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Panel on Health Services and Panel on Commerce and Industry

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

Meeting on 25 March 2019

Background brief on regulatory measures relevant to the beauty industry under the policy purview of health

Purpose

This paper provides background information and summarizes the concerns of members of the Panel on Health Services ("the HS Panel") and the Bills Committee on Private Healthcare Facilities ("the Bills Committee") on regulatory measures in relation to private healthcare facilities and medical devices which were relevant to the beauty industry.

Background

2. At present, there is no specific regime to regulate the provision of beauty services. Various aspects of these services, including professional conduct of the personnel (including registered medical practitioners and registered dentists) providing the services, premises, drugs, devices and advertising and sales practices are regulated under different pieces of legislation enforced by different Government departments such as the Department of Health ("DH") and the Customs and Excise Department.

3. The Government established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee) in October 2012 to conduct a holistic review of the regulation of private healthcare facilities. The Working Group on Differentiation between Medical Procedures and Beauty

Services and the Working Group on Defining High-risk Medical Procedures/ Practices Performed in Ambulatory Setting set up under the Steering Committee were respectively tasked to study the regulation of cosmetic services that should only be performed by registered medical practitioners or registered dentists, and the regulation of ambulatory facilities where high-risk medical procedures were performed. The Private Healthcare Facilities Bill ("the Bill") which regulates, through a new licensing system, premises where registered medical practitioners and registered dentists practise was passed by the Legislative Council ("LegCo") on 15 November 2018. The Private Healthcare Facilities Ordinance ("the Ordinance") was published in the Gazette on 30 November 2018 and will come into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette. Separately, the Administration is preparing to introduce two new pieces of legislation to regulate medical devices and advanced therapy products.

Deliberations of the HS Panel and the Bills Committee

4. The HS Panel held a number of meetings between June 2002 and July 2018 to discuss issues relating to the proposed regulatory measures on private healthcare facilities and medical devices. The subjects were also discussed 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 Bills Committee was formed in June 2017 to study the Bill. The deliberations and concerns of members are summarized in the following paragraphs.

Regulation of private heathcare facilities

5. Members noted that a beauty centre providing medical beauty services to its customers, with the services provided by a registered medical practitioner or a registered dentist (irrespective of whether the registered medical practitioner or registered dentist was employed by the centre or not under the employment of the centre), would fall within the meaning of "day procedure centre" or "clinic" under the Bill, as the case may be. In addition, it would be an offence for a person who was not a healthcare professional to purportedly perform, on premises other than certain excepted premises, a medical treatment or medical procedure for another person who was (or might be) suffering from a disease, injury or disability of mind or body; and to cause personal injury to the other person during the treatment or procedure. Some members considered that care should be taken to prevent the net from being cast unduly wide that beauty practitioners performing cosmetic procedures, such as body tattooing and eyebrow tattooing, would be unnecessarily caught. They were particularly concerned about whether the administration of local anaesthetic containing

lignocaine, which had been registered with the Pharmacy and Poisons Board of Hong Kong and was legally obtained, at a beauty centre to a person for preventing pain during tattooing would constitute a medical procedure.

6. The Administration advised that to be caught by the offence, the person concerned had to purportedly perform, on the premises concerned, a medical treatment or medical procedure for a person who was or might be suffering from a disease, injury or disability of mind or body, and caused personal injury to that person during the treatment or procedure. The Administration further advised that the Working Group on Differentiation between Medical Procedures and Beauty Services set up under the Steering Committee had identified the procedures, irrespective of whether they were for cosmetic or medical purposes, that should only be performed by registered medical practitioners or registered dentists because of their inherent risks. Traditional body tattooing and piercing were exempted from being considered as a medical procedure, whereas depending on the circumstances, the administration of local anaesthetics to a person for the purpose of pain control was an act of practising Western medicine. Separately, the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156) had respectively made it an offence for a person to practise medicine or surgery without registration; and for a person, who was not a registered dentist, to practise dentistry within Hong Kong, irrespective of whether the act had caused personal injury. In view of the concern of members and stakeholders from the beauty sector on the administration of local anaesthetic for preventing pain during cosmetic tattooing, the Administration undertook to relay the issue to the Pharmacy and Poisons Board of Hong Kong, which was responsible for, among others, the registration and classification of pharmaceutical products, for consideration.

Proposed regulatory framework for medical devices

Definition and classification of medical devices

7. Members note that following the public consultation on the regulation of medical devices conducted in 2003, the Administration had proposed to develop a risk-based regulatory framework on medical devices to protect public health. It was proposed that to ensure consistency with international practices, the definition of medical devices formulated by the International Medical Device Regulators Forum ("IMDRF")[1] would be adopted. That was, medical device generally referred to any instrument, apparatus or appliance that was used for diagnosis, treatment or monitoring of diseases and injuries. It covered devices

[1] 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.

that were used for the purposes of investigation, replacement, modification or support of the anatomy or physiological process of the human body. These ranged 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 were also regarded as medical devices.

8. Some members were gravely concerned that certain devices commonly used for cosmetic purpose would fall under the proposed regulatory framework for medical devices. To avoid stifling the development of the beauty industry, devices solely used for cosmetic purpose should be subject to separate regulatory framework. At the meeting of 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 multiparty discussion platform comprising representatives from all the relevant sectors to gauge their views over the regulation of medical devices.

