香港理工大學康復治療科學系
香港物理治療學會
香港物理治療關注組
香港物理治療師協會
物理治療起動

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食物及衞生局局長
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敬啓者：

回應有關「規管醫療儀器的立法建議」的建議書
(LC Paper No. CB(2)545/16-17(01))

就　立法會衞生事務委員會將於 1 月 16 日討論有關「規管醫療儀器的立法建議」，物理治療業界一致認為，建議內容未能釋除業界對醫療儀器可能構成公眾健康風險的疑慮。簡單而言，若建議中的規管架構不經任何修訂，**實施後將對公眾安全及健康構成莫大風險**。註冊物理治療師，作為臨床應用醫療儀器的專業人員，對此深表關注。

為守護市民的安全及健康，物理治療業界（包括：「香港理工大學康復治療科學系」、「香港物理治療學會」、「香港物理治療師協會」、「香港物理治療關注組」及「物理治療起動」）就顧問文件內容，聯署提出以下意見：

1. 物理治療業界原則上同意設立醫療儀器的規管架構，採用以風險為本的方針，按醫療儀器所評定的風險級別，釐定規管的程度，以保障公共衞生利益。我們亦支持建議文件中，就相關儀器實施三級規管：推出市面前的規管、推出市面後的規管及特定醫療儀器的使用管制。

   然而，我們要求政府澄清於上述文件中「最新建議的規管架構」所指的是否泛指**所有醫療儀器(包括物理治療師常用的儀器)？或只是以美容為用途的儀器？**我們建議政府在立法過程中，**必須參考國際就醫療儀器的規管作為基準**。

2. 於顧問報告中被列為臨床風險水平 III 及 IV 的儀器，部份亦為物理治療師臨床應用儀器（見下表），卻被定為低風險，甚至沒有使用者限制的要求！事實上，海外及本地的物理治療師必須接受嚴格訓練，認識不同醫療儀器的頻率、波段、輸出能量及應用方式，使用前需評估病人的病歷、症狀、禁忌症等，治療期間亦需持續評估病人的反應及治療效果，以確保病人安全及有效地接受治療。以衝擊波為例，專業醫療人員可應用衝擊波原理，用於擊碎腎石，治療未癒合骨折等。**該等儀器屬高能量，不應納入為「臨床風險水平 IV」，物理治療業界實不能接受是項分類建議**。

臨床風險水平	物理治療師使用的儀器
臨床風險水平 III （中級臨床風險）	遠紅外線(IR) 微波 (Microwave)
臨床風險水平 IV （低級臨床風險）	衝擊波(Extracorporeal Shockwave – ESWT) 高電壓電流治療 (High Voltage Pulsed Current – HVPC) 微電流治療 (Microcurrent Electrical Neuromuscular Stimulation) 脈衝磁療 (Pulsed Electromagnetic Field – PEMF)

同樣，不正確使用醫療儀器，包括：遠紅外線，微波，衝擊波，脈衝磁療，可能引致非常嚴重的後果，包括灼傷、組織受傷、血管破損、中風、心臟病，甚至死亡。使用該等醫療儀器，**實非顧問報告中所述屬低風險**。政府必須高度正視醫療儀器的潛在風險，並嚴格分類及規管。

3. 現時本港未有就醫療儀器訂立法例規管，任何人可隨意買賣及操作，過去曾造成致命的意外。由無註冊牌照或無任何訓練的經營者，以「治療師」或「理療師」誤導公眾，為病人進行電療期間，病人心臟病發猝死，請參考以下個案:
   http://hk.apple.nextmedia.com/news/art/20150622/19193706

   部份以養生館、保健中心等名義取得商業牌照，實質為無牌行醫，危害公眾安全。問題急需解決。

   我們希望政府正視這些悲劇，盡快草擬相關法案，堵塞漏洞，保障市民的安全。就有關文件的改善建議，我們亦詳列於附件一，供　閣下參考。

4. 討論文件中並沒有清楚交待，是否只規管研究中所列出的二十項醫療儀器。我們建議應廣泛就醫療儀器進行規管，而非限於所列出的二十項。隨著醫療科技日新月異，法例更應具備有效涵蓋推陳出新的醫療儀器的機制。

5. 物理治療業界要求加入上述有關醫療儀器規管的法定諮詢委員會，貢獻所長，共同制定相關法例，以確保醫療儀器的安全使用及規管，保障病人福址。

冀望能盡快與　閣下會面，向　閣下闡明物理治療業界的意見及關注。如蒙應允，不勝感激。

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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 what 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 shockwave, high-voltage pulsed current, iontophoresis, pulsed electromagnetic field…". This would

	device under Use Control Category IV.	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 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	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 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

	successfully completed the relevant training programme as recognized by the Government (similar to use control Category III of the Study).	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