



香港醫學會 LC Paper No. CB(2)809/16-17(10)
The Hong Kong Medical Association

FOUNDED IN 1920-INCORPORATED IN 1960 AS A COMPANY LIMITED BY GUARANTEE
MEMBER OF WORLD MEDICAL ASSOCIATION AND CONFEDERATION OF MEDICAL ASSOCIATIONS IN ASIA & OCEANIA

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2016 - 2017

13 February 2017

PRESIDENT 會長
Dr. CHOI Kin 蔡堅醫生

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,

**Submission to the LegCo
on the Proposed Regulatory Framework for Medical Devices**

The Hong Kong Medical Association supports the regulation of medical devices.

Medical devices must be effective and safe. These devices come with potential dangers of inflicting grievous bodily harm to patients, especially if used improperly. Think of diathermy, high energy ultrasound devices used inside the body during surgery and laser used on the eyes. The Government owes the public a duty to regulate medical devices, an obligation long overdue.

Devices are dangerous by virtue of the mechanics, and also by use. Therefore regulation on the use of medical devices is only logical. The use of such devices by non-medically trained personnel must be an exception rather than the rule, and such restriction must be effective to protect the public from injury consequent to the use of such devices.

This is not to say, that any doctor knows how to use all the medical devices used in the cosmetic or beauty industry, but that is of secondary importance. Of primary concern is the person receiving treatment. A doctor knows whether a skin blemish is a disease or "just a blemish". He can tell whether a lesion is premalignant or malignant, with biopsy if necessary. To treat a premalignant skin lesion as though it were nothing but a blemish forfeits the patient of timely treatment of an early, highly curable disease. Doctors diagnose, nobody else does.

Doctors recognize injury: injury to the skin where the device is applied and adjacent organ structures such as the eyes. A high energy device used on the skin causes not only pain and discomfort, but tissue burn, and other injury. Pain and discomfort are warning to imminent or real injury. Pain and discomfort are never normal, as some might misconceive. Severe injury has occurred because the operator did not recognize injury has occurred, and this is dangerous.

Once recognized, injury has to be treated. Doctors know how to manage the emergency and the more long term, definitive treatment. Doctors are trained to know their limits, and to refer where appropriate.

Finally, doctors are regulated by the Medical Council of Hong Kong. Doctors face disciplinary inquiry if their conduct fall below the standard expected of a doctor.

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Once found guilty of professional misconduct, a doctor can have his license revoked, and loses his right to practice as a doctor.

What is better to the public than to have high risk energy devices used under supervision of doctors, who can tell whether a lesion is a disease or "just a blemish", who recognize injury as soon as it is inflicted, who knows how to treat such emergency, and who are regulated by an impartial statutory body, the Medical Council of Hong Kong? Perhaps the exclusive use of medical devices by doctors themselves. We are not pressing for the latter, but what is currently proposed by the Government is balanced and fair in principle.

The risk levels of such devices should be assessed by doctors specializing in the treatment of such diseases and injury consequent to the treatment, including injury from medical devices.

Yours sincerely,

Dr. LAM Tzit Yuen, David
Hon. Secretary