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Panel on Health Services

Updated background brief prepared by the Legislative Council Secretariat for the meeting on 16 July 2018

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

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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.

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), 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 Panels

7. The HS Panel held a number of meetings between June 2002 and February 2017 to discuss the proposal on the regulation of medical devices and received the views of deputations on the proposal at two meetings. 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

[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.

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 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. There was a view that all users of devices for cosmetic purposes, regardless of their background, should be required to undergo training before operating the devices concerned. 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

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[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 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.

devices to be subject to use control.[6] Some members considered that the physiotherapy profession had not been properly consulted on the proposed use control of selected medical devices. They 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. There was a view that the Administration should clearly specify the use control and user qualification requirements for using ESWT devices for different purposes. Some members considered that different level of use control should be imposed on medical devices according to their level of energy output.

20. The Administration explained that the ESWT devices were used by beauticians and registered healthcare professionals for different purposes. For devices adopting the same technology, it was difficult to differentiate devices by level of energy output as there could be overlap in the range of energy output of these devices or the parameter might be similar. At the same time, there was no standardized format in specification on the energy output level internationally. In addition, the risk of a device was not only dependent on its energy output level. Other factors such as the design of the device, the operating mode (such as pulse mode or continuous mode), the duration of the treatment might also affect the risk.

21. 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. It was also impracticable to require the thousands beauty companies to employ registered medical professionals, including registered medical practitioners, to supervise the use of these devices by beauty practitioners. They urged the relevant bureaux and government departments to join hands to set up a statutory accreditation system or build

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[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).

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. The Administration explained that a reason why it was proposed that users of specific medical devices for cosmetic purposes had to be supervised on site by a registered medical practitioner was for overseeing treatment planning and providing intervention in case any complications arose.

Impact of the proposed regulation on the stakeholders

22. 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.

23. 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.

Way forward

24. Members in general considered that the latest regulatory framework proposed by the Administration on medical devices was prepared in a slipshod manner. Some members urged the Administration to hold its legislative work in this regard in abeyance given the absence of consensus views of the public

and the stakeholders on the use control of specific medical devices. There was a suggestion that devices solely used for cosmetic purposes should be subject to a separate regulatory framework. Some other members, however, considered that Hong Kong had lagged far behind the global practices in respect of the regulation over medical devices. These members were concerned about the slow progress of the Administration in putting in place the regulatory control on the supply and use of medical devices to safeguard consumers, as the first proposed framework to regulate medical devices was unveiled in 2003. At the meeting on 28 February 2017, the HS Panel passed three motions urging the Administration to, among others, re-examine the proposed regulatory framework for medical devices; differentiate amongst the devices according to their intended purposes and intended users; and establish a multi-party discussion platform comprising representatives from all the relevant sectors to gauge their views over the regulation of medical devices.

25. Members were subsequently advised that the stance of the Administration was that in case the devices used for cosmetic purposes meet the IMDRF's definition of "medical device", they should be regarded as medical devices and be regulated under the proposed legislation for medical devices. The Administration would first focus efforts to take forward the legislative proposals relating to the pre-market control and post-market control for medical devices. Given the actual situation that a number of medical devices used for cosmetic purposes would not be able to fulfill the registration requirements under the proposed regulatory framework, efforts would be made to adjust the registration requirements as appropriate so that most up-to-standard devices used for cosmetic purposes could also be registered. This apart, a listing mechanism would be established for those devices used for cosmetic purposes but could not fulfill the refined registration requirements. Devices applied for listing had to be active devices (e.g. source of power other than human power or gravity), and only be supplied for use by beauty practitioners or the public. On the use control for specified medical devices, the Administration would revisit and consider the issues of use control categorization of such medical devices and related matters at a later stage.

Recent developments

26. An oral question concerning the regulation of medical devices and a written question concerning the regulation of corrective and non-corrective contact lenses were raised at the Council meetings of 1 March 2017 and 17 January 2018 respectively. The questions and the Administration's replies were in **Appendices I and II** respectively.

