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Proposed regulatory framework of medical devices

Purpose

This paper provides background information and summarizes the concerns of members of the Panel on Health Services ("the HS Panel") on the proposed regulatory framework of medical devices.

Background

2. Medical device generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It covers devices that are used for the purposes of investigation, replacement, modification or support of the anatomy or physiological process of the human body. These range from simple devices like hot/cold pads to sophisticated devices like breast implants and high power laser machines. Devices used for examination of human specimens are also regarded as medical devices.

3. At present, there is no specific legislation to regulate the import, distribution, sale or use of medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionizing radiation. Pharmaceutical products are regulated under the Pharmacy and Poisons Ordinance (Cap. 138) whereas devices emitting ionizing radiation or contain radioactive substances are regulated under the Radiation Ordinance (Cap. 303).

4. Following the public consultation on the regulation of medical devices conducted in 2003, the Government proposed to develop a risk-based regulatory framework on medical devices so as to protect public health. A voluntary Medical Device Administration Control System ("MDACS") has been established by the Department of Health ("DH") since 2004 to raise public

awareness of the importance of medical device safety and pave the way for implementing the long-term statutory control. MDACS comprises (a) a listing system for medical devices under which manufacturers and importers of medical devices can voluntarily listed their medical devices with DH; and (b) an adverse incident reporting system through which the manufacturers, importers, users and the general public can report adverse incidents to DH.

5. At the HS Panel meetings on 8 November 2010 and 16 June 2014, members were briefed on the proposed regulatory framework for medical devices which would comprise the areas of pre-market control, post-market control and use control.[1] In September 2015, the Administration commissioned an external consultant to conduct an in-depth study regarding the control of use in Hong Kong of 20 types of selected medical devices for cosmetic purposes[2] ("the study"). The use control assessment framework developed by the Consultant comprises (a) a selection process for determining whether or not a medical device used for cosmetic purposes should be subject to use control assessment; (b) classification of use control categories; and (c) a three-pronged use control assessment on the medical devices' clinical risk, regulatory requirements, and knowledge and skills requirements.

6. At the HS Panel meeting on 16 January 2017, members were briefed on the latest proposed regulatory framework which largely followed the previous proposal. A risk-based approach is adopted whereby the level of control will be proportional to the degree of risk associated with the medical devices according to the classification rules recommended by the International Medical Device Regulators Forum ("IMDRF")[3]. Medical devices other than in-vitro diagnostic medical devices ("IVDMD") are classified into four classes, namely Class I (low risk level), Class II (medium to low risk level), Class III (medium to high risk level) and Class IV (high risk level). IVDMDs are also classified into four classes, namely Class A (low individual risk, low public health risk),

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[1] According to the Administration, pre-market control is aimed to ensure medical devices conform with the requirements on safety, quality, performance, and efficacy before allowing them to be placed on the market. Post-market control is aimed to enable swift control measures against defective or unsafe medical devices. Use control is for restricting the possession and use of certain high-risk medical devices.

[2] To be included in the use control assessment framework under the study, a medical device should be defined as an "active" non-home-use device (i.e. source of power other than human power or gravity) or an "invasive" non-home-use device that penetrates inside the body, either through the surface of the body or a natural orifice; and be used for the cosmetic purposes of skin resurfacing, hair removal or restoration, body contouring, metabolism improvement, weight reduction and general wellness treatment.

[3] IMDRF was formed in 2011 to build upon the foundational work of Global Harmonization Task Force (which was formed in 1992 and disbanded in 2011) to accelerate international medical device regulatory harmonization and convergence.

Class B (medium individual risk, low public health risk), Class C (high individual risk, medium public health risk) and Class D (high individual risk, high public health risk).

Deliberations of the Panel

7. The HS Panel held a number of meetings between June 2002 and January 2017 to discuss the proposal on the regulation of medical devices and received the views of deputations on the proposal at one meeting. The subject was also discussed at several HS Panel meetings in the context of discussing the regulation of medical beauty treatments/procedures, and at a joint meeting of the HS Panel and the Panel on Commerce and Industry in the context of discussing the regulation and development of beauty services. The deliberations and concerns of members are summarized below.

