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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

Minutes of the fifth meeting
held on Thursday, 2 May 2019 at 2:30 pm
in Conference Room 3 of the Legislative Council Complex

Members present	:	Hon Tommy CHEUNG Yu-yan, GBS, JP (Chairman) Dr Hon Elizabeth QUAT, BBS, JP (Deputy Chairman) Prof Hon Joseph LEE Kok-long, SBS, JP Hon Jeffrey LAM Kin-fung, GBS, JP Hon WONG Ting-kwong, GBS, JP Hon YIU Si-wing, BBS Hon CHAN Chi-chuen Hon Alice MAK Mei-kuen, BBS, JP Dr Hon KWOK Ka-ki Dr Hon Helena WONG Pik-wan Hon CHUNG Kwok-pan Hon SHIU Ka-fai Dr Hon Pierre CHAN
Public Officers attending	:	Agenda item I & II Mr Howard CHAN, JP Deputy Secretary for Food & Health (Health)1 Food and Health Bureau Ms Leonie LEE Principal Assistant Secretary for Food & Health (Health)1 Food and Health Bureau

Mr Steve LAI
General Manager
Qualifications Framework Secretariat

Ms Elaine MAK
Principal Assistant Secretary (Further Education)
Education Bureau

Mr Patrick PANG
Deputy Executive Director (Training Services)
The Employees Retraining Board

Dr Tina CHAN
Assistant Director of Health (Special Health Services)
Department of Health

Dr Terence CHEUNG
Principal Medical & Health Officer (5)
Department of Health

Clerk in attendance : Ms Angel WONG
Chief Council Secretary (4)4

Staff in attendance : Miss Mandy NG
Senior Council Secretary (4)4

Miss Rachel WONG
Council Secretary (4)4

Ms Sandy HAU
Legislative Assistant (4)4

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I. Regulation and use of beauty devices

(LC Paper No. CB(4)671/18-19(01) -- Paper provided by the Administration)

LC Paper No. CB(4)671/18-19(02) -- Background brief on regulatory measures relevant to the beauty industry under the policy purview of health prepared by the Legislative Council Secretariat)

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The Subcommittee deliberated (index of proceedings attached at **Annex**).

Declaration of interest

2. The Deputy Chairman declared that she was the honorary member of several beauty industry associations. Also, her family member(s) owned beauty parlour(s) in which she had no pecuniary interest.

Briefing by the Administration

3. Principal Medical & Health Officer (5), Department of Health ("PMO(5), DH") gave a PowerPoint presentation on the regulatory framework of medical devices in other jurisdictions.

(*Post-meeting note*: The PowerPoint presentation materials were issued to members via LC Paper No. CB(4)831/18-19(01) on 2 May 2019.)

Major views and concerns

Regulation of medical devices

4. Given the broad definition of medical devices to be adopted under the proposed regulatory framework for medical devices, Mr SHIU Ka-fai questioned whether home-used abdominal muscle fitness devices for modifying or supporting the anatomy or a physiological process will be regarded as medical devices and regulated as such. He was worried that many home-used devices sold over the counter at electrical appliance shops would fall under the proposed framework. The Deputy Chairman shared similar concern and enquired whether Class II and Class III medical devices sold at electrical appliance shops would be regulated under the proposed framework.

5. Deputy Secretary for Food & Health (Health)1, FHB ("DS(H)1, FHB") and PMO(5), DH explained that a device which was intended to be used for modifying the anatomy of human bodies would meet the definition of medical devices formulated by the International Medical Device Regulators Forum (previously known as the Global Harmonization Task Force ("GHTF")) and would be regulated under the framework for medical devices, regardless of the place of sale. Devices classified as Class II to Class IV medical devices would be required to make registration under the framework.

6. Dr Helena WONG and Mr YIU Si-wing expressed concerns that the Administration could not differentiate between medical devices and beauty devices. Mr YIU considered that the proposed broad-brush approach to classify

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devices used for cosmetic procedures as medical devices was inappropriate and unfair to the beauty industry. The Administration should at least classify medical devices into medical devices for cosmetic purposes and medical devices for diagnostic purposes.

7. DS(H)1, FHB advised that there is currently no statutory definition for devices for cosmetic procedures in the international community. In order to bring Hong Kong on par with international development, the proposed regulatory framework for medical devices had made reference to the definition of medical device as recommended by GHTF.

8. While appreciating that the definition of medical devices was clear and the regulation was risk-based, Prof Joseph LEE suggested that further consideration should be given to providing a matrix system to show the risk level of medical devices by energy output level, intended purposes and intended users.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)1080/18-19(01) on 27 June 2019.)

9. The Deputy Chairman pointed out that the beauty industry did not object to a registration and licencing system with a view to regulating the beauty industry. However, many small and medium-sized beauty salons were worried about the difficulties in operation upon enactment of the legislation on medical devices. She enquired whether the Administration had an estimation of the number and types of devices used by the beauty industry and whether a business impact assessment had been conducted to assess the impact of the legislation on the beauty industry.

