For information
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Legislative Council Panel on Health Services and
Panel on Commerce and Industry

Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of Beauty Industry

Regulation and Use of Medical Devices Including those for use in Cosmetic Procedures

Purpose

This paper outlines the proposed framework for the regulation of medical devices including those for use in cosmetic procedures.

Regulation of medical devices

2. To protect public health while ensuring continued access to the benefits of new technologies, the Government has planned to introduce a statutory regime for the regulation of medical devices. We last briefed the Legislative Council Panel on Health Services (the "Panel") on 16 July 2018 on the development on the proposed regulatory regime (vide LC Paper No. CB(2)1787/17-18(03)).

3. 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.

4. 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 Harmonisation Task Force [1]

[1] GHTF was formed in 1992 by regulatory authorities and trade representatives of the United States, Canada, Australia, Japan and the European Union to harmonise the standards and principles of regulating medical devices.

("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.

Differentiation between "medical devices" and "beauty devices"

5. While the purpose of certain medical devices used in cosmetic procedures (i.e. sometime referred to as "beauty devices") is to enhance physical appearance, they bring about effect on human tissues and cells through the application of medical principles at the same time, similar to those medical devices intended for treatment or rehabilitation in terms of the technology deployed, mechanism of action and risk profile on human body.

6. Taking into account the fact that "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, 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 ensure equal level of safety and performance.

7. 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. The Governmenat has not identified any jurisdictions with a separate regulatory system for "beauty devices", and is not aware of jurisdictions with a regulatory regime of medical devices in place which do not regulate "beauty devices" as part of the regime.

8. Having critically reviewed the issue in delineating "beauty devices" from medical devices, the Government considers that segregating the regulatory regime for medical devices and "beauty devices" would not be practical (since the latter is invariably a subset of the former) and is inconsistent with the prevailing regulatory practices in other jurisdictions. The details of the considerations are set out in a written response to the Panel dated 10 July 2017

(via LC Paper No. CB(2)1769/16-17(01)), with relevant parts as extracted in the **Annex A**.

Latest legislative proposal for regulation of medical devices

9. The proposed regulatory framework adopts a risk-based approach whereby the level of control would be proportionate to the degree of risk classified for medical devices according to the recommended classification scheme of the IMDRF. It comprises pre-market control to ensure medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market; and post-market control to enable swift control measures against defective or unsafe medical devices. Details of the proposed regulatory framework for pre-market control and post-market control of medical devices are set out in **Annex B**.

10. To address some stakeholders' concerns that certain "beauty devices" commonly used by the industry at the moment may not be ready to fulfil the proposed registration requirements, the Government has offered the following refinements to the legislative proposal –

(a) the documentary evidence submitted for application assessment would be suitably adjusted to facilitate the registration of devices that have acquired marketing approvals from certain jurisdictions (e.g. Mainland China and South Korea) in addition to those approved by the founding members of the GHTF, which otherwise would require third-party conformity assessment to certify safety and performance requirements; and

(b) a 5-year transitional **"**listing mechanism**"** would be established for "beauty devices" which could not fulfil the registration requirements for medical devices. Within the 5-year window, Government can accept applications for listing. Devices that meet the listing requirement may qualify for a permit to be granted and/or renewed once every five years.

11. The Government will monitor the implementation of the listing system taking into account the local situation. We believe that the transitional arrangement would allow the industry to migrate to and familiarise with the statutory registration regime, with a view to raising the standard of "beauty devices" in Hong Kong in the long run.

12. Taking into account the feedback from stakeholders during the consultation, the current proposal would focus on pre-market control and post-market control and would not include use control of specified medical devices (i.e. not to restrict the use of specific types of medical devices to users with certain qualifications). The Government would revisit the issue of use control of specific medical devices and related matters at a later stage and would maintain close communication with the stakeholders in mapping out the way forward.

13. The Government is working on the Medical Devices Bill (the "Bill") on the basis of the above proposal. We aim to introduce the Bill into the Legislative Council in the current legislative session.

Advice sought

14. Members are invited to note the content of the paper.

Food and Health Bureau
Department of Health
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Annex A

Considerations in Not Segregating the Regulatory Regime for Medical Devices and "Beauty Devices"

Extract from the LC Paper No. CB(2)1769/16-17(01)

Energy output level

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 standardised 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

2. 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

3. 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 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.

Annex B

Proposed Regulatory Framework for Pre-market Control and Post-market Control of Medical Devices

Pre-market control

Pre-market control is levied on two dimensions, viz, the medical devices and the traders that introduce the medical devices into the local market. It also includes other ancillary issues such as labelling and advertisement associated with the medical devices.

