Bills Committee on Smoking (Public Health) (Amendment) Bill 2019
List of follow-up actions arising from the discussion at the meeting on 25 June 2019

The Administration's response on the items raised by Members is set out as follows.

Comparison of a full ban proposal with regulatory approach

Health risks of alternative smoking products

2. There is increasing evidence that alternative smoking products ("ASPs") are definitely harmful to health and would bring about gateway effects. Apart from the information on the health risks, gateway and renormalisation effects, prevalence, the World Health Organisation ("WHO") recommendation, etc., in relation to ASPs which is detailed under Annex B of the Legislative Council brief (FH CR 1/3231/19) issued on 13 February 2019, we provide the latest evidence on the health risks of electronic-cigarettes ("e-cigarettes") and heat-not-burn ("HNB") products in the following paragraphs.

3. Between 2010 and 2019, the United States Food and Drug Administration (FDA) has received 127 reports of seizure or other neurological symptoms associated with e-cigarette use. In April 2019, FDA alerted the public on the increase in reports of seizure associated with e-cigarette use, mostly involving youth or young adult users. In August 2019, the US Centers for Disease Control and Prevention announced that it would investigate 193 potential cases of severe lung illnesses reported within a two-month period in 22 states and urged for reporting of unexpected health or safety issues. As at 5 November 2019, 2,051 lung injury cases (including 39 fatal cases) associated with the use of e-cigarette have been reported to the Centers for Disease Control and Prevention from 49 states, the District of Columbia, and one United States territory. These reports illustrate the level of uncertainties associated with the health risks of e-cigarettes.

4. As for HNB products, WHO released in July 2019 a report on the global tobacco epidemic to further summarise the health risks related to the

use of these products. The report pointed out that HNB products contain tobacco and produce toxic emissions similar to toxicants found in cigarette smoke. Although the levels of some toxicants in HNB products are lower than those found in conventional cigarettes, the levels of others are higher. In addition, latest studies again found that consumers incorrectly interpreted "reduced exposure" in the use of HNB products as "reduced risk", showing that the claim of "lower exposure/emission", as deliberately and aggressively advanced by HNB products manufacturers, is inherently misleading[1, 2]. The industry-promoted misconception that "lighter" products are safer has already been proven difficult to dispel. Indeed, we must reiterate that a lower level of some toxicants does not necessarily mean a reduction in health risk. Based on the scientific evidence currently available, the claim that ASPs, including e-cigarettes or HNB products, are less harmful is unfounded.

5. The latest incidents of serious illnesses and deaths associated with e-cigarettes, as well as the false claim and public misunderstanding on the potential harm of HNB products, are vivid examples of serious public health consequences of delayed actions in curbing the marketing of toxic and addictive products. Allowing the introduction of ASPs into the Hong Kong market, though regulated, is against our established tobacco control policy, which is to discourage the use of tobacco products and protect the public from the harm of second hand smoke to the greatest extent possible.

6. In addition, the devices of ASPs carry functions that have been non-existent in conventional smoking products. Some HNB product devices are electronic gadgets with the capability to collect data on users' preferences and use patterns, directly communicate with individual users to influence their smoking behaviours, and potentially remotely control of device performance. Designed to appeal to the young generation who are readily drawn to new technology[3], these devices would aid the tobacco industry to market their addictive products more effectively and undermine

[1] McKelvey K, Popova L, Kim M, Lempert LK, Chaffee BW, Vijayaraghavan M, et al. IQOS labelling will mislead consumers. Tobacco Control. 2018;published Online First: 29 August 2018:doi: 10.1136/tobaccocontrol-2018-054333.

[2] El-Toukhy S, Baig SA, Jeong M, Byron MJ, Ribisl KM, Brewer NT. Impact of modified risk tobacco product claims on beliefs of US adults and adolescents. Tobacco Control. 2018;published Online First: 29 August 2018:doi: 10.1136/tobaccocontrol-2018-054315.

[3] McKelvey K, et al. Heated tobacco products likely appeal to adolescents and young adults. Tob Control. 2018 Nov;27(Suppl 1):s41-s47. doi: 10.1136/tobaccocontrol-2018-054596.

the existing tobacco control measures for regulating the content, sale and promotion of tobacco products.

