For Discussion on
16 July 2018

Legislative Council Panel on Health Services
Proposed Regulatory Framework for Medical Devices

PURPOSE

This paper briefs Members on the latest development on the legislative proposal on regulation of medical devices.

BACKGROUND

2. Unlike many advanced economies or health regimes, there is currently no specific legislation or statutory regime to regulate the manufacture, import, distribution, supply and use of medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionising radiation[1]. A voluntary administrative regime has been introduced since 2004. The Administration last briefed the Legislative Council Panel on Health Services (the Panel) on 16 January 2017 on the proposed regulatory framework for medical devices (vide LC Paper No. CB(2)545/16-17(01)).

3. Since then, some stakeholders reiterated concerns that certain medical devices used in cosmetic procedures (i.e. the so-called "cosmetic devices") are unable to fulfil the proposed registration requirements. They suggested delineating such devices by energy output levels, intended purposes, intended users, etc. for regulation under a separate regulatory regime. Having critically reviewed the suggestion, we are satisfied that segregating the regulatory regime for medical devices and so-called "cosmetic devices" would not be practical (since the latter is invariably a subset of the former) and would be inconsistent with the prevailing regulatory

[1] Devices which contain pharmaceutical products or emit ionising radiation are respectively regulated under the Pharmacy and Poisons Ordinance (Cap. 138) and the Radiation Ordinance (Cap. 303).

practices in most other jurisdictions[2]. We have set out our considerations in a note for the Panel dated 10 July 2017 (referenced LC Paper No. CB(2)1769/16-17(01)). We have nonetheless offered the following refinements to the legislative proposal –

(a) the application procedure **streamlined** with documentary evidence submitted for 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 Global Harmonisation Task Force (GHTF)[3] (now the International Medical Device Regulators Forum (IMDRF)), which otherwise would require third-party conformity assessment to certify safety and performance requirements;

(b) a **"listing mechanism"** would be established for "cosmetic devices" which could not fulfil the registration requirements for medical devices; and

(c) the current legislative proposal on medical devices would focus on **"pre-market" and "post-market" control**, and would not include **"use control"** of specified medical devices pending further discussions with stakeholders.

THE REFINED PROPOSAL

4. Details of the proposed regulatory framework as refined are explained below.

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2 The regulatory frameworks of Australia, Canada, Mainland China, the United States as well as the new EU Medical Device Regulation invariably include and regulate the so-called "cosmetic devices" as medical devices.

3 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.

PRE-MARKET CONTROL

5. Pre-market control is to ensure that the medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market. The proposed regulatory framework as set out in the Panel paper of 16 January 2017 is extracted at **Annex A**. It will incorporate two refined features –

(a) streamlining application procedure by adjusting documentary evidence submitted for registration of medical devices, and

(b) introducing a transitional listing system for medical devices.

Pre-market control will also be imposed on traders/suppliers of medical devices in Hong Kong through registration or licensing arrangements.

Adjusting Documentary Evidence Submitted for Registration of Medical Devices

6. Following the risk-based approach[4], the proposed regulatory framework will impose registration requirement on higher-risk general medical devices and in vitro diagnostic medical devices (IVDMDs)[5] before they can be supplied to the local market. Among these devices, some devices may alternatively be listed under the transitional listing system (see paragraphs 10 to 14 below). Other lower-risk general medical devices and IVDMDs[6] are **not** required to be registered. Nevertheless, traders of such medical devices will still be required to obtain relevant licence(s) from the DH and fulfil trader requirements including compliance with product recall notices and record keeping requirements. A local trader of the medical device must register with the DH as the authorised representative (AR) before filing the registration application to the DH.

7. Having considered that many ARs are small and medium-sized enterprises, the Government plans to adjust the documentation requirements

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4 The level of control applicable to a medical device will be proportional to the degree of risks classified for the medical device with reference to the definition of "medical device" and classification scheme as recommended by the former Global Harmonisation Task Force (GHTF), now the International Medical Device Regulators Forum (IMDRF) at **Annex B.**

5 i.e. Class II, III and IV general medical devices and Class B, C and D IVDMDs.

6 i.e. Class I general medical devices and Class A IVDMDs.

for registration of medical devices by phases without compromising the quality of conformity assessment. Under the refined proposal, in the initial phase, DH plans to accept direct application for registration medical devices which have acquired marketing approvals from the Mainland and South Korea, in addition to those approved by founding members of the GHTF (now IMDRF), sparing the requirement for third-party conformity assessment.

8. The Government will also implement administrative measures and provide assistance to traders, such as training workshops and standard templates for applications so as to reduce the costs for placing medical devices in the local market and minimise their efforts in complying with the statutory requirements.

9. While public safety is overriding, we recognise the need to avoid unnecessary business interruption. Our preliminary proposal is for the permit for each medical device to be granted and/or renewed every five years.

Introducing a Transitional Listing System for Medical Devices

10. We propose to introduce a transitional listing system so that those medical devices falling short of the registration requirements but still complying with basic listing requirements set by DH, can still be tolerated for supply and use for a short period. For the better protection of public interest, the ultimate target is for **all** medical devices for use in Hong Kong to **fully** meet all registration requirements.

