



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 周瑞澂先生
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

16 December 2013

By Fax: 2185 7845

Email: lwcyu@legco.gov.hk

Dear Dr. Hon. Leung,

Re:- Recommendations of the Working Group on Differentiation between Medical Procedures and Beauty Services

We refer to the special meeting of "Working Group on Differentiation between Medical Procedures and Beauty Services" to be held on 23 December 2013.

The Hong Kong Medical and Healthcare Device Industries Association ("HKMHDA") has the opportunity to review the *Report of the Working Group on Differentiation between Medical Procedures and Beauty Services* issued by the Department of Health in November 2013 (the "Report").

In summary, HKMHDA agrees the following as proposed by the Working Group (as defined therein the Report):-

1. the establishment of guiding principles for differentiating between medical treatment and beauty service as reference for future adaptation under sub-section 5.4; and
2. all the recommendations put forward under Section 7 of the Report, and in particular recommendations (6) and (7).

Furthermore, HKMHDA is also interested in participating in the panel to be established in recommendation (7) of Section 7.

In addition, HKMHDA recommends the following for further discussion:-

Mailing Address:

Office of Secretariat

c/o HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Hong Kong.

Tel : (852) 2788 5625 Fax : (852) 3187 4543 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



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 蔣麗苓小姐
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 周瑞麒先生
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

1. The differentiation of medical treatment and beauty service involves professional medical judgment. HKMHDIA urges the HKSAR Government to make codified classification after consulting different groups of professional bodies and balancing the interest of public health and safety as well as economical impact.

2. To determine whether a procedure is a medical treatment or beauty service, the aim, the process, the outcome of the procedure and the device(s) to be used during the procedure should all be considered in order to make a proper and balance determination.

3. HKSAR Government is to raise public awareness and increase resources on public education in relation to patient/client/consumer's understanding of the inherent risks of a procedure and any decision made shall be an "informed decision".

4. HKMHDIA emphasizes that classification of medical devices will not provide any definition to the differentiation between medical treatment and beauty service. The decision on the differentiation is a professional one and to be codified by the HKSAR Government. However, HKMHDIA is opined that by looking at the classification and understanding the intended use of a medical device being used in a procedure, one could derive the risk associated with the procedure (whether it is a medical treatment, medical diagnostic or beauty service) and whether the operators have to qualify under professional requirements.

5. HKMHDIA is of the view that the higher the device's classification, the more likely that such device should be operated by a registered/trained/licensed personnel or medical practitioner. However, such rationale shall not mean that a lower classification of a medical device can be operated by any lay person.

6. Under medical device classification system, the final classification of the whole device will be determined by the highest classification of the component or the subsystem of the device. In scenario where multiple medical devices are in use during a procedure (whether it is medical treatment or beauty service), the device that bears the highest classification could also be used as a guideline to determine the risk of the procedure and therefore, the likeliness of whether it should be considered as a medical treatment or beauty service and/or whether the procedure should be operated by medical practitioner,

Mailing Address:

Office of Secretariat

c/o HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Hong Kong.

Tel : (852) 2788 5625 Fax : (852) 3187 4543 E-mail : info@medicaldevice.org.hk

http://www.medicaldevice.org.hk

同心展關懷

2009-12

caringorganisation

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



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 周瑞麒先生
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

registered/trained/licensed personnel, or non-trained personnel.

7. Whether it is possible to add new definitions to include registered/trained/licensed personnel recognized by approved institutions to operate certain procedures in addition to the definition of "practitioner" contained in Cap 161. Certain procedures, particularly those using higher risk medical devices or high power/high energy source equipment, should only be operated by registered/trained/licensed personnel regardless of whether those procedures are considered as medical treatments.

8. HKMHDIA supports and vows for the need to establish vigilant regulations on medical devices, in particular whereas such regulations will provide registrars on the manufacturers, importers, distributors and local responsible persons who deal with the devices throughout the entire product life cycle and will be able to provide traceability. Necessary in all medical device regulations is Adverse Event Reporting procedures. The procedures per se do not prevent misuse or unauthorized use of medical device. They do require importers and distributors of higher risk medical device to report adverse events to the regulating authority. While the society sees the need to press forward the differentiation between medical treatment and beauty service; promoting safe use of medical device, and allowing the regulating authority to respond to adverse events timely and appropriately should not be neglected. As such HKMHDIA urges the legislation of medical device regulations with urgency.

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. Beverly Cheung, Secretariat of HKMHDIA at +852 27885625.

Yours sincerely,



Albert Lee

Chairman

Hong Kong Medical and Healthcare Device Industries Association

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

Mailing Address:

Office of Secretariat

c/o HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Hong Kong.

Tel : (852) 2788 5625 Fax : (852) 3187 4543 E-mail : info@medicaldevice.org.hk

http://www.medicaldevice.org.hk