香港醫療及保健器材行業協會
Hong Kong Medical and Healthcare Device Industries Association

5 years+ 同心保關懷 caringorganisation

Clerk to Joint Subcommittee
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

15th Feb 2019

By Fax: 2573 7432
Email: hsci_dbi@legco.gov.hk

Dear Sir / Madam,

Re: - Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of Beauty Industry

The Hong Kong Medical and Healthcare Device Industries Association ("HKMHDIA") represents stakeholders who design, manufacture, distribute and provide professional services in medical devices (the "Industry"). HKMHDIA has been submitting views in the past on our standing position in relation to the operations of the proposed regulation framework. This current response is made in additional to all our previous responses and should be considered as a whole.

Referring to your **(1) Pre-Market and Post-Market Control**: -

a) It is our general views that any devices, if they fall under the definition of medical devices should be regulated regardless of the industries of those medical devices being used or deployed.

b) While special consideration has been provided to certain categories of stakeholders, HKMHDIA see the more importance of maintaining Hong Kong as the centre of medical technology advancement. We urge the implementation of a fast track system in order to allow medical device which may also fulfil certain regulatory compliance to be used in a control setting by designated professional in order to assist the medical device technological development. Such special arrangement could be overseen by a vetting panel with members from the administration, medical professional (or HCP) and the industries. The type of engagement could also provide Hong Kong a very strong support and backing in the development of innovative bio-tech, med-tech and health-tech industries.

Regarding your **(2) 5-year transitional listing system**: -

a) We do not support the unnecessarily segregation of so call "cosmetic device" which in many cases may have the same risk and intended use as

medical device and we disagree to the proposed five-year period of the transition listing system; unless the administration see this is so necessary balancing the entire benefits of the society and such benefits must outweigh any risk, such as threatening the life of the public. We are also aware that international standards and requirements (such as EU MDR) on medical devices, including those of cosmetic nature are becoming more stringent and demanding. As a result, we are concerned whether this five-year window would create a floodgate and attract sudden influx of devices (including sub-standard devices) into Hong Kong during the short-term since it is still unknown to the public and the administration the quantity and quality of devices which are being used in the market as of today. It is therefore recommended to implement a mechanism to gain visibility on how many devices that the administration will be dealing with and the level of compliance readiness of those devices during the five-year period for sufficient resource planning.

b) We suggest MDCO to provide a clear and official definition of Cosmetic Devices and maintain a comprehensive updated list of these registered cosmetic devices available to practitioners and the general public in the near future.

HKMHDIA supports and vows for the need to establish vigilant regulations on listing and registration of medical devices for the benefits of Hong Kong and the general public, and not just for a particular industry. At the same time, we urge the need to accelerate the establishment of a more coherent regulation that align with international standards to govern the usage of medical devices locally.

We hope that our submission will help providing your panel with additional information from the Industry. Should you have any question about our submission, please do not hesitate to contact the undersigned or Ms Cathy Wong, Secretariat of HKMHDIA at 2191 0923.

Yours sincerely,

Ms. Martha HAO
Chairman
Hong Kong Medical and Healthcare Device Industries Association

Hong Kong Medical and Healthcare Device Industries Association Limited
LG1, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Hong Kong.
Tel：(852) 2191 0923 Fax：(852) 2194 5082 E-mail：info@medicaldevice.org.hk
http://www.medicaldevice.org.hk