

Japan Tobacco (Hong Kong) Limited

Response to the Department of Health's Legislative Council Brief on the Smoking (Public Health) (Amendment) Bill 2019 of 13 February 2019

6 April 2019

1. EXECUTIVE SUMMARY

- Japan Tobacco (Hong Kong) Limited (*JTHK*) is fundamentally opposed to the ban on electronic cigarettes (*e-cigarettes*) and heated tobacco products (*HTPs*) set out in the Smoking (Public Health) (Amendment) Bill 2019.
- 1.2 Regulation, rather than prohibition, is the most appropriate policy.
- 1.3 JT Group defines reduced-risk products (*RRPs*) as those with potential to reduce the health risks associated with smoking. E-cigarettes and HTPs are RRPs which have real potential to benefit public health, and therefore should not be prohibited. Further information about JT Group's e-cigarettes and HTPs are at Annex 1.
- 1.4 Regulatory frameworks exist. There are precedents in 56 countries. The government has already acknowledged that it can essentially apply the Hong Kong smoking regulations to alternative smoking products.
- 1.5 The government is concerned that e-cigarettes and HTPs may pose health risks to minors. JTHK agrees that regulation should aim at keeping e-cigarettes and HTPs out of the hands of minors.
- 1.6 The process is wrong. The current government proposal (ban) is fundamentally different from its proposal in 2018 (regulate), and therefore a proper reconsultation is necessary. No consultation simply ignores the public and relevant companies.
- 1.7 If the government insists on a ban (which JTHK strongly oppose), it should introduce a transhipment exemption which (a) is wider than as it is currently proposed; and (b) takes into account the fact that many of these products are typically manufactured in China, transferred to Hong Kong by truck and exported internationally.
- 1.8 JTHK is happy to provide more information on how regulations on e-cigarettes and HTPs could be formulated in Hong Kong to benefit public health, based on its long-standing experience.

2. JTHK'S POSITION

2.1 JTHK is fundamentally opposed to a ban on alternative smoking products proposed in the 2019 Legislative Council Brief.¹ It is disproportionate, unnecessary and an ineffective legislative response. **Regulation**, rather than prohibition, is the most appropriate policy.

E-cigarettes and HTPs have potential to reduce the risks associated with smoking

- 2.2 We consider e-cigarettes and HTPs to be RRPs, as they are alternatives to conventional tobacco products and have the potential to reduce the risks associated with smoking. RRPs have real potential to benefit public health, this has been acknowledged by authoritative bodies, such as Public Health England² and the UK Royal College of Physicians.³
 - The Science and Technology Committee of the UK House of Commons published its report on e-cigarettes in August 2018 stating that "There is clear evidence that e-cigarettes are substantially less harmful than conventional cigarettes". ⁴
 - A report commissioned by Public Health England published in February 2018 stated that "The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes". ⁵
- 2.3 There is now a rapidly emerging scientific consensus reflected in published reports⁶ that the absence of a combustion process in RRP makes them potentially less harmful choices for adult consumers. Below you can find some of the conclusions made by independent experts in aforementioned reports.
 - E-cigarettes

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The Department of Health's Legislative Council Brief on the Smoking (Public Health) (Amendment) Bill 2019 of 13 February 2019 (FH CR 1/3231/19).

² Executive Summary, "Evidence review of e-cigarettes and heated tobacco products 2018", MAE https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary

^{3 &}quot;Nicotine without smoke: Tobacco harm reduction", UK Royal College of physicians, 2016 https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

⁴ See page 15 of the report by the Science and Technology Committee of the UK House of Commons, published in August 2018 and available at: https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/505.pdf. It reinforces Public Health England's findings that e-cigarettes "are substantially less harmful—by around 95%—than conventional cigarettes" (page 7) and refers to the National Institute for Care and Excellence's recent guidance on e-cigarettes, which similarly states that "although not completely risk free, e-cigarettes are comparatively less harmful than conventional cigarettes" (page 8).

See page 24 and 220 of the report commissioned by Public Health England titled 'Evidence review of e-cigarettes and heated tobacco products 2018' published in February 2018 and available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_ofe-cigarettes_and_heated_tobacco_products_2018.pdf.

⁶ See Public Health England (PHE) report at https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-productsevidence-review

See Royal College of Physicians' report at https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report

See evaluation and statement of UK Government's independent advisory Committees on Toxicity, Carcinogenicity, and Mutagenicity in Food, Consumer Products and the Environment regarding heated tobacco products at https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products

- "E-cigarettes are not a gateway to smoking"
- "E-cigarettes do not result in normalization of smoking"
- o "The possibility of some harm from long-term e-cigarette use cannot be dismissed due to inhalation of the ingredients other than nicotine, but is likely to be very small, and substantially smaller than that arising from tobacco smoking"
- "in the interest of public health it is important to promote the use of e-cigarettes"
- "The current best estimate is that e-cigarettes are around 95% less harmful than smoking"
- o "To date, there have been no identified health risks of passive vaping to bystanders"
- o "Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. The previous estimate that, based on current knowledge, vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping"

• HTPs

- o "The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes"
- o "Heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds"
- "Compared with the known risks from conventional cigarettes, they are probably less harmful"
- o "The exposure to compounds of concern in using heat-not-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products"
- "A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products"
- 2.4 For completeness, we wish to point out that, at present, JT Group is conducting studies to evaluate scientifically its RRPs. These include chemical and toxicological analyses of product emissions as well as human clinical studies. Results of JT Group's studies are available to the public on its science web page at www.it-science.com.

2.5 There is no reliable evidence that supports prohibiting e-cigarettes or HTPs. On the contrary, authoritative reports⁷ conclude that e-cigarettes are likely to be beneficial to public health. And, there is an established and reputable global platform⁸ where public health officials, regulators and academics agree that any policy and regulatory decision affecting e-cigarettes should be guided by evidence. Further, recent authoritative report⁹ concludes it is likely that there is a reduction in overall risk to health for conventional smokers who switch to HTPs.

Regulation is the most appropriate policy

2.6 JTHK supports the development of appropriate, targeted and proportionate regulation for e-cigarettes and HTPs that meets internationally accepted principles of Better Regulation as defined by the Organization for Economic Co-operation and Development and endorsed by numerous organizations such as the World Bank and Asia Pacific Economic Cooperation.

2.7 JTHK believes that:

- Adults should be free to choose whether they wish to use e-cigarettes and HTPs and no one should use them without understanding the risks associated with doing so;
- All marketed e-cigarettes and HTPs should comply with all relevant regulations, such as those concerning general consumer product safety, electrical safety and consumer protection from misleading marketing claims;
- Minors should not use e-cigarettes or HTPs and should not be able to obtain these products. Regulation of e-cigarettes and HTPs should aim to keep e-cigarettes and HTPs out of the hands of minors and to remind users of the risks associated with their use; and
- Governments and regulators should avoid excessive regulation that prevents adult consumers from choosing these products and that hinders the development of this category.
- 2.8 JTHK believes that e-cigarettes and HTPs should comply with high safety and quality standards, and proportionate regulations of those products should consist of requirements on:
 - clear definitions that cover both e-cigarettes and HTPs;
 - product specifications;

Nee Public Health England (PHE) report at: https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-productsevidence-review. See also, the Royal College of Physicians (RCP) report at: https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report

9 See evaluation and statement of UK Government's independent advisory Committees on Toxicity, Carcinogenicity, and Mutagenicity in Food, Consumer Products and the Environment regarding heated tobacco products at https://cot.food.gov.uk/committee/committee-on-toxicity/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products

^{8 &}lt;u>http://www.e-cigarette-summit.com/resources/</u>

- insert, packaging and labeling;
- advertising and sales including prohibition on sales to and by minors;
- usage of e-cigarettes and HTPs in public places; and
- manufacturing and measures on safety and quality of products.
- 2.9 JTHK would be happy to elaborate these proposals in more detail and provide information on how regulations on e-cigarettes and HTPs could be improved in Hong Kong to benefit public health, based on its long-standing experience.

A regulatory framework has been proposed by the Department of Health

- 2.10 In June 2018, the Department of Health proposed a regime to regulate (rather than ban) e-cigarettes and HTPs. The framework of regulation was set out in a document prepared by the Department of Health for the Legislative Council Panel on Health Services at that time (2018 Paper). That proposed regime was similar to the current regulatory regime of cigarettes and tobacco products". ¹⁰
- 2.11 That regime is clearly more considered and proportionate than the current proposal of a ban. In 2018, the Department of Health specifically mentioned that it had already "critically reviewed the scientific evidence, overseas practices and WHO recommendations, taking into account the emergence of other new products".¹¹

Fifty-six other jurisdictions regulate, not ban

- 2.12 Regulators in many developed countries have decided to explore options to regulate e-cigarettes and HTPs, instead of banning these products.
- 2.13 The 2019 Legislative Council Brief states that the sale of e-cigarettes is banned in 30 jurisdictions. However, what it has failed to point out is that, among the 83 countries that have put in place specific regulations for e-cigarettes as at October 2017, only 27 prohibit sales of all types of e-cigarettes, and <u>56 allow</u> the sale of e-cigarettes with regulations pertaining to product requirement, sale and age restriction.

Paragraph 22, the Department of Health's document "Legislative Council Panel on Health Services – Legislative Proposal to Regulate Electronic Cigarettes and Other New Tobacco Products" of June 2018 (LC Paper No. CB(2)1578/17-18(05)). It stated that "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.

Paragraph 22, the Department of Health's document "Legislative Council Panel on Health Services – Legislative Proposal to Regulate Electronic Cigarettes and Other New Tobacco Products" of June 2018 (LC Paper No. CB(2)1578/17-18(05)).

