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
Your ref:

Tel no: 3509 8957
Fax no: 2840 0467

10 July 2017

Ms Maisie LAM
Clerk to Panel
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Hong Kong
(Fax: 2185 7845)

Dear Ms LAM,

Legislative Council Panel on Health Services

Motions passed in relation to the Administration's proposed regulatory framework for medical devices

We refer to the motions passed at the meeting of Legislative Council Panel on Health Services (the Panel) on 28 February 2017. In response to the three motions moved by Dr Hon Elizabeth QUAT, Dr Hon Fernando CHEUNG Chiu-hung and amended by Dr Hon Junius HO Kwan-yiu, as well as Hon SHIU Ka-fai respectively, our consolidated reply in consultation with the Department of Health (DH) is as follows.

Differentiation between "medical devices" and "cosmetic devices"

2. We understand from the engagement with the beauty industry

over the past few months that the industry also attaches great importance to the safety of clients and does not object to the introduction of registration and regulatory regime for devices used for cosmetic purposes. However, the industry considers devices solely used for cosmetic purposes are not medical devices and suggests a separate regulatory regime.

3. The purpose of our proposal to regulate medical devices is to ensure the safety, quality, performance and efficacy of medical devices under the premise of protecting public health while enabling our community's continued access to the benefits of new technologies. When considering the definition of "medical devices" under the proposed regulatory framework, it is necessary to take reference from the definition widely adopted by the international society so as to bring Hong Kong on par with international development and regulatory trends of the manufacture, import, distribution, sale and use of medical devices. Therefore, we propose adopting the comprehensive definition of medical devices formulated by the International Medical Device Regulators Forum (IMDRF). That is, the term "medical device" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It also covers devices that are used for the purposes of investigation, replacement, modification or support of the anatomy or physiological process of the human body. Therefore, if a device is intended for use on the person to replace or modify related structures (e.g. damage or remove the undesirable tissues and cells) or physiological process (e.g. enhance skin absorption of certain substances) whereby a more satisfactory body state is attained (e.g. aging skin tissues replaced with newer regenerated tissues, subcutaneous tissues with less fat after destruction of adipose cells via absorption and metabolism of the released fat) to give a better appearance, the device is a "medical device" by definition.

4. Many advanced jurisdictions/regions such as the United States of America (USA), Canada, Australia, Japan, Mainland China and Singapore etc. have also included devices used for cosmetic purposes and met the definition of "medical devices" under the local regulatory framework for medical devices to protect public health. The technology deployed; energy output; theory in producing effects; and risks used on

human body of these devices are similar to those of the medical devices intended for treatment or rehabilitation. Recently, in order to align the understanding regarding definition of medical devices in European countries, the European Union (EU) has indicated in the revised directives that certain aesthetic devices including electromagnetic field emitting devices for skin rejuvenation and hair removal (e.g. laser and intense pulse light device); and devices which reduce, remove or damage fats, should be regarded as medical devices and are subject to the EU's Medical Device Directives.

5. That said, the beauty industry in general does not agree that if devices used for cosmetic purposes meet the definition of "medical device", they should be regulated as medical devices. They consider that the Administration should delineate "medical devices" and "beauty devices" by energy output; intended purposes or intended users etc., and formulate less stringent registration requirements for "cosmetic devices". We have thoroughly considered the suggestion made by the industry, gathered information from other regions; as well as consulted local industry to attempt the differentiation of devices by their energy output, intended purposes and intended users. However, the proposal is impractical as detailed in ensuing paragraphs.

Energy output level

6. For devices adopting the same technology, it is difficult to differentiate cosmetic devices from medical devices by level of energy output as there can be overlap in the range of energy output of these devices or the parameter may be similar. At the same time, there is no standardized format in specification on the energy output level internationally. Also, the risk of a device is not only dependent on its energy output level. Other factors may also affect the risk, for example, the design of the device, the operating mode (such as pulse mode or continuous mode), the duration of the treatment, etc.

Intended purposes

7. Many devices that are not intended for treating diseases could also be considered as medical devices. Also, it is arguable if some

intended uses, for example, treatment of acne, scars, pigmented and vascular lesions of the skin, etc., are "medical purposes" or "cosmetic purposes".

