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Clerk to Panel
Panel on Health Services
Legislative Council
Legislative Council Building
8 Jackson Road
Hong Kong

Dear Sir

Response to the consultation document on the regulation of medical devices

We welcome the Hong Kong SAR government's proposal to regulate the use of medical devices. However, it is our position that the use of such devices by non-medical personnel without direct medical supervision is inappropriate as intense pulsed light source as well as Class 3b and class 4 laser systems are high-energy devices that are designed to be used by qualified medical and/or dental practitioners or their authorized persons. The reasons are as follows:

1. Medical/Dental practitioners are best to diagnose disease and offer treatment options other than laser

Medical/Dental practitioners would be able to diagnose disease states and offer treatment options that may or may not necessarily be laser. For example, patients with skin cancer should be treated with excision rather than laser.

The proposal of offering training courses to non-medical operators is unacceptable as the standard and experience of such operators vary widely. Furthermore, it will be most difficult for the Government to supervise the large numbers of different devices and the subsequent training courses that surface the market annually.

To safeguard the public interest, it is important to follow overseas examples such as the United States Food and Drug Administration whereby such kind of devices can only be used upon authorization of a practitioner. It is therefore our opinion that such devices should be licensed to medical practitioners who then carry the responsibility of ensuring adequate safety and usage of such systems. Such license system is important as the medical profession has the appropriate

insurance and regulatory body (Hong Kong Medical Council) to protect the public interest.

It is worthwhile to point out that accordingly to the American Society of Laser Medicine and Surgery (ASLMS), under the following criteria non-physician can use laser and related technology under the authorization of a medical practitioner:

- a) Any physician who delegates a procedure to a non-physician must be qualified to do these laser and related procedures himself by virtue of having received appropriate training in physics, safety, surgical techniques, pre- and post-operative care, and be able to handle the resultant emergencies or sequelae.
- b) Any licensed medical professional employed by a physician to perform a procedure must have received appropriate documented training and education in the safe and effective use of each system, be a licensed medical professional in their state, and carry adequate malpractice insurance for that procedure.
- c) A properly trained and licensed medical professional may carry out these specifically designed procedures only under direct, on-site physician supervision and following written procedures and/or policies established by the specific site at which the procedure is performed.
- d) Since the ultimate responsibility for performing any procedure lies with the physician, the supervising physician should be available on-site to respond to any untoward event that may occur. Ultimate responsibility lies with the supervising physician. The guiding principle for all physicians is to practice ethical medicine with the highest possible standards to ensure that the best interest and welfare of each patient is guaranteed. The ASLMS endorses the concept that the use of properly trained and licensed medical professionals, under appropriate supervision, allows certain laser and related procedures to be performed safely and effectively.

2. Medical/Dental practitioners are best to determine clinical end point

Medical/dental practitioners in the relevant field would be in the best position to determine the clinical end point achieved by these systems. For example, dermatologists or plastic surgeons would be able to assess the appropriate clinical end point achieved by a laser device designed for the treatment of skin conditions. This is important as excessive energy could lead to inappropriate end point causing complication such as permanent scarring.

3. Medical/Dental practitioners are best to detect and manage complications

Laser surgery, like other forms of surgical procedure, is associated with known complications. Medical/dental specialists in the relevant field would be able to early detect and manage the complications accordingly. This would lead to a better clinical outcome and reduce the morbidity associated with the complications.

4. Medical/Dental practitioners are best to observe laser safety

Inappropriate observation of laser safety when using class 3b and 4 laser systems could lead to blindness, burn injury and even fire.

Finally it is important for us to emphasize the use of such devices related to training not only in their operation but the detail knowledge in the study of skin (Dermatology). Such training started in the undergraduate teaching of medical schools and most medical practitioners received further clinical dermatology training during their post-graduation years. It is also important for us to stress that depending upon the specialties, there are now well designed programs for specialty trainees to receive the appropriate training in these technology before they are accredited to be a specialist and as a rule specialty training in medicine takes at least 6 years after completion of not only medical school but also internship.

It will be impossible to train people without basic medical professional training in clinical diagnosis (disease diagnosis and complications) and observation (treatment endpoint). Enclosed is a picture that shows a patient that has received laser resurfacing 2 days postoperatively. Clearly such devices should be operated by medical practitioners. This illustrates the importance in the regulation of high power lasers and IPLs.

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2 days after