- 2.14 According to the Information Note titled "Regulation of e-cigarettes and heated tobacco products in selected places" published by the Research Office of the Legislative Council Secretariat (2018 Information Note), these 56 countries include major jurisdictions such as the United States, Canada and many European countries.
- 2.15 Two main regulatory frameworks for e-cigarettes are the revised European Tobacco Products Directive (EU TPD2) and the US Food and Drug Administration's (FDA) New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products, both of which are not calling for a ban on e-cigarettes:
 - The revised EU Tobacco Products Directive (2014/40/EU)¹³ allows the sale of e-cigarettes if they comply with the Directive and its requirements, including reporting, product specifications and health warnings. The EU TPD2 contains strict regulations on (among other things) product quality, labelling, consumer information and advertising and promotion, but permits the sale of e-cigarettes in the EU provided that these conditions are met.
 - The United States is an early adopter of e-cigarettes, with regulations currently in place governing the ingredient packaging, sale, advertisement and sponsorship. Subject to these requirements, in the United States, e-cigarettes can be sold to persons aged 18 or above at retail outlets registered with the relevant government authorities. 14
 - In Canada, the sale and import of nicotine containing e-cigarettes have been legalized since May 2018. Health Canada stated in a document for consultation published in August 2017 that "The opportunity presented by vaping products is that they may provide adult smokers with a less harmful alternative to tobacco". ¹⁵
 - In New Zealand, the sale and import of e-cigarettes with nicotine have been also legalized since May 2018. The government in New Zealand has been working on a creation of regulatory framework for e-cigarettes. The Ministry of Health in New Zealand has acknowledged the reduced-risk potential of e-cigarettes in an Impact Statement published in January 2019, stating that "it is clear that vaping is significantly less harmful than smoking". ¹⁶

Paragraph 3.2, Information Note – Regulation of e-cigarettes and heated tobacco products in selected places, by the Research Office of the Legislative Council Secretariat (IN11/17-18)

¹³ See DIRECTIVE 2014/40/EU, available at http://ec.europa.eu/health/sites/health/files/tobacco/docs/dir 201440 en.pdf.

¹⁴ Paragraph 1.5 and Table 2, Information Note – Regulation of e-cigarettes and heated tobacco products in selected places, by the Research Office of the Legislative Council Secretariat (IN11/17-18)

¹⁵ See page 2 of Proposal for the Regulation of Vaping Products, document for Consultation published in August 2017 and available at: https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulation-vaping-products/pub1-eng.pdf

See page 7 of 'Impact Statement: Supporting smokers to switch to significantly less harmful alternatives' published in January 2019 and available at: https://www.health.govt.nz/system/files/documents/pages/ris-support-smokers-to-switch-to-alternatives-jan-2019.pdf

Keeping e-cigarettes and HTPs out of the hands of minors

- 2.16 JT Group's position is clear minors should not use e-cigarettes or HTPs and should not be able to obtain these products. Regulation of e-cigarettes and HTPs should aim to keep e-cigarettes and HTPs out of the hands of minors and to remind users of the risks associated with their use.
- 2.17 Many jurisdictions which regulate e-cigarettes and HTPs have imposed a minimum age for purchasing these products. According to the 2018 Information Note, there are age restrictions on purchase of e-cigarettes in 32 countries, "mostly the US, Canada and European countries", and "most of them set the age limit at 18". 17

Not a "gateway" to conventional cigarettes

- 2.18 JTHK rejects the argument that e-cigarettes and HTPs may "lead" young people to conventional tobacco products.
- 2.19 The 2019 Legislative Council Brief suggested that alternative smoking products "open a gateway to the eventual consumption of conventional cigarettes" for "youth and young people".¹⁸
- 2.20 JTHK disagrees with this proposition, for two reasons:
 - JTHK's position is that minors should not use e-cigarettes or HTPs and should not be able to obtain these products.
 - According to the Royal College of Physicians, "e-cigarettes are not a gateway to smoking". ¹⁹ In its report published in April 2016, it was also stated that "E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do have smoked in the past, or are current smokers". ²⁰

¹⁷ Paragraph 3.6, Information Note – Regulation of e-cigarettes and heated tobacco products in selected places, by the Research Office of the Legislative Council Secretariat (IN11/17-18). See also paragraph 4.11 of the Information Note, which reads: "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 age limit for purchasing e-cigarettes and HTPs, and most of them have set 18 as the age threshold..."

¹⁸ Footnote 2 of the 2019 Legislative Council Brief: "Gateway effect refers to the possibility that youth and young people getting used to e-cigarettes and ultimately turn to smoking cigarettes."

¹⁹ See the website of Royal College of Physicians at: https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report

²⁰ See page 186 of the report titled 'Nicotine without smoke – Tobacco harm reduction' by the Tobacco Advisory Group of the Royal College of Physicians published in April 2016 and available at: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

3. NEGATIVE CONSEQUENCES OF A BAN

Infringement of fundamental rights

- 3.1 The Department of Health boldly asserts that a ban on e-cigarettes and HTPs is "in conformity with the Basic Law, including the provisions concerning human rights". ²¹
- 3.2 JTHK disagrees. The 2019 Legislative Council Brief does not provide any analysis to support this assertion. JTHK considers that proposal infringes a wide range of rights of manufacturers, retailers and the public, which are protected either under the Basic Law and fundamental human right principles.

