立法會
Legislative Council

LC Paper No. CB(4) 674/19-20
(These minutes have been seen by the Administration)

Ref : CB4/PS/1/18

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 second meeting held on Friday, 25 January 2019 at 8:45 am in Conference Room 1 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 Dr Hon CHIANG Lai-wan, SBS, JP Hon CHUNG Kwok-pan Hon SHIU Ka-fai Dr Hon Pierre CHAN
Public officers attending	:	Mr Howard CHAN, JP Deputy Secretary for Food & Health (Health)1 Ms Leonie LEE Principal Assistant Secretary for Food & Health (Health)1 Ms Betty HO Principal Assistant Secretary for Commerce & Economic Development (Commerce & Industry)5

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

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

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

Ms Sandy HAU
Legislative Assistant (4)4

Action

I. Government's measures and initiatives to regulate beauty devices and develop beauty industry

(LC Paper No. CB(4)443/18-19(01) -- Paper provided by the Administration)

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

Declaration of interest

2. Prof Joseph LEE declared interest as the Chairman of Federation of Beauty Industry (HK). 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. Assistant Director of Health (Special Health Services), Department of Health ("AD(SHS), DH"), Principal Assistant Secretary for Commerce & Economic Development (Commerce & Industry)5, Commerce and Economic Development Bureau ("PAS(CI)5, CEDB"), Principal Assistant Secretary (Further Education), Education Bureau and Deputy Executive Director (Training

Action

Services), The Employees Retraining Board ("Deputy Executive Director (Training Services), ERB") gave a PowerPoint presentation on the existing measures to regulate medical devices and support beauty industry.

(*Post-meeting note*: The PowerPoint presentation materials were issued to members via LC Paper No. CB(4)471/18-19(01) on 25 January 2019.)

Major views and concerns

Regulation of medical devices

4. Dr Helena WONG recalled that in view of the adverse incidents related to high-risk cosmetic procedures, there was general agreement among stakeholders to regulate medical beauty devices. As the Administration was planning on introducing the Medical Devices Bill ("the Bill") for regulation of medical devices, she enquired whether cosmetic-related devices would be regulated under the Bill.

5. AD(SHS), DH advised that in defining the term "medical device" for the Bill, DH had adopted the definition of "medical device" as recommended by the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force ("GHTF")). Under the definition, the term "medical device" referred to any instrument, apparatus or appliance that was used for diagnosis, treatment or monitoring of diseases and injuries. It also covered devices that were used for the purposes of replacement or modification of related body structures or physiological process whereby a more satisfactory body state was attained to give a better appearance. As certain devices used in cosmetic procedures altered the skin physiological processes by means of medical technology whereby achieving the effect of modifying skin structures, such as Extracorporeal Shockwave Therapy (ESWT) device and High Intensity Focused Ultrasound (HIFU) device, they therefore fell within the definition of "medical device" that would be regulated under the proposed Bill.

6. Mr WONG Ting-kwong pointed out that many adverse incidents related to cosmetic procedures involved the use of invasive devices supervised by medical practitioners on site. Cosmetic-related devices should not be classified as medical devices across the board. The Administration should have a clear definition of "medical beauty device" and "beauty device" for regulatory purpose. Mr SHIU Ka-fai shared similar view and suggested that separate regulatory regimes should be put in place respectively for devices used for medical purposes and those used for cosmetic purposes. Moreover, since different countries had different criteria for defining a medical device and a cosmetic device, Mr SHIU considered it not appropriate for DH to adopt IMDRF's definition of "medical device".

Action

7. Deputy Secretary for Food & Health (Health)1, Food and Health Bureau ("DS(H)1, FHB") advised that the Administration had not identified any jurisdictions with a separate regulatory system for "beauty devices" and were not aware of jurisdictions with a regulatory regime of medical devices in place which did not regulate "beauty devices" as part of the regime.

Transitional listing system

8. Noting that a five-year transitional listing mechanism would be introduced for medical devices falling short of the registration requirements but complying with basic listing requirements set by DH, Dr Helena WONG sought further information on the registration and listing requirements of a medical device. She expressed concern about the potential risks associated with the medical devices not fulfilling the registration requirements.

9. AD(SHS), DH advised that the proposed transitional listing mechanism would be introduced as an interim measure for five years to allow traders of medical devices time to introduce overseas devices meeting the registration requirements and to familiarize themselves with the statutory registration regime. Under the mechanism, traders and manufacturers could apply for listing of medical devices falling short of the registration requirements but conforming to general electrical equipment safety requirements. Meanwhile, they had to undertake post-market surveillance and report adverse incidents associated with the medical devices. By doing so, the Administration could monitor the use of devices and enable product recalls when necessary.

