Bills Committee on Smoking (Public Health) (Amendment) Bill 2019 (2020-2021 session)
List of follow-up actions arising from the discussion
at the meeting on 17 November 2020

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

Comparison of the regulatory measures implemented by the Food and Drug Administration of the United States for electronic cigarettes and heated tobacco products

2. In the United States, the manufacture, marketing, sale and distribution of tobacco products, such as electronic nicotine delivery systems, i.e. nicotine-containing electronic cigarettes ("e-cigarettes"), and heated tobacco products ("HTPs"), are regulated by the Food and Drug Administration ("FDA") in accordance with the Federal Food, Drug, and Cosmetic Act ("FFDCA"). All tobacco products are subject to the same set of requirements under FEDCA, with exception for issues unique to certain classes of products.

Marketing authorisation of e-cigarettes and HTPs

3. Under the FFDCA, any tobacco product, be it a nicotine-containing e-cigarette or an HTP, that is not commercially marketed on or before February 2007[1] must be granted marketing authorisation by FDA through one of the following pathways before it can be legally marketed - (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[2]. To legally market a new product with reduced risk claim, or to modify a legally marketed product to make a reduced risk claim, the manufacturer must also apply for a modified risk tobacco product order.

4. Generally speaking, any HTP or e-cigarette product that is marketed after 2007 must obtain premarket authorisation (most likely through the PMTA path) before they could be legally sold in the United States. The FFDCA requires PMTA applicants to submit, among others, full reports of health risk investigation; a full statement of what is in the product (e.g. components, ingredients, additives, properties, and principles of operation); full description of methods, facilities, and controls for manufacture, processing, packing and/or installation of the product; compliance with

[1] FDA has the power to determine whether a tobacco product is substantially equivalent to a predicate tobacco product or exempt from demonstrating substantial equivalence.
[2] https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product

tobacco product standards; samples of components of the product; and proposed labelling of the product[3]. These requirements apply to all PMTAs concerning HTPs or nicotine-containing e-cigarettes.

5. FDA grants marketing authorisation order product by product. On granting marketing authorisation, FDA may impose restrictions on the sale and distribution of the product concerned. FDA has the power to require the applicants to establish and maintain records, and provide postmarket surveillance reports following its marketing authorisation[4]. It also has the power to suspend or withdraw its marketing authorisation order in a number of circumstances as well as to order market recall[5]. As of 3 November 2020, FDA had received 10 870 PMTAs for new tobacco products and has issued 14 marketing authorisation orders including two for cigarettes of one brand, five for HTPs of one brand, and eight for smokeless tobacco products of one brand. No e-cigarette products have obtained marketing authorisation so far. It is of note that marketing authorisation granted by FDA to the HTPs from one manufacturer in 2019 does not extend to other HTPs in the market.

FDA's review for marketing authorisation of e-cigarettes and HTPs

6. FDA admitted that it was still gaining experience in applying statutory authorisation standard to PMTAs. The requirements in relation to the content and format of PMTAs, as well as the procedures of review have not been finalised [6]. Whilst the FFDCA also authorises FDA to issue tobacco product standards, FDA has not issued any tobacco product standard for any product.

7. In June 2019, FDA released a guidance document on the premarket authorisation requirements for nicotine-containing e-cigarettes[7]. The document sets out information that FDA considers to be important for its assessment of PMTAs for nicotine-containing e-cigarettes, for example information related to nicotine exposure warning, protective packaging, certain specified chemicals in e-liquids or aerosols, the way a consumer could operate the product or change the product characteristics and performance, and the functions of the software in software-driven devices (e.g. controlling temperature, nicotine content, flavour delivery). The guidance document serves to communicate FDA's current thinking on PMTAs to improve the efficiency of application

[3] FEDCA section 910(b)(1)
[4] FEDCA section 910(c)(2)
[5] FEDCA section 908(a)
[6] Premarket Tobacco Product Applications and Recordkeeping Requirements. A Proposed Rule by the Food and Drug Administration on 25/9/2019. https://www.federalregister.gov/documents/2019/09/25/2019-20315/premarket-tobacco-product-applications-and-recordkeeping-requirements
[7] Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems. Guidance for Industry. US Department of Health and Human Services. Food and Drug Administration Centre for Tobacco Products.

submission and review, and the recommendations therein are non-binding[8]. On the other hand, FDA has not issued any guidance document on premarket authorisation for HTPs.