Definition and classification of medical devices

8. Members noted that the proposed regulatory control over medical devices would be proportional to the level of risk associated with a medical device. Concern was raised about the standard to be adopted in classifying the risk levels of medical devices, in particular that of the Chinese medicine medical devices as no international reference on their classification was available. There was a question as to whether the use of electrocardiogram devices and lung ventilators would be subject to regulatory control. The Administration advised that for the purpose of the proposed legislation, the definition and the classification of medical device would be based largely on the recommendation of IMDRF with a view to ensuring consistency with international practices. Modifications would however be made to suit local circumstances. The principle was that the imposition of regulatory control should not place an unnecessary burden on the regulators, the trade and the industry nor delay the introduction of new products that would benefit patients.

9. Members noted that while both corrective and non-corrective contact lens were intended for use on human body with similar potential adverse effect, the former would be classified as Class II medical device subject to statutory control under the proposed regulatory framework whereas the latter would be included for regulatory control through listing in a Schedule of the proposed legislation. Question was raised about the factors to be taken into account by DH in determining which of those products that did not fall within the definition of medical device should be included in the Schedule for regulatory control.

10. The Administration advised that experience of countries with regulatory control showed that, despite the attempt to provide a clear definition for medical device, a number of products appeared to be borderline cases. While these products did not fall squarely within the definition of medical device, they were intended for use on human and carried the potential of causing adverse effect on human body in a similar way to a medical device. It was therefore proposed that the Director of Health ("DoH") should be empowered under the legislation to designate through a form of Schedule those products which were to be included for regulatory control having taken into account factors such as the sale and use of the product in the local market; the risk of the product in causing adverse effect on human body; the frequency of adverse incidents arising from the use of the product; as well as the views of the sellers and users.

11. Some members considered that such an approach would cause confusion to the public and place unnecessary burden on the trade and industry. There was a view that an independent committee should be set up to advise DoH on which products should be included in the Schedule of the proposed legislation. Members were advised that any amendments to the Schedule would be subject to negative vetting of the Legislative Council. Similar to the arrangements under other legislation, the regulatory authority, rather than another committee, would be empowered to determine the products to be designated in the Schedule.

12. Members noted the Administration's proposals to set up an appeal board to handle appeal cases relating to licensing and registration, as well as an advisory committee to advise DH on the classification of medical devices and issues relating to the implementation and administration of the future legislation. Both the appeal board and the advisory committee would be made up of members from trade associations, medical associations, engineering institutions and academic institutes. Some members expressed concern that membership of the two committees might largely comprise medical practitioners. They urged that views of the local beauty and optical trades as well as frontline beauty practitioners should be fully represented in both committees.

Pre-market control of medical devices

13. Members noted that traders (including authorized representatives, local manufacturers, importers and distributors) who introduced medical devices into the local market would be required to register with or obtain a licence from DH. This apart, medical devices with risk level of Class II or above and IVDMDs with risk level of Class B or above would be required to register with DH before they could be supplied to the local market. As regards Class I medical devices (such as bandages, dressings and surgical masks), their traders would be required to maintain a list of Class I medical devices supplied by them in the

local market and provide the list to DH upon request. Members called on the Administration to ensure that DH would have adequate manpower and resources to effectively perform the assessment work, so as to ensure that a medical device was safe and would perform as intended before market entry.

14. According to the Administration, the proposed legislation would empower DH to recognize conformity assessment bodies ("CABs") to perform conformity assessment on medical devices, as well as to provide third party conformity assessment services to traders. CABs would be required to register with DH so that their performance could be periodically monitored.