Intended users

8. Healthcare professionals are not necessarily the only users of medical devices. Many medical devices, such as insulin pump and positive airway pressure machines, are used by patients themselves or with assistance of their family members. Besides, many automated external defibrillators (AED) are intended for use by trained members of the public. Therefore, we cannot conclude that a device intended for use by beauty practitioners is not a medical device.

9. Against the above considerations, in case the devices used for cosmetic purposes meet the IMDRF's definition of "medical device", they should be regarded as medical devices and be regulated under the proposed legislation for medical devices. However, the beauty industry is quite concerned because some devices used for cosmetic purposes in the market now do not fulfill the "Essential Principles of Safety and Performance of Medical Devices", thus will not be able to fulfill the registration requirements under the proposed regulatory framework. In light of the situation of related cosmetic devices, the Food and Health Bureau (FHB) and the DH have studied feasible proposal to facilitate the industry in complying with the regulatory requirements under the premise of protecting public health. The enhanced proposal was presented at the exchange session with device traders on 12 May 2017.

Enhanced proposal

10. We understand from some stakeholders of the beauty industry that if the proposed statutory regulatory framework adopts the registration requirements under the voluntary Medical Devices Administration Control System (MDACS) set up by the DH in 2004, a number of medical devices used for cosmetic purposes will not be able to fulfill the registration requirements. We take note of the actual situation of the beauty industry, and understand that majority of cosmetic devices

manufacturers have been recognized for "Good Manufacturing Practice" by local regulatory authorities although they do not fulfill MDACS's requirements regarding Quality Management System. We also note that the concerned devices have also acquired home country marketing approvals as a proof in attaining medical device standard. Therefore, under the premise of achieving safety, quality, efficacy and efficiency, we propose adjusting the statutory registration requirements for medical devices as appropriate so that most up-to-standard cosmetic devices can also be registered.

11. Besides, we suggest establishing a "listing mechanism" under the enhanced proposal for devices used for cosmetic purposes but cannot fulfill the refined registration requirements for medical devices at set out in paragraph 10 above. Devices applied for listing must be active devices (e.g. source of power other than human power or gravity), and only be supplied for use by beauty practitioners or the public. Under the proposed "listing mechanism", the agent of concerned device has to register with the DH as the authorized representative before filing the listing application to the DH. It also has to furnish the required documents, such as proof of the qualification of the manufacturer (e.g. ISO 9001 or other establishment registration/licence issued by overseas regulatory authorities); proof of home country approvals (e.g. Certificate of Free Sale or Certificate to Foreign Government etc.); as well as other supporting documents. Listed devices should also comply with the advertisement and labelling requirements under the legislation for medical devices. In order to let the public understand the differences between registered devices and listed devices, we will specify in the legislation that the listed devices have not been demonstrated to be in compliance with the "Essential Principles of the Safety and Performance of Medical Devices".

12. With reference to international experience, we consider that products fall under definition of "medical devices" should be regulated as medical devices. Considering the actual situation and operation of the beauty industry, we will not set a definite time limit for the listing mechanism under the proposed legislation for medical devices. When the listing mechanism has been in place for a period of time, we will evaluate the mechanism taking into account the market situation.

Use control for specified medical devices

13. The Administration received views and concerns from different sectors on the regulation of medical devices over the past few months. We understand that consensus over the part on "use control" may not be reached any time soon. As the general public expects that "pre-market control" and "post-market control" for medical devices can be introduced as soon as practicable, the Administration will first focus efforts to take forward the legislative work on the above two areas. After we have made substantive progress on the legislative proposals for "pre-market control" and "post-market control", we will revisit and consider the issues of use control categorization of specified medical devices and related matters with regard to the latest situation. Therefore, when drafting the current bill on medical devices, we will not include the part related to "use control".

Overall development of the beauty industry

14. As for other issues concerning the development of beauty industry such as promoting the professionalization of beauticians and monitoring of trade and sales practices, they fall outside the policy purview of the FHB.

15. We thank Members for their attention to this matter.

Yours sincerely,

(Miss Yvonne TAM)
for Secretary for Food and Health

c.c. Director of Health
(Attn: Assistant Director (Special Health Services))