



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. John Chai 查煥超教授  
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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

22<sup>nd</sup> June 2015

By Fax: 2185 7845

Email: panel\_hs@legco.gov.hk

Dear Prof Hon Lee,

Re:- Regulation and development of beauty services

We refer to the Joint Meeting of Panel on Health Services and Panel on Commerce and Industry to be held on 23 June 2015 on Regulation and development of beauty services.

The Hong Kong Medical and Healthcare Device Industries Association ("HKMHDA") have the opportunity to participate in previous Panel Meetings and review the paper on regulation of aesthetic practices in selected places and research report entitled "*Regulation of aesthetic practices in selected places*" ("Reports").

The current voluntarily Medical Device Administrative Control System established by the Medical Device Control Office of the Department of Health procedures per se do not prevent misuse or unauthorized use of medical device for medical or non-medical treatment. It also doesn't govern the places where such devices are permitted to use. There are other legislations, which govern the use/place of use of some devices and are already explained in details in your Reports. HKMHDA is of the view that the use (as well as misuse) of medical device is just as important and have the following comments:-

1. HKMHDA represents a group of stakeholders who are making and selling medical devices. It is important to note that all medical devices are well governed by international established standards as well as local





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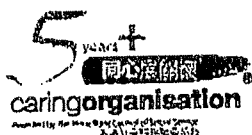
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registration requirements to ensure that safety and efficacy are prudently examined before devices are released to the market. Such process also includes ongoing post market surveillance such as recall procedures or adverse incident reporting requirements. HKMHDIA is of the view while there are stringent requirements imposed on our members on the design, manufacturing and distribution of medical device, the local governance on the use (or misuse) of medical devices are not on par.

- All medical devices come with an instruction for use ("IFU") and the contents of which are part of the compliance requirement of the sale of the device. All relevant parties who aim to deliver treatment using the device should be drawn to the attention of this important document, particular in higher risk device, as it contains important information to the use of a device.
- 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.
- When a manufacturer appoints a distributor, it is very common that the commercial arrangement will include training as one of the major contractual terms of the distribution agreement. The HKSAR government could use such evidence to determine whether a distributor has received proper training on the use of medical device and also review relevant training materials to determine its sufficiency.

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 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 Mr. Henry Fong, Liaison Office of HKMHDIA at 2788 6354.



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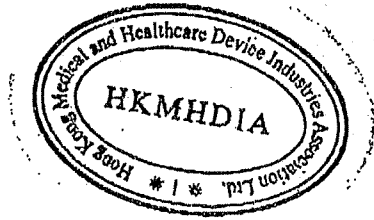
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Yours sincerely,



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



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