7. On the whole, there is increasing evidence that regulating ASPs on par with conventional cigarettes will not match up to our current control of conventional cigarettes, in particular when the devices and accessories of ASPs render them substantially different products. To bring HNB devices under effective control, measures to counteract their appeal, prohibit their data collection and transmission, and prohibit any functions that give remote modification of nicotine delivery, to say the least, are required. That said, regulatory measures by legislation would most likely lag behind the technological advances that are possible with these electronic devices. To institute regulation against such rapidly evolving products would also incur enormous public resources which cannot be justified for a class of products that bring no social good but addiction, diseases and deaths. Given the inadequacy of a regulatory approach, we consider that a full ban of ASPs including their devices and accessories is the most effective control in prohibiting these emerging ASPs with health risks and marketing appeal from entering and taking root in the local market.

Population impact

8. The formal introduction of ASPs into the local market could reverse Hong Kong's downward trend of conventional cigarette use and lead to the emergence of a new generation of smokers using these new smoking products. With respect to the youth uptake of ASPs, the latest reports in the United Kingdom, Canada and the United States all revealed that the prevalence of e-cigarette use among young people has substantially increased in recent years.

9. A report published by **Public Health England** in February 2019 showed that the prevalence of current **e-cigarette use** among people aged 11 to 18 increased from 1.6% in 2014 to 3.4% in 2018. The proportion of e-cigarette experimenters who had never smoked or experimented cigarettes had increased from 18% in 2014 to 30% in 2018, meaning that increasingly e-cigarettes are taken up by those who had never tried or were

addicted to cigarette tobacco.[4] **Canada** has experienced a staggering increase in youth **use of e-cigarettes** since the legalisation of nicotine-containing e-cigarettes as consumer products in May 2018. A study found that the use of e-cigarettes among those aged 16-19 years old increased significantly from 8.4% in 2017 to 14.6% in 2018, and that cigarette smoking among 16-19 year-olds in the same period increased from 10.7% to 15.5%. Prior surveys up to and including 2017 had shown a continuing decline in youth smoking.[5] In **the United States**, the latest national survey on youth smoking pattern showed that in 2019, youth **e-cigarette use** is at an alarming level, with 27.5% of high school students and 10.5% of middle school students were current users of e-cigarette. In total, 1.4 million more students in middle and high schools took up e-cigarettes in the one-year period from 2018 to 2019.[6]

10. The findings of population studies on **HNB products** in **Japan and Korea** are also alarming. A longitudinal study in Japan revealed that not only the current use of HNB products increased more than 10 times, from 0.1% in 2015 to 1.3% in 2017, the use among persons aged 15-19 showed a more than 3 times increase, from 0.6% in 2015 to 2% in 2017.[7] The latest population data published in August 2019 on youth use of HNB products, based on a study conducted on a much larger sample of 59 000 Korean adolescents aged 12 to 18, showed that 2.8 % of them had used HNB products in the one year after the introduction of the products into the Korean market. Considering the recent introduction of HNB products into the market and comparing with the less than 1% prevalence of e-cigarette use when the latter was first introduced, the authors found the ever use of HNB products among Korean adolescents to be an important concern.[8]

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[4] McNeill A, Brose LS, Calder R, Bauld L & Robson D (2019). Vaping in England: an evidence update February 2019. A report commissioned by Public Health England. London: Public Health England. Available at https://www.gov.uk/government/publications/vaping-in-england-an-evidence-update-february-2019

[5] Hammond D, et al. Prevalence of vaping and smoking among adolescents in Canada, England, and the United States: repeat national cross sectional surveys. BMJ. 2019 Jun 20;365:l2219. doi: 10.1136/bmj.l2219.

[6] https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey

[7] Tabuchi T, et al. Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. Tobacco Control. 2017;10.1136/tobaccocontrol-2017-053947

[8] Kang H, Cho S-i. Heated tobacco product use among Korean adolescents. Tobacco Control. 2019:tobaccocontrol-2019-054949.