11. A device would only qualify for listing if –

(a) it is a Class II or III non-invasive active[7] general medical device, 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 (the classification of medical devices is at **Annex B**); and

(b) it complies with the safety and labelling requirements stipulated by

[7] Active medical device means a device whose operation depends on a source of power other than human power or gravity, e.g. electrical energy.

the Director of Health (e.g. general requirements for household and electrical appliance).

As with registrable medical devices, a local trader of the concerned device must register with the DH as the AR before filing the listing application to the DH.

12. Taking into account views of the stakeholders, we propose to limit the transitional period to five years. Within the five-year transitional 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.

13. Beyond the five-year transitional window, Government will not allow new applications for devices to be listed. Devices that have been listed within the five-year transitional window may still be subject to renewal of the listing status.

14. 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 "cosmetic devices" in Hong Kong in the long run.

POST-MARKET CONTROL

15. It is the responsibility of the trader in ensuring the safety of a medical device supplied in the market. There is a need for a post-market surveillance system to monitor the performance of devices and reporting of problems associated with the use of devices, in other words, to enable swift control measures against defective or unsafe medical devices. It is a general duty of suppliers of medical devices (including ARs, local manufacturers, importers and distributors of registered and listed medical devices) to maintain records of supply and produce such records to the DH for inspection upon request. As for certain high-risk medical devices (e.g. implantable pacemakers), ARs are also required to put in place a system to track these devices down to patient level or as stipulated by the DH. Traders are 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. No change is proposed to post-market control as compared with the proposal set out on 16 January 2017 (vide LC Paper No. CB(2)545/16-17(01)).

USE CONTROL OF MEDICAL DEVICES

16. The Government noted the views and concerns of stakeholders over the introduction of statutory control to restrict the use of specific medical devices used in cosmetic procedures to certain users. As the general public expects that pre-market and post-market control for medical devices be introduced as soon as practicable and that consensus over use control may not be reached soon, the current proposal will not include use control of specified medical devices. Nevertheless, the Government will continue to communicate with the stakeholders over this issue and will work with the industry to promote training regarding the proper use of these medical devices.

CONSULTATION WITH STAKEHOLDERS

17. Over the past year, the Government has met with and consulted various groups of stakeholders, including the medical sector, the beauty industry and traders of medical devices on the above refined proposal. The stakeholders were generally supportive of the introduction of a regulatory regime for medical devices to ensure the safety, quality and performance of medical devices supplied in the local market. While there are diverse views on whether use control should be pursued, the stakeholders generally agreed that this could be pursued separately and be dropped from the current legislative proposal. Subject to further discussion on implementation details, stakeholders are largely receptive of the listing regime which allows medical devices not fully complied with registration requirements to be listed in the meantime for better protection of public health. We will continue to engage stakeholders in finalising details of the legislative proposal.

WAY FORWARD

18. The Government is working on the Medical Devices Bill (the Bill) on the basis of the above refined proposal. We aim to introduce the Bill to the Legislative Council in the coming legislative session.

ADVICE SOUGHT

19. Members are invited to note and comment on the above proposal.

Food and Health Bureau
July 2018

Annex A

Extract from LC Paper No. CB(2)545/16-17(01)
On Proposed Regulatory Framework for Medical Devices

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Pre-market control

18. 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

19. 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 (the different classification of medical devices is set out at **Annex VI**). 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 three years, and can be renewed every three years. Moreover, a registered medical device can only be supplied for the purpose(s) as approved by the DH.

20. 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 are 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.

Registration and licensing of traders

21. 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 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 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.

22. Local manufacturers will be required to conform to Quality Management System ("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.

23. In line with the validity period of medical device registration (see paragraph 19 above), the validity period of all trader registrations will be aligned to three years, which can also be renewed every three years.

Recognition of conformity assessment bodies ("CABs")

24. 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.

Import / export control

25. 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.

Appeal mechanism

26. 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 ("SFH") would be set up to handle appeals relating to registration of medical devices, licence issuance and CAB recognition.

Labelling requirements and control over advertisements

27. 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 the corresponding labelling requirement. 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.

Post-market control

28. 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.

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Annex B

Definition and classification of medical devices

Definition of medical devices

According to GHTF's (now IMDRF) recommendation, medical device means –

"any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of –

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means"; and

2. Accessory to a medical device means –

"an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use".

Classification of medical devices

3. According to the rules of the GHTF, general medical devices are classified into four classes based on their risks (e.g. invasiveness, length of retention in body, location of implant, etc.). Examples of respective classes of medical devices are shown as follows –

Class	Risk Level	Examples
I	Low	Tongue depressor, bandage, dressing, walking aid
II	Medium – Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator, acupuncture needle, corrective contact lenses
III	Medium – High	External defibrillator, lung ventilator, contact lens disinfectant, orthopaedic implant, laser
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter

4. For in vitro diagnostic medical devices (IVDMDs), they are also classified into four classes according to another set of classification rules with respect to their risks to individual user and the public health as follows –

Class	Risk Level	Examples
A	Low individual risk Low public health risk	Clinical chemistry analyser, prepared selective culture media
B	Medium individual risk Low public health risk	Pregnancy self-testing kit, Tests to detect infection by helicobacter pylori, urine test strips
C	High individual risk Medium public health risk	Blood glucose self-testing kit, Screening test for rubella

D	High individual risk High public health risk	Test for human immunodeficiency virus (HIV) blood donor screening, Test for diagnosis hepatitis C virus (HCV)