbal cigarettes leads to DNA damages that are potentially carcinogenic.

[25] Bak JH, Lee SM, Lim HB. Safety Assessment of Mainstream Smoke of Herbal Cigarette. Toxicological Research. 2015;31(1):41-48. doi:10.5487/TR.2015.31.1.041.

e-cigarettes, compared with the findings in 2015 of less than 1 000 persons. The findings of the 2016/17 school-based survey on smoking conducted by the University of Hong Kong showed that 2 340 Primary 4-6 students (1.4%) had ever used e-cigarettes, down from 2.6% in 2014/15. The numbers of ever and current e-cigarette users among Secondary 1-6 students were 29 380 (8.7%) and 2 770 (0.8%) respectively (down from 9.0% and 1.3% respectively in 2014/15). While the number of smokers using e-cigarettes and other new products in Hong Kong is not yet significant, overseas experience suggests that this may change very quickly. Once such use has taken root it could be very difficult to introduce meaningful regulation.

22. Since consultation of the Panel on Health Services in May 2015, we have critically reviewed the scientific evidence, overseas practices and WHO recommendations, taking into account the emergence of other new products. We now **propose** a regulatory regime to prevent youth and non-smokers from picking up the smoking habit, and to remind smokers and ex-smokers that these new products are harmful. Smoking (Public Health) Ordinance (Cap. 371) ("Cap. 371") will be amended to provide for the definition of e-cigarettes, HNB products and herbal cigarettes, with the regulatory regime under Cap. 371 suitably adjusted or clarified to cater specifically to these new products. Any definitional issues involving other legislation should also be resolved. The proposed regulation of e-cigarettes, HNB products and herbal cigarettes would be **similar to the current regulatory regime of cigarettes and tobacco products**. The proposed regulatory regime would include the following:

(a) prohibition of sale to minors;
(b) prohibition of advertisement, promotion and sponsorship;
(c) prohibition of sale unless in retail package bearing health warning;
(d) prohibition of sale from vending machines;
(e) a ban on use in no smoking areas;
(f) relevant labelling requirements, including indication of the presence of tar and nicotine, and a ban on any claims or suggestions that are not backed by scientific evidence;
(g) a ban on certain additives (such as vitamins) in e-cigarettes which may create an impression that such products have health benefits or present reduced health risks, and any promotion that suggests that the products may contain any appealing flavour; and
(h) taxation on any tobacco component.

23. With reference to (f) above, there remains a need to inform the public of the presence of tar and nicotine in all tobacco products, without giving the impression that products lower in yields of tar and nicotine are safer. We thus **propose** also to replace the requirement currently under Cap. 371 to display the

numerical yields of tar and nicotine on packages and retail containers of cigarettes[26] with the display of descriptive information about the presence of these chemicals, in line with the WHO Guidelines[27].

24. To effectively enforce the new regulatory regime, we **propose** to empower Tobacco Control Inspectors of the Department of Health with the necessary powers under Cap. 371.

ADVICE SOUGHT

25. Members are invited to comment on the legislative proposal to regulate e-cigarettes, HNB products and herbal cigarettes.

Food and Health Bureau
Department of Health
June 2018

[26] Under section 8(1) of Cap. 371, no person shall sell, offer for sale or possess for the purposes of sales any cigarettes unless they are in a packet of at least 20 sticks and the packet and the retail container bear in the prescribed form and manner a health warning and the tar and nicotine yields.

[27] According to the WHO Guidelines for implementation of Article 11 of the WHO FCTC (Packaging and labelling of tobacco products), each unit packet and package of tobacco products, and any outside packaging and labelling of such products, shall, in addition to the warnings, contain information on relevant constituents and emissions of tobacco products as defined by national authorities. In implementing this obligation, Parties should require that relevant qualitative statements be displayed on each unit packet or package about the emissions of the tobacco product. Examples of such statements include "smoke from these cigarettes contains benzene, a known cancer-causing substance" and "smoking exposes you to more than 60 cancer-causing chemicals".