Regulation and enforcement in respect of flavoured e-cigarettes and HTPs

8. The FFDCA specifically prohibits cigarettes from containing characterising flavours other than the flavour of tobacco or menthol[9]. HTPs that fulfill the legal definition of cigarettes under the FFDCA, for example the HTPs currently authorised for sale by FDA, are so regulated.

9. Although there is not yet any tobacco product standard concerning flavour made for e-cigarettes, FDA announced in April 2020 that it intended to prioritise enforcement against, among others, all flavoured, cartridge-based nicotine-containing e-cigarettes (other than those that are tobacco- or menthol-flavoured) that were currently on the market without premarket authorisation[10].

Comparison of regulation between e-cigarettes and HTPs

10. In summary, both nicotine-containing e-cigarettes and HTPs, amongst other new tobacco products, are subject to the same product-by-product marketing authorisation mechanism by FDA under the FFDCA. FDA has not yet set detailed rules and product standards for e-cigarettes and HTPs that allow comparison of the regulation of these two classes of products.

11. We must point out that FDA's premarket authorisation of a brand of HTPs cannot serve as the basis for permitting the market launch of HTPs in Hong Kong. FDA's pre-market application and authorisation (including suspension and the withdrawal of authorisation) mechanisms, as outlined in the preceding paragraphs, do not exist in Hong Kong. FDA grants premarketing authorisation for new tobacco products on a product-by-product basis and has not allowed unchecked introduction of a whole class of new tobacco products.

Overseas regulatory approach for e-cigarettes

Countries that prohibit the sale or import of e-cigarettes

12. According to Johns Hopkins Bloomberg School of Public Health[11], sale of all types of e-cigarettes is banned in about 30 countries/regions including Argentina, Brazil, Brunei Darussalam, Cambodia, Colombia, Egypt, Gambia, India, Iran, Kuwait, Lao People's Democratic Republic, Lebanon, Macau, Mauritius, Mexico, Nepal, Nicaragua, Oman, Panama, Qatar, Seychelles,

[8] https://www.fda.gov/media/127853/download
[9] FEDCA section 907(a) (1) (A)
[10] https://www.fda.gov/media/133880/download
[11] https://www.globaltobaccocontrol.org/e-cigarette_policyscan

Singapore, Sri Lanka, Suriname, Syrian Arab Republic, Thailand, Timor-Leste, Turkey, Turkmenistan, Uganda, and Uruguay.

Countries that regulate e-cigarettes

13. There are 52 countries/regions which permit the sale of e-cigarettes with restrictions including Australia, Austria, Belgium, Bulgaria, Canada, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, El Salvador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Maldives, Malta, Moldova, Netherlands, New Zealand, Northern Ireland, Norway, Palau, Philippines, Poland, Portugal, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, United States, Venezuela, England and Wales[12].

Overseas regulatory approach for HTPs

14. According to the decision of the eighth session of the Conference of the Parties to the World Health Organisation Framework Convention on Tobacco Control ("FCTC"), HTPs are to be classified as tobacco products and are therefore subject to the provisions of FCTC[13]. Regulatory measures in respect of HTPs in individual countries vary.

Countries that prohibit the sale or import of HTPs

15. According to the Campaign for Tobacco-Free Kids[14] and Johns Hopkins Bloomberg School of Public Health, HTPs are banned from sale and/or import in about 20 countries/regions. In Singapore, the Philippines, Panama, Ethiopia, India, Mexico and Turkey, specific legislations were enacted to ban the sale or import of HTPs. In some other countries/regions, the sale and/or import of HTPs are prohibited under pre-existing legislation. In Australia, HTPs are classified as dangerous poison and prohibited from sale and import. In Brazil, Macau, Norway, Thailand, Cambodia, Qatar, Uganda, Iran, Timor-Leste and Turkmenistan, HTPs are prohibited as e-cigarettes or novel nicotine products. In Brunei, Malta and Sri Lanka, HTPs are banned as smokeless tobacco or other tobacco products.

Countries that regulate HTPs

16. HTPs are marketed in about 40 countries/regions including Japan, United States, Canada, Switzerland, Jamaica, Maldives, Nepal, Senegal, Seychelles, Slovenia, South Africa, New Zealand,

[12] https://www.globaltobaccocontrol.org/e-cigarette_policyscan
[13] www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(22).pdf
[14] https://www.tobaccofreekids.org/assets/global/pdfs/en/HTP_regulation_en.pdf

Belarus, Moldova, Georgia, Israel and Portugal, where HTPs are regulated as tobacco products, while in some countries/regions, such as within the European Union, South Korea, Ecuador and Fiji, HTPs are regulated as novel products or e-cigarettes.

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