



29<sup>th</sup> January, 2017

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

Our Society strongly supports the Government to introduce measures to regulate medical devices for cosmetic purposes. This regulation is long overdue and passage of this important piece of ordinance is extremely important to safeguard public interest.

We, as dermatologists, have frequently encountered horrific complications that occurred as a result of inappropriate use of such devices by non-health care workers and this was most regrettable, putting public interest at risk.

While we support this regulation, we do feel that several issues need to be addressed:

- 1) In terms 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?
- 2) The consultant reported and stated that home based devices will not be regulated. But in US, devices are labeled to be home used by their local health care authority. Please clarify which authority in Hong Kong and under what criteria will home use device be classified?
- 3) 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 copycat devices?
- 4) In Annex II, paragraph 16 table 2, cryolipolysis and plasma skin resurfacing are considered by ECRI to be under control category III and therefore will not require 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). 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.

Yours sincerely

Dr. Chi-keung Yeung  
On behalf of The Hong Kong Society of Dermatology and Venereology

# Figure 1 before and after plasma skin resurfacing



Pre-Op



Day 1



Day 2



Day 3



Day 4



Day 5



Day 6



Day 7