11. The abovementioned countries have all experienced rapid increase in youth use in spite of prohibition of sale to minors. The phenomenon is similar to what had happened with conventional cigarettes, of which addiction develops mostly in teenage despite the prohibition of sale to minors. **Sale restriction to minors** simply will **not** be **as effective as a full ban** in respect of containing youth uptake of smoking products. The smoking prevalence in Hong Kong is now among the lowest in the world, at 10% in 2017, as a result of comprehensive tobacco control measures now underpinned by the Framework Convention on Tobacco Control (FCTC). The smoking prevalence among our young people is even lower: 1% among those aged 15-19 and 6.7% among those aged 20-29. A full ban of ASPs as opposed to mere regulation will be necessary in achieving the aim of making it difficult for the public to get access to these harmful ASPs products, to prevent the introduction of a new class of addictive, harmful consumer products like conventional cigarettes for which the society has already paid a heavy price.

Legal and illicit trade of ASPs

12. WHO points out that the tobacco industry systematically uses the threat of a rise in illicit trade to oppose the tobacco control policies set forth by the FCTC, including increase of tobacco tax, packaging and labelling policies and banning of tobacco marketing.[9] In fact, illicit trade may take place whether a full ban or regulation with taxation exists. Moreover, any control short of a full ban is prone to create demand for ASPs in the population, resulting in an increase of those that may run the risk of buying illicit ASPs as long as there is price difference between the legitimate and illicit products. On the other hand, the intent of the proposed full ban is to curb the demand for ASPs and make it difficult for potential consumers to get access to such products before they become widely popular.

13. While illegal activities associated with smuggling, distribution and sale of relevant prohibited products may arise after the proposed ban comes into effect, we shall deploy additional resources for the enforcement departments including the Department of Health (DH) and the Customs and Excise Department (C&ED) to tighten enforcement efforts against any

[9] World Health Organization. The Tobacco Industry and the Illicit Trade in Tobacco Products. https://www.who.int/fctc/publications/The_TI_and_the_Illicit_Trade_in_Tobacco_Products.pdf

illicit trade of ASPs. We are nevertheless unable to make any ballpark assessment on the extent of the illicit trade, whether under the proposed ban or a regulatory regime, which will depend on a host of different factors.

14. If ASPs are to be regulated in a way similar to conventional smoking products which are dutiable commodities under the Dutiable Commodities Ordinance (Cap. 109), any legal trade will be subject to a taxation and regulatory regime which includes the licensing of the import, export, manufacture and storage of the ASPs; assessment and collection of duties and related charges on the tobacco components of ASPs; and regulation of the movement of ASPs by permit, etc. We consider that allowing the marketing of ASPs in Hong Kong would undermine ongoing efforts on tobacco control and would also require a complex enforcement regime with a whole new set-up involving disproportionate resources, the use of which we do not consider justified. Reference can be made to the success we had achieved with the ban of smokeless tobacco under the Smokeless Tobacco Products (Prohibition) Regulations (Cap. 132BW) enacted in 1987. It has demonstrated the Administration's determination and decisive approach to contain the proliferation of any harmful smoking products by adopting a full ban.

Duty revenue from ASPs

15. We do not have any scientific methodology to gauge the impact on tax revenue under a regulatory approach as opposed to a full ban of ASPs. While under a regulatory regime, if a duty is to be levied on ASPs containing tobacco, a straightforward prediction will be an increase in duty revenue collected from the new smoking products. That said, we are not able to project the consumer behaviour such as the possible shift of smokers from smoking conventional tobacco to new smoking products which will be marketed aggressively as has been the case overseas where conventional advertising has already been banned, and its overall effect on duty revenue.

16. In any case, the Administration's primary concern in proposing a full ban of ASPs is the protection of public health, instead of duty revenue.

Justification for the change in the legislative direction

17. Taking protection of public health as our prime consideration, the Administration's determination to discourage smoking, contain the proliferation of tobacco use and protect the public from passive smoking has remained unchanged over the years. To this end, we consider that a full ban of ASPs is the most effective to prevent the harm of ASPs from entering and taking root in Hong Kong. In fact, when the former proposal to regulate ASPs was introduced in June 2018, we had acknowledged that a regulatory approach was not optimal but it was only due to the lack of substantive scientific evidence on the harmful health effects of ASPs at the time and the intent to minimise the harm brought about by these new products as soon as practicable that the Administration decided to introduce the regulatory legislative proposal. The proposal was heavily criticised by the medical professions, education sector, parents and many members of the public as being inadequate to protect public health in particular the health of youth.

