25th September 2003

Director of Health
Department of Health
21st Floor Wu Chung House
213 Queen's Road East
Wanchai
Hong Kong

Attention: Dr. Monica Wong

Dear Dr. Wong,

Consultation on Regulation of Medical Devices in Hong Kong

We would like to commend you for drafting the very important Consultation Document on "Regulation of Medical Devices in Hong Kong". We believe this is a very useful document which is addressing an issue of major public concern. Our Society supports most of the suggestions in the Document, perhaps with the exception of two areas which we feel compelled to express our concern. These are areas which are related directly to the clinical activities of many members of our Society.

We as one of the most frequent users of laser equipment in medicine are concerned about the classification of medical devices involving the use of lasers. We would like to emphasize in particular the danger to public when higher energy laser equipment is used by personnel lacking adequate training and experience. High energy laser can cause various permanent sight-threatening ophthalmic injuries. Without proper classification of laser equipment, it will not be possible to properly control the use of this equipment by personnel with different training and experience. We suggest medical lasers such as CO2 laser and Erbium-YAG laser should be classified as Category IV devices, whereas intense Pulse Light (IPL) equipment and similar devices should be classified as Category IIIB or above. We fully echo the view of HKMA that the IPL machine is capable of generating high energy and cause significant and permanent damage to human body.

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Public safety cannot be assured with a proper classification system alone. It is equally important that the use of different classes of devices be matched to the expertise and experience of the operator. We believe the safe operation of medical devices of Category IIIB or above requires sound knowledge on the basic sciences of these devices, thorough understanding of the physiological and pathological changes these devices can induce in the human body as well as the precautions and variations in responses expected when these devices are used in patients or organs with diseases. Adequate operation skill achieved through proper supervised training is also very important. As such we recommend devices of Category IIIB and above can only be operated by properly trained, registered medical or dental practitioners. Our professional knowledge and insurance will avoid mishap as well as provide maximum patient protection.

We have made the above suggestions after consulting our members and believe these suggestions are imperative to assuring public safety when they receive treatment involving the use of medical equipment. We appreciate your attention to our suggestions and are looking forward to seeing regulations of medical devices, which incorporate our suggestions, be implemented.

Yours sincerely,

Dr. Ko Tak Chuen
President
The Hong Kong Ophthalmological Society

c.c. Dr. E.K. Yeoh, JP, Secretary for Health, Welfare & Food
c.c. Dr. John Ling, Hong Kong Dental Association
c.c. Dr. Mok Chung On, President, Hong Kong Surgical Laser Association
c.c. Dr. Henry Chan, Chairman, Hong Kong Society of Dermatology and Venereology

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