Bills Committee on Smoking (Public Health) (Amendment) Bill 2019
(2020-2021 session)

List of follow-up actions required of the Administration
Arising from the Letter from Hon SHIU Ka-fai dated 12 July 2021

The Administration's response to the matter raised by Hon Shiu Ka-fai in his letter dated 12 July 2021 ("the Letter") is set out as follows.

Toxicants in Heated Tobacco Products

HTPs in General

2. Unlike conventional cigarettes that are relatively homogenous in design, heated tobacco products ("HTPs") are a class of highly heterogeneous products. While the part containing tobacco is mainly produced by several large tobacco companies, there are at least dozens of heating devices, many without product specifications, available in the market to date. HTPs vary widely in terms of construction, composition, device setting and mechanisms for heating tobacco and generating aerosol. As a result, they differ in terms of the ingredients used in the tobacco part, the way that the tobacco is heated, the puffing regime, and the temperature reached in the devices, among other things.

3. Apart from the constituents of the tobacco part, the effect of temperature on the formation of harmful constituents in emissions of tobacco products is well documented.[1] Some of the tobacco sticks manufactured for one device can be used with other devices. Use of different devices with different puffing patterns (e.g. puffing frequency and intensity) can also result in large differences in the toxicant emissions[2,3]. Therefore, HTPs may emit unique harmful chemicals because of their distinctive characteristics and how they are used.[4] Currently, research data on the chemical profile and toxicity of the emissions are lacking for most of the HTPs.

4. The currently marketed HTPs were introduced relatively recently, in 2015. Most of the scientific data on HTPs were generated and published by the tobacco industry or funded by affiliates of the industry and mainly concerned one product. Information on the content, emissions, exposure, and effects in HTP users from independent research groups are very

[1] WHO. Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Available at https://www.who.int/publications/i/item/9789240022720
[2] WHO. Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Available at https://www.who.int/publications/i/item/9789240022720
[3] Uchiyama S, Noguchi M, Takagi N, Hayashida H, Inaba Y, Ogura H et al. Simple determination of gaseous and particulate compounds generated from heated tobacco products. Chem Res Toxicol. 2018;31(7):585–93.
[4] WHO. Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Available at https://www.who.int/publications/i/item/9789240022720

limited in general. There exists large data gap in respect of HTP emissions and their toxicities, human use pattern, nicotine uptake, potential health effects, impacts of dual/poly-product use, and long-term health outcomes.

5. The World Health Organization ("WHO") pointed out that there are sufficient variations among HTP brands to suggest that technologies in HTPs will continue to evolve. They may bring about changes in the chemical compositions of HTP aerosols and in subsequent exposure and effects in users. Therefore, the limited data available on the currently marketed HTPs, most of which was generated by the tobacco industry, may not be directly applicable in the future.[5]

6. In view of the forgoing, any data available on one particular HTP cannot be directly apply to HTPs at large unless it is supported by evidence.

An HTP Authorised for Sale in the United States

7. The Letter refers to a list of 80 chemicals which the Administration provided upon the request of the Members of the Bills Committee raised at the meeting on 30 March 2021. These are chemical substances that were found in an HTP ("the Product") but were not present in conventional tobacco products, or were in higher levels in HTPs, as disclosed by the Food and Drug Administration ("FDA") of the United States in the decision document on its marketing authorisation of the Product.[6]

8. WHO, in response to the said marketing authorisation by FDA, published a statement[7] pointing out that "some toxins are present in higher levels in HTP aerosols than in conventional cigarette smoke, and there are some additional toxins present in HTP aerosols that are not present in conventional cigarette smoke. **The health implications of exposure to these are unknown** *(emphasis added)*".

9. In August 2020, the Therapeutic Goods Administration ("TGA") of Australia made a final decision of not exempting nicotine contained in HTPs from the regulation of nicotine as dangerous poisons, which in effect prohibits the distribution and sale of HTPs as consumer products in Australia. TGA has considered, among other things, the clinical data submitted and the claims made by manufacturer of the Product and the marketing authorisation granted to the same manufacturer by FDA. In setting out the considerations that led to the final

[5] WHO. Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Available at https://www.who.int/publications/i/item/9789240022720

[6] FDA. PMTA Technical Project Lead Review. Available at https://www.fda.gov/media/124247/download

[7] https://www.who.int/news/item/27-07-2020-who-statement-on-heated-tobacco-products-and-the-us-fda-decision-regarding-iqos

decision, TGA stated that "HTPs can expose users in the long term to **a range of known and unknown toxicants** *(emphasis added)*".[8,9]

10. The 80 chemicals that are found to be either present in higher concentration in aerosols of the Product or not found in conventional cigarette smoke include four chemicals that are possibly carcinogenic, 19 chemicals that are identified with genotoxic and/or carcinogenic potential, and 20 chemicals exhibiting potential health effects.[10] FDA pointed out many of the chemicals did not have sufficient inhalation toxicity or genotoxicity/carcinogenicity data to inform the toxicology evaluation of HTPs. Therefore, the number of carcinogens and genotoxic substance in HTPs can be greater than that set out above, pending more independent research data being available in the future. Likewise, the number of chemicals unique to HTPs or in higher levels than conventional cigarettes can be more than 80.