3.3 Infringing the right to free trade

- In the latest Policy Address of the government, the Chief Executive stated that Hong Kong has remained steadfast to its firm commitment to free trade principles.²² A ban of e-cigarettes and HTPs contradicts this commitment of the government by prohibiting the sale of these products in Hong Kong.
- A ban on e-cigarettes and HTPs will interfere with manufacturers' and retailers' commercial rights, many of which are protected by national and international law. It unjustifiably infringes fundamental legal rights to trade as protected by international trade treaties, such as the World Trade Organization Agreements.
- In Hong Kong, these fundamental rights are also enshrined under the Basic Law. Articles 115 and 119 of the Basic Law prescribe that Hong Kong "shall pursue of free trade and safeguard the free movement of goods, intangible assets and capital", and "shall formulate appropriate policies to promote and co-ordinate the development of various trades...".
- To justify any infringement or contradiction of these constitutionally recognised rights, the relevant legislative proposal has to be proportionate. JTHK understands that the key purpose of the current proposed legislation is to keep e-cigarettes and HTPs out of the hands of minors. To achieve this aim, a complete ban on e-cigarettes and HTPs is obviously not a proportionate measure. A less restrictive and equally effective measure is clearly available, namely, to regulate these products and prohibit sale to minors.

3.4 Interfering with freedom of movement of goods

• Articles 115 of the Basic Law prescribe that Hong Kong shall "safeguard the free movement of goods".

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²¹ Paragraph 25, 2019 Legislative Council Brief.

²² Paragraph 126, The Chief Executive's 2018 Policy Address.

- A ban on e-cigarettes and HTPs interferes with the free movement of goods by prohibiting e-cigarettes and HTPs from entering into Hong Kong, thereby restricting the free movement of these products.
- Under the current proposed legislation, an exemption from ban is available for articles in transit or air transhipment cargos. However, as discussed in section 5 below, such exemption is narrow and restricts the mode of import and export to a large extent. Hong Kong is renowned as a free port and it promotes the import and export industry. A ban on ecigarettes and HTPs with such a narrow exemption will restrict the movement of these products (which are otherwise legal, regulated products in the source and destination jurisdictions) through Hong Kong and is not desirable.

3.5 Infringing freedom of choice and right to private ownership of property

- Adults should be free to choose whether they wish to use e-cigarettes and HTPs.
- The prohibition of e-cigarettes and HTPs limits adult consumer choice between legal products. It infringes rights protected under Articles 4 and 6 of the Basic Law, which provide that the Hong Kong Special Administrative Region "shall safeguard the rights and freedoms" of its residents and "shall protect the right of private ownership of property in accordance with law". These rights should not be overridden without justification. The government fails to justify its decision to ban ecigarettes and HTPs in the circumstances that regulation is clearly a more proportionate option.

3.6 **Discrimination**

• A ban on e-cigarettes and HTPs effectively discriminates between different legally available products for adult purchase. As discussed above, e-cigarettes and HTPs are RRPs that are potentially less harmful to health than conventional cigarettes. Accordingly, they should not be regulated materially differently from conventional cigarettes.

• Hong Kong has been a WTO member since 1 January 1995. E-cigarettes, HTPs and conventional cigarettes are potentially "like products" under WTO's likeness assessment, because they have similar physical properties, offer similar sensory experience and perform similar functions.²³ A ban on e-cigarettes and HTPs means that these products will be treated less favourably than their "like product" conventional cigarette, and accordingly can be discriminatory under WTO rules.²⁴

See section "WTO trade discrimination, Foltea, M., International Trade Rules for banning e-vapor products: http://209ub0417chl2lg6m43em6psi2i-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/104A.pdf: "In the event that a banned product is found to be 'like' another products that is not banned, it is feasible the less-favorable treatment of [E-vapor products] may be found illegal by the WTO judiciary."

See section "WTO 'likeness' assessments", Foltea, M., International Trade Rules for banning e-vapor products: http://2o9ub0417chl2lg6m43em6psi2i-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/104A.pdf

3.7 Depriving adults of the right to use RRPs

- As stated above, e-cigarettes and HTPs are RRPs. Accordingly, a ban prevents adult smokers from choosing a potentially less harmful alternative to smoking. To reiterate, adults should be free to choose whether they wish to use e-cigarettes and HTPs as long as they understand the risks associated with doing so.
- We should also view it in another angle a ban on e-cigarettes and HTPs will likely lead to some existing users of these RRPs to switch to conventional cigarettes. The government has overlooked this unintended potential consequence.

Discouragement of innovation and technology

- Article 139 of the Basic Law²⁵ provides that the government shall "formulate 3.8 policies on science and technology".
- 3.9 The innovation and technology industry is "one of the key economic areas that the government seeks to further develop". 26 The Chief Executive also mentioned that the government must "keep reinforcing and upgrading [the government's capability" and "provide a conducive eco-system for innovation and technology".²⁷
- E-cigarettes and HTPs have come into existence because of advancement of 3.10 technology. A ban on e-cigarettes and HTPs is against the government's policy objective of promoting innovation and technology.

Increase of opportunity for illicit trade

A prohibition of e-cigarettes and HTPs will increase opportunities for illicit trade, as it will create a void that will be filled by new opportunities for illicit market.²⁸ As can be seen from history, prohibition increases opportunities for illicit trade. As with the prohibition of alcohol in the US during the early 20th century, the continued demand for alcohol was satisfied by unregulated and illicit product. Such products were often of poor quality, with consequent increased health risks associated with their consumption.