9. The Administration advised that having critically reviewed the suggestion, it was satisfied that segregating the regulatory regime for medical devices and devices commonly used for cosmetic purpose would not be practical since the latter, as the case might be, was invariably a subset of the former. The technology deployed, energy output, theory in producing effects, and risks used on human body of the latter were similar to those of the medical devices intended for treatment or rehabilitation. It should be noted that many advanced jurisdictions such as Australia, Canada, the Mainland and the United States had included devices used for cosmetic purpose and met the definition of medical devices under the local regulatory framework for medical devices. To align the understanding regarding definition of medical devices in European countries, the European Union had recently indicated in the revised Medical Device Directives that certain aesthetic devices including electromagnetic field emitting devices for skin rejuvenation and hair removal (e.g. laser and intense pulse light device); and devices which reduced, removed or damaged fats, should be regarded as medical devices and were subject to the Directives.

10. On members' concern about the standard to be adopted in classifying the risk levels of medical devices, the Administration advised that the classification of medical device for the purpose of the proposed legislation would be based largely on the recommendation of IMDRF whereby medical devices other than in-vitro diagnostic medical devices ("IVDMD") were 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 were 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). Modifications would however be made to suit local circumstances.

Pre-market control of medical devices

11. 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) and Class A IVDMDs, 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.

12. According to the Administration, the proposed legislation would empower DH to recognize conformity assessment bodies to perform conformity assessment on medical devices, as well as to provide third party conformity assessment services to traders. DH would monitor the performance of the recognized conformity assessment bodies regularly. Some members expressed concern about the rationale that under the latest legislative proposal, DH would accept in the initial phase direct application for registration medical devices which had acquired marketing approvals from the Mainland and South Korea, in addition to those approved by founding members of GHTF (now IMDRF), sparing the requirement for third-party conformity assessment.

13. The Administration explained that the adjustment in the documentary requirements for registration of medical devices by phases had given due regard to the fact that many authorized representatives of medical devices were small and medium-sized enterprises. While public safety was overriding, there was a need to avoid unnecessary business interruption. The Administration would also provide training workshops and standard templates for applications so as to reduce the costs of traders for placing medical devices in the local market and minimize their efforts in complying with the statutory requirements.

14. Members note that under the latest legislative proposal, a transitional listing system for medical devices would be introduced so that certain Class II or III non-invasive general medical device which might 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 but fell short of the registration requirements could still be allowed to supply and use for a short period. The period for applying for the transitional listing was proposed to be five years. Some members considered that the transitional arrangement would render public health and safety at risk. Some other members, however, were of the view that the arrangement would help the industry to migrate to the statutory registration regime in steps.

15. According to the Administration, amongst these medical devices, only those which complied with the safety and labeling requirements to be stipulated by DH, such as general requirements for household and electrical appliance, would be qualified for listing. The Administration assured members that its ultimate target was for all medical devices for use in Hong Kong to fully meet all registration requirements. While those medical devices that had been listed might renew their listing status once every five years, no new applications for listing would be accepted after the five-year window period.

Use control of specific medical devices

16. When the HS Panel was briefed on the proposed regulatory framework for medical devices in 2017, it was proposed that there would be two levels of use control on specific medical devices which were often used by persons other than registered healthcare professionals, 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 was recognized as having successfully completed the relevant training programme. Various concerns and views were raised by members over the proposal. These included: (a) the proposal would not restrict the use of any medical devices by a registered healthcare professional; (b) different level of use control should be imposed on medical devices according to their level of energy output; and (c) some devices commonly used for cosmetic purpose, such as Class 3B and Class 4 lasers, monopolar radiofrequency device and high-intensity focused ultrasound device, were classified as having to be operated by a registered healthcare professional or supervised by a registered healthcare professional on site. In their view, the proposal was prepared in a slipshod manner and without sufficient consultation.

17. Members were subsequently advised in 2018 that the given the views and concerns of stakeholders over the introduction of statutory control to restrict the use of specific medical devices used for cosmetic purpose to certain users, the relevant bill on medical devices to be introduced into LegCo in the 2018-2019 legislative session would only cover pre-market and post-market control for medical devices but not use control of specified medical devices. The Administration would continue to communicate with the stakeholders over the

issue and would work with the industry to promote training regarding the proper use of these medical devices.

18. Members in general were disappointed that the Administration had yet mapped out how the proposed use control of specific medical devices should be taken forward. At the meeting on 16 July 2018, the HS Panel passed a motion expressing regret that the latest proposed regulatory framework for medical devices did not include the use control of medical devices, and requesting that the Government should immediately commence the legislative exercise to regulate medical devices, including the use control of medical devices.

Development of a regulatory regime for the beauty industry

19. In the context of discussing the above two proposed regulatory regimes, some members shared the view of the beauty industry that it was necessary for the Administration to formulate a regulatory regime for the beauty profession in order to promote the sustainable development of the industry. To facilitate the long-term development of the industry, there was a need for the Food and Health Bureau, the Commerce and Economic Development Bureau, Education Bureau and Labour and Welfare Bureau to join hands in enhancing the regulation and professionalism of the beauty industry and its practitioners. Two motions urging the Government to, among others, establish a regulatory and training regime for the beauty sector and formulate a comprehensive strategy for the industry's development in order to facilitate sustainable development of the beauty industry and enhance the protection for the public in the use of beauty services were passed by the HS Panel at its meetings on 18 November 2013 and 28 February 2017 respectively.

Relevant papers

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

Council Business Division 4
Legislative Council Secretariat
21 March 2019

Appendix

Relevant papers on regulatory measures relevant to the beauty industry

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)
Bills Committee on Private Healthcare Facilities Bill	--	CB(2)61/18-19
Panel on Health Services	16.7.2018 (Item III)	Agenda

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