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

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Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN
Panel Chairman
Panel on Health Services
Legislative Council
Hong Kong SAR Government

16th July 2018

By Fax: 2185 7845
Email: panel_hs@legco.gov.hk

Dear Prof Hon Lee,

Re: - Proposed Regulatory Framework for Medical Devices ("Proposed Regulation Framework")

We refer to the Special Meeting of the Panel on Health Services to be held on 16th July 2018 on the Proposed Regulatory Framework.

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. With respect to the latest development of the Proposed Regulatory Framework, our comments are as below: -

1. 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.

2. In general, we support the proposed five-year period of the transition listing system. We are, however, concerned whether this five-year window would attract sudden influx of devices (including sub-standard devices) to Hong Kong in the short-term. As of today, it is still unknown to the public and the administration the quantity and quality of devices which are being used in the market. 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.

3. While special consideration has been provided to certain categories of stakeholders, HKMHDIA see the more importance of maintaining Hong

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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.

HKMHDIA supports and vows for the need to establish vigilant regulations on listing and registration of medical devices. 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,

Ir Prof Andros Chan
Chairman
Hong Kong Medical and Healthcare Device Industries Association

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