Response to the Proposed Regulatory Framework for Medical Devices

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1. In the proposed regulatory framework, as stated in the LC Paper No. CB(2)545/16-17(01), this legislation is planned to regulate the sale and use of ALL medical devices. As a registered physiotherapist and an educator, I would support such a regulation, if it is truly able to regulate ALL medical devices.

2. Professional people such as medical doctors, physiotherapists and biomedical engineers should be consulted in establishing the Risk Classification System. The risk classification from the Consultancy Report was NOT correctly done. The ratings of clinical risk, knowledge and skills, and Control of Use recommendations are highly controversial in the Consultancy Report. 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, microcurrent, or shortwave diathermy. 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.

3. As an academic faculty member of the BSc (Hons) Physiotherapy program in the Hong Kong Polytechnic University, I have been teaching the use of electrotherapy machines for over 20 years. We want to stress that our students spend over 200 hours in the 4-year curriculum to learn the theory and practice of using Electrotherapy machines, as well as 1000 hours in Clinical Education to practice the assessment of patients and the application of physiotherapy treatment on real patients.

   It is NOT acceptable that some of these machines such as high voltage electrical stimulation, microcurrent, pulsed electromagnetic field, ultra-sound, shortwave and shockwave therapy were classified as “LOW RISK” in the LC paper. These machines may have been safely applied on patients due to the stringent training we have given to the students. However, if given to those without such intensive training, ALL machines can become “High Risk” if wrongly used. This is most clearly demonstrated in the fatal incident that was reported in the news in 2015 http://hk.apple.nextmedia.com/news/art/20150622/19193706

4. The Government needs to be aware of the increasing number of “alternative therapy” clinics that are rapidly developing in the community. Those medical devices that were wrongfully classified as “low risk” in the LC Paper – based on the Consultancy Report, can cause tremendous harm to peoples’ lives if such devices are inappropriately used. If the regulation on medical devices is enforced and only “certain” types of devices are

governed by this regulation. Other devices that are NOT governed by the Regulation would be seen as "permissible" to use and it may lead to an indirect "endorsement" by the government to use certain types of devices. Hence, for the safety of the people of HK, to regulate the use control of ALL types of medical devices, rather than only a few selected types of devices.

There are many clinics or centres in Hong Kong, that use the term "理療" or "通經活絡", or "保健" "養生" "按摩" as the trade or business, and they are actually performing treatment that are "therapeutic" in nature. These practitioners may have no professional training and there are no regulations to govern their practice. This is highly dangerous especially if electrical machines are used.

5. It is stated that a "Voluntary Medical Device Administrative Control System" has been established since 2004. There is no information provided by the Govt on "how successful" this system has been. If such a system is already in place, the regulatory framework should be referenced to this system. How many known medical devices have been registered under such a system? What are the mechanisms of such an administrative system?

6. The three components of "pre-market control", "post-market control" and "use control" should NOT be considered as separate aspects. The consideration for "use control" should be linked with the pre- and post-market control.

   For example, the use of Extra-corporeal Shockwave should be considered in 3 main categories of use control. The manufacturers should be the ones to provide detailed information about **the specific range of energies** and **specific Use Categories that different machines are designed for. For example, just the shockwave machines alone, there will be different ones built specifically for these different use purposes, as listed in the Table.**

	Use Category 1	Use Category 2	Use Category 3	Use Category 4
Use Control Categories	Medical Use - Only to be used by medical doctors	Therapeutic Use -only to be used by healthcare professionals with appropriate training (e.g. Physiotherapists)	Others (non-professional service, training is still required)	Home use
Aims of treatment	for the treatment of kidney stones (lithotripsy) and other invasive procedures	For the treatment of soft tissue injuries, e.g. tennis elbow, heel spur	For cosmetic purposes, health promotion purpose	For people to buy and use at home

Pre-Market Control	Devices to be checked to be suitable for the specific use category and meeting recognized safety standards and quality control.			
Post-market Control	Sales of Machines in each use category is restricted to *that group* of persons. That is, Shockwave machines designed for Use Category 1 should only be sold to medical doctors or hospitals. Machines in Use Category 2 should only be sold to healthcare professionals such as Physiotherapists. A Post-Market and Use Control Surveillance System should be established to monitor this process.			

Other medical devices may only fit into 1 or 2 categories. For example, high voltage pulsed current – doctors may not use it, but Physiotherapists will use it to treat soft tissue injuries, wound healing and pain management.

7. A comprehensive Medical Device Registration System should be implemented in order to register every single known medical device. This system can be similar to the administration of drugs and medications. Companies MUST register a product before it can be placed on the market for sale.

   The guidelines provided in the ASEAN Medical Device Directive is a very useful reference that the HK Government should consider in drafting this legislation.

8. The rating of "Risk" can be integrated into this Use Category System. Each device should be issued a label to show all the relevant information. Internationally, different countries are also working on producing such systems, and the Bureau should take reference from other countries. "Unique device identification" is an approach that is being developed by different countries, including the IMDRF, which the Bureau has used as a reference to their paper.

