

**Summary of Meeting with Representatives of Food and Health Bureau (FHB) and
Department of Health on Proposed Regulatory Framework for Medical Devices**

Date: 25 Jan 2017 (Wed)
 Time: 9:15 – 10:45
 Venue: Room 1801, 18/F, East Wing, Central Government Office, Tamar
 In Attendance: **Food and Health Bureau (FHB)**
 Mr. Patrick NIP, Permanent Secretary (Health)
 Mr. Howard CHAN, Deputy Secretary(Health)1
 Mr. James LAM, Atg Assistant Secretary (Health)3 / Assistant Secretary (Health) 2
 Ms. Fiona CHAU, Principle Assistant Secretary (Health)
Department of Health (DH)
 Dr. Tina CHAN, Assistant Director(Special Health Services)
 Dr. WAN Yuen Kong , Principal Medical Officer(5)
Representatives from Physiotherapy Profession
 Ms. Priscilla POON, Chairperson HKPA
 Ms. Eleanor CHAN, Chairperson HKPU
 Ms. Ming Wai LIT, Convener of Physio Action
 Mr. Alexander WOO, representative from Hong Kong Polytechnic University
 Ms. Anna Bella SUEN, Honorary Secretary HKPA

	Government responses	Our responses
1.	Mr. Patrick NIP, representative of FHB, accepted the letter from HKPA to Dr. KO Wing-man, BBS, JP (Secretary for Food and Health) on " <u>Clarification and Objection on the False Accusation on the Role of HKPA on the Consultancy Study (the Study)</u> "	Ms. Priscilla POON, on behalf of the HKPA, showed objection on the false accusation on the role of HKPA on the Consultancy Study conducted by the Emergency Care Research Institute ("the Consultant"). In actual fact, the Consultant has invited HKPA to contribute to the Study by completing the questionnaire on 31 Oct 2015 with an interview and site visit conducted on 2 Dec 2015. HKPA suggested to set up a regulatory framework of high,

		<p>medium and low risks. The equipment should be operated by different types of operators on a risk-based stratification. In addition, we have stated that further details of the parameters of the device have to be provided to solicit more valid comment. HKPA have NOT been asked for the details of the risk stratification system.</p>
2.	<p>Dr. Y. K. WAN, representative from DH, presented and reinforced that the existing proposed regulatory framework mainly focus on the use of medical device in non-medical settings since the use of medical device in medical settings has been well controlled by relevant professionals' regulations.</p>	<p>This point has not been clearly stated in the document.</p> <p>In actual fact, the existing professional regulation is unable to regulate the use of equipment by non-registered personnel.</p> <p>DH and PT board frequently refereed cases to HKPA in recent years but the existing professional regulation failed to put cases forward for into legal prosecution.</p>
3.	<p>Dr. Y. K. WAN, representative from DH, presented the proposed regulatory framework related to the pre-market control, post-market control and use control of specific medical devices.</p>	<p>Our group, in principle, agrees to the setting up of a regulatory framework for medical devices on a risk-based approach in order to protect the public health interest. We also support the recommendation for imposing pre-market control, post-market control and use control of specific medical devices.</p> <p>Ms. LIT reinforced the importance of regulation in the control of import for high risk medical equipment. The use of high risk medical equipment should be recorded by relevant control office as used only in the vicinity of</p>

		registered medical professionals.
4.	Mr. Patrick NIP and Mr. Howard CHAN, representative of FHB, explained there will be administrative difficulty in regulating home use equipment as it has to be controlled at retailer level.	Ms. LIT reinforced the importance to regulate the location of application for medical equipment especially for those equipment being used at home with identifiable risks. The Government has to consider the issue seriously in order to protect public interest.
5.	Dr. Y. K. WAN, representative from DH, presented on the risk stratification of medical device into category A and category B which was not well listed in previously released paper. (Most of the equipment commonly used by Physiotherapists and previously listed as category III and category IV e.g. Infra-red (IR), Microwave, Extracorporeal Shockwave (ESWL), High Voltage Pulsed Current (HVPC), Microcurrent electrical neuromuscular stimulation, Pulsed Electromagnetic Field (PEMF) are NOT listed in the current proposed category)	Our group made an enquiry on how to control other equipment which are not listed in category A and B. Our group reinforced the clinical risk ratings as presented by the Consultancy Report are NOT entirely accurate especially those listed as the Low Risk Categories. To ensure public health and safety, the Government must address this issue seriously and seek wider consultations from appropriate medical and health care professions.
6.	Mr. Howard CHAN, representative from FHB, reported that the “Working Group on Differentiation between Medical Procedures and Beauty Services under the Steering Committee on Review of Regulation of Private Healthcare Facilities” (the Working Group) examined the safety and health risks of commonly used medical devices. Department of Health commissioned the Consultant to conduct the Study from September 2015 to September 2016 during which the Consultant conducted extensive information	Our group replied that the study conducted by the Consultant is mainly on 20 medical devices for cosmetic purposes. Physiotherapists suggested to conduct an international benchmarking on regulatory framework for medical devices in general to facilitate the legislation process. Our group sought clarification on the definition of adverse incidents reported in literature and to regulatory authorities. If those

	<p>searches on the selected devices, including their uses for cosmetic purposes, associated adverse incidents reported in literature and to regulatory authorities, and complaints made to Consumer Council; as well as the practices and regulations on the use of the selected medical devices in five major economies.</p>	<p>devices such as infra-red, microwave, ESWL devices are not used properly, or with incorrect dosages, they can lead to skin burn, tissue damage, burst blood vessels, and in the worst case scenario, may cause stroke, heart attack or even death to patients. These clinical risks should be well considered in risk stratification in the Consultancy Report.</p>
7.	<p>Mr. Patrick NIP, representative from FHB, reinforced that a mechanism will be established in order to regulate the newly introduced medical devices owing to the advancement in medical technology. Also an advisory committee, chaired by Secretary of FHB, will be set up after the establishment of the regulation in order to update the list of category in due course.</p>	<p>Our group reinforced the importance of Physiotherapy profession to participate in the mentioned statutory Advisory Committee for a more effective & safe implementation and administration of the future legislation.</p>
8.	<p>Mr. Patrick NIP, representative from FHB, sought our comment and concern on the medical devices as listed in the Category III & IV of the Consultancy Study (the Study).</p>	<p>We reinforced that in actual clinical practice, registered physiotherapists in local and international context have to be well trained with clinical pathologies, patient screening, good clinical judgment during treatment and application of medical devices. Such training is mandatory to ensure safety of the clients. The frequencies, wavelengths, power, intensity and application methods of all these kinds of physical energies on the Electromagnetic Spectrum must be clearly stated instead of just naming the equipment.</p>

9.	Dr. Tina CHAN, representative from DH, pointed out that for those devices required non-registered personnel undergo training before usage. The training has to be registered under the Qualification Framework of the HKSAR.	Our group reinforced the importance of structured regulation and credentialing system, in order to ensure quality and standard of relevant training.
10.		Ms. Eleanor CHAN pointed out that the document should clearly list out the health care professionals to be entitled for application / supervision on the use of medical devices. Physiotherapists are the only professionals being well trained in the use of some of the named medical devices during undergraduate training.

Post meeting FU

1.	The Physiotherapists joint group will submit a document on the classification of user control for different medical devices according to different frequencies, wavelengths, power, intensity, application methods to use, especially to those medical equipment commonly used in physiotherapy profession.
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The meeting was adjourned at 10:45