8 February 2017

Prof. Hon Joseph LEE Kok-long, SBS, JP
Chairman
Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Prof. Hon LEE,

Views on Proposed Regulatory Framework for Medical Devices

The Hong Kong Academy of Medicine is a statutory body for the accreditation and training of medical and dental specialists in Hong Kong, and has been serving to foster postgraduate specialist training for over 20 years.

The Academy welcomes the Government's initiative to review the existing regulatory framework for medical devices and its plan to introduce measures to step up relevant controls. Specifically, the suggestion to include the three main areas, namely pre-market, post-market and use control, in the proposed statutory regulatory regime is considered significant and supported.

In addition, the Academy supports the proposed adoption of a risk-based approach for imposing use control on specific medical devices, which would help maintain balanced regulatory standards and achieve the most appropriate restriction. We concur that the framework should focus on limiting the use of specific medical devices which are commonly used by persons other than healthcare professionals registered under relevant legislation in Hong Kong. Proportionate risk-based supervision is necessary to ensure that the use of high-risk medical devices is restricted to well-trained and qualified personnel.

<u>Views from Specialty Colleges</u>

1) The Hong Kong College of Radiologists suggests that:
   (i) For any medical equipment allowed to be sold in Hong Kong, all spare parts enabling normal functioning of that certain equipment has to be guaranteed by the company with continuous supply for a reasonable length of time after installation, which is commensurate with that of the life span of the device, especially for expensive equipment like linear accelerators, CT scan, MRI scan and PET scan. In Hong Kong, quite a few items of medical equipment run out of spare parts within a few short years and the customers is forced to

10/F, HKAM Jockey Club Building, 99 Wong Chuk Hang Road, Aberdeen, Hong Kong
Telephone (852) 2871 8888 Facsimile (852) 2505 5577 Email hkam@hkam.org.hk Website http://www.hkam.org.hk

buy a new model.

(ii) There is also a need to impose regulations on the manufacturing and quality control of medical devices.

2) Some other Academy's specialty Colleges have also submitted views on the subject directly to the Panel on Health Services. The written submissions by The Hong Kong College of Family Physicians, College of Ophthalmologists of Hong Kong and The College of Surgeons of Hong Kong are enclosed for reference.

The Academy recognises the Government's efforts made to date in formulating a regulatory framework for medical devices with an aim to protect public health. We support this initiative and will continue to contribute further views to enhance the recommended framework in future. We believe the experts in our different specialty Colleges will be able to provide inputs into various issues related to the implementation and administration of this future legislation, for example, through participation in the suggested statutory Advisory Committee or Appeal Board. Moreover, the Academy is strongly in favour of there being regulatory oversight in the recognition and provision of device-based training where required. We are willing to explore and look into the associated training aspects, where considered appropriate and supported by relevant resources from the Government.

The Academy deems that the legislation of the proposed framework is essential and should be fixed as soon as possible. We look forward to further collaborating with the Government on the development of this regulatory system.

Yours sincerely,

Prof. LAU Chak-sing
President

Enclosure

Submissions by specialty Colleges:

1) The Hong Kong College of Family Physicians;
2) College of Ophthalmologists of Hong Kong;
3) Hong Kong College of Radiologists; and
4) The College of Surgeons of Hong Kong

香 港 家 庭 醫 學 學 院
The Hong Kong College of Family Physicians
Rooms 803-4, 8/F, HKAM Jockey Club Building, 99 Wong Chuk Hang Road, Aberdeen, Hong Kong
Tel: (852) 2871 8899 Fax: (852) 2866 0616
E-mail: hkcfp@hkcfp.org.hk Website: www.hkcfp.org.hk
香港仔黃竹坑道99號香港醫學專科學院賽馬會大樓8樓803-4室

Enclosure 1

6 February 2017

Prof. Hon Joseph LEE Kok-long, SBS, JP
Chairman , Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Prof. Hon LEE,

RE: Proposed Regulatory Framework for Medical Devices

The Hong Kong College of Family Physicians (HKCFP) strongly supports the Government to introduce measures to regulate medical devices for cosmetic purposes.

We have the following comments:

1. Family Physicians may opt to participate in aesthetic procedures. HKCFP strongly recommends that they receive proper training by accredited institutions.

2. Plasma skin resurfacing is an invasive procedure with significant potential complication and must be considered under Use Control Category II.

3. For medical doctors involved in cosmetic treatment, a much higher premium is demanded for medical indemnity which is occurrence based. For beauty parlour, the indemnity is a key area to explore especially the same operator (if he / she is not a medical professional) can close down the company and reopen under a different name.

4. All cosmetic procedures no matter how small the risk is and as long as risk and complications exist should be operated or supervised by registered Health Care Professionals as their practice will be subjected to the respective Professional Code of Conduct. Therefore for patient's safety and indemnity purpose, both Category II and Category III of the Study should be grouped together and solely supervised on site by a registered medical practitioner.

5. HKCFP is keen to participate in the statutory Advisory Committee to advise SFH on the implementation and administration of future legislation.

