Department of Rehabilitation Sciences, The Hong Kong Polytechnic University
Hong Kong Physiotherapy Association
Hong Kong Physiotherapy Concern
Hong Kong Physiotherapists' Union
Physiotherapy Action

11 Jan 2017

Dr. KO Wing-man, BBS, JP
Secretary for Food and Health
18/F, East Wing, Central Government Office
2 Tim Mei Avenue, Tamar, Hong Kong
By Email

Dear Dr. KO,

Re: Feedback on the Proposed Regulatory Framework for Medical Devices (LC Paper No. CB(2)545/16-17(01))

In response to the Captioned to be discussed on 16 Jan 2017, the **Physiotherapy** profession shows great concern that public health interest will still be at risk, if this proposed regulatory framework is to proceed without further refinement. As Registered Physiotherapists form the major user group of the medical devices under Category III and IV as stated, we would like to express our views to the LegCo on this issue.

In order to strive for the safety and health benefits of the public, physiotherapy representatives from the Hong Kong Polytechnic University, Hong Kong Physiotherapy Association, Hong Kong Physiotherapists' Union, Hong Kong Physiotherapy Concern and Physiotherapy Action would jointly provide our professional input to identify the gaps and loopholes of the Captioned for the protection of public interest.

1. We, in principle, **agree 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.

   We would like to seek clarification from the Government on whether "The Latest Proposed Regulatory Framework"" of the captioned LC Paper is related to regulatory framework for **medical devices in**

general, or that of the medical devices for cosmetic purposes ONLY. We as physiotherapists therefore suggest for an **international reference on regulatory framework for medical devices in general to be benchmarked** in the legislation process.

2. Some of the medical devices as listed in the Category III & IV of the Consultancy Study (the Study) are commonly used by registered physiotherapists. However, these medical devices, as listed in the **Category IV of the Study**, as classified as **low clinical risk and thus no user restriction**, is required! Moreover, the ones listed in Category III of the Study are proposed to be applied by personnel with relevant training program.

Clinical Risk Category	Listed Devices Used by Physiotherapist
Category III (Medium Clinical Risk)	• Infra-red (IR) • Microwave
Category IV (Low Clinical Risk)	• Extracorporeal Shockwave (ESWT) • High Voltage Pulsed Current (HVPC) • Microcurrent electrical neuromuscular stimulation • Pulsed Electromagnetic Field (PEMF)

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. In Physiotherapy undergraduate training, we need to learn the appropriate frequencies, wavelengths, power, intensity and application methods to use all these different kinds of physical energies on the Electromagnetic Spectrum. (See ANNEX I for details). In particular, Extracorporeal Shockwave has been traditionally used by doctors for breaking up renal stones, and also used to treat mal-union of fractures. It is totally unacceptable that such a machine would be classified as "Low Risk" in the consultancy report.

If these devices such as infra-red, microwave, ESWL devices are not used properly, or with incorrect dosages, they can result in skin burns, tissue damage, burst blood vessels, and in the worst case scenario, may cause stroke, heart attack or even death to patient. Hence, the clinical risk ratings presented by the Consultancy Report are NOT entirely accurate especially regarding 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.

3. The fatal incidence resulting from the inappropriate application of electro-medical device by layman under no restriction has become an unresolved issue in the related field. Hopefully this recapped incident helps to alert concerned parties when drafting related Bills for legislation.
http://hk.apple.nextmedia.com/news/art/20150622/19193706
(See ANNEX II for details)

These incidents were the result of electrotherapy machines inappropriately used by those who have

not received proper formal training such as those required for the Registered Physiotherapists.

In order to identify the gaps and loopholes of the caption, we have formulated the concerned issues in the attached table (ANNEX I) for your consideration.

4. The Discussion Paper has not clearly stated whether ONLY the 20 medical devices as listed in the Study will be regulated. We, therefore, suggest regulating a broader spectrum of medical devices, instead of just the 20 enlisted devices. In addition, it is necessary to impose mechanism to regulate the newly introduced medical devices owing to the advancement in medical technology.

5. We in the Physiotherapy profession will be happy to participate in the mentioned statutory Advisory Committee for a more effective & safe implementation and administration of the future legislation.

We look forward to have a meeting with you if possible well before the related LEGCO meeting to be held on 16th January ,2017 such that our views and concerns for the public interests could be well channeled for your understanding.