18. Thereafter, there is increasing scientific evidence on the risk and public health impacts of the new smoking products. For example, a study published in August 2018 showed no statistical difference between HNB product and conventional cigarette users for 23 of the 24 examined biomarkers of potential harm and thus rebutted the claim that HNB product has lower risks of harm in human use than conventional cigarettes.[10] There was an increasing amount of evidence on gateway effect in particular among adolescents since July 2018, followed by more recent surveys in the United Kingdom, Canada and the United States which showed marked increase in e-cigarette use amongst youth as mentioned in paragraph 9 above. On the other hand, further to the seventh session of the Conference of the Parties to the 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, the eighth session held in October 2018 proposed the same for HNB products. It was based on scientific evidence on the harm of the new smoking products, recommendations of WHO, views from

[10] Glantz SA. PMI's own in vivo clinical data on biomarkers of potential harm in Americans show that IQOS is not detectably different from conventional cigarettes. Tobacco Control. 2018;27(Suppl 1):s9-s12.

different sectors, the local smoking prevalence, etc., that we drew up the current legislative proposal of a full ban as opposed to regulation. There are no less restrictive measures that are capable of achieving the high level of public health protection as a full ban.

Use or possession of ASPs for self-use

19. Under the legislative proposal which prohibits the import, manufacture, sale, distribution and advertisement of ASPs, it is expected that the public will not be able to obtain these products after the new legislation, in particular the ban on import and distribution, comes into effect. The use or possession of ASPs for self-use is not prohibited as it is not our intent to push ahead an excessively stringent regulation on individual's domestic life. From the enforcement perspective, there is also difficulty to carry out enforcement action against the possession of ASPs, which could involve search of domestic premises or any person.

20. C&ED is committed to combating smuggling activities of ASPs. Based on an effective risk-assessment strategy, Customs Officers vigorously conduct checks on passengers, cargoes, postal packets and conveyances at various control points and sea boundary for combating smuggling of contrabands. Upon implementation of the Bill, C&ED will further step up enforcement against smuggling of ASPs from countries of provenance and mount focused operations targeting ASPs from time to time. C&ED will enhance co-operation as well as intelligence exchange with DH and other overseas law enforcement agencies to fight against smuggling attempts.

21. Besides, DH will follow up and carry out investigation on every cases related to distribution and sale of ASPs, by collecting intelligence and arranging joint enforcement operations with the Police and C&ED against illegal activities. We will continue to closely monitor the local situation and the latest development of ASPs, as well as the smoking prevalence for considering whether it is necessary to further tighten the regulation in the future.

Translation of FDA's report

22. As explained at the Bills Committee meeting on 25 June 2019, the Administration is not in a position to directly translate the full report of FDA without FDA's authorisation and confirmation on the accuracy of the translation in interpreting its report. That said, to facilitate the discussion of the Committee, we provide a bilingual summary on FDA's report and its decision to permit the sale of IQOS, together with the Administration's response at **Annex**.

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Annex

Bills Committee on Smoking (Public Health) (Amendment) Bill 2019

Information paper on the United States Food and Drug Administration's Report

This paper sets out the United States Food and Drug Administration (FDA)'s decision to permit the sale of a heat-not-burn (HNB) product called "IQOS" (the Product), and the Administration's response to FDA's report and the control of these products.

FDA Regulation of Heat-not-burn Products

2. In the United States, the Family Smoking Prevention and Tobacco Control Act provides FDA with comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products.

3. Marketing of any tobacco product not commercially available in the United States as of February 15, 2007 is required by law to obtain authorisation from FDA through one of the three pathways, namely (i) Substantial Equivalence, which applies to a tobacco product that, when compared to tobacco products that are already commercially available in the United States market, has the same characteristics, or has different characteristics but does not raise different questions of public health; (ii) exemption from Substantial Equivalence, which applies to a tobacco product that is a modification of another tobacco product legally marketed by the same organisation and the modification is minor; or (iii) Premarket Tobacco Product Application (PMTA), which applies to new tobacco products.[1]

4. PMTA must be made with submission of scientific data to demonstrate the impact on the population as a whole including users and non-users. The demonstration shall take into account the increased or decreased likelihood that existing tobacco users will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using them.[2]

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[1] https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product

[2] Federal Food, Drug, and Cosmetic Act Section 910(c)(4)

5. In marketing a tobacco product, it is prohibited to make any claim of reduced exposure to harmful substances or reduced risk of tobacco–related disease unless approval is obtained from FDA to market the product as a Modified Risk Tobacco Product (MRTP) product or such claim is approved by FDA. FDA requires MRTP applicants to demonstrate that their products, as actually used by consumers, will reduce harm in individuals and benefit the health of the population overall.

