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

Dr Hon LEUNG Ka-lau
Panel Chairman
Panel on Health Services
Legislative Council
Hong Kong SAR

21 November 2012

By Fax: 2185 7845

Dear Dr Hon Leung,

Re:- Submission on Regulation on medical beauty treatments/procedures

We refer to the special Panel meeting to be held on 27th November 2012 on the captioned matter.

The Hong Kong Medical and Healthcare Device Industries Association ("HKMHDIA") is concerned of and alarmed by the recent incidents happened which caused serious injuries and fatality to patients who allegedly received medical treatments during beauty procedures ("Incidents").

Although it is unknown whether malfunctioning or improper usage of a medical or healthcare device had contributed to the incidents, HKMHDIA is of the view that such Incidents could be prevented from if the following regulatory measures are in place:-

1) definitions and distinctions of medical treatment/procedure vs beauty treatment/procedure;
2) a clearly defined registration system/license requirement with proper training/qualification on those personnel or practitioner of a service provider who handles/operates a medical device, [for commercial use] whether it is for the purpose of medical or beauty treatment/procedure;
3) Statutory regulation of medical devices modelled largely after international accepted regulatory frameworks and standards.

Mailing Address:
Office of Secretariat
c/o 5/F., HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Hong Kong.
Tel：(852) 2788 5625 Fax：(852) 2788 5522 E-mail：info@medicaldevice.org.hk
http://www.medicaldevice.org.hk

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In particular, HKMHDIA has long advocated and supported the need to regulate medical device since 2004 for the following reasons:- (a) to promote medical safety and performance as intended; (b) that medical device should be handled with higher standard for the protection of public health; and (c) to align our local regulatory status to match with international practice and hence increasing our competency and competiveness. During the past years, HKMHDIA has responded and made recommendations on all the proposed regulatory documentations issued by the Medical Device Control Office of Department of Health, including the Regulatory Impact Assessment in September 2007 and the Business Impact Assessment in August 2011. All responses issued by HKMHDIA are available at http://www.medicaldevice.org.hk/en_publications3.php. Whilst HKMHDIA has on numerous occasions expressed its support on regulating medical devices, we are also concerned that there has been very little development on the progress and we urge that the HKSAR Government should put resources on the administration of; and to re-introduce the regulatory timeframe on medical devices without further delay.

We hope that our submission will help providing your panel different perspectives on those issues commonly being discussed recently in relation to the Incidents. Should you have any question about our submission, please do not hesitate to contact the undersigned or Ms. Beverly Cheung, Secretariat of HKMHDIA at +852 27885625.

Yours sincerely,

Albert Lee
Chairman
Hong Kong Medical and Healthcare Device Industries Association

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