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Yours truly,

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ANNEX I: Detailed Comments on Specific Points in the LC Paper

Item	Text	Comment
P. 1 : Purpose	"This paper briefs Members on the results of the consultancy study on the control of use of selected medical devices and the latest legislative proposal on regulation of medical devices."	1. In this statement, it seems to imply **all "medical devices"** are to be regulated and there is no mention of "cosmetic purposes". Does this mean this proposed regulation is intended to include all the "named" equipment to be used for all medical and therapeutic purposes?
p. 4-5: Use Control Categories	Category I: User must be a registered healthcare professional Category II: User must be a registered HCP or a person supervised by a registered HCP on site Category III: User meets the requirement of either Cat I or II, or has completed device-specific training through training programme recognized by the Government Category IV: No user restriction	1. There needs to be more clear description of what HCP represent. Registered Physiotherapists in Hong Kong is the only healthcare profession who received formal training in the theory and practical skills of operating electrophysical therapy modalities. Physiotherapy students need to take two courses related to electrophysical therapy and must pass the theory and practical assessment for the two subjects. In order to safeguard all safety measures on applying electroohysical therapy have been taken care of, students need to pass clinical placement under supervision of experienced physiotherapy clinical educator before they can register as a physiotherapist. 2. Cat III – There is no clear description of what "device –specific training" involves. If this training programme is "recognized by the government" – it would not be equivalent to the training that manufacturers provide with the sales of the equipment. If the government is willing to take up this responsibility, it is a positive step to ensure public safety. However, it can be an enormous task. 3. Cat IV – According to the Consultancy Report, in the list of the "20 selected equipment" (listed in **Annex V**), there are many devices such as "Extracorporeal Shockwave, High Voltage pulsed current, microcurrent, electromagnetic field" etc. These devices are also the electro-therapeutic devices that are used by Registered Physiotherapists in their daily treatment of patients with pain or various conditions in clinical setting. Yet, these devices are listed as Cat IV – "No user restriction". If these machines can be used by any lay person without professional training, there is a potential and high chance of causing injury to the tissues, burn to the skin, and possibly permanent tissue damage and even ***death.***
P. 5: Three-pronged use control	(i) *Clinical risk assessment* 12. The consultant has recommended four levels of	1. There is no definition of <u>what</u> the clinical "risks" refer to, and "how" these 4 risk levels were rated. Does the risk involve possible burn to the skin? Infection to the skin?

assessment	clinical risk for medical devices, namely "Extreme", "high", "moderate" or "low"….	2. "Risk" is only a very general term. It is important to examine more explicitly what the "risks" involve and it can be different for different devices and it can also affect different body systems. For example, in physiotherapy, we have to study the body's responses to change in temperature. [1] If a person has high blood pressure (BP), and is given treatment of "heat" or "cold" that affects the whole body system, it could cause a big change in their BP, and may possibly lead to a ***heart attack***, a ***stroke*** or even ***death***. 3. There is also no explanation of "who" and "how" the 4 ratings of "Extreme", "high", "moderate" or "low" were defined. The risk ratings are affected by "who" is using the machine. For example, the " Extracorporeal Shockwave" machine can be used by a physiotherapist safely, then the risk would be low. If it is used by a "lay person", it would become a High risk! 4. Hence to rate the machine as "low" or "high" risk and then assign it to different user categories – especially Cat IV (no user restriction) is highly dangerous and NOT acceptable.
	(ii) *Regulatory assessment* 13. .....Category IV will be given if the use of the medical device does not involve any such requirements.	1. Currently, in the Regulation for Registered Physiotherapists, there are NO specific *regulatory requirement* regarding the use for many electrotherapy machines such as Ultrasound, Electrical Stimulation, Electromagnetic Field, Extracorporeal Shockwave, Microcurrent etc. However, it is well known and internationally accepted that these machines are most commonly used by Physiotherapists. <u>It would be a total backward move of the Hong Kong healthcare system in protecting the rights of its citizens in accessing safe and quality assured healthcare services and also violates the professional rights of Physiotherapists</u> if such machines can be used by persons under "Category III" (with some training) or Category IV (no user restriction).
	(iii) *Knowledge and skills assessment* 14. … the Consultant proposed a list of guidance questions (at Annex IV) to assess the level of knowledge and skills (K&S) required for proper and safe operation of a medical device. Highest level of K&S will render this device under Use Control Category II , … lowest level of K&S will render the	1. It is NOT clear "who" were the stakeholders involved to provide judgement of the level of "Knowledge and Skills" involved in using such medical devices. It is possible that these stakeholders are NOT familiar with the nature of the various types of medical devices at all, as reflected by the results. 2. Based on this system, in Annex V – for the summary of the recommendations under "Knowledge and Skills", 11 types of medical devices were rated as Category IV – meaning no specific training or knowledge is required. This includes the devices of "whole body cryotherapy, extracorporeal