11. Among the 80 chemicals, the manufacturer submitted that 30 are identified as "Generally Recognized as Safe" ("GRAS") and 46 are additional ingredients (mostly flavouring ingredients). The GRAS chemicals must not be construed as "safe substance" ("安全物質", bullet 1 of paragraph 3 of the Letter refers) when they are used in HTPs, until it is so proven. Under the Federal Food, Drug, and Cosmetic Act, GRAS applies only to food. The product safety of chemicals granted GRAS status is evaluated only for use in food but not products to be inhaled such as HTPs.[11,12] Further analysis of these 30 GRAS chemicals found 11 of them to have genotoxic potential, and 20 with potential adverse health effects. Further analysis of the remaining 46 chemicals indicated that eight of them were potentially genotoxic and/or carcinogenic.[13]

12. Paragraph 3 of the Letter quoted from FDA that the four possible carcinogens do not pose a toxicological concern because the levels are below recognised dietary or occupational exposure limits. The quote is incorrect. FDA expressly rebutted such claim made by the manufacturer of the Product. FDA found that the risk assessment conducted by the manufacturer based on occupational exposure limits was inappropriate because occupational exposure limits were not intended for use to evaluate potential health hazards from inhaled tobacco products. FDA also found the manufacturer's use of dietary limits for inhalation exposure to be inappropriate.[14] Moreover, although FDA considers the level of these possible

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[8] Notice of interim decisions on proposed amendments to the Poisons Standard - ACMS/ACCS/Joint ACMS-ACCS meetings, March 2020. https://www.tga.gov.au/book-page/32-nicotine-heated-tobacco-products

[9] Public notice of final decisions - ACMS#29, ACCS#27, Joint ACMS-ACCS#24, March 2020. August 2020. https://www.tga.gov.au/book-page/332-nicotine-heated-tobacco-products

[10] FDA. PMTA Technical Project Lead Review. Available at https://www.fda.gov/media/124247/download

[11] https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works

[12] https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

[13] FDA. PMTA Technical Project Lead Review. Available at https://www.fda.gov/media/124247/download

[14] FDA. PMTA Technical Project Lead Review. Available at https://www.fda.gov/media/124247/download

carcinogens to be low, we must point out that there is no safe level of exposure to carcinogens and exposure to carcinogenic chemicals should therefore be minimised as much as possible.[15]

13. In authorising the marketing of the Product and issuing an exposure modification order, FDA concluded that the **manufacturer of the Product has not demonstrated that, as actually used by consumers, the products sold or distributed with the proposed modified risk information will significantly reduce harm and risk of tobacco-related disease to individual tobacco users** *(emphasis added)*. FDA found the claims made by the manufacturer that "scientific studies have shown that switching completely from conventional cigarettes to [the Product] can reduce the risk of tobacco-related diseases" and "switching completely to [the Product] presents less risk of harm than continuing to smoke cigarettes" not substantiated.[16]

Relevance of the Marketing Authorisation in the United States to the proposed HTP ban in Hong Kong

14. The Letter cited FDA's conclusion that the levels of exposure to the possible carcinogens appear low and when considered with other data does not preclude a conclusion that the products are appropriate for protection of public health. The phrase "appropriate for protection of public health" must be interpreted in its proper context as set out in the ensuing paragraphs.

15. 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 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.[17] 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 considerations must also be population-specific. The regulatory standard, together with the considerations in its application, for marketing approval of tobacco products in the United States cannot be directly applied to Hong Kong where the smoking prevalence, the policy and progress made in tobacco control, and obligations under the Framework Convention on Tobacco Control, to which China is a party and the United States is not, are all different. 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.

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[15] https://www.cdc.gov/niosh/topics/cancer/policy.html

[16] FDA. Decision summary of Modified Risk Orders for IQOS System Holder and Charger. Available at https://www.fda.gov/media/139796/download

[17] 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.

16. We must reiterate that the regulatory framework for tobacco products in the United States is entirely different from that in Hong Kong. FDA grants pre-market approvals to new tobacco product on a product-by-product basis. Without the proposed ban, the introduction of HTPs into Hong Kong under the existing law will be equivalent to an unscrutinised, blanket approval of all new HTPs, which is a situation non-existent even in the United States.

Purpose of the proposed HTP Ban

17. The purpose of introducing the Smoking (Public Health) (Amendment) Bill 2019 is to prevent the introduction of new smoking products into the local market, which 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. This is critically important for products that are expected to be aggressively marketed in whatever way possible.

18. As mentioned in the Administration's earlier response, the electronic devices of HTPs carry functions that have been non-existent in conventional smoking products. They 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 exert control of device performance. Designed to appeal to the younger generation who are readily drawn to new technology, these devices would aid the tobacco industry to develop more addictive products, market their products more effectively, and undermine the existing tobacco control measures for regulating the content, sale and promotion of tobacco products. In views of rapid development in product designs, WHO has rightly pointed out that such a product may be a "moving target" after its introduction.[18] The technological developments in these products will easily outpace the regulatory capacities of a country or region.

19. From the public health perspective, HTPs entail risks beyond those brought about by tobacco as we know them in conventional products. They are highly addictive and toxic products coupled with digital technologies. In Hong Kong where there are no marketing approval mechanisms, introduction of a whole class of HTPs, with their unlimited technological potentials to promote use and increase addictiveness, can bring disastrous public health consequences.

Food and Health Bureau
Department of Health
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[18] World Health Organization. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. Geneva: World Health Organization; 2019. Report No.: 9241210249. https://apps.who.int/iris/handle/10665/329445