Unwarranted application of the precautionary principle

An overly risk averse approach by regulators has driven them to resort to 3.12 unwarranted application of the precautionary principle. The precautionary principle means regulating for a threat of serious or irreversible harm, where there is scientific uncertainty about the nature and the extent of the risk. This

Article 139 of the Basic Law: "The Government of the Hong Kong Special Administrative Region shall, on its own, formulate policies on science and technology and protect by law achievements in scientific and technological research, patents, discoveries and inventions.

The Government of the Hong Kong Special Administrative Region shall, on its own, decide on the scientific and technological standards and specifications applicable in Hong Kong.'

https://www.gov.hk/en/residents/communication/government/innovation.htm

Paragraph 69, The Chief Executive's 2017 Policy Address.

With respect to tobacco products, similar issues have arisen in Bhutan. Following a ban on the sale of tobacco products, Bhutan has a thriving illegal tobacco market.

- principle has to be applied with a view to encouraging innovation and further scientific research and only to the extent necessary to prevent the threat.²⁹
- 3.13 The main problem with a prohibition of e-cigarettes and HTPs is that it is substantiated on the notion "prevention is better than the cure" and thus aims to reduce the potential risks associated with the use of e-cigarettes and HTPs without having a clear assessment of these risks, their probability of occurrence and possible effects.
- 3.14 Given that there is no reliable scientific evidence supporting a prohibition of ecigarettes and HTPs, and that prohibition would have a number of negative effects (as described above), reasonable and proportionate regulation of ecigarettes and HTPs, after full public consultation and detailed study, is a more appropriate response.

See: WHO: The precautionary principle: protecting public health, the environment and the future of our children, http://www.euro.who.int/ data/assets/pdf_file/0003/91173/E83079.pdf

4. THE TRANSHIPMENT EXEMPTION

- 4.1 The transshipment exemption needs widening to deal with the realities of Hong Kong as a trading hub.
- 4.2 Under the current legislative proposal, there is a narrow exemption for articles in transit or air transhipment cargos. However, the exemption will not apply in the following situations:
 - "(a) for an article in transit on an aircraft the product is removed from the aircraft other than in the specified cargo transhipment area;
 - (b) for an article in transit in a vessel the product is removed from the vessel: or
 - (c) for an air transhipment cargo the product is removed from the specified transhipment area."³⁰
- 4.3 This exemption is too narrow. It does not take into account how e-cigarettes and HTPs are typically imported into and exported out of Hong Kong. Many of these products are manufactured in China and exported globally. They often enter into Hong Kong by truck, are temporarily stored in premises in Hong Kong, and are then exported by other modes of transport. The current proposed exemption only applies to products that enter Hong Kong by air or vessel, and therefore does not cover this common mode of transhipment.
- 4.4 In this regard, broader shipment exemptions are available for other types of regulated products (including pharmaceutical products).³¹ These regimes allow:
 - import and export of the product in a **vehicle**, not just aircraft and vessels. This caters for the practical reality that products are often manufactured in China and are imported into Hong Kong by truck or other vehicle;
 - export of the product in a vessel, aircraft or vehicle other than the one by which the product is imported; and
 - the product to be stored in Hong Kong pending exportation. This makes import and export scheduling arrangements easier and more flexible.
- 4.5 JTHK strongly urges the Department of Health to widen the scope of its proposed transhipment exemption for e-cigarettes and HTPs in accordance with a model that we have prepared (Annex 2).

31 Under the Transhipment Cargo Exemption Scheme, shipping companies, airlines and freight forwarders registered under the Scheme are, subject to certain conditions, exempted from import and export licensing requirements in respect of any imported article that:

Section 15DD(2) of the Smoking (Public Health) (Amendment) Bill 2019.

[&]quot;(a) is consigned on a through bill of lading or a through air waybill from a place outside Hong Kong to another place outside Hong Kong; and

⁽b) is or is to be <u>removed from the vessel</u>, <u>aircraft or vehicle in which it was imported</u> and either returned to the same vessel, aircraft or vehicle or transferred <u>to another vessel</u>, <u>aircraft or vehicle before being exported</u>, whether it is or is to be transferred directly between such vessels, aircraft or vehicles or <u>whether it is to be landed in Hong Kong and stored</u> after its importation pending exportation." (our emphasis)

5. PROCEDURAL UNFAIRNESS

Unjustified change of Government policy

- 5.1 The government proposed regulation of e-cigarettes and HTPs in 2018. It now proposes a ban. But, what has changed? Nothing. The change in policy has not been justified by the evidence, arguments, etc.
- 5.2 In 2018, in coming up with that proposed regulatory regime, the Department of Health stated that it had "critically reviewed scientific evidence, overseas practices and WHO recommendations".32
- 5.3 In the absence of any material change in scientific evidence, overseas practices or WHO recommendations, the Department of Health has failed to justify its abrupt change of proposal in 2019 from regulation "similar to the current regulatory regime of cigarettes and tobacco products" to prohibition. In other words, by putting the proposal of ban for first reading in the Legislative Council, the government has failed to respect basic principles of good governance and due process, in a manner that leaves JTHK substantially prejudiced by the procedure.
- 5.4 Consultation is part of the administrative law concept of fairness, a concept that all administrators must follow. Under common law there is a need for the administrator to conduct re-consultation after a fundamental change of position.³³ The Department of Health's current proposal of banning e-cigarettes and HTPs is fundamentally different from its proposal in 2018 to regulate these products. A re-consultation, which allows different stakeholders to contribute their opinion to the proposal in question, is necessary.
- 5.5 Alternatively, even if one does not consider that the shift from regulation to prohibition constitutes a fundamental change of position, there is a question mark about whether the Department of Health's current legislative proposal has fulfilled the basic requirement for constituting "adequate consultation" by an