27. The Administration will brief the Panel on 16 July 2018 on the refined proposed regulatory framework for medical devices.

Relevant papers

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

Council Business Division 2
Legislative Council Secretariat
12 July 2018

Press Releases *1 March 2017*

LCQ6: Regulation of medical devices
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Following is a question by the Hon Shiu Ka-fai and a reply by the Secretary for Food and Health, Dr Ko Wing-man, in the Legislative Council today (March 1):

Question:

The Government put forward a proposed regulatory framework for medical devices last month. Quite a number of members of the beauty industry have relayed to me that at present, beauticians commonly use various types of high-technology devices for cosmetic purposes, and many of them have taken courses and obtained certificates of qualification on the operation of such devices. However, such devices will be categorised under the new legislation as medical devices the use of which requires supervision on site by a registered medical practitioner. They are worried that upon the implementation of the new legislation, quite a number of beauty salons may close down as they fail to recruit medical practitioners to station on site or cannot afford the relevant expenses. Consequently, the livelihood of many beauticians will be affected and the development of the industry will be hindered. In this connection, will the Government inform this Council:

(1) given that there is currently no internationally adopted and full-fledged regulatory approach for medical devices, whether the authorities, apart from adopting the risk-based classification rules recommended by the International Medical Device Regulators Forum and making reference to the measures and requirements implemented among the five major economies (i.e. the United States, Australia, United Kingdom, Mainland China and Singapore), have made reference to the relevant practices and regulations of other overseas countries or regions when formulating the aforesaid regulatory framework; if so, of the relevant countries and regions, and the details;

(2) whether it has assessed the impacts to be brought about by the aforesaid regulatory framework on the business environment of the medical profession, the beauty industry and their related industries, the consumers receiving cosmetic services as well as the Hong Kong economy; if so; of the details; if not, the reasons for that; and

(3) whether it has studied the feasibility of adopting two separate frameworks for regulating matters (including definition, registration, sale and use) concerning medical devices and devices for cosmetic purposes; if so, of the details; if not, the reasons for that?

Reply:

President,

Currently, there is no specific legislation to regulate medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionising radiation. To protect the safety and health of the public, there is a pressing need to impose "pre-market control" and "post-market control" for all medical devices, as well as "use control" for specific medical devices.

The Government conducted a Business Impact Assessment between 2011 and 2013 to assess the impact of the proposed statutory regulatory regime for medical devices on the trade. Stakeholders interviewed generally supported enacting legislation to regulate medical devices, as the safety and quality of medical devices placed on the market could be ensured through regulation, thereby protecting public health and reducing patients' risk of complications and injuries caused by problematic medical devices. Besides, Hong Kong has far lagged behind other places in terms of regulating medical devices. The proposal will help bring Hong Kong on par with other major markets in the regulation

of medical devices, thus raising industrial standards and facilitating development of the industry.

Recently, we received views from different sectors on the regulation of medical devices, to which I would like to respond. We observe that some medical devices are frequently used for non-medical purposes, of which mostly for cosmetic purposes. The Consumer Council has established an information exchange mechanism with the Department of Health (DH) since October 2012. As of February 5, 2017, the mechanism had recorded a total of 164 complaints by consumers on adverse events related to cosmetic procedures performed at beauty parlours, a large proportion of which involved the use of energy-emitting apparatus (100 complaints). Of these cases, most of them were performed by non-registered healthcare professionals (HCPs). In this connection, to protect public health, there is a need to impose "use control" on specific medical devices which are often used by non-registered HCPs for non-medical purposes. There is a general consensus on the above need, although different sectors have different views regarding "use control" categorisation of the devices.