Annex A

Testing of Chemicals in Electronic Cigarettes by Government Laboratory

Five rounds of tests have been conducted and the following chemicals have been tested:

(a) formaldehyde[28];
(b) tobacco-specific nitrosamines [29] (TSNAs) including N-nitrosonornicotine (NNN) and 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK);
(c) flavourings[30] including diacetyl, acetyl propionyl, and acetoin; and
(d) heavy metals [31] including lead, arsenic, cadmium, antimony, chromium, and nickel.

2. The table below summarises the test results :

Date	Source	Chemical tested	No. of samples tested (No. of positive samples)	Presence of tested chemical(s)
Sep 2015	E-liquid	Formaldehyde	37 (26)	5.6mg/kg to 9600mg/kg
Feb 2016	Aerosol	Formaldehyde	20 (10)	0.07 to 8.1µg/100ml puff.
Jul/Aug 2016	Aerosol	TSNAs	20 (0)	Not detected
Feb 2017	Aerosol	• Diacetyl • Acetyl propionyl • Acetoin	• Diacetyl: 20 (0) • Acetyl propionyl: 20 (0) • Acetoin: 20 (2)	0.7µg/100ml puff for both samples
Apr 2017	Aerosol	• Lead • Arsenic • Cadmium • Antimony • Chromium • Nickel	20 (0)	Not detected

[28] Formaldehyde is an irritant and can produce irritation of the nose and pharynx. It is also classified by WHO as Group 1 carcinogen i.e. there is sufficient evidence in humans for the carcinogenicity of formaldehyde.
[29] TSNAs occur widely in tobacco and tobacco smoke and are formed from the chemical reactions of nicotine and other tobacco alkaloids. They are known carcinogens, and both NNN and NNK are Group 1 carcinogens as classified by WHO.
[30] Flavourings are often complex mixtures of natural and manmade substances. Although they are safe to eat, these chemicals might be harmful to breathe in the forms and amounts to which food may be exposed.
[31] Many heavy metals are carcinogenic e.g. cadmium and nickel are Group 1 carcinogens as classified by WHO or harmful to body organs e.g. lead can damage renal and nervous systems.

Annex B

Overseas Regulation of E-cigarettes

European Commission

The European Union ("EU") Tobacco Products Directive (2014/40/EU)[32], among other things, sets out new rules for e-cigarettes with nicotine which aim at harmonising product quality and safety requirements. The new requirements :

(a) prohibit sales of e-cigarettes to under 18 years old;
(b) require health warnings to advise consumers that these products contain nicotine and should not be used by non-smokers;
(c) require packaging to include a list of ingredients contained in the product, information on the product's nicotine content, instructions for use and information on adverse effects, risk groups, addictiveness and toxicity;
(d) ban promotional elements on e-cigarette packaging;
(e) ban cross-border advertising and promotion of e-cigarettes;
(f) restrict maximum nicotine concentration of nicotine-containing liquid to not exceeding 20mg/ml;
(g) require e-cigarettes and refill containers to be child- and tamperproof; and
(h) ban vitamins, colourings and prohibited additives.

2. The Directive also lays down monitoring and reporting requirements for manufacturers and importers, EU countries and the Commission.[33]

United Kingdom

3. The Tobacco and Related Products Regulations 2016 implemented the Tobacco Products Directive in the United Kingdom, and came into force in May 2016. The Regulation sets out the requirements for e-cigarettes and refill containers, including product information and labelling, and vigilance requirements.

Canada

4. The Government of Canada submitted a bill to amend the Tobacco Act and the Non-smokers' Health Act in Parliament in November 2016. The bill

[32] https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf
[33] https://ec.europa.eu/health/tobacco/ecigarettes_en

proposes to amend the related ordinances in order to enhance the regulation of e-cigarettes including sale, ingredients (e.g. a ban on the use of certain ingredients), promotion and advertising, and labelling (e.g. health warning, list of ingredients)[34]. The bill received royal assent in May 2018 and the various new regulatory measures have taken immediate effect[35].

United States

5. The Food and Drug Administration ("FDA") finalised a rule in 2016 to regulate all tobacco products including ENDS that meet the definition of a tobacco product[36]. FDA now regulates the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of ENDS, including components[37] and parts of ENDS but excluding accessories. In this rule, the FDA also included the requirements for a nicotine warning and for premarket review and approval.