Yours sincerely,

Dr CHAN Ming Wai Angus
President

Enclosure 2

香 港 眼 科 醫 學 院
The College of Ophthalmologists of Hong Kong

(Incorporated in Hong Kong with limited liabilities)
a Constituent College of the Hong Kong Academy of Medicine

Clerk to Panel on Health Services
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

1 February 2017

Re: Proposed Regulatory Framework for Medical Devices

The College of Ophthalmologists of Hong Kong supports the Government to introduce measures to regulate medical devices for cosmetic purposes.

We would like to emphasize our stand for the use of all class 3B and above Laser on human body for whatever purposes, be it diagnostic, cosmetic or therapeutic, should be limited to registered medical or dental practitioners. The same applies to High-intensity focused ultrasound (HIFU), Infrared (IR) and Radiofrequency (RF) that are operated around the eye

Yours sincerely,

P C Chow

Dr. CHOW, Pak Chin
President
The College of Ophthalmologists of Hong Kong

Room 802, 8/F Hong Kong Academy of Medicine Jockey Club Building, 99 Wong Chuk Hang Road, Aberdeen, Hong Kong
Tel: (852) 2761 9128 Fax: (852) 2715 0089 Email: cohk@netvigator.com

HONG KONG COLLEGE OF RADIOLOGISTS
香 港 放 射 科 醫 學 院

Founder College of the Hong Kong Academy of Medicine

(Incorporated in Hong Kong with limited liability)

6 February 2017

Prof. Lau Chak Sing
President
Hong Kong Academy of Medicine
10/F, Hong Kong Academy of Medicine Jockey Club Building
99 Wong Chuk Hang Road, Aberdeen, Hong Kong

Dear Prof. Lau,

Re: Legislative Council Panel on Health Services "Proposed Regulatory Framework for Medical Devices"

Thank you for the email dated 1 February 2017 from HKAM Secretariat inviting Colleges to express views on the Proposed Regulatory Framework for Medical Devices. Opinions were solicited from the Council of College and we would like to tender the following views.

The College notes the document "Proposed Regulatory Framework for Medical Devices" is mainly concerned with medical devices for *cosmetic* purposes, though it also specifically indicated those apparatus contains pharmaceutical products or emits ionizing radiation be separately regulated. However, there seems to be the Government policy to overhaul the statutory regulations covering *all* medical devices. With this understanding our College would like to propose two points for consideration by the Authority that, apart from the measures against defective and unsafe medical devices:

(1) Any medical equipment allowed to be sold in Hong Kong, all spare parts which enable normal functioning of that certain equipment has to be guaranteed by the company with continue supply for a reasonable length of time after installation commensurate with that of the life span of the device, especially for expensive equipment like linear accelerators, CT scan, MRI scan, PET scan. Guarantee of continuous manufacture and supply of spare parts for a lengthy period are enforced in many other countries including USA and many European countries. In Hong Kong, quite a few items of medical equipment run out of spare parts within a few short years and the customer is forced to buy a new model although the old model is still perfectly functioning otherwise.

(2) The part on manufacturing and quality control of medical devices needs also be controlled.

We appreciate the opportunity to express our views.

Yours sincerely,

Dr. Law Chun Key
President
Hong Kong College of Radiologists

Secretariat Office: Room 909, 9/F, Hong Kong Academy of Medicine Jockey Club Building, 99 Wong Chuk Hang Road, Aberdeen, Hong Kong
Tel: (852) 2871 8788 Fax: (852) 2554 0739 E-mail: Enquiries@hkcr.org Homepage: http://www.hkcr.org

Proposed Regulatory Framework for Medical Devices – Deputation Meeting held by Legislative Council Panel on Health Services, 13 Feb 2017

Views submitted by the College of Surgeons of Hong Kong

1. The proposed regulatory framework is welcomed and the College of Surgeons of Hong Kong agrees with the approach of the proposed regulation.

2. The proposal formalizes and improves upon the existing Medical Device Administration Control System into a more comprehensive statutory regime for the regulation of medical devices with pre- and post-market control measures. In addition, it establishes a mechanism for the control of usage of devices also being employed for cosmetic applications, which currently is being operated by a great number of non-registered healthcare professionals. These measures should be conducive to public safety.

3. On use control concerning devices also being used for cosmetic purposes, the categorical assignment of the researched medical devices in Table 2 (Recommended Medical Device Use Control Categories) of Annex II of the proposal, i.e. the Executive Summary of the Report of the Study on the Control of Use of Selected Medical Devices in Hong Kong, is built upon a reasoned and researched foundational basis. Flexibility, nevertheless, cannot be over-emphasized. Some device types in Category III or IV may arguably be put under Category II or III because different makes and models of the same type of medical device can still vary in clinical risks and requirements of knowledge and skills. The ultimate safety of any precise piece of device is accordingly dependent on its particular specifications and the operators. It is therefore imperative that the details of the use control category allocation be reviewed before the final implementation of the legislation. As already in the proposal, there must be a mechanism for regular re-examination and update of this table.

4. We want to emphasize that the categorization of the devices should be adjusted on an individual basis. Since the energy and power delivered can vary, devices can potentially cause harm to patients if not controlled and delivered by qualified person according to set guidelines.