Besides, some organisations consider that separate regulatory regimes should be put in place respectively for devices used for medical purposes and those used for cosmetic purposes. The definition of "medical devices" made under the current proposed regulatory framework adopts the comprehensive definition of medical device formulated by the International Medical Device Regulators Forum (IMDRF). The term "medical device" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It also covers devices that are used for the purposes of investigation, replacement, modification or support of the anatomy or physiological process of the human body. As certain devices used in cosmetic procedures such as lasers, intense pulsed light equipment and device emitting micro-current achieve cosmetic effect through medical means such as modifying the anatomy or physiological processes of human bodies by the energy emitted, they therefore fall under the definition of "medical device" stipulated by IMDRF. Generally speaking, the level of energy output used for cosmetic purposes and that used for medical purposes for energy-emitting devices may not have significant difference. As such, the level of energy output alone cannot be used to distinguish a "cosmetic device" from a "medical device". This is also not a criteria for defining a medical device internationally.

There is currently no statutory definition or separate regulatory legislation for "cosmetic device" in the international community. In case the devices used in cosmetic purposes meet the definition of "medical device", they are generally regulated under the medical device legislation internationally.

According to the Research Report on "Regulation of aesthetic practices in selected places" (the Report) published by the Legislative Council Secretariat in November 2014, in South Korea where beauty industry is flourishing, medical devices cover devices that can be used for cosmetic treatment, such as intense pulsed light devices and high-power lasers. These devices are regulated under the medical device legislation. Also, medical devices used in beauty procedures are regarded as medical procedures in South Korea, which must be carried out by medical practitioners in licensed hospitals or medical clinics. Beauty parlours can only provide general beauty services without using any medical devices. Apart from the Report above, the DH also commissioned an independent consultant from September 2015 to September 2016 to conduct a study on the use control of 20 types of selected medical devices for cosmetic purposes. It was observed that although Australia, Singapore and the United Kingdom have little or no qualification requirements for medical devices used for cosmetic purposes, use of most medical devices for cosmetic purposes in the Mainland China and in some states of the United States is restricted to medical practitioners or HCPs under supervision by medical practitioners.

In sum, there is no standardised regulatory approach on the use of

medical devices for cosmetic purposes in the international community. Taking into consideration the information and views collected during the course of the study, the independent consultant conducted separate assessments respectively on clinical risk, regulatory, as well as knowledge and skills for the devices concerned when they are being used for non-medical purposes. The most stringent category of use designation among these three assessments has become the recommended use control category of the device concerned when used for non-medical purposes.

We understand that the part on "use control" may require further deliberation. In this regard, while the Government is taking forward the legislative proposal on the regulatory regime for medical devices, a multi-party platform will be set up concurrently to invite participation from different stakeholders to provide practicable and constructive views on "use control" categorisation of specific medical devices under the premise of protecting public health. Balanced participation from various sectors in the discussion of the multi-party platform will be ensured.

Ends/Wednesday, March 1, 2017
Issued at HKT 16:20

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Appendix II

Press Releases *17 January 2018*

LCQ10: Regulating corrective and non-corrective contact lenses
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Following is a question by the Professor Hon Joseph Lee and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (January 17):

Question:

According to the Supplementary Medical Professions Ordinance (Cap 359), only registered optometrists or persons who are exempted from regulation by the relevant section according to Schedule 4 to the Optometrists (Registration and Disciplinary Procedure) Regulation (Cap 359 sub leg F) (such as registered medical practitioners while practising medicine), (approved persons) are allowed to prescribe, fit or supply on prescription optical appliances (e.g. corrective contact lenses). However, it is doubtful whether the sale of non-corrective contact lenses is subject to regulation by the Ordinance. It has been reported that there have been cases from time to time in recent years in which members of the public suffered from eye diseases or visual impairment after wearing contact lenses bought from shops or through the Internet. In this connection, will the Government inform this Council:

(1) whether the authorities investigated in the past five years the situation of non-approved persons selling corrective and non-corrective contact lenses at shops and through the Internet; if so, of the details; if not, the reasons for that;

(2) how the authorities currently monitor the situation of non-approved persons selling non-corrective contact lenses; and

(3) whether the authorities will consider, by making reference to the practice of the United Kingdom, enacting legislation to explicitly prohibit non-approved persons from selling non-corrective contact lenses; if so, of the details (including the legislative timetable); if not, the reasons for that?

