



中華人民共和國香港特別行政區

Hong Kong Special Administrative Region of the People's Republic of China



立法會議員(醫學界) 陳沛然 醫生

Legislative Councillor (Medical) **Dr. the Honorable Pierre CHAN**

立法會 衛生事務委員會主席 李國麟教授 台鑒：

規管醫療儀器建議架構的意見書

就衛生事務委員會將於今天討論規管醫療儀器的建議架構，現附上香港皮膚科醫學院對此議題的意見書，供閣下及委員參閱及討論。

祝

台安

陳沛然

陳沛然議員 謹啟

二零一七年一月十六日

COUNCIL

12th January, 2017

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Dr. LEUNG Sze-kee

Dear Dr. Chan

Honorary Secretary

Dr. LAI Cham-fai

Re: LC paper No CB(2)545/16-17(01) Proposed Regulatory Framework for Medical Devices

Our College welcomed the Government to introduce measures to regulate medical devices but do feel that various issues with the current proposal should be addressed.

Honorary Treasurer

Dr. LO Kuen-kong

1) In term of post-marketing control, it is not uncommon for devices distributors to cease their operation, in which case, will the end user have any liability?

Members

Dr. FUNG Kin-kong, William

Dr. HO Hing-fung, Henry

Dr. YEUNG Chi-keung

Dr. YEUNG Kwok-hung

2) The ECRI consultant proposed different categories that should or should not be regulated, however their research was based upon previous publications that involved devices that are usually approved by regulatory authorities such as US FDA. Many copycat devices existed that do not have any regulatory approval and their safeties as well as efficacy are in doubt. Whereas new devices will be regulated, what action will be done with the existing devices?

3) In paragraph 16 table 2, cryolipolysis and plasma are considered to be control category III and therefore will not be required supervision by a registered Health Care professional (HCP). Plasma skin resurfacing is a highly invasive technology with significant potential complication. (See figure 1 for before and immediately after plasma skin resurfacing). Such recommendation raises doubt regarding the expertise and accuracy of the consultant's report. Another technology is cryolipolysis whereas previously the safety study indicated treatment of localized area is safe without any impact on liver function and blood lipid profile. Such technology is designated to be used by HCP to prevent excessive treatment. Beauty parlor being a commercial entity will encourage as much treatment as possible for commercial gain. The scenario is like eating a steak once a month is safe but daily consumption of 10 steaks would be a different matter. As such type of non-invasive fat reduction devices would lead to biological alternation, we urge the government to put both devices under category II.

We would appreciate it if you could look into these. Your kind consideration to the above issues is highly appreciated !

Yours sincerely



Dr. Henry Chan
Vice President
Hong Kong College of Dermatologists

SECRETARIAT

MIMS (Hong Kong) Limited, 27/F., OTB Building, 160 Gloucester Road, Wanchai, Hong Kong
Tel: (852) 2155 8557 Fax: (852) 2559 6910 E-mail: meeting.hk@mims.com

Figure 1 before and after plasma skin resurfacing



Pre-Op



Day 1



Day 2



Day 3



Day 4



Day 5



Day 6



Day 7