HONG KONG COLLEGE OF PHYSICIANS
香港內科醫學院

(Incorporated in Hong Kong with limited liability)

9 February 2017

Prof. Hon Joseph LEE Kok-Long, SBS, JP.
Chairman
Panel on Health Services
The Legislative Council of the Hong Kong Special Administrative Region

Dear Prof. Hon Joseph Lee,

Response from the Hong Kong College of Physicians on the Proposed Regulatory Framework for Medical Devices

The Hong Kong College of Physicians welcomes the Proposed Regulatory Framework for Medical Devices. The framework strives to uphold the safe and appropriate use of medical devices while ensuring the community's access to benefits of new technologies. There are, however, a few issues that need further clarification and deliberation.

Generic medical devices

The Emergency Care Research Institute (ECRI) formulates the risk categories of medical devices that are formally approved by regulatory bodies like U.S. Food and Drug Administration (FDA). Regulatory bodies in turn make the recommendations based on published research data on those medical devices. There are, however, many generic medical devices in the market. Variations in the machinery structures in these devices are common and thus rendering wide variation in their performance and safety. There are very few, if any, published research data on their efficacy and safety. Data derived from studies of the original devices cannot be generalized to these generic devices. Many of these devices have not actually been approved for medical-cosmetic application by the regulatory authorities of their manufacturers in their own countries. Patients receiving cosmetic procedures from these generic devices may experience complications such as infection, scarring, distortion, skin necrosis and burn. On the other hand, these generic devices may lack efficacy and produce little or no effect. The control of these generic medical devices has to be addressed.

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Plasma device

Plasma device is in the Control of Use Recommendation Category III. The procedure can be performed by any person who has received recognized device-specific training without a registered healthcare professional (HCP). Plasma skin resurfacing involves an energy delivering device that may cause potential complications e.g. excessive desquamation, swelling, erythema or hyperpigmentation, especially if high energy settings are used in the cosmetic procedures. We suggest re-evaluating the categorization of plasma device.

Cryolipolysis device

Cryolipolysis device is in the Control of Use Recommendation Category III. Although published research data demonstrate good safety profile without liver and lipid level adverse effects, it depends heavily on the self-discipline of HCP adhering to international guidelines in treating a localized area in a single session. Without the professional background and the bound of professional conduct of a registered HCP, cryolipolysis can be associated with significant risks. We suggest re-evaluating the categorization of cryolipolysis device.

In summary, the Hong Kong College of Physicians supports the direction of a risk-based regulatory framework for medical devices.

Regards,
Sincerely

Prof. LI Kam Tao Philip
President

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