(b) prohibition of advertisement, promotion and sponsorship;

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:

The relevant paragraph of the 2018 Paper reads: "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 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 the 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:

prohibition of sale to minors;

prohibition of sale unless in retail package bearing health warning; (c)

⁽d) prohibition of sale from vending machines;

a ban on use in no smoking areas;

a ban on certain additives (such as vitamins) in e-cigarettes which may (g) 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 taxation on any tobacco component." (our emphasis)

R (Carton) v Coventry City Council (2001) 4 CCLR 41, 44C-E (further consultation required where fundamental change).

administrator under "the Sedley requirements". The fourth limb of "the Sedley requirements" is as follows:

- "... fourthly ... the product of consultation must be conscientiously taken into account in finalising any ... proposals". 34
- In changing the proposal from regulation to prohibition, the Department of Health has failed to conscientiously take into account the views of stakeholders who supported the regulation proposal during the 2018 consultation. In this regard, the Department of Health has indicated that, in the 2018 round, it received "close to 2 000 letters or email messages" supporting regulation. In the 2019 Legislative Council Brief, the Department of Health has failed to (a) state clearly whether it had given sufficient consideration to the views of these stakeholders; and (b) if it had given such consideration, provide detailed, compelling reasons to explain why, despite these stakeholders' views, it considered that a ban is appropriate.
- 5.7 JTHK believes that a new and proper consultation should be held.

Inappropriate to interpret WHO recommendations differently in 2018 and 2019

- 5.8 The Department of Health interpreted the same text from the seventh session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control differently in 2018 and 2019. The quotation was seemingly to suit its legislative proposals at the relevant times.
- 5.9 In paragraph 9 of the 2019 Legislative Council Brief the Department of Health emphasised the word "prohibit", and subsumed the word "restrict" under the phrase "inter alia", as follows:
 - "... Further to the seventh session of the Conference of the Parties ("COP") to the WHO Framework Convention on Tobacco Control ("FCTC") which proposed, in November 2016, to its Contracting Parties to consider applying regulatory measures to, inter alia, **prohibit** the manufacture, importation, distribution, sale, presentation, etc., of e-cigarettes,..." (emphasis in original)
- 5.10 In contrast, the 2018 Paper referred to the same COP proposal but placed an emphasis on "applying regulatory measures":
 - "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, sale and use of e-cigarettes, as appropriate to their national laws and public health objectives." 35 (emphasis in original)
- 5.11 In JTHK's view, this is wholly inappropriate. An administrator is supposed to be unbiased, and should present information relating to its proposal in a fair, balanced manner, in order to allow stakeholders to make an informed

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³⁴ R v. Brent London Borough Council, Ex p Gunning (1985) 84 LGR 168, cited in R v. North and East Devon HA, Ex p Coughlan [2001] QB 213 at 258. See also, Lam Yuet Mei v. Permanent Secretary for Education and Manpower of the Education and Manpower Bureau [2004] 3 HKLRD 524; Tang Shuk Chun V. Director Of Food And Environmental Hygiene, HCAL18/2013

³⁵ Paragraph 10, 2018 Paper.

assessment about which stance they should take in the proposal in question. The way that the WHO's position is paraphrased in the 2019 Legislative Council Brief is simply misleading.

6. CONCLUSION

6.1 In conclusion:

- E-cigarettes and HTPs should be regulated, rather than banned.
- Regulation of e-cigarettes and HTPs should aim to remind users of the risks associated with their use, and keep e-cigarettes and HTPs out of the hands of minors.
- The current government proposal is fundamentally different from its proposal in 2018, and therefore a proper re-consultation is necessary.
- If the government insists on a ban (which JTHK strongly oppose), it should introduce a transhipment exemption which (a) is wider than as it is currently proposed; and (b) takes into account the fact that many of these products are typically manufactured in China, transferred to Hong Kong by truck and exported internationally.
- 6.2 JTHK would be happy to provide more information on how regulations on ecigarettes and HTPs could be formulated in Hong Kong to benefit public health, based on its long-standing experience.