15. Given that some importers might not apply for registration of some medical devices due to low market demand in Hong Kong, there was a concern about whether a mechanism would be put in place to allow medical practitioners who wished to use these medical devices to patients for the purpose of medical treatment to seek approval from DH on individual patient basis. The Administration advised that exemptions would be granted to the supply of unregistered medical devices under certain special circumstances, such as for the purpose of clinical research, on a named-patient due to special needs, or under public health emergencies.

Control over the use of selected medical devices

16. Members noted that the Administration proposed to restrict the use of selected medical devices to specified personnel in order to safeguard public health. They noted that the view of deputations from the medical sector was that the use and operation of high-powered lasers and intense pulsed light equipment should be confined to qualified doctors and dentists and personnel authorized by them. However, deputations from the beauty trade had grave concern over a restrictive use of these cosmetic-related medical devices, as the business generated by those procedures involving the use of lasers and IPL was fast becoming its main source of income.

17. According to the Administration, a risk-based approach would be adopted to impose use control on specific medical devices used by persons other than registered healthcare professionals. Based on the recommendations of the study,[4] it was proposed that there would be two levels of use control, namely

[4] According to the use control categories recommended by the study, users of those medical devices that were classified into use control category I had to be a registered healthcare professional. Users of those medical devices that were classified into use control category II had to be a registered healthcare professional or a person supervised by a registered healthcare professional on site. For those medical devices being classified into use control category III, they could be used by persons meeting the requirements of either

users had to be supervised on site by a registered medical practitioner; and users had to be supervised on site by a registered medical practitioner or be a personnel who had successfully completed the relevant training programme as recognized by the Government. The Secretary for Food and Health ("SFH") would be empowered under the legislation to specify the types of medical devices which should be subject to the use control and their respective use control categories. A statutory advisory committee would be set up to advise SFH on various implementation and administration of the future legislation.

18. Some members were concerned that the proposed regulatory framework would not restrict the use of any medical devices by a registered healthcare professional. The Administration explained that since the practice of registered healthcare professionals would be subject to the respective professional code of conduct, the proposed regulatory framework would focus on the use control on specific medical devices which were often used by persons other than registered healthcare professionals, and the use of these devices might pose a high risk of serious injury or harm to the public if the users had not undergone proper training and acquired appropriate qualifications.

19. Members noted that the use control assessment framework for specific medical devices commonly used for cosmetic purposes[5] and the use control categories proposed in the study would form the basis on selection of medical devices to be subject to use control.[6] Some members shared the concern raised by the physiotherapy profession that the study had recommended to classify some types of medical devices, which in their views were of high risk of serious injury or harm (such as those for extracorporeal shock wave therapy ("ESWT") and those emitting high voltage pulsed current), into use control category IV whereby no user restriction would be imposed. The Administration explained that the ESWT devices were used by beauticians and registered healthcare professionals for different purposes. There was a view that the Administration

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use control category I or II, or who had completed device-specific training through recognized training programme. No use control would be imposed on those medical devices being classified into use control category IV.

[5] The use control assessment covered a clinical risk assessment of the medical device at the levels of extreme, high, medium and low; a regulatory assessment as to whether a medical device should be used by a registered healthcare professional or its use should be supervised by a registered healthcare professional; and an assessment on the level of knowledge and skills required for proper and safe operation of a medical device.

[6] Under the study, seven types of medical devices had been assigned to use control category II; ten types of medical devices had been assigned to use control category III; and eight types of medical devices had been assigned to use control category IV. No medical device researched in the study required that the use had to be a registered healthcare professional (i.e. use control category I). Details are set out in Annex V to LC Paper No. CB(2)545/16-17(01).

should clearly specify the use control and user qualification requirements for using ESWT devices for different purposes.

20. Some other members noted with grave concern that Class 3B and Class 4 lasers, monopolar radiofrequency device and high-intensity focused ultrasound device were classified into use control category II in the study that they had to be operated by a registered healthcare professional or a person supervised by a registered healthcare professional on site. Given the tight medical manpower supply and that many of the cosmetic-related devices were commonly used by trained beauticians in the local beauty industry, these members considered that beauticians fulfilling a set of skills and competency requirements should be allowed to operate and use these devices. They urged the relevant bureaux and government departments to join hands to set up a statutory accreditation system or build upon the Qualifications Framework to develop such competency requirements for beauty practitioners. In their view, this would facilitate the development of the beauty industry on the one hand, and on the other hand enable consumers to access to safe and reasonably priced cosmetic procedures.