10. The Chairman enquired about the time needed for approving applications for listing or registering new-to-the-market medical/beauty devices. In his view, DH should process an application expeditiously and make a practical performance pledge on the processing time. AD(SHS), DH advised that a voluntary Medical Device Administrative Control System had been launched since 2004 to ensure that listed medical devices were safe before they were placed on the local market. Under the system, a manufacturer of medical devices imported from overseas countries should designate a local responsible person to serve as the hub of communication between the manufacturer, importers, distributors and the Government. Documents related to the manufacturer's manufacturing quality management system, and the safety and performance of the imported medical devices should be provided. Upon receipt of the completed application form and the necessary supporting documents, DH would normally complete the processing and approval of an application within 12 weeks. Information on the listed medical devices and listed traders would then be uploaded on the website of DH for public access.

Action

Use control of medical devices used in cosmetic procedures

11. Dr Helena WONG and Dr KWOK Ka-ki urged for the inclusion of use control of specified medical devices (i.e. to restrict the use of specific types of medical devices used in cosmetic procedures to users with certain qualifications) under the Bill for better protection of public health. Dr WONG considered that the Bill which only focused on pre-market and post-market control could not fully achieve the policy objective of safeguarding the public health interests. The operation of a medical device by a person without proper training might pose health risks to the customers. Imposing control over the use and operation of medical devices used in cosmetic procedures would prevent unnecessary harm or complications arising from their improper use. She suggested that the Administration should consider introducing a transitional period of, for example, five years to allow sufficient time for operators of medical devices used in cosmetic procedures to acquire the necessary training regarding the proper use of these devices.

12. Mr WONG Ting-kwong and Mr SHIU Ka-fai considered that for regulatory purpose, the Administration should identify the medical devices that should be operated by medical practitioners and those operated by beauty practitioners. Mr SHIU further suggested that the Administration should provide training to beauty practitioners to recognize their competencies in operating certain beauty devices.

13. Mr YIU Si-wing was of the view that to ensure the safety and quality of medical devices, there was a need to restrict the use of certain types of medical devices used in cosmetic procedures to users who had completed basic training on the operation of the devices.

14. DS(H)1, FHB advised that the Administration considered it more desirable to impose pre-market control and post-market control for all medical devices, as well as use control for specific medical devices. However, when the Administration consulted the medical sector, the beauty industry, traders of medical devices and Legislative Council Members on the Bill, there were diverse views on whether use control should be pursued. As the general public expected that pre-market and post-market control for medical devices should be introduced as soon as practicable and that consensus over use control might not be reached soon, the Bill would not include use control of specified medical devices at the present stage. It had already been put in place that cosmetic procedures associated with high risk of complications should be performed by medical practitioners.

Training and accreditation for beauty practitioners

15. Mr YIU Si-wing noted that beauty practitioners' participation in

Action

Qualifications Framework ("QF") in Hong Kong was voluntary. He considered that to enhance industry standards, the Administration should require beauty practitioners to undergo mandatory training for the use of beauty devices and provision of beauty services in the long run.

16. Mr WONG Ting-kwong pointed out that the beauty industry had proactively called for the upgrading of the service standards and healthy development of the trade. The Administration should develop training, appraisal and registration systems for beauty practitioners, with a view to professionalizing the beauty industry.

17. DS(H)1, FHB advised that the Administration saw the need of enhancing competency of beauty practitioners. In fact, training programmes and attainment of qualifications through the Recognition of Prior Learning mechanism were available under QF which was a voluntary system. The Administration would continue to communicate with the industry and Subcommittee members on whether mandatory training should be required by all beauty practitioners. Deputy Executive Director (Training Services), ERB supplemented that in general, ERB would consult the beauty sector in developing relevant training courses to cater for the training needs of the beauty industry.

18. Prof Joseph LEE pointed out that apart from the provision of training support, the Administration should make reference to Korea and Japan to establish a mechanism for the accreditation of qualifications for the beauty practitioners so as to promote the development of the industry. He suggested that FHB should consider applying the spirit of the Accredited Registers Scheme for Healthcare Professions ("AR Scheme") to establish an accreditation mechanism for beauty practitioners with a view to ensuring their professional competency. DS(H)1, FHB advised that AR Scheme aimed to enhance the society-based registration arrangements for healthcare professions which were currently not subject to statutory registration, with a view to ensuring the competence of healthcare professionals and providing more information for the public to make informed decision. As most of the beauty practitioners did not perform medical procedures, AR Scheme might not be the best option for beauty practitioners.

19. The Chairman urged the Administration to discuss the establishment of a training system with the Education Bureau ("EDB") and the beauty sector including front-line staff; and to explore the feasibility of adopting AR Scheme for the beauty industry.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)573/18-19(01) on 22 February 2019.)

Action

Regulation and development of beauty industry

20. Mr YIU Siu-wing opined that the aims of the regulation of beauty services should be two-fold; first to protect public health and second, to facilitate the development of the beauty industry. In view of the booming beauty industry in Korea and Japan, he strongly urged the Administration to conduct a detailed study to examine the experience and practices in these two countries and consider measures to improve the standard for beauty services and develop the beauty industry in Hong Kong. Dr Helena WONG considered it necessary for the Administration to set up a dedicated task force to coordinate cross-bureaux and cross-departmental work to facilitate a healthy development of the beauty industry.