FDA's Decision to Authorise the Marketing of the Product

6. FDA announced on 30 April 2019 that it authorised the marketing of the Product. The Product is a tobacco product new to the United States market, and as such the authorisation was made via the PMTA route.[3] So far, no MRTP approval or order for any HNB products has been issued by FDA. In marketing the Product in the United States, it is illegal for the manufacturer to make any claim of reduced exposure to harmful substances, or reduced risk of tobacco-related diseases, until its MRTP application or such claim is approved by FDA.

7. In its press statement on the approval, FDA stated that while its authorisation permits the tobacco products to be sold in the US, it does **not mean that these products are safe or "FDA approved"**. Although FDA found that the Product produced fewer or lower levels of some toxins than combustible cigarettes, it reminded the public that "all tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to".[4]

8. A summary of FDA's review of the Product, detailed in the document titled "PMTA Cover Sheet - Technical Project Lead Review" and based on which FDA granted the marketing authorisation, is at **Appendix**. The full text of the document can be accessed on FDA's website at https://www.fda.gov/media/124247/download.

FDA's Review of the Product

9. In reviewing the application, FDA assessed the Product's toxicology risks, behavioral and clinical pharmacological effects, as well as individual and population health impacts. It also assessed the product labelling, consumer apprehension and

[3] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/commonly-asked-questions-about-center-tobacco-products#29

[4] https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

marketing plan submitted by the manufacturer. FDA concluded that none of the legal grounds for rejection applied to the Product and granted marketing authorisation.

10. Although FDA granted marketing authorisation, the data submitted by the applicants to FDA have revealed alarming information on the risk of the Product.

A) Toxic Substances in the Product and Effect on Individual Health

11. From FDA's review, aerosols generated by the Product contains some 80 chemicals that are either unique to the Product or present in higher concentrations when compared to conventional cigarettes, many of which do not have sufficient inhalation toxicity or genotoxicity or carcinogenicity data available. Among these 80 chemicals, four are probable or possible carcinogens, 15 others have potential genotoxicity, and 20 exhibit concerns for potential health effects.

12. Therefore, the Product introduces new health risks that are not known to be present in conventional cigarettes. It may take decades before data on the long-term effects of these new toxicants are available. Any claim on reduction of tobacco-related disease risk cannot be supported by the existing data.

12. FDA did not find the data to support that the Product could reduce disease risks relative to conventional cigarettes.[5] FDA concluded that there was potential to reduce exposure to harmful substances in users who completely switched to the Product, though it found that dual use of the Product with conventional cigarettes had been common. These findings are consistent with those found by the Tobacco Products Scientific Advisory Committee (TPSAC), which assessed the MRTP application submitted for the same product. TPSAC did not find that the applicant had demonstrated with evidence that the reduction in exposure of harmful substances was reasonably likely to translate to a measureable and substantial reduction in diseases and deaths on the population level. TPSAC considered that the possibility of complete switch in smokers was low, and it expressed concerns over the lack of data to support theories of switching.[6] Analysis by independent researcher also found that the applicant's data on the short-term adverse effect among those who switched to the

[5] FDA. Decision summary of Premarket Tobacco Product Marketing Orders for iQOS. Available at https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders

[6] https://www.fda.gov/media/111455/download

Product did not demonstrate a reduction in long-term health risk relative to conventional cigarettes.[7]

B) Population Impact

13. FDA found that the addictive potential and abuse liability of the Product were similar to conventional cigarettes and there was a risk that tobacco-naïve new users will develop nicotine addiction when initiating use of these products.[8] FDA had acknowledged the lack of information in the use and uptake of the Product among youth under age 18, the potential for initiation of use among adolescent and young adult never smokers, the subsequent switching to conventional cigarettes (i.e. gateway effect), and the potential for dual use among current cigarette smokers. Nevertheless, it concluded that the uptake by youth was low, based on limited data from only two surveys in Italy[9]and Japan[10].

