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

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

10th Feb 2017

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 13 February 2017 on captioned matter.

The Hong Kong Medical and Healthcare Device Industries Association ("HKMHDIA") has had the opportunity to participate in the development on the captioned matter since 2002. With respect to the latest Proposed Regulatory Framework, HKMHDIA has the following comments:-

A. General Comments

1. HKMHDIA represents a group of stakeholders who are designing, manufacturing, distributing and provided related professional services to medical devices (the "Industry"). It must be noted that all medical devices are well governed by international established standards as well as foreign local registration requirements to ensure that safety and efficacy are prudently examined before devices are put on market. Ongoing post market surveillance such as recall procedures or adverse incident reporting requirements are also standard requirements and has been mostly practice by relevant parties. HKMHDIA is confident that the industry is ready to receive the new regulation but at the same time, the industry is also expecting that the HKSAR Government will allocate appropriate and sufficient resources for the transition from voluntary to compulsory registration.

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2. In additional to the external compliance requirements, the industry currently is also highly self-regulated on process, traceability and risk management of the design, manufacturing and distribution of medical device, the local governance on the use (or misuse) of medical devices are not on par.

3. The current voluntary Medical Device Administrative Control System ("MDACS") established by the Medical Device Control Office of the Department of Health has remained voluntary for too long and the Government should send a firm message to the industry and the public whether it will remain voluntary or it will be regulated, and in the latter, a definitive schedule should be provided.

4. The current voluntary MDACS procedures per se do not prevent misuse or unauthorized use of medical device for medical or non-medical treatment. It doesn't govern the places where such devices are permitted to use. HKMHDIA welcome the fact that Use Control is introduced to the Proposed Regulatory Framework. However, HKMHDIA will continue to support regardless whether Use Control will be included in the forthcoming bill.

5. The voluntary registration system allows newer yet safe and effective medical technology to be deployed and practiced in Hong Kong by responsible clinicians and medical device companies and this often make Hong Kong one of the best, if not the best, medical technology advancing hub for international medical device companies amongst all the ASEAN economies. The Proposed Regulatory Framework in its current form does not differentiate that and HKMHDIA hopes special measures could be provided (in additional to clinical trial, named patients …) so that companies can assist Hong Kong clinicians to be the leader in deploying world class public health and medical technology to the Hong Kong public.

6. It is HKMHDIA's position to reinforce the need that all users and operators should be fully trained and informed on the use of medical devices by those who know the use of such devices. All users, patients or beneficiaries of medical device should be fully informed on the indication for use as well as the contraindication for use of a medical device.

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B. Specific Comments

7. HKMHDIA is of the view that all permits, licenses, registrations shall be of five (5) years instead of three (3). The 5 year rule has been practiced under the voluntary system and there has not been any deficiency.

8. HKMHDIA is of the view that the current labelling requirement is sufficient and there should not create additional customary requirements as Hong Kong has been regarded as a relative small market and any localization requirements should be balanced.

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 standard 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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