21. Mr WONG Ting-kwong opined that industrialization of the beauty sector should not be hindered by the regulatory measures. He suggested that the relevant Bureaux/departments should collaborate with the beauty sector in establishing a separate regime for the sector and promoting its development.

22. The Deputy Chairman opined that a flourishing beauty industry could create employment opportunities and wealth for Hong Kong. The Administration should formulate a holistic policy for the development of the industry and asked whether FHB would be responsible for that. DS(H)1, FHB responded that the Chief Secretary for Administration would steer FHB, EDB, Commerce and Economic Development Bureau ("CEDB") and Labour and Welfare Bureau to address issues arising from the discussion on the regulation and development of the beauty industry. FHB would serve as the main contact point before a most suitable lead bureau could be identified.

Implementation of cooling-off period in the beauty industry

23. In the light of the numerous complaints about unfair trade practices in the beauty industry, Mr WONG Ting-kwong expressed support to enhance consumer protection by imposing a cooling-off period on the trade and reminded the Administration to take into account the operational difficulties that would be faced by the beauty sector during the implementation. Mr SHIU Ka-fai and the Deputy Chairman expressed concern that the trade would face enormous operational difficulties if the cooling-off period was implemented. The Deputy Chairman requested the Administration to provide support measures to assist the trade.

24. While welcoming the implementation of cooling-off period to regulate the beauty industry, Dr KWOK Ka-ki suggested that the Administration should consider developing regulatory measures such as licensing system and marking scheme for beauty practitioners and beauty parlour proprietors to tackle unfair trade practices so as to protect consumer rights.

Action

25. PAS(CI)5, CEDB noted that a 3-month public consultation to gauge views on the cooling-off period of the beauty industry had started. The Panel on Economic Development would hold a meeting on 28 January 2019 to invite public views on the cooling-off period. The public may also express views on related issues during the public consultation.

II. Any other business

26. Members suggested and the Chairman agreed that a meeting should be held to invite public views on the regulation and development of beauty industry. The Chairman also invited members to inform the Secretariat of the issues they would like to discuss in future Subcommittee meetings.

27. Due to the diverse views on whether a duty visit should be conducted, the matter would be discussed at a later stage.

28. There being no other business, the meeting ended at 10:41 am.

Council Business Division 4
Legislative Council Secretariat
5 June 2020

Annex

Panel on Health Services and Panel on Commerce and Industry

Proceedings of the second meeting of the Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry on Friday, 25 January 2019 at 8:45 am in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s)	Action required
Agenda Item I – Government's measures and initiatives to regulate beauty devices and develop beauty industry			
000405-000634	Chairman	Opening remarks	
000635-002839	Chairman The Administration	Administration's briefing on the existing measures to regulate medical devices and support beauty industry	
002840-004046	Dr Helena WONG The Administration	Implementation details of the proposed Medical Devices Bill ("the Bill") including the definition of the term "medical device" and the introduction of five-year transitional listing system for medical devices Inclusion of use control for specific medical devices under the Bill	
004047-004657	Mr YIU Si-wing The Administration	Inclusion of use control for specific medical devices under the Bill Measures to regulate and develop the beauty industry in Hong Kong Mandatory training for beauty practitioners	
004658-005616	Chairman Mr WONG Ting-kwong The Administration	Regulation of beauty devices Implementation of the proposed cooling-off period in the beauty industry Development of training, appraisal and registration systems to enhance competency of beauty practitioners	
005617-010547	Chairman Prof Joseph LEE The Administration	Declaration of interest Adoption of the Accredited Registers Scheme for Healthcare Professions for beauty practitioners	

Time marker	Speaker(s)	Subject(s)	Action required
010548-011644	Mr SHIU Ka-fai The Administration	Definition of the term "medical device" under the Bill and regulation of beauty devices Use control of medical devices used in cosmetic procedures Training for beauty practitioners Implementation of cooling-off period in the beauty industry	
011645-012302	Chairman Mr SHIU Ka-fai Mr WONG Ting-kwong The Administration The Deputy Chairman	Invitation of public views on regulation and development of beauty industry Training for beauty practitioners	
012303-013447	Chairman Deputy Chairman The Administration	Declaration of interest Implementation of cooling-off period in the beauty industry Measures to support the development of the beauty industry	
013448-014111	Dr KWOK Ka-kei The Administration	Measures to tackle unfair trade practices in the beauty industry including the implementation of cooling-off period	
014112-014559	Chairman The Administration	Mechanism for approving applications for listing/registering new-to-the-market medical devices	
014600-015052	Chairman Deputy Chairman Mr SHIU Ka-fai The Administration	Implementation of cooling-off period in the beauty industry	
015053-015537	Dr Helena WONG Dr KWOK Ka-kei The Administration	Use control of medical devices used in cosmetic procedures	
Agenda Item II – Any other business			
015538-015926	Chairman Dr Helena WONG Mr SHIU Ka-fai	Discussion items for future meetings Overseas duty visit Closing remarks	