9. This will not be an easy process, but if the HK Government is determined to develop the legislation to govern ALL medical devices, it should be ready to do it properly. The Government should invite the appropriate stakeholders to form an Advisory Committee. Medical doctors, physiotherapists, biomedical engineers, electrical & electronic engineers, and other relevant professionals should be included.

10. A list of specifications and physiotherapy usage of selected medical devices that have been mentioned in the LC paper is attached with this document (Annex I). This is for the reference of the Bureau in considering further refinement to the regulatory framework.

Annex I: Selected Medical Devices commonly used in Physiotherapy : Applications, specifications and contraindications

Selected Medical Devices	**Use in Physiotherapy treatment**	**Specification**	**Contraindications and Risks**
Extra-corporal shockwave 體外衝擊波	It is used to treat chronic tendon, joint and muscle conditions. It is also used to treat bone spur, promote wound and bone healing.	Peak pressure typically 10- 120MPa with fast pressure rise usually less than 10 ns and short duration for 10 microseconds or less. Energy flux density commonly used in physiotherapy can be grouped into low energy level (up to 0.08mJ/mm^2), medium energy level (up to 0.28mJ/mm^2) and high energy level (over o.6mJ/mm^2).	1. Malignancy 2. Areas close to spinal column, nerve plexus, brain, lung and intestine regions are contraindicated 3. Skin infection 4. Epiphyseal cartilage in young children or adolescents 5. Unstable angina, uncompensated congested heart failure 6. Cardiac pacemaker in the body is contraindication 7. Blood clotting disorders and use of anti-coagulants will increase risk of excessive bleeding 8. Pregnancy
Microcurrent 微電流	It is used for soft tissue healing, wound healing and pain management by bioelectricity	Output current is usually between 10-600μA with adjustable polarity and frequency between 1-990Hz. Maximum output voltage is about 50-60V and pulse width around 50-150μs.	1. Malignancy 2. Cardiac pacemaker in the body is contraindication 3. Transthoracic stimulation should not be applied to patients with cardiac problems 4. Transthoracic stimulation should not be applied to patients with epilepsy 5. Pregnancy
Pulsed Electromagnetic Field 磁力脈衝	It is used for soft tissue healing, wound healing and pain management	Low frequency: <200Hz Intensity range: 1-5 Tesla Pulse width: <300μs	1. Cardiac pacemaker 2. Pregnancy 3. Malignancy 4. Active bleeding
High Voltage Pulsed Current 高壓脈衝電流	It is used to stimulate muscle contraction, for strengthening weak muscles.	Pulse durations: 200μs, interpulse interval: 9800 μs, frequency range: 1-	1. Cardiac pacemaker or metal implant in the body is contraindication. 2. Impaired circulation

	It is also used for wound healing and pain management.	100Hz, current voltage: 150-500V.	3. Impaired skin sensation 4. Pregnancy – not to apply near the womb
Laser 激光	It is used to treat soft tissue injury and pain conditions, suitable for small localized areas. For example, tennis elbow, heel spur.	Lasers used in Physiotherapy are usually in Class 2, 3A, 3B. Class 2: Low power (up to 1mW) Class 3A: Low-medium power (up to 5 mW) Class 3B: Medium up to 500mW Two common types: Helium-neon and diode lasers, Wavelengths in 600 – 1600 nm	Class 2 – safe on skin and eyes (no need goggles but avoid prolonged exposure) Class 3A (protective goggles advised) Class 3B (protective goggles must be worn) Other contraindications include defective e circulation, skin sensation, pregnancy, cancer etc.
Shortwave Diathermy 短波頻	It is used to treat joint pain, reduce swelling in muscles, improve circulation. It produces a deep form of heating through muscles and joints.	Frequency: 10-30 MHz (10^6) Wavelength: 7-22m Power Output range: 0-1000 Watts	1. Cardiac pacemaker or metal implant in the body is absolute contraindication. 2. Metal in the clothing 3. Circulatory disease or active bleeding will also cause increased risk of excessive bleeding. 4. Defective skin condition or devitalized skin may also increase risk of getting burn. 4. Eyes and genital organs should be avoided. 5. Pregnant women –avoid over womb area.
Cryotherapy 冷凍治療	Usually applied in the form of an ice pack to one body region.	Applications of ice pack usually last 15-20 mins Skin temperature may drop from 30°C to 5-10°C	If this is applied over large body area (e.g. whole body cryotherapy), it may cause a drop in core body temperature, and result in large change in blood pressure, and for those who

		Muscle temperature may drop from 35^{o}C to 25 ^{o}C	have heart disease, it may possibly cause a heart attack.
Infrared Lamp (IR) 紅外線	It is used to produce superficial heating of skin and superficial muscles for reducing pain and inflammation.	Infrared lamps should be kept at a distance from the skin. Near IR: 760-1500nm Far IR: 1500-15,000nm Lamps come as "luminous" or "non-luminous" – can contain a mixture of near and far IR. Power: 200-1500 Watts	1. Recommended distance is 50-80cm from the skin. 2. Metal in the area 3. Defective circulation 4. Acute skin disease (e.g. dermatitis, eczema) 5. Superficial infection or tumours 6. Prolonged exposure can cause eye damage