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. **HKPA 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, or microcurrent, or ultra-sound. 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. HKPA showed great concerns that **public interests will still be at risk** with the proposed regulatory framework. **Further refinement on the types of medical devices** subjected to be controlled, the proposed use control and their respective use control categories are required before the setting up a new bill **for a real protection to the public interest**. 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. **Several incidents by the proposed classified Category IV device resulting in death** have terribly more frequently been reported and thus more stringent control has been urged by the public http://hk.apple.nextmedia.com/news/art/20150622/19193706

4. The Latest Proposed Regulatory Framework as stipulated in page 7 of the captioned LC Paper is related to regulatory framework for **medical devices in general**. **Unexpectedly, the proposed two levels of use control is based on the category (Category II and III) and the recommendation of the Study, which is ONLY a study for safe and effective operation of 20 types of specified medical devices for cosmetic purpose**, as prepared by the ECRI Institute in Sep 2016. Therefore, international reference on regulatory framework for medical devices should be benchmarked in the legislation process.

   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' life 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. 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.

6. 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.

7. 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.

8. 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.