中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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香港中區
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立法會綜合大樓
美容業儀器規管和發展事宜聯合小組委員會秘書
黃安琪女士

黃女士：

立法會衞生事務委員會及工商事務委員會
美容業儀器規管和發展事宜聯合小組委員會
2019年3月25日會議的跟進事項

多謝你於本年3月26日致食物及衞生局局長的信件，本人獲授權回覆如下。

醫療儀器的分級

2. 建議的醫療儀器法定規管制度是根據國際醫療器械監管機構論壇(下稱「IMDRF」)(前身為全球協調醫療儀器規管專責小組(GHTF))建議的醫療儀器分級制度，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。IMDRF的分級制度是一個基於規則的系統，透過運用一系列以多種方式組合的準則來釐定儀器的風險等級，例如儀器與身體接觸之時間、侵入程度及局部與全身效應等。我們並不知悉有司法管轄區所採用的醫療儀器分級系統，只基於能量

輸出水平、原擬用途或原擬使用者為醫療儀器分級。

3. 就以能量輸出水平、原擬用途或原擬使用者等準則來區分用於美容程序的醫療儀器(有時也被稱為「美容儀器」)及其他醫療儀器，政府已在較早時向衞生事務委員會(2017年7月的立法會CB(2)1769/16-17(01)號文件)以及聯合小組委員會(2019年3月的立法會CB(4)671/18-19(01)號文件)提交的資料文件中闡述有關考慮因素。

醫療儀器在其他司法管轄區的定義

4. 就來信提及的七個司法管轄區，即澳洲、加拿大、歐盟、日本、內地、南韓及美國(以下統稱為「七個司法管轄區」)，他們對醫療儀器的定義均與IMDRF所建議的定義類似。除了儀器製造商所擬訂用於診斷、治療或監察疾病及傷勢的儀器外，上述司法管轄區的醫療儀器定義也涵蓋用以替補或調節相關的身體結構或生理過程的儀器。有關司法管轄區對醫療儀器的定義載於**附件A**。

醫療儀器在其他司法管轄區的銷售核准證明

5. 設有醫療儀器規管制度的司法管轄區均要求醫療儀器推出市面前須獲得批准，以確保醫療儀器為安全、有質素和符合廠方訂定的效能。在適用情況下，申請人必須提交證明文件(例如製造商的品質管理系統、技術文件摘要、符合基本原則核對表、風險評估報告、臨床評估報告、認證評核證書、其他司法管轄區的銷售核准證明等)以證明醫療儀器的安全性、質素和性能。在發出醫療儀器銷售核准證明前，監管機構會對申請資料進行審查或評估。在某些司法管轄區(例如歐盟和日本)，監管機構會指定第三方機構(相當於建議的醫療儀器規管制度下的認證評核機構)對醫療儀器進行認證評核，以證明該儀器符合安全和性能要求，但監管機構仍保留醫療儀器註冊的最終決定權。

6. 事實上，七個司法管轄區就醫療儀器安全和性能要求的規管架構與IMDRF的建議十分相似。醫療儀器在這些司法管轄區獲得銷售核准證明的詳細程序載於**附件B**的超連結。根據最新的規管建議，政府建議接受已獲得七個司法管轄區

中至少一個的銷售核准證明的醫療儀器直接申請註冊，不論該醫療儀器是否在這些司法管轄區內製造或進口到這些司法管轄區，以省卻須由第三方認證評核其安全及性能的要求。該措施在不影響認證評核質素的情況下，可減省業界遵守法定規定所需的工作，並降低把醫療儀器推出本地市場的成本。

7. 如有任何查詢，請致電3509 8957與本人聯絡。

食物及衞生局局長

(羅盈盈 代行)

2019 年 4 月 24 日

附件 A

七個司法管轄區對醫療儀器的定義

司法管轄區	醫療儀器的定義	來源
澳洲*	A medical device is any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological process; (iv) control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.	s41BD, Therapeutic Goods Act 1989
加拿大*	Device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals, (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals, (c) diagnosing pregnancy in human beings or animals, (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring,	s2, Food and Drugs Act

司法管轄區	醫療儀器的定義	來源
	including caring for the offspring, or (e) preventing conception in human beings or animals; however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.	
	Medical device means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.	s1, Medical Devices Regulations
歐盟*	Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: - devices for the control or support of conception;	Article 2(1), Regulation (EU) 2017/745

司法管轄區	醫療儀器的定義	來源
	- products specifically intended for the cleaning, disinfection or sterilisation of medical devices.	
日本*	The term "medical device" as used in this Act refers to appliances or instruments, etc. which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals (excluding regenerative medicine products), and which are specified by Cabinet Order. The term "in-vitro diagnostic" as used in this Act refers to pharmaceuticals intended exclusively for use in the diagnosis of diseases, which are not directly used in the bodies of humans or animals.	Cabinet Order. Law (PMD Act) No. 145 Chapter 1, Art. 2 paragraphs and 14
內地	醫療器械，是指直接或者間接用於人體的儀器、設備、器具、體外診斷試劑及校準物、材料以及其他類似或者相關的物品，包括所需要的電腦軟體；其效用主要通過物理等方式獲得，不是通過藥理學、免疫學或者代謝的方式獲得，或者雖然有這些方式參與但是只起輔助作用；其目的是： （一）疾病的診斷、預防、監護、治療或者緩解； （二）損傷的診斷、監護、治療、緩解或者功能補償； （三）生理結構或者生理過程的檢驗、替代、調節或者支持； （四）生命的支援或者維持； （五）妊娠控制； （六）通過對來自人體的樣本進行檢查，為醫療或者診斷目的提供資訊。	醫療器械監督管理條例，第七十六條
南韓*	Medical device, as referred to in this Act, shall mean any instrument/machine/device/material or other similar product, used alone or in combination, for human beings or animals, as specified in any of the following Subparagraph: provided that drugs and quasi-drugs, as defined in the Pharmaceutical Affairs	Article 2(1), Medical Device Act

司法管轄區	醫療儀器的定義	來源
	Act, and prosthetic limbs/aids among the assistive devices for persons with disabilities, as defined in the Act on Welfare of Persons with Disabilities Article 65, are excluded here from: 1. A product used for the purpose of diagnosis/cure/alleviation/treatment or prevention of disease; 2. A product used for the purpose of diagnosis/cure/alleviation or supplement of injury or impairment; 3. A product used for the purpose of test/replacement or modification of anatomy or physiologic function; or 4. A product used for the purpose of contraception.	
美國*	Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.	s321(h), Chapter 9, Federal Food, Drug, and Cosmetic Act, Subchapter II-Definitions

註：

* 該司法管轄區就醫療儀器的定義只有英文。

附件 B

在七個司法管轄區獲得醫療儀器銷售核准證明的程序

司法管轄區	獲得醫療儀器銷售核准證明的程序
澳洲*	https://www.tga.gov.au/how-make-application-through-tga-ebusiness-services
加拿大*	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-complete-application-new-medical-device-licence.html
歐盟*	歐盟成員國獲授權實施歐盟醫療儀器監管框架。例如，在英國： https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements
日本*	https://www.pmda.go.jp/english/review-services/reviews/0001.html
內地	http://www.nmpa.gov.cn/WS04/CL2201/325754.html
南韓*	https://www.mfds.go.kr/eng/wpge/m_39/de011026l001.do
美國*	https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/

註：上述網站於 2019 年 4 月 15 日瀏覽。

* 該司法管轄區就獲得醫療儀器銷售核准證明許可的程序只有英文。