	device under Use Control Category IV.	shockwave, high-voltage pulsed current, iontophoresis, pulsed electromagnetic field...". This would contradict the common practice of Registered Physiotherapists who receive extensive training in the BSc degree program and after graduation, and they use such equipment/ devices to treat patients with soft tissue injuries and various conditions.
p. 6. Device-specific control recommendations	15. ..the Consultant has assessed the clinical risk, regulatory as well as knowledge and skills requirements for the 20 types of selected medical devices and recommended use control categories for these devices. A summary of these assessments is provided in **Annex V**. With device sub-classification..... eight types of medical devices have been assessed as use control Category IV. No medical device researched in the Study requires that the user must be a registered HCP.	1. There are 26 medical device items listed in Annex V. These names were not exactly the same as the "20 types of medical devices" listed in Annex I. This issue of different names of devices need to be clarified. 2. In naming the medical devices as "Infra-red", "extracorporeal shockwave", "pulsed electromagnetic field" etc, there is no detail description of the specifications of these machines, e.g. what frequency, wavelength, and power/intensity range being produced by these machines. For example, in Physiotherapy, the "shortwave therapy" machine for treating muscles and joints are usually produced with a fixed operating frequency for 27.12 MHz. The energy produced can be up to 1,000Watts for thermal effects, and for "pulsed" shortwave, the power is reduced to 150-200Watts.[1] This is used for treating acute phase of soft tissue injury. For extracorporeal shockwave, energy is produced in very concentrated doses of 0.08mJ/mm^2 which is considered a "low" dose.[2] Without such specifications, such a list of medical devices would imply that the regulation would also be applicable to these machines with the same names that are being used in Physiotherapy treatment. In actual fact, the therapeutic effects and clinical risks vary with the specifications (such as wavelength, frequency and power) of the equipment/ devices. Therefore, just quoting the name of equipment/ devices for regulation is very confusing and leads to implementation difficulties in regulation. 3. The recommendations in Annex V have listed 8 types of medical devices as "Control of Use Recommendation" **Category IV**: **This means "No user restriction"** and anyone can use it. This includes devices of Extracorporeal shockwave therapy (ESWT), High voltage pulsed current, Microcurrent electrical neuromuscular stimulation, iontophoresis, electromagnetic field, shortwave (hair removal) device. **We consider this recommendation to be totally unacceptable, and will pose**

		a serious danger to the public –as these machines can post harm to the recipient if not properly used. 4. It is totally erroneous to say that "No medical device researched in the study requires the user to be a registered HCP". The Physiotherapy Professionals would strongly object to such a statement. If the consultant means this in the context of "cosmetic purposes", then it is different. However, in the whole paper, it is not clear whether the regulation is meant to govern the use of medical devices for cosmetic purposes only? Or use of these medical devices in general?
p. 6. Public Registry of Recognised Training Programmes	16. The Consultant has also recommended that the Government.... Should publish a list of recognized training programmes which offer recognized training for operating specified types of medical devices.	1. **We recommend that such "recognized training programmes" are more than just the basic training that the manufacturers of the devices will provide.** The Government should set up an Advisory Committee to screen and accreditate such training programmes. **The Committee should consist of professionals with suitable knowledge, such as medical doctors, physiotherapists and biomedical engineers.**
p. 8. Recognition of conformity assessment bodies ("CABs")	24. The proposed legislation will empower the DH to recognize CABs to perform conformity assessment on medical	1. Physiotherapy professional associations can be invited to participate as CABs.
p. 9-10. User control of specific medical devices	30. The Government will adopt a risk-based approach to impose use control on specific medical devices. In this regard, we will not impose use control on medical devices associated with low risk in their use. Based on the recommendations of the study, the proposed regulatory framework will adopt the following two levels of use control: (a) Users must be supervised on site by a registered	1. If the definition of "low risk" is totally determined based on the Consultancy Study – the devices of "Infra-red", "extracorporeal shockwave", "pulsed electromagnetic field", "high-voltage pulsed current", microcurrent for neuromuscular stimulation, whole body cryotherapy device, **all these devices are Incorrectly classified as "low risk". By deciding on the use control based on the Consultancy Study, it will increase the risk of harm to the public.** **We demand that the Government should start a new round of consultation seeking advice from suitable stakeholders such as the recognized professional bodies e.g. Hong Kong Physiotherapy Association, Hong Kong Physiotherapist Union and academic institutions.** 2. This proposed two levels of use control is controversial, as the use control levels in the Consultancy