Impact of the proposed regulation on the stakeholders

21. While members generally supported the broad direction of formulating a statutory regulatory framework for medical devices for the sake of public health and interest, some of them expressed grave concern that the proposed use control of medical devices commonly used for cosmetic purposes was impractical and would stifle the development of the beauty industry. These members called on the Administration to further communicate with and consult the beauty industry and the healthcare profession prior to taking forward the legislative proposal. There was a suggestion that the Administration should consider regulating medical devices and cosmetic interventions under separate legislation.

22. On members' concern about the cost of compliance under the proposed regulatory framework, the Administration advised that the compliance cost mainly included the administrative costs, fees for registrations and licenses, and cost of obtaining ISO certification and re-certification to meet the requirements for traders registration. Having considered that authorized representatives, importers and distributors of medical devices were largely small and medium-sized enterprises ("SMEs"), the latest proposal of the Administration was that these traders would only be required to adhere to a set of essential requirements for the quality management system ("QMS"). They would not be required to conform to the QMS certification requirements which applied on local manufacturers of medical devices. In addition, the Administration would provide assistance to traders, especially SMEs, with support packages to fulfill

the requirements. It was anticipated that the compliance cost could be substantially reduced.

Timetable for introducing the regulatory framework

23. Concern was raised about the slow progress of the Administration in putting in place the regulatory control on the supply and use of medical devices, as the first proposed framework to regulate medical devices was unveiled in 2003.

24. The Administration advised that as the first step, a voluntary MDACS had been launched by DH since 2004 in phases to facilitate the transition to long-term legislative control. A Regulatory Impact Assessment was conducted from 2007 to 2008 to examine the implications of the possible options for the proposed statutory regulation of medical devices. A Business Impact Assessment was then carried out from 2011 to 2013. In view of the deliberation of the Working Group on Differentiation between Medical Procedures and Beauty Services set up under the Steering Committee on Review of the Regulation of Private Healthcare Facilities to examine, among others, the safety and health risks of medical devices commonly used in beauty procedures, DH commissioned an external consultant to conduct a detailed study on the use control of selected medical devices for cosmetic purposes. The latest proposed regulatory framework for medical devices had taken into account the recommendations of the study which was completed in September 2016.

Relevant papers

25. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
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Appendix

Relevant papers on the proposed regulatory framework of medical devices

Committee	Date of meeting	Paper
Panel on Health Services	10.6.2002 (Item IV)	Agenda Minutes
	12.5.2003 (Item IV)	Agenda Minutes
	22.3.2004 (Item I)	Agenda Minutes
	19.7.2005 (Item II)	Agenda Minutes CB(2)1034/06-07(01)
	8.11.2010 (Item V)	Agenda Minutes CB(2)625/10-11(01)
	26.10.2012 (Item I)	Agenda Minutes
	27.11.2012 (Item I)	Agenda Minutes
	18.11.2013 (Item IV)	Agenda Minutes
	23.12.2013 (Item I)	Agenda Minutes
	20.1.2014 (Item III)	Agenda Minutes
	16.6.2014 (Item IV)	Agenda Minutes CB(2)2025/13-14(01) *(Restricted to members only)*

Committee	Date of meeting	Paper
Panel on Health Services	16.3.2015 (Item IV)	Agenda Minutes CB(2)2212/14-15(01)
Joint meeting of the Panel on Health Services and the Panel on Commerce and Industry	23.6.2015 (Item II)	Agenda Minutes CB(2)46/15-16(01) CB(2)46/15-16(02)
Panel on Health Services	16.1.2017 (Item VI)	Agenda

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