ANNEX 1

CHARACTERISTICS OF E-CIGARETTES AND HTPS

1. E-cigarettes and HTPs differ from conventional tobacco products (such as cigarettes) in product characteristics.

E-cigarettes

- 2. E-cigarettes are battery-powered consumer products that provide an inhalable vapor by turning a solution into aerosol via electrical means such as electrical heating. This solution is called an 'e-liquid' intended for transformation into an aerosol and then inhaled with an e-cigarette.
- 3. E-liquids usually contain nicotine, but do not contain tobacco. Other typical components of e-liquids are carrier liquid such as Propylene Glycol (PG) and Vegetable Glycerol (VG) and flavors. At JT Group, we use food-grade flavoring and pharmaceutical-grade nicotine, PG, and VG in our e-liquids to ensure the quality of the vaping experience.
- 4. Logic Compact (see Figure 1 below) one of JT Group's e-cigarettes with a product characteristic of '95% reduction in 9 toxic substances'. We believe Logic Compact has strong potential to be a reduced risk product. We cannot say today that Logic Compact is safer than smoking regular cigarettes, but tests have shown that Logic Compact has a 95% reduction in the constituents recommended by WHO for reduction in cigarette smoke.

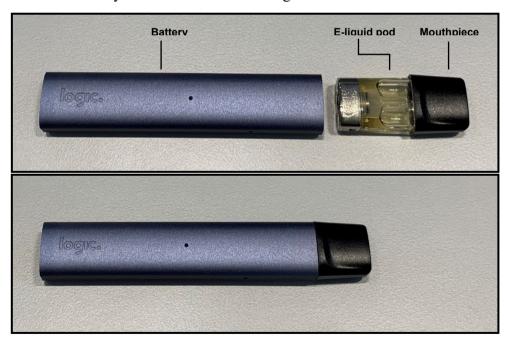


Figure 1: JTHK's e-cigarette – Logic Compact. Logic Compact provides an inhalable vapor by turning an e-liquid into aerosol via electrical heating

³⁶ *Based on the comparison of 9 harmful constituents, recommended for reduction by the World Health Organization in Cigarette Smoke, measured in the smoke of a standard reference cigarette (3R4F) versus the vapor from Logic Compact. Use of this product does not mean it is necessarily safer than smoking regular cigarettes.

- 5. Logic Compact has a sleek shape with the length of 10 cm. A magnetic e-liquid pod pre-filled with approximately 1.7 ml of e-liquid is inserted to the device for use. Logic Compact has a 350 mAh battery to heat the e-liquid. The battery needs approximately 74 minutes to be fully charged. Logic Compact also has a magnetic charging function to plug into a USB port.
- 6. When the user takes a puff, the battery supplies power to the atomizer. The atomizer heats and vaporizes the e-liquid. The e-liquid turns into the vapor and it can then be inhaled by the user through the mouthpiece (see Figure 2 below).

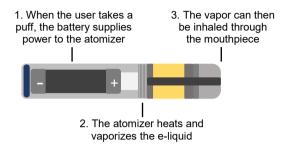


Figure 2: Mechanism of action

HTPs

7. HTPs are tobacco products in which tobacco is heated, either directly or indirectly, without combustion to create an inhaable vapor. Some directly heat tobacco, and some indirectly heat it. Existing direct heating products heat tobacco to between 200°C and 300°C, and indirect heating products can heat tobacco to as low as around 30°C to 50°C. This compares to the combustion in a cigarette, at around 800°C.

- 8. HTPs do not involve combustion process and have the potential to reduce the risks associated with smoking. A scientific study³⁷ has shown that as the temperature of tobacco increases, the levels of harmful chemicals formed increase. A report³⁸ commissioned by Public Health England has also stated that "The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes [...]".
- 9. Ploom TECH (see Figure 3 below), is JT Group's HTP with a product characteristic of '99% reduction in 9 toxic substances'.³⁹ JT Group believes Ploom TECH has strong potential to be a RRP. While we take a prudent approach and do not say today that Ploom TECH is safer than smoking regular

³⁷ Formation of Polycyclic Aromatic Hydrocarbons from Tobacco: the "Link" between Low Temperature Residual Solid and PAH Formation, McGrath, T.E., Wooten, J.B., Chan W.G. and Hajalogol, M.R. Food and Chemical Toxicology, 45, 6, 1039-1050, 2017

Evidence review of e-cigarettes and heated tobacco products 2018, A report commissioned by Public Health England, Ann McNeill, Leonie S Brose, Robert Calder, Linda Bauld, Debbie Robson, February 2018: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf

³⁹ Based on the comparison of 9 harmful constituents, recommended for reduction by the World Health Organization in Cigarette Smoke, measured in the smoke of a standard reference cigarette (3R4F) versus the vapor from Ploom Tech. Use of this product does not mean it is necessarily safer than smoking regular cigarettes.

cigarettes, tests have shown that Ploom TECH has a 99% reduction in the constituents recommended by WHO for reduction in cigarette smoke.



Figure 3: JTHK's HTP – The Ploom TECH device. The Ploom TECH device indirectly heats a nicotine-free e-liquid which passes through tobacco contained in a capsule

- 10. The product consists of two main elements:
 - A battery powered electronic device to generate vapor, which is equipped with a battery segment and a cartridge segment housing an atomizer, a liquid chamber and a liquid;
 - A tobacco capsule that contains a flavored tobacco blend.
- 11. When used, the two elements are combined into a single unit via a specific connector.
- 12. The product differs from e-cigarettes in that the tobacco capsule contains tobacco. Unlike conventional smoking tobacco products, the product does not burn tobacco; instead, a vapor is generated from the pre-filled liquid in the liquid chamber and passes through the tobacco capsule (see Figure 4 below). In doing so, evaporated constituents arising from the tobacco blend, including nicotine and flavors, pass into the vapor which can then be inhaled by the user.
- 13. The liquid in the Ploom TECH cartridge does <u>not</u> contain nicotine, and consists of a carrier, such as propylene glycol and glycerol.