Reply:

President,

(1) The Optometrists Board (the Board), under the Supplementary Medical Professions Council (the Council), is a statutory body established under section 5 of the Supplementary Medical Professions Ordinance (Cap 359) (the Ordinance). The Board is responsible for registration and regulation of professional conduct and act of optometrists. At present, the Board handles complaints related to optometrists in accordance with the Optometrists (Registration and Disciplinary Procedure) Regulation (Cap 359F) (the Regulation).

According to section 21 of the Ordinance and section 6 of the Regulation, only registered optometrists in Part I, Part II and some in Part IV of the register, or persons who are exempted from regulation by the Ordinance according to Schedule 4 to the Regulation (such as registered medical practitioners while practising), are allowed to prescribe, fit or supply on prescription optical appliances (including contact lenses). Any person who practises the optometry profession without being registered or exempted from registration, or employs such a person to practise the optometry profession, commits an offence and is liable on conviction to a fine of $5,000 and imprisonment for six months.

Members of the public may report any suspected violation of the Ordinance to the Police. In the past five years, the Council and the Board have not received any requests from the Police for their professional advice on complaints related to the sale of contact lenses by non-registered healthcare professionals.

(2) and (3) At present, the Ordinance does not impose any restrictions on the sale of contact lenses by non-registered healthcare professionals. To enhance public education on the proper use of contact lenses, the Department of Health (DH) has published on its website information leaflets on using contact lenses (including decorative contact lenses), covering "Know More About Contact Lenses" and "Tips on Using Contact Lens Solution", as well as a video on "Proper Use of Contact Lenses" which is also broadcast regularly at public venues. The information leaflets and video remind members of the public to strictly follow the instructions of qualified registered optometrists or ophthalmologists to ensure proper use and care of contact lenses. In addition, the DH will promote the message of "Proper Use of Contact Lenses" during festivals (such as Halloween, Christmas and New Year) through television and radio broadcasting.

Notwithstanding the above, the Government is in the process of drafting legislation related to the regulation of medical devices which would cover product safety and quality of contact lenses. Although non-corrective contact lenses (such as decorative contact lenses) do not fall within the defined scope of medical devices, their use and the potential risks posed to the human body are similar to those of corrective contact lenses, which are defined as medical devices. The Government is now considering bringing non-corrective contact lenses under regulatory control. According to the legislative proposal now being drafted, contact lenses (both corrective and non-corrective) are classified as general medical devices at a low-moderate or moderate-high risk level. The devices and their authorised representatives (ARs) are required to be registered with the DH, and the importers and distributors of such devices must have obtained a licence from the DH before they can supply the medical devices in Hong Kong. The ARs, licensed manufacturers, licensed importers and licensed distributors or suppliers of such medical devices are also subject to the mandatory requirements of reporting and investigating adverse incidents associated with the medical devices, and implementing the corresponding remedial measures to the satisfaction of the DH. The Food and Health Bureau is actively communicating with and seeking the views of different stakeholders, with the aim of introducing the Bill to the Legislative Council as soon as possible after fine-tuning the legislative proposal.

Ends/Wednesday, January 17, 2018
Issued at HKT 14:25

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Appendix III

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 Minutes CB(2)1820/16-17(01)
	13.2.2017 (Item I)	Agenda Minutes
	28.2.2017 (Item III)	Agenda Minutes CB(2)1769/16-17(01)
Legislative Council	1.3.2017	Official Record of Proceedings (Question 6)
	17.1.2018	Official Record of Proceedings (Question 10)

Council Business Division 2
Legislative Council Secretariat
12 July 2018