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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22 March 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 26 February 2019

Thank you for your letter dated 27 February 2019 to the Secretary of Food and Health. The Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry held its meeting on 26 February 2019. The Administration was requested to provide supplementary information and our response is set out in the ensuing paragraphs.

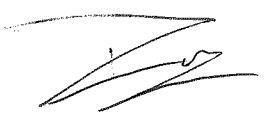
2. The purpose of the regulatory proposal of medical device is to ensure the safety, quality, performance and efficacy of medical devices supplied in Hong Kong under the premise of protecting public health while ensuring continued access to the benefits of new technologies. When considering the definition of "medical devices", it is necessary to take reference from that widely adopted by the international society so as to bring Hong Kong on par with

international development and prevailing regulatory practice of manufacture, import, distribution and supply of medical devices.

3. To this end, the Government proposes to adopt the definition of "medical device" as recommended by the International Medical Device Regulators Forum ("IMDRF") (previously known as the Global Harmonization Task Force ("GHTF")). Under the proposed definition, the term "medical device" refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of disease and injuries. It also covers devices that are used for the purposes of replacement or modification of related body structures or physiological process whereby a more satisfactory body state is attained to give a better appearance.

4. Given that the devices used in cosmetic procedures (i.e. sometimes referred to as "beauty devices") are similar to those medical devices that are intended for treatment or rehabilitation in terms of the technology deployed, mechanism of action and risks profile on human body, many advanced jurisdictions such as Australia, Canada, the European Union, the United States and South Korea, as well as the Mainland, have included "beauty devices" meeting the definition of "medical devices" under their local regulatory framework for medical devices to protect public health. These countries recognise that these "beauty devices" can cause the same potential side-effects and risks as medical devices with therapeutic purposes such as burn, scarring, permanent disfigurement and eye damage, and that they should be regulated under the same regulatory system to ensure equal level of safety and performance. In fact, the scope of medical devices used in cosmetic procedures is not limited to beauty "machines" as it also covers products like dermal fillers and breast implants. The mere fact that these "beauty devices" improve the external appearance only does not preclude them from having a profound impact on the health and wellbeing of the consumers. We have not identified any jurisdictions with a separate regulatory system for "beauty devices", and are not aware of jurisdictions with a regulatory regime of medical devices in place which do not regulate "beauty devices" as part of the regime.

Yours sincerely,



(Ronald Ho)
for Secretary for Food and Health