14. We do not agree with FDA's conclusion on low youth uptake based on very limited data as conceded by FDA. Neither do we consider it scientifically sound to draw conclusion on population impact with such limited data. Instead, a recently published study, which was conducted on a much larger sample of 59 000 Korean adolescents aged 12 to 18, found that 2.8 % of respondents had used HNB products in just one year after the introduction of HNB products into the Korean market. Compared with the less than 1% prevalence of e-cigarette when it was first introduced, the authors found the ever HNB products use among Korean adolescents to be an important concern.[11]

15. Another study in Korea also revealed that a great majority of users of HNB products in Korea are dual users.[12] There is so far no evidence that smokers could

[7] Moazed F, Chun L, Matthay MA, Calfee CS, Gotts J. Assessment of industry data on pulmonary and immunosuppressive effects of IQOS. Tobacco Control. 2018; doi:10.1136/tobaccocontrol-2018-054296

[8] FDA. Decision summary of Premarket Tobacco Product Marketing Orders for iQOS. Available at https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.

[9] Tabuchi T, Gallus S, Shinozaki T, Nakaya T, Kunugita N, Colwell B. Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. Tobacco Control. 2018;27:e25-e33.

[10] Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Gallus S. Heat-not-burn tobacco products: concerns from the Italian experience. Tobacco Control. 2018;Published Online First: 26 January 2018:doi: 10.1136/tobaccocontrol-2017-054054.

[11] Kang H, Cho S-i. Heated tobacco product use among Korean adolescents. Tobacco Control. 2019:tobaccocontrol-2019-054949.

[12] Hwang JH, Ryu DH, Park S-W. Heated tobacco products: cigarette complements, not substitutes. Drug and Alcohol Dependence. **2019**; Available online 21 September 2019:doi.org/10.1016/j.drugalcdep.2019.107576.

completely switch to HNB products as the tobacco industry claims or that HNB products will become a substitute of conventional cigarettes in real life usage.

Relevance of FDA's Marketing Authorisation to Hong Kong

16. The World Health Organization (WHO) urges Parties to the Framework Convention on Tobacco Control (FCTC) to consider to "regulate, including restrict, or **prohibit**, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products, as appropriate to their national laws, taking into account a **high level of protection for human health**".[13] To date, the United States is not a Party to the FCTC, which has been ratified by 181 countries including China. Unlike Hong Kong and most of the countries, the United States is not bound to implement tobacco control policies and measures in accordance with the provisions of FCTC.

17. As tobacco products are inherently dangerous, the Family Prevention and Tobacco Control Act gives FDA the power to regulate tobacco products "as appropriate to the protection of public health", which is thus the standard adopted by FDA for tobacco products in general as opposed to the standard of "safe" or "safe and effective" applied to other FDA-regulated products such as drugs and medical devices.[14] Besides, it will be grossly misleading to construe FDA's determination of "appropriate for protection of public health" as "benefitting the public health". Whether the marketing of a tobacco product is appropriate for protection of public health is based on an assessment of the overall impact on the population, and the consideration must also be population-specific. In other words, although the Product may be considered as "appropriate to the protection of public health" in the United States, it may not be applicable to Hong Kong as our situation such as the tobacco control regulations and smoking prevalence, etc., is not the same as the United States. Taking into account the progress in tobacco control achieved by Hong Kong, introduction of any new smoking product to the population of Hong Kong cannot be appropriate for public health protection unless there is clear scientific evidence of benefit.

18. The regulatory framework for tobacco products in the Untied States is entirely different from that in Hong Kong. FDA grants pre-market approvals to new tobacco

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[13] WHO FCTC entered into force in 2005. Parties are obliged to take a number of steps to reduce demand and supply for tobacco products. China is one of the signatories to and has ratified WHO FCTC, the application of which has been extended to Hong Kong since 2006.