10. DS(H)1, FHB advised that as medical devices were not required to register at present, the Administration did not have an estimated number of devices for cosmetic procedures being used by beauty salons. Nevertheless, through rounds of communication with the industry stakeholders, the Administration had a grasp of the types of medical devices commonly used by the beauty industry, and the needs and difficulties of the beauty industry. On business impact assessment, Assistant Director of Health (Special Health Services), DH advised that the Administration had conducted regulatory impact assessment between 2007 and 2008, and business impact assessment between 2011 and 2013. In the course of drafting the legislation, the Administration had taken into account the recommendations from the assessment studies, such as exemption of registration for Class I medical devices.

11. The Chairman requested the Administration to provide lists of to-be-regulated medical devices that must be operated by registered medical practitioners, and those that could be operated by beauty practitioners who had

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taken relevant training programmes offered by the Employees Retraining Board or under the Qualifications Framework.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)1080/18-19(01) on 27 June 2019.)

Use control of medical devices

12. The Chairman, Mr SHIU Ka-fai, Dr Helena WONG, Ms Alice MAK and Dr KWOK Ka-ki expressed concerns about the shelving of use control of specific medical devices. The Chairman, Mr SHIU and Ms MAK noted that adverse incidents regarding improper cosmetic procedures were conducted by medical practitioners. They cast doubt on the effectiveness of the proposed framework in preventing the occurrence of these adverse incidents and considered it necessary to impose use control of high-risk medical devices.

13. Dr Helena WONG considered that the exclusion of use control under the proposed framework for medical devices was inconsistent with the prevailing regulatory practices in other jurisdictions. She was concerned about the party to be held liable for the adverse incidents arising from improper use of medical devices.

14. Dr KWOK Ka-ki recalled that the Administration had proposed use control of specific medical devices under the proposed regulatory framework for medical devices. He enquired whether the Administration had shelved the proposal because there had been a decrease of the number of complaints concerning cosmetic procedures since 2017, and when the Administration would impose use control.

15. DS(H)1, FHB advised that taking into account the feedback from stakeholders, use control for specific medical devices will not be imposed at the present stage. The Administration would revisit the use control at a later stage so as to allow more time for reaching consensus with stakeholders. Meanwhile, traders and manufacturers had to report to DH adverse incidents in connection with their medical devices. DH would then require traders and manufacturers to take remedial actions and conduct product recall if necessary. On a member's concern as to whether Hong Kong is consistent with other jurisdictions, PMO(5), DH advised that there was no legislation on use control of medical devices used for cosmetic procedures in countries such as the United Kingdom and Australia while regulations of medical devices and use control of medical devices used for cosmetic procedures were under separate regimes in some other countries such as the United States and South Korea.

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16. Mr SHIU Ka-fai supplemented that between 2017 and 2018, the number of complaints against beauty services received by Consumer Council had decreased from 1 147 to 1 058, and the number of medical service complaints increased from 703 to 2 462. Dr KWOK Ka-ki further requested the Administration to provide information regarding the number of complaints concerning cosmetic procedures received by the Consumer Council and DH in 2017, 2018 and 2019, and information on beauty service incidents arising from the lack of regulation on devices used for cosmetic procedures.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)1080/18-19(01) on 27 June 2019.)

Transitional listing system

17. Mr SHIU Ka-fai relayed the concerns of device suppliers that the devices used by the beauty industry would not be able to obtain marketing approvals upon expiry of the five-year transitional period because they were not designed for medical purposes. Moreover, many traders could not afford the high costs for conformity assessment. As a result, these devices could no longer be imported to Hong Kong. He therefore urged for a separate regime for regulating devices used for cosmetic procedures.

18. Ms Alice MAK raised concern about the potential safety risks associated with the use of medical devices falling short of registration requirements.

19. DS(H)1, FHB advised that the transitional listing system was introduced in response to the concerns of the beauty industry that a number of devices commonly used by the industry at the moment would not be able to fulfill the proposed medical device registration requirements. It was hoped that the beauty industry would have sufficient time to change to import registered devices from authorized channels. DH would provide information and assistance to beauty industry and traders in the registration of devices for cosmetic procedures. The ultimate goal of the transitional arrangement was for all medical devices including those for cosmetic procedures in Hong Kong to fully meet all registration requirements. In fact, certain devices used for cosmetic procedures had met medical device registration requirements and listed on the current Medical Device Administrative Control System.

20. The Deputy Chairman enquired about the registration arrangement for imported devices for cosmetic procedures after the five-year transitional period. DS(H)1, FHB advised that all new medical devices have to meet registration requirements after the transitional arrangement. The Administration would continue to maintain a close communication with beauty industry to minimize the impact on the industry.

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Registration of traders

21. Dr Helena WONG and Ms Alice MAK enquired about the licencing requirements for traders under the proposed framework for medical devices and whether traders were required to comply with certain post-market control measures, such as providing users with training and manuals for operating the supplied medical devices. Dr WONG also expressed concern as to whether legal action would be taken against them for non-compliance.

