



Honorary Chairman 名譽主席

Prof. John Chai 查逸超教授
Prof. John Mok 莫建鄰教授

Chairman 主席

Mr. Albert Lee 李耀林先生

Deputy Chairman 常務副主席

Ir Dr Andros Chan 陳令名博士工程師

Vice-Chairman 副主席

Mr. Benjamin Chan 陳偉傑先生
Ms. Maria Chiang 蔣麗琴小姐
Ms. Martha Hao 郝梅鳳小姐
Ms. Teresa Li 李家寶小姐

Secretary General 秘書長

Ir Richard Lun 倫知聰工程師

Treasurer 司庫

Mr. Otto To 陶基祥先生

Executive Board Members 執行理事

Ir Dr William Cheung 張樹生博士工程師
Mr. Mark Ho 何志天先生
Mr. Henry Lam 林記和先生
Mr. James Li 李俊榮先生
Mr. Wilfred Li 李國明先生
Mr. William Mok 莫俊偉先生
Mr. Kevin Orr 柯家洋先生
Mr. Stephen Siu 蕭智堅先生
Mr. Fred Tung 董行兆先生

Honorary Board Members 名譽理事

Mr. Ralph Chow 周瑞麟先生
Mr. Lee Kwok Keung 李國強先生
Ir Derek Louie 雷致行先生
Mr. Joseph Poon 潘永生先生

Honorary Legal Advisor 名譽法律顧問

Mr. Nicholas Chan 陳曉峰律師

Honorary Auditor 名譽核數師

RSM Nelson Wheeler Certified
Public Accountants
中瑞岳華(香港)會計師事務所

Honorary Advisors 名譽顧問

Prof. King L. Chow 周敬流教授
Dr. Lilian Leong, BBS, JP 梁馮令儀醫生
Prof. Arthur F. T. Mak 麥福達教授
Ir Albert Poon 潘家發先生
Prof. Ed Wu 吳學奎教授
Prof. Michael M. Yang 楊夢甦教授
Prof. Zheng Yongping 鄭永平教授

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

同心展關懷

caringorganisation

Awarded by The Hong Kong Council of Social Service
香港社會服務聯會頒發



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

Honorary Chairman 名譽主席

Prof. John Chai 查逸超教授
Prof. John Mok 莫建鄰教授

Chairman 主席

Mr. Albert Lee 李耀林先生

Deputy Chairman 常務副主席

Ir Dr Andros Chan 陳令名博士工程師

Vice-Chairman 副主席

Mr. Benjamin Chan 陳偉傑先生
Ms. Maria Chiang 蔣麗琴小姐
Ms. Martha Hao 郝梅鳳小姐
Ms. Teresa Li 李家寶小姐

Secretary General 秘書長

Ir Richard Lun 倫知聰工程師

Treasurer 司庫

Mr. Otto To 陶基祥先生

Executive Board Members 執行理事

Ir Dr William Cheung 張樹生博士工程師
Mr. Mark Ho 何志天先生
Mr. Henry Lam 林記和先生
Mr. James Li 李俊榮先生
Mr. Wilfred Li 李國明先生
Mr. William Mok 莫俊偉先生
Mr. Kevin Orr 柯家洋先生
Mr. Stephen Siu 蕭智堅先生
Mr. Fred Tung 董行兆先生

Honorary Board Members 名譽理事

Mr. Ralph Chow 周瑞騁先生
Mr. Lee Kwok Keung 李國強先生
Ir Derek Louie 雷致行先生
Mr. Joseph Poon 潘永生先生

Honorary Legal Advisor 名譽法律顧問

Mr. Nicholas Chan 陳曉峰律師

Honorary Auditor 名譽核數師

RSM Nelson Wheeler Certified
Public Accountants
中瑞岳華(香港)會計師事務所

Honorary Advisors 名譽顧問

Prof. King L. Chow 周敬流教授
Dr. Lilian Leong, BBS, JP 梁馮令儀醫生
Prof. Arthur F. T. Mak 麥福達教授
Ir Albert Poon 潘家發先生
Prof. Ed Wu 吳學奎教授
Prof. Michael M. Yang 楊夢魁教授
Prof. Zheng Yongping 鄭永平教授

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 competitiveness. 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

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>

同心展關懷

caringorganisation 2009-12

Awarded by The Hong Kong Council of Social Service
香港社會服務聯會頒發