Registration of medical devices

2. Following the risk-based approach, the Government will not impose registration requirement on Class I general medical devices / Class A in vitro diagnostic medical devices ("IVDMDs") due the low risk posed. For Class II-IV general medical devices and Class B-D IVDMDs, they are required to be registered with the DH before they can be supplied to the market. Registration of a medical device will be granted for a period of five years, and can be renewed every five years. Moreover, a registered medical device can only be supplied for the purpose(s) as approved by the DH.

3. Without compromising public health, the proposed regulatory framework will allow the supply of unregistered medical devices under special circumstances and must be with prior approval granted by the DH as required. Examples of special circumstances include the medical devices supplied for the purpose of clinical trial; for non-clinical purpose like exhibition; on a named-patient due to special needs; or under public health emergencies.

Listing of medical devices

4. The Government proposes to establish a "listing mechanism" for "beauty devices" which could not fulfill the registration requirements for medical devices. A device would only qualify for listing if it is a Class II or III non-invasive general medical devices the operation of which depends on a source of electrical energy, which may be used by the beauty industry or the public for the purpose of modifying the anatomy or physiological process of skin of a person to preserve, restore or enhance physical appearance; and complies with the safety

and labelling requirements stipulated by the Director of Health (for example general requirements for household and electrical appliance). The trader has to furnish the required documents, such as proof of the qualification of the manufacturer (for example ISO 9001 or other establishment registration/licence issued by overseas regulatory authorities), proof of home country approvals (for example Certificate of Free Sale or Certificate to Foreign Government, etc.), as well as other supporting documents. Listed devices should also comply with the advertisement requirements under the proposed legislation for medical devices.

5. As set out in paragraph 10(b) of the main paper, a 5-year transitional period will be allowed for the "listing mechanism". Within the 5-year window, Government can accept applications for listing. Devices that meet the listing requirement may qualify for a permit to be granted and/or renewed once every five years. Beyond the 5-year transitional window, no new application for listing would be accepted.

Registration and licensing of traders

6. Traders including authorised representatives ("ARs"), local manufacturers, importers and distributors of medical devices must be registered with or have obtained a licence from the DH before they can supply medical devices in Hong Kong, regardless of whether the medical devices concerned are subject to registration or listing requirement. They will be subject to respective registration requirements or licensing conditions, which include holding a valid business registration certificate; maintaining a recognised quality management system ("QMS") for the supply of medical devices; and fulfilling any criteria as specified by the DH. They are also required to maintain a list of medical devices supplied by them in the local market and provide to DH upon request, as well as comply with the post-market requirements. The validity period of all trader registrations will be aligned to three years, which can also be renewed every three years.

7. Local manufacturers will be required to conform to QMS certification requirements. Having considered that ARs, importers and distributors are largely small and medium enterprises ("SMEs"), the Government plans to introduce a set of essential requirements for QMS for them to adhere to. The Government will further provide assistance to the traders (especially the SMEs) with support packages to fulfil the essential requirements. It is anticipated that

the compliance cost can be substantially reduced by using this approach.

Recognition of conformity assessment bodies ("CABs")

8. The proposed legislation will empower the DH to recognise CABs to perform conformity assessment on medical devices, as well as to provide third party conformity assessment services to traders. DH will monitor the performance of the recognised CABs regularly.

Labelling requirements and control over advertisements

9. To provide users with essential information for the proper and safe use of medical devices and to identify the traders which have been engaged in the supply of the medical devices concerned, medical devices will also be required to meet relevant labelling requirements. As for advertisement, misleading or fraudulent advertising of medical devices will be prohibited. Promotion of medical devices for use other than their approved use is also forbidden.

Appeal mechanism

10. An appeal board with members comprising representatives from the medical devices industry, medical associations, engineering institutions and academic institutes appointed by the Secretary for Food and Health would be set up to handle appeals relating to registration of medical devices, licence issuance and CAB recognition.

Import / export control

11. As reported to the Panel in 2014, in view of the concerns about the amount of administrative work involved, and the overall lead-time required for importing products, especially for fast moving consumer goods, the Government proposes not to introduce any import / export licensing control for medical devices.

Post-market control

12. As the responsibility of the trader for the safety of a medical device does not end when it is put on the market, there will be a post-market surveillance

system to monitor the performance of devices and reporting of problems associated with the use of devices. It is a general duty of ARs, local manufacturers, importers and distributors of medical devices, as well as suppliers of unregistered medical devices in accordance with the specified exemption conditions, to maintain records of supply and produce such records to the DH for inspection upon request. As for certain high-risk medical devices, ARs are also required to put in place a system to track these devices down to patient level or down to a level stipulated by the DH. Traders are also subject to mandatory requirements for reporting adverse incidents associated with the medical devices and investigation results, as well as implementing remedial measures to the satisfaction of the DH.