	medical practitioner (similar to user control Category II of the Study); and (b) Users must be supervised on site by a registered medical practitioner or be a personnel who has successfully completed the relevant training programme as recognized by the Government (similar to use control Category III of the Study).	Study referred to the term "HCP" – healthcare professionals, whereas in this part – the proposed users only include "medical practitioners" – which presumably refer to "medical doctors" and not other health care professions such as physiotherapists, nurses, etc. 3. Again, it is not clear whether this "use control" refers to only "cosmetic purposes" or other forms of use.
p. 10. The way forward	31. .... The use control assessment framework proposed by the Consultant will form the basis on selection of medical devices to be subject to use control and corresponding use control categories.	1. We strongly urge the Government to seek more suitable opinions from various stakeholders such as the Physiotherapy professional bodies, biomedical engineers, etc. **To solely adopt the recommendations of the Consultancy Report will lead to the disastrous consequences**: One - **Many devices which should be listed as high or moderate risk levels were incorrectly classified as low risk,** and no knowledge /skills required. Two – The Government will give a wrong message to the public that these devices such as "extracorporeal shockwave" can be easily used by anyone, and the **manufacturers can ride on this note and promote the sales to untrained persons or the general public.** As a result, **serious harm can be caused to the general public**, and it is not clear "who" should bear such responsibility.
p. 11, ANNEX I	List of 20 types of selected medical devices studied	1. Only a simple name of each type of device is stated. There is NO specification given for each type of device.
P. 24, ANNEX V	Summary of Recommendations for Control of Use of Selected Medical Devices	1. The ratings of clinical risk, knowledge and skills, and Control of Use recommendations are highly controversial. The health conditions of the recipients of these devices are important considerations to check. For example, in Physiotherapy, Cardiac Pacemakers is an Absolute Contraindication for using any electrical current on the patient such as high voltage, or microcurrent, or ultra-sound.[1,3] There are published international guidelines on Contraindications for use of various electrotherapy devices. These factors do not seem to be

		taken into consideration in this consultancy report.
p. 26, ANNEX VI	Classification of medical devices	1. This classification system does NOT include the 20 types of selected medical devices that were listed by the Consultancy Study. Only "laser" is listed in Class III, and in Class II – "transdermal stimulator" may be considered to include "high-voltage pulsed current" and "microcurrent", Acupuncture needle may include the "micro-needles" as listed in Annex V. Other devices named in Annex I and V are NOT mentioned in this classification system of ANNEX VI.

References:

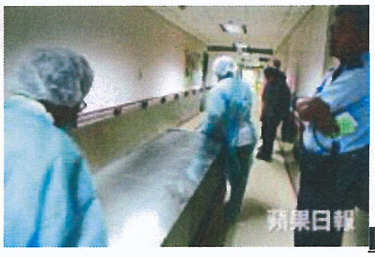
1. Robertson V, Ward A, Low J, Reed A. Electrotherapy Explained: Principles and Practice. 4th Edition Butterworth Heimann Elsevier: Edinburgh. 2006.
2. Watson T. Shockwave Therapies. http://www.electrotherapy.org/modality/shockwave-therapies-
3. Houghton PE, Nussbaum BL, Hoens A. Electrophysical agents: Contraindications and Precautions. Physiotherapy Canada 2010, 62(5), 1-83.

ANNEX II:

【本報訊】一名年輕時喪夫、一個人含辛茹苦將三名女兒撫養成人的好媽媽，由於多年來身兼多份工作養家，積勞成疾經常周身痠痛。她昨日到大角嘴一間通絡理療中心，接受通經絡脈衝治療以舒緩痛楚，其間由一名女「理療師」為她在腰部貼上膠貼進行通電流治療，女事主突然昏迷，送院搶救後不治。旺角警區重案組接手調查，至深夜將女理療師拘捕，並撿走有關儀器，初步不排除她在治療期間心臟病發猝死。

記者：文兆麟　梁澤岡　司徒韋桐　徐雲庭

猝死婦人何碧華，59 歲，體形略胖，患有初期糖尿病，無心臟病紀錄。醫學會會董何鴻光醫生表示，如死者患有糖尿病，而糖尿病可致血管收窄引致心臟病及冠心病，亦可能本身患有隱性心臟病而不自知，一旦電流突然傳入身體，無論是隱性心臟病，就算是健康的人，也會被擾亂心跳，導致心律不正，引發心臟病發死亡。



59 歲女子在理療中心通經絡期間昏迷，送院後不治。梁澤岡攝