香港物理治療師協會
HONG KONG PHYSIOTHERAPISTS' UNION
H.K.G.P.O.BOX 889

LC Paper No. CB(2)809/16-17(04)

12th February, 2017

Response to the proposal for Regulatory Framework on Medical Devices

Upon recapping the discussion on the LC Paper No.CB(2)545/16-17(01) at the Health Care Services meeting held on 16th January, 2017 in LEGCO and the follow-up meeting with the regulatory party on 24th January,2017, we have no hesitation to provide our expert input to assist the Government in tendering the "Regulatory Framework for Medical Devices"

In order to protect the wellness of the public health and to assure the appropriateness of the regulatory framework for physiotherapy related medical devices, it is the professional obligation of Hong Kong Physiotherapists' Union (HKPU) to rectify and to clarify the following issues,

1. It is considered as an undesirable administrative gap that physiotherapy professionals have never been contacted or alerted for the "Voluntary Participation in the Administrative Control of Medical Devices" launched in 2004. The track record of this scheme has been so concealed that there's no effective safety measures on the use control. Hence its aims and effectiveness needed to be reviewed and revised.

2. Ever since the professional registration of physiotherapy in 1998, there hasn't been any use control on the non-professional application of physiotherapy electro-medical devices in the public. This has put the public at a health risk whereas any layman can loosely and extensively apply the physiotherapy electro-medical devices on oneself or on their customers. The recently occurred fatal incident was alarming when the victim was receiving electrical stimulation from a layman service provider of a Health Shop.

3. With respect to the physiotherapy undergraduate curriculum and the post-graduate continuous education, the intensive theoretical contact hours and stringent clinical training on the application of electro-medical devices, registered physiotherapists are the major users of electro-medical devices during their clinical intervention. Their professional competence guarantees application safety and liability to the public. It will be totally misleading and will put the public health at high risk if there is no use control for the listed device(s)

4. In order to assure public health safety, we demand that physiotherapists should be included in the penal to provide their expert input for the legislation of medical devices.

5. The risk levels of medical devices should be reclassified according to their parameters such as energy levels, wavelengths, frequency, intensity, mode of applications and specifications on effects, side-effects and etc.

6. To make sure the list of medical devices is not exclusive and regular update with respect to time and advanced technology is mandatory.

HKPU would like to see a clear delineation on the risk-based classification of the general medical devices from that of the medical devices related to cosmetics. Please also differentiate the use control between health care professional and non-health care professionals. It is also important to clarify the liability of this regulatory framework if implemented.

Thank you for your attention and looking forward to your prompt response!

Yours sincerely,

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President, HKPU