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.: CB4/PS1/18

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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 2 May 2019

Thank you for your letter of 7 May 2019 to the Secretary of Food and Health. I am authorised to reply to your letter.

Classification of medical devices by energy output level, intended purposes and intended users

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. Due to the large number and wide variety of medical devices, it is not possible to use a simple matrix system to map the risk into a risk class. Taking reference from the regulatory frameworks in overseas jurisdictions, the risk classification of medical devices will adopt the rule-based system recommended by the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force ("GHTF")). The classification scheme uses a set of criteria that can be combined in various ways in order to determine the risk classification, 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 purpose or intended users.

3. The full set of classification rules for general medical devices ("General MDs") and in vitro diagnostic medical devices ("IVDMDs") have been published by the Department of Health ("DH") under the voluntary Medical Device Administrative Control System ("MDACS") set up in 2004 and can be accessed online[1]. A web-based tool is also available on the webpage[2] of the DH to facilitate users to determine the risk classes of General MDs and IVDMDs.

Number of complaints relating to beauty services

4. The Consumer Council does not maintain complaint statistics related to cosmetic procedures. The numbers of complaints on beauty services in general received by the Consumer Council are 1 147 and 1 058 in 2017 and 2018 respectively, and 307 from 1 January to 30 April 2019. In addition, the Medical Device Control Office under DH handled 32 and 14 enquires/complaints related to beauty services in 2017 and 2018 respectively.

5. As there could be many possible factors contributing to "beauty service incidents" (e.g. use errors, device problems, client factors), we do not have information on beauty service incidents specifically arising from lack of

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[1] Please refer to https://www.mdco.gov.hk/english/mdacs/mdacs_gn/files/TR003E.pdf for general MDs and https://www.mdco.gov.hk/english/mdacs/mdacs_gn/files/TR-006E.pdf for IVDMDs.

[2] For the web-based tool, please refer to https://www.mdco.gov.hk/english/faq/question.html for general MDs and https://www.mdco.gov.hk/english/faq/ivdquestion.html for IVDMDs.

regulation on "beauty devices".

List of to-be-regulated "beauty devices" to be operated by registered medical practitioners and/or by trained beauty practitioners

6. As reported to the Panel on Health Services via LC Paper No. CB(2)1787/17-18(03) in July 2018, the current legislative proposal will focus on "pre-market control" and "post-market control" and will not include the "use control" of specified medical devices (i.e. not to restrict the use of specific types of medical devices to users with certain qualification). Meanwhile, the Government will continue to maintain communication with the stakeholders in mapping out the way forward.

List of manufacturers exporting non-registered "beauty devices" to Hong Kong and the exported "beauty devices"

7. We do not have information on manufacturers exporting non-registered "beauty devices" to Hong Kong and the exported "beauty devices". We note that some medical devices with beauty application listed under the MDACS (e.g. high intensity focused ultrasound ("HIFU"), laser, intense pulsed light ("IPL"), radiofrequency, cryotherapy) could be found under the medical device registries of other jurisdictions e.g. Australia, Canada, South Korea and the United States.

Yours sincerely,

(Fung Long-yin)
for Secretary for Food and Health