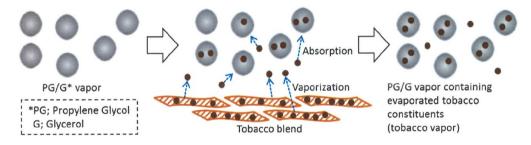


Figure 4: Mechanism of action

ANNEX 2
PROPOSED AMENDMENT TO THE TRANSHIPMENT EXEMPTION

Proposed bill	Suggested amendment	Effect / reason for amendment
15DD. Exemption for articles in transit or air transhipment cargos (1) Section 15DA(1)(a) does not apply in relation to an alternative smoking product that is an article in transit or air transhipment cargo.	are imported into Hong Kong for the purpose of export (1) Section 15DA(1)(a) does not apply in relation to an alternative smoking product if the product is imported into Hong Kong for the purpose of export, and is either (a) not removed from the vessel, aircraft or vehicle in which it was imported after its importation pending exportation; or (b) is or is to be removed from the vessel, aircraft or vehicle in which it was imported and either returned to the same vessel, aircraft or vehicle or transferred to any vessel, aircraft or vehicle before being exported, whether it is or is to be transferred directly between such vessels, aircraft or vehicles or whether it is to be landed in Hong Kong and stored after its importation pending exportation."	 These proposed changes widen the exemption in the bill by allowing: import and export of the product in a vehicle, rather than just by vessel or aircraft; export of the product in a vessel, aircraft or vehicle other than the one by which the product is imported; and the product to be stored in Hong Kong pending exportation. This caters for the practical reality that many alternative smoking products are manufactured in China, transferred to Hong Kong by vehicle and exported to overseas by vessel or aircraft. This also allows these products to be stored in Hong Kong pending exportation, making import and export scheduling arrangements easier and more flexible.

(2) However, section 15DA(1)(a) does apply in relation to an alternative smoking product if; at any time between its being brought into and taken out of Hong Kong—	Suggest deletion
(a) for an article in transit on an aircraft—the product is removed from the aircraft other than in the specified cargo transhipment area;	
(b) for an article in transit in a vessel—the product is removed from the vessel; or	
(c) for an air transhipment cargo—the product is removed from the specified cargo transhipment area.	

- (3) If section 15DA(1)(a) applies in relation to a product because of subsection (2), for the purposes of the application-
- (a) the product is deemed to be imported at the time of the removal mentioned in subsection (2); and
- (b) the person who brought the product, or caused it to be brought, into Hong Kong as an article in transit or air transhipment cargo is deemed to be the person who imported the product
- (4) It is a defence for a person mentioned in subsection (3)(b) who is charged under section ISDA(4) in relation to importing a product to show that the person took all reasonable steps and exercised reasonable diligence to avoid the removal mentioned in subsection (2).
- (5) Subsection (6) applies if a defence under subsection (4) involves an allegation that the offence was committed because of—
- (a) another person's act or default; or
- (b) the defendant's reliance on information given by another person.

Suggest deletion.

Subsections (3) and (4) relate to subsection (2). Since we are suggesting deletion of subsection (2), subsections (3) and (4) will have to be deleted as well.

Subsections (5), (6) and (7) relate to subsection (4), which means that they have to be deleted as well.

Since the revised exemption no longer refers to "air transshipment cargo", "article in transit" or "specified cargo transshipment area", subsection (8) can be deleted as well.

- (6) Without the leave of the court, the defendant may not rely on the defence unless, at least 10 days before the hearing of the proceedings, the defendant has served a written notice on the prosecutor giving particulars of—
- (a) the person who allegedly committed the act or default, or allegedly gave the information; and
- (b) the act, default or information concerned,

of which the defendant is aware at the time the notice is served.

- (7) The defendant may not rely on a defence under subsection (4) claiming that the offence was committed because of the defendant's reliance on information given by another person unless the defendant shows that the reliance was reasonable in all the circumstances, having regard in particular to—
- (a) the steps that the defendant took, and those which might reasonably have been taken, for verifying the information; and

(b) whether the defendant had any reason to disbelieve the information.	
(8) In this section—	
air transhipment cargo (RJMAAR j) has the meaning given by section 2 of the Import and Export Ordinance (Cap. 60);	
article in transit (gigitg) has the meaning given by section 2 of the Import and Export Ordinance (Cap. 60);	
specified cargo transhipment area (triE9jk gm) means—	
(a) any part of the Hong Kong International Airport that is designated under section 35 of the Aviation Security Ordinance (Cap. 494) as a restricted area; or	
(b) an area approved by the Commissioner of Customs and Excise under section 2AA of the Import and Export Ordinance (Cap. 60).	