22. DS(H)1, FHB responded that the agent of concerned devices has to register with DH as the authorized representative before filing medical device registration application to DH. For registration of medical devices, the Administration would accept direct applications from medical devices with marketing approvals issued by GHTF countries, Mainland China and South Korea, as equivalent to satisfying the third-party conformity assessment requirements. DH would have a dedicated office to handle medical device registration issues. For better protection of public safety, the Administration would require traders to fulfil after-sale obligations, provide training and manuals to users for operating the supplied medical devices, etc. as the licencing requirements.

23. Ms Alice MAK expressed concern as to whether manufacturers in countries which required registration for marketing medical devices for cosmetic procedures had exported non-registered devices to Hong Kong. She requested the Administration to provide a list of such manufacturers and exported devices, if any.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)1080/18-19(01) on 27 June 2019.)

II. Implementation of Qualifications Framework in the beauty industry

(LC Paper No. CB(4)808/18-19(01) -- Paper provided by the Administration)

24. Due to time constraint, the Subcommittee was unable to discuss the item on "Implementation of Qualifications Framework in the beauty industry".

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III. Any other business

25. To allow sufficient time for discussion, the Chairman directed that the Subcommittee would continue the discussion of item "Regulation and use of beauty devices", and discuss "Implementation of Qualifications Framework in the beauty industry" at the next meeting.

26. There being no other business, the meeting ended at 4:33pm.

Council Business Division 4
Legislative Council Secretariat
5 June 2020

Annex

Panel on Health Services and Panel on Commerce and Industry

Proceedings of the fifth meeting of the Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry on Thursday, 2 May 2019 at 2:30 pm in Conference Room 3 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s)	Action required
Agenda Item I – Regulation and use of beauty devices			
000741-002336	Chairman The Administration	Opening remarks Administration's briefing on regulatory framework of medical devices in other jurisdictions	
002337-003349	Chairman Mr SHIU Ka-fai The Administration	Definitions of medical devices and beauty devices Beauty device registration arrangement upon expiry of the five-year transitional listing period Regulation of medical and beauty devices in overseas countries	
003350-004018	Chairman Dr Helena WONG Administration	Definitions of medical devices and beauty devices Medical device registration requirements Use control of medical devices After-sale obligations of traders	
004019-005127	Chairman Prof Joseph LEE The Administration	Definitions of medical devices and beauty devices The Administration was requested to provide a matrix system to show the risk level of medical devices by energy output level, intended purposes and intended users	
005128-010033	Chairman Deputy Chairman The Administration	Definitions of medical devices and beauty devices The need of a business impact assessment to assess the impact of the proposed regulatory framework for medical devices on the beauty industry	

Time marker	Speaker(s)	Subject(s)	Action required
010034-010911	Chairman Dr KWOK Ka-ki The Administration	Use control of specific medical devices The Administration was requested to provide the number of complaints concerning cosmetic procedures received by the Consumer Council and Department of Health in 2017, 2018 and 2019, and information on beauty service incidents arising from the lack of regulation on devices used for cosmetic procedures	
010912-011519	Chairman Mr YIU Si-wing The Administration	Definitions of medical devices and beauty devices Possible consequences resulting from the broad definition of medical devices	
011520-012136	Chairman Ms Alice MAK The Administration	Regulation of medical devices Potential health risks associated with devices not meeting registration requirements Registration and after-sale obligations of traders	
012137-013217	Chairman The Administration	Use control of medical devices	
013218 - 013629	Chairman	Suspension of meeting to facilitate members to attend the meeting of Bills Committee on National Anthem Bill	
013630-014825	Chairman Mr SHIU Ka-fai The Administration	Number of complaints against beauty and medical services received by the Consumer Council in 2017 and 2018 Impact of the proposed regulatory framework for medical devices on device suppliers Use control of medical devices	
014826-015545	Chairman Ms Alice MAK The Administration	Use control of medical devices Registration of traders	
015546-020223	Chairman Deputy Chairman The Administration	Declaration of interest The need of a business impact assessment to assess the impact of the proposed regulatory framework for medical devices on the beauty industry Enhancement of the competency of beauty practitioners for operating beauty devices	

Time marker	Speaker(s)	Subject(s)	Action required
020224-020619	Chairman Ms Alice MAK	The Administration was requested to provide the following information: (a) list of to-be-regulated medical devices that must be operated by registered medical practitioners; (b) list of to-be-regulated medical devices that could be operated by beauty practitioners who had taken relevant training programmes offered by the Employees Retraining Board or under the Qualifications Framework for the beauty industry; and (c) list of manufacturers in countries which required registration for marketing medical devices for cosmetic procedures exporting non-registered devices to Hong Kong and the exported devices.	
Agenda Item III – Any other business			
020620-020649	Chairman	Closing remarks	

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