[14] U.S. Congress, House Committee on Energy and Commerce, *Family Smoking Prevention and Tobacco Control Act, Part 1*, Report to accompany H.R. 1256, 111th Cong., 1st sess., March 26, 2009, H.Rept. 111-58, p.3, p.39.

product on a product-by-product basis. In this case, other new tobacco products that are not substantially equivalent to the Product must obtain its own pre-market approval from FDA. FDA may also withdraw or suspend the authorisation order whenever it considers the authorisation is no longer appropriate or when the relevant regulation or standards are not conformed to. Without the proposed full ban, the introduction of HNB products into Hong Kong under the existing law will be equivalent to an unscrutinised, blanket approval of all new smoking products, which is a situation non-existent in the United States. Therefore, the pre-marketing authorisation of the Product in the United States serves no useful reference for Hong Kong in banning or regulation of HNB products.

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Appendix

FDA's Review of the Pre-Market Tobacco Product Application

FDA received PMTA for a heated tobacco product called IQOS made by the Philip Morris Products S.A. in May 2017. The Product consists of (i) a heatstick, which is made of tobacco; (ii) a holder, which is the electrical powered and rechargeable unit designed to hold the tobacco heatstick for generating aerosol during use; and (iii) an electrical charger to charge the holder.

2. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that whether the marketing of a product for which a PMTA is submitted would be appropriate for the protection of public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[15]

3. In accordance with section 910 of the FFDCA, FDA will deny a PMTA if it finds that –

- there is a lack of a showing that permitting the product to be marketed would be appropriate for the protection of public health;
- the method, facilities, or controls used in manufacturing, processing, packing do not conform to manufacturing regulations issued under section 906(2) of FFDCA;
- based on a fair evaluation of all material facts, the proposed labelling is false or misleading; or
- it was not shown that the product complies with any tobacco product standard in effective and there is not adequate information to justify the deviation from the standard.

4. FDA granted the marketing authorisation of the Product based on the following findings from its review of the Product –

- There are adequate process controls and quality assurance procedures to

[15] Federal Food, Drug and Cosmetic Act Section 910(c)(4)

help ensure that the Product is manufactured consistently to meet the applicant's specifications;

- The product aerosols contain some chemicals which are different from those found in conventional cigarettes. Although some of the chemicals are genotoxic or cytotoxic, these chemicals are present in very low levels. FDA opined that the potential effects are outweighed by the substantial decrease in the number and levels of harmful substances found in conventional cigarettes;

- The toxicological data indicates the potential for a relative benefit compared with conventional cigarettes for smokers who switch completely to the Product.

- The Product has nicotine delivery, addiction potential, and abuse liability similar to conventional cigarettes. The nicotine levels do pose an addiction risk for non-tobacco users who initiate use of these products; however, the risk is no higher than for other currently available tobacco products and initiation is expected to be low generally.

- The 5-day studies demonstrated improved biomarker of exposure, which indicated reduced HPHC exposures and these improvement trends persisted in the 90-day studies despite reduced compliance and use of other tobacco products. Although the studies conducted by the applicant did not demonstrate reduction in long-term disease risks, the currently available evidence indicated conventional cigarette smokers who switched completely to the Product would have reduced toxic exposures. FDA opined that this was likely to lead to less risk of tobacco-related diseases.

- There had been no specific, long-term health-related or product quality issue unique to the Product in the clinical studies, the current world-wide market, or the published literature.

- Misuse of the Product was uncommon and the product design made it unlikely users would have a satisfactory experience.

- Dual use of the Product and conventional cigarettes was common in all countries in the pre-and post-market studies. Available evidence showed no increase in harmful substance exposures for those who dual used.

- Although the data for the Product uptake by never smokers, former smokers, and youth was limited, there were some data from Italy and Japan, where data showed low uptake by youth and current nonsmokers. In these

countries, the likelihood of uptake was slightly higher in former smokers. FDA opined that the proposed marketing and advertising restrictions would help ensure lower youth exposures and access to the products. Applicant would be required to monitor consumer use patterns and demographic information and provide FDA with regular reports.

5. As data showed that consumers did not accurately perceive the addiction risks of the Product, the review recommended that new warning which read "WARNING: This product contains nicotine. Nicotine is an addictive chemical", must be included on the package as well as in all advertisements.

6. The review of the Product concluded that none of the grounds for rejection specified in the FFDCA applied and recommended the granting of marketing authorisation of the Product by FDA.