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

Our Ref.: FH CR 6/3921/09 Tel.: 3509 8957
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24 April 2019

Ms Angel Wong
Clerk to Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Ms Wong,

Panel on Health Services and Panel on Commerce and Industry
Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry

Follow-up to meeting on 25 March 2019

Thank you for your letter of 26 March 2019 to the Secretary of Food and Health. I am authorised to reply on her behalf.

Classification of medical devices

2. The proposed statutory regulatory regime for medical devices adopts a risk-based approach whereby the level of control would be proportional to the

degree of risk associated with the medical devices according the recommended classification scheme of the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force ("GHTF")). The IMDRF classification scheme is a rule-based system that uses a set of criteria that can be combined in various ways in order to determine the risk class of the devices, e.g. duration of contact with the body, degree of invasiveness, and local versus systemic effect, etc. We are not aware of any jurisdiction that has adopted a classification system for medical devices that is solely based on energy output level, intended purposes or intended users.

3. As regards "delineating" medical devices used in cosmetic procedures (i.e. sometimes referred to as "beauty devices") from other medical devices based on energy output level, intended purposes or intended users, our considerations have been set out in previous submissions to the Panel on Health Services (via LC Paper No. CB(2)1769/16-17(01) in July 2017) and the Joint Subcommittee (via LC Paper No. CB(4)671/18-19(01) in March 2019).

Definition of medical device in other jurisdictions

4. The definitions of medical devices in the seven jurisdictions mentioned in your letter, namely Australia, Canada, the European Union, Japan, Mainland China, South Korea and the United States (hereafter collectively referred to as the "Seven Jurisdictions"), are similar to the one recommended by the IMDRF. In addition to devices intended by the manufacturers to be used for diagnosis, treatment or monitoring of diseases and injuries, the definitions of medical device in the above-mentioned jurisdictions also cover devices that are used for the purposes of replacement or modification of related body structures or physiological process. The definitions of medical device in these jurisdictions are at **Annex A**.

Marketing approval for medical device in other jurisdictions

5. To ensure a medical device is safe, of good quality and performs as intended, jurisdictions with a regulatory regime for medical devices in place subject medical devices to pre-market approval requirements. Applicants have to submit documentary evidence where applicable (e.g. quality management system of the manufacturer, summary of technical documents, essential principles checklist, risk assessment report, clinical evaluation report,

conformity assessment certificate, marketing approvals in other jurisdictions, etc.) to demonstrate the safety, quality and performance of the medical devices. These submissions would undergo review or assessment conducted by the regulatory authority before the devices are granted marketing approvals. In some jurisdictions (e.g. the European Union and Japan), the regulatory authority designates third parties (equivalent to the Conformity Assessment Bodies under the proposed medical device regulatory regime) to carry out conformity assessment to certify compliance with safety and performance requirements, but the final decision on device registration remain with the regulatory authority.

6. In fact, the regulatory frameworks of the Seven Jurisdictions related to the safety and performance requirements of medical devices are similar to those recommended by the IMDRF. Please refer to the hyperlinks at **Annex B** regarding the process for obtaining marketing approval for medical device in these jurisdictions. Under the latest regulatory proposal, we propose accepting direct application for registration of medical devices which have acquired marketing approvals from at least one of the Seven Jurisdictions, regardless of whether the device is manufactured in or imported into these jurisdictions, thereby sparing the requirement for third-party conformity assessment. The measure will minimise the efforts of the industry in complying with the statutory requirements and reduce the costs for placing medical devices in the local market without compromising the quality of conformity assessment.

7. For enquiries, please contact me at 3509 8957.

Yours sincerely,

(Miss Anita Lo)
for Secretary for Food and Health

Annex A

Definition of medical device in the Seven Jurisdictions

Jurisdictions	Definition of medical device	Source
Australia	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
Canada	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

Jurisdictions	Definition of medical device	Source
	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
European Union	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:	Article 2(1), Regulation (EU) 2017/745

Jurisdictions	Definition of medical device	Source
	- devices for the control or support of conception; - products specifically intended for the cleaning, disinfection or sterilisation of medical devices.	
Japan	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, Article 2 paragraphs 4 and 14
Mainland China	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

Jurisdictions	Definition of medical device	Source
South Korea	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 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.	Article 2(1), Medical Device Act
United States	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

Annex B

Procedure for obtaining marketing approval for medical device in the Seven Jurisdictions

Jurisdictions	Procedure for obtaining marketing approval for medical device
Australia	https://www.tga.gov.au/how-make-application-through-tga-ebusiness-services
Canada	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
European Union	Member States are conferred the authority to implement the European Union medical device regulatory framework. For example, in the United Kingdom: https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements
Japan	https://www.pmda.go.jp/english/review-services/reviews/0001.html
Mainland China	http://www.nmpa.gov.cn/WS04/CL2201/325754.html
South Korea	https://www.mfds.go.kr/eng/wpge/m_39/de011026l001.do
United States	https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/

Note: The above websites were accessed on 15 April 2019.