Countries where e-cigarettes are banned[38]

6. The sale of e-cigarettes is banned in the following countries: Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Gambia, Greece, Jordan, Kuwait, Lebanon, Mauritius, Nepal, Nicaragua, Oman, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, Turkmenistan, Uganda, United Arab Emirates and Uruguay.

Countries with minimum age requirement for purchasing e-cigarettes[38]

7. The minimum age of purchase is 16 years in Belgium; 18 years in Bulgaria, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Malaysia, Netherlands, New Zealand, Norway, Poland, Portugal, Scotland, Slovenia, Spain, Togo, Ukraine, United States and Vietnam; 19 years in South Korea and 21 years in Honduras.

[34] http://www.parl.ca/DocumentViewer/en/42-1/bill/S-5/third-reading

[35] https://www.canada.ca/en/health-canada/news/2018/05/new-tobacco-and-vaping-products-legislation-receives-roya l-assent.html

[36] https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm

[37] Including e-liquids, cartridges, certain batteries, digital display or lights to adjust settings, tank systems, etc.

[38] https://www.globaltobaccocontrol.org/e-cigarette/policy-domains

Countries with restriction on advertising, promotion and sponsorship of e-cigarettes[38]

8. The following countries prohibit or regulate advertising, promotion, or sponsorship of e-cigarettes: Argentina, Australia, Austria, Bahrain, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, England, Estonia, Fiji, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, Hungary, Iceland, Ireland, Italy, Japan, Jordan, Latvia, Lithuania, Luxembourg, Malta, Mexico, Nepal, Netherlands, New Zealand, Northern Ireland, Norway, Panama, Poland, Portugal, Qatar, Republic of Korea, Romania, Saudi Arabia, Scotland, Serbia, Seychelles, Slovakia, Slovenia, Spain, Sweden, Togo, Turkmenistan, United Arab Emirates, United States, Uruguay, Venezuela, Vietnam and Wales Among these countries, Canada, Costa Rica, Ecuador, Japan, Mexico and New Zealand only apply the advertising restrictions to e-cigarettes that contain nicotine or that are regulated as medicines.

Annex C

Overseas Regulation of HNB Products

United States

Philip Morris International ("PMI") submitted a modified risk tobacco product[39] ("MRTP") application for its HNB product iQOS to FDA[40] on 5 December 2016. FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") voted unanimously, with one abstention, against PMI's claim that switching completely from cigarettes to iQOS can reduce the risks of tobacco-related diseases. The TPSAC also rejected PMI's claim that switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes.

European Commission

2. In response to a parliamentary questions raised in February 2017, the Commission stated that given the lack of evidence to the short-term and long-term health effects and use patterns of such products, the Commission favours a cautious approach[41] and that the relevant provisions of the Tobacco Products Directive apply and should be enforced against the sale, presentation and manufacturing of HNB products.

Singapore

3. Under the Tobacco (Control of Advertisement and Sale) Act, HNB products are considered emerging and imitation tobacco products and their importation, distribution, sale, purchase, use and possession are prohibited[42].

[39] Modified risk tobacco products are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

[40] Section 911 of the Federal Food, Drug and Cosmetic (FD&C) Act, as amended by the Tobacco Control Act, gives FDA responsibility to establish rigorous criteria to be met before authorising the market of a MRTP.

[41] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2016-009704&language=EN#def1

[42] https://www.moh.gov.sg/content/moh_web/home/pressRoom/Current_Issues/2018/faqs-on-e-cigarettes--vaporisers-and-heat-not-burn-tobacco-produ.html

Annex D

Overseas Regulations of Herbal Cigarettes

European Commission

"Herbal products for smoking[43]" are also regulated under the Tobacco Products Directive. Each unit packet and any outside packaging shall carry health warnings. Manufacturers and importers of herbal products for smoking should submit a list of all ingredients prior to the placing on the market.

United Kingdom

2. The Tobacco and Related Products Regulations 2016 also regulates herbal products for smoking, including health warning requirement and prohibition of any element that suggests that a particular product aims to reduce the effect of some harmful components of smoke.

[43] "Herbal product for smoking" means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process.