HONG KONG PHYSIOTHERAPY ASSOCIATION LIMITED
香 港 物 理 治 療 學 會 有 限 公 司

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15th March 2004

Hon Michael Mak,
Panel Chairman,
Panel on Health Services
– Regulation of Medical Devices
3/F Citibank Tower
3 Garden Road
Central, Hong Kong

Dear Hon Michael Mak,

Re: View Points on Proposed Regulation of Medical Devices by the Administration

Further to the submitted collective view-points of the Hong Kong Physiotherapy Association (HKPA) on the captioned dated 25th September 2003 to the Medical Device Task Force of Department of Health (as attached), our association would like to supplement on the following two issues.

I. Control on the Use and Operation of Medical Devices by Non-health Care Personnel

- Emphasis should be focused on limiting the use or operation of medical devices, in particular to intrinsically high risk devices such as Transdermal stimulator under Class II Medical Devices, by non-health care personnel so as to safeguard public interest & safety.
- Same degree of control should be exercised on the operation of medical devices or devices alike, regardless of the aims of the procedure, is for evaluation and/or therapeutic intervention or beautification. It is noteworthy that the potential hazard is device and procedure linked rather than purposes dependent. Hence, similar level of vigilance and requirement on screening of contraindication such as electronic implants including cardiac pacemaker or deep brain stimulator as well as precaution measures is warranted to uphold the quality and safety on operation of the devices.

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II. Application / Misapplication of the Title of Physiotheraputic Devices by Non-health Care Personnel

- Regulation should also be extended to the control on the application/ misapplication of title on devices termed “Physiotherapy devices” by non-health care personnel in order to avoid confusion or mis-interpretation by the public.
- All registered Physiotherapists in Hong Kong are governed by the Supplementary Medical Professions Ordinance (Cap 359) and subjected to legal requirement on local registration and regulation. It would be a reasonable anticipation for the public to expect the similar level of stringency on regulation and service quality for the application of such devices entitles “physiotherapeutic device” on them, in analog to or not less than those administered by registered physiotherapist. Hence, it will be inappropriate for personnel without the qualification of physiotherapist or equivalence to operate physiotherapeutic devices.

Should further information be required, please do not hesitate to contact the undersigned.

Yours truly,

Polly Lau

c.c. Dr. Dawson Fong, President of the Federation of Medical Societies of Hong Kong

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25th September 2003

Medical Device Task Force
Department of Health
21/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, HK

Dear Madame/ Sir,

Re: View Points on the Consultation Document
on Regulation of Medical Devices in Hong Kong 2003

In response to the invitation for the views & suggestion from health care professionals, we are writing to express the collective view-points of the Hong Kong Physiotherapy Association (HKPA) on the captioned. Physiotherapeutic devices embrace medical devices from class I to III. Having established recognition and networking with international counterparts, HKPA is the sole existing professional organization for physiotherapist, representing more than 70% of the total registered physiotherapist in Hong Kong.

The association shares the viewpoints with consensus on the existing problems and the emerging needs to establish a mandatory regulatory system over the supply and use of medical devices in Hong Kong for safeguarding public health & ensuring the quality, safety and effectiveness of medical devices. We support the principles of regulation on linking the level of regulatory control with the degree of risk and benefits offered by utilization of the devices while addressing the concern on avoidance of unnecessary burden on regulators, concerned parties of the medical devices trade and industry.

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We support in principle the proposed 3-tiers regulatory framework covering pre-market control, control on the use of selected medical devices and post-market control but would like to draw your attention to the followings recommendation from HKPA:

I. Pre-market Control on Class I Medical Devices

- Separate consideration of ***sophisticated electrical ambulatory devices*** such as electrical wheelchair & stair climbers from walking aid category. Faulty operation of those ambulatory devices analogous to automobiles & vehicle, either at home or community settings, will endanger the users & other people at close proximity of the mobility devices. Pre-market control with equivalence to Class II is warranted in view of the impact.

II. Control on Use and Operation of Selected High Risk Medical Devices

- Emphasis should be focused on limiting the use or operation of certain medical devices to specified non-health care personnel for public interest & safety, as there is already stringent regulations and code of practice regulating physiotherapists to ensure the safe and appropriate treatment of patients including local & international bench on proper utilization & operation of medical devices.
- Contribution from health professionals on the regulatory mechanism including types of selected devices & code of practice setting out the requirements on operators in terms of training, safety precautions and maintenance of devices is pivotal. Training should be conducted by qualified professionals with validated course contents.

III. Post-market Control : Adverse incident reporting

- Mandatory reporting of serious device problems by manufacturers and non-health personnel are necessary to ensure the safety of medical devices. The information should be disseminated to relevant concerned parties.

IV. Non-orthodox Devices

- Special attention to ***Fitness devices*** such as gymnasium equipment should be warranted while taking into consideration of the potential hazard and incidence of injuries to the users upon improper or mismatch handling & utilization.

Should further information be required, please do not hesitate to contact the undersigned.

Yours truly,

Polly Lau