11February, 2017

Proposed Regulatory Framework for Medical Devices submitted by the Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons.

The Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons is a professional organization comprising of more than 90% of Specialists in Plastic Surgery in Hong Kong. The main concern of our Members is to ensure the safety of our patients and provide them with the best possible care.

We strongly support the proposed regulation framework in medical advices. In contrast to the appropriate regulation of food and pharmaceuticals in Hong Kong, the absence of any regulation of medical devices is undesirable. Hong Kong is well behind the standard of our neighboring countries and not to mention the rest of the world.

The pre-marketing registration and post-marketing control of the medical devices proposed would significantly improve the safety of the devices and protect the public from unnecessary harm. It has to be appreciated that a significant proportion of the undesirable effects related to high energy medical devices are related to copycat devices not properly registered in their country of origin.

With reference to the use control for specific medical devices, we would like to point out that these high energy medical devices are developed after years of research and innovations of plastic surgeons and dermatologists. They are specifically designed for medical use and are extremely powerful but safe in the use of the hands of trained medical professionals. They are capable of treating difficult cutaneous and subcutaneous conditions though they could also be adopted for cosmetic improvements. We are, therefore, highly concerned when these medical devices are being used without any restriction in non-medical premises. The proposed regulation of the use of these medical devices under the supervision of health care personnel is already a compromise taking into account of the interests of different parties and safety of the public.

The presence of medical personnel would be superfluous if the device in used by the beautician is solely for cosmetic use. However when a medical device is use for cosmetic purpose, adequate supervision from a medical personnel with respect to proper diagnosis, assessment and timely and appropriate management in case of complications should be in place to safeguard the public safety. The medical personnel concerned should exercise personal effective supervision and retains personal responsibility for the treatment.

In addition, we think that it is essential to provide regulation to the existing medical devices used in non-medical premises and this is not covered in this proposal. These medical devices may fall below the standard of registration and pose danger to the public for years.

Yours sincerely,

The Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons