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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 fourth meeting
held on Monday, 25 March 2019 at 2:15 pm
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 Hon SHIU Ka-fai Dr Hon Pierre CHAN
Member absent	:	Hon CHUNG Kwok-pan
Public officers attending	:	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

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

Ms Sandy HAU
Legislative Assistant (4)4

Action

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)

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

Action

Briefing by the Administration

2. With the aid of PowerPoint presentation, Assistant Director of Health (Special Health Services), Department of Health ("AD(SHS), DH") briefed members on the regulation of medical devices including those for use in cosmetic procedures as detailed in the Administration's paper (LC Paper No. CB(4)671/18-19(01)).

(*Post-meeting note:* The PowerPoint presentation materials were issued to members via LC Paper No. CB(4)678/18-19(01) on 25 March 2019.)

Major views and concerns

Regulation of beauty devices

3. Prof Joseph LEE requested the Administration to give clear definitions of medical devices and beauty devices under the Medical Devices Bill ("the Bill"). Deputy Secretary for Food & Health (Health)1, Food and Health Bureau ("DS(H)1, FHB") advised that the Bill was proposed to regulate medical devices. Hence, medical devices used by the beauty industry would also be subject to the regulation of the Bill. In fact, the Administration only had a definition on medical devices. To have a clearer definition of medical devices, Prof LEE requested the Administration to provide a matrix showing classification of medical devices by risk level, 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)803/18-19(01) on 24 April 2019.)

4. Mr WONG Ting-kwong considered that the Administration should not classify beauty devices as medical devices across the board. Clear definitions of medical and beauty devices should be provided to avoid hindering the development of beauty industry. To further facilitate beauty industry development, the Administration should make reference to the experiences and practices of Japan, South Korea and Taiwan in regulating medical devices. DS(H)1, FHB shared Mr WONG's view that regulation of medical devices should not hinder the development of beauty industry. He advised that the Administration would maintain a close communication with the beauty industry over the regulation of medical devices. He further advised that medical device regulation in these countries were similar to that proposed under the Bill.

Action

5. Mr SHIU Ka-fai drew the Administration's attention that the general public could purchase Extracorporeal Shockwave Therapy (ESWT) device and High Intensity Focused Ultrasound (HIFU) device which were classified as Class II and Class III medical devices from electrical appliance shops. He enquired whether these devices would be regulated under the Bill. AD(SHS), DH advised that these medical devices for home use would be regulated under the Bill and could be listed under the transitional listing system if unable to meet the registration requirements of medical devices.

Transitional listing system

6. Mr SHIU Ka-fai enquired about the application procedures for listing beauty devices used by the beauty industry and those for home use under the transitional listing system. Dr Helena WONG sought further information on the arrangement of the listed beauty devices after the five-year transitional period.

7. AD(SHS), DH advised that medical devices for home use which had already obtained marketing approval from recognized countries could be registered as medical devices after the enactment of the Bill. For devices falling short of registration requirements but complying basic listing requirements set by DH, they could be listed under the listing system for five years, subject to renewal of the listing status every five years.

8. Dr Helena WONG further enquired whether the Administration had an estimation of the number and types of beauty devices that would likely be listed under the transitional listing system. DS(H)1, FHB advised that devices such as ESWT device, laser device, intense pulsed light device were commonly used by the beauty industry. As these devices were not required to register at present, the Administration did not have an estimated number of beauty devices that would be listed under the transitional listing system. Also, given the rapid pace of technological advancement, there were always new devices in the market. The Administration believed that not many devices would apply for renewal after the five-year window.

9. Ms Alice MAK enquired about the delisting criteria under the transitional listing system and whether a medical device model would be delisted if a device of that model was found to be problematic. AD(SHS), DH advised that investigation would be conducted when there were reportable adverse incidents of a listed medical device. If the medical device model was found to be problematic, DH would require traders to take remedial action and conduct product recalls whenever necessary. If the device posed a serious threat, the device would be delisted.

Action

Registration of traders and medical devices

10. Ms Alice MAK enquired about the requirements for being a registered trader of medical devices under the Bill and the monitoring measures to ensure that these traders would maintain proper records of the devices and would not supply unregistered devices. AD(SHS), DH advised that traders of medical devices must register with or obtain a licence from DH before they could supply medical devices in Hong Kong. To ensure the safety of a device in the market, traders must comply with certain registration requirements or licensing conditions, which included maintaining records of supply and producing such records to DH for inspection upon request, providing training on how to operate the devices and guidance on their maintenance, providing detailed labels and instructions for use on the devices, etc. DH would take enforcement action if unregistered devices were found in the market.

11. Dr KWOK Ka-ki expressed dissatisfaction that for medical device registration, the Administration would exempt devices which had acquired marketing approvals from the founding members of the Global Harmonization Task Force ("GHTF") (now known as International Medical Device Regulators Forum ("IMDRF")) and certain jurisdictions such as Mainland China and South Korea from submitting third-party conformity assessment to certify compliance with safety and performance requirements. He cast doubt over the credibility of the marketing approvals from Mainland China, South Korea and GHTF founding members and considered the exemption unfair to other countries. He further enquired about the criteria for accepting the marketing approvals of these countries and whether the Administration had sought Department of Justice's ("DoJ") advice on the exemption arrangement.

12. DS(H)1, FHB advised that DoJ had been consulted on the Bill. AD(SHS), DH explained that the Administration's original proposal was to require traders applying for medical device registration to submit either third-party conformity assessment certificates from Conformity Assessment Bodies or marketing approvals from five GHTF founding members: Australia, Canada, European Union, Japan and the United States of America together with relevant technical documents. Marketing approval meant that the safety and performance of these devices had been assessed by an organization and cleared for marketing by a regulatory authority. Marketing approval did not mean exemption from safety and performance requirements. Under the refined proposal, in addition to marketing approvals provided by GHTF founding members or the third-party conformity assessment, those approvals issued by countries with mature medical device regulation system such as Mainland China and South Korea would also be accepted. Moreover, DH would assess each application for medical device registration before issuing approval for registration. On Dr KWOK's concern about the credibility of the approvals made by GHTF/IMDRF founding members, AD(SHS), DH advised that GHTF

Action

(now IMDRF) was a forum set up to work for standardization of medical device regulation across the world via the publication and dissemination of harmonized guidance documents for regulatory practices. IMDRF was recognized by the World Health Organization who was its official observer.

13. Mr SHIU Ka-fai expressed concerns that different countries might have different definition of medical device. A device might not be able to obtain marketing approvals from GHTF founding members, Mainland China and South Korea if it was not classified as a medical device in these countries. As a result, the device could not be introduced to the market. PMO(5), DH explained that DH adopted the comprehensive definition of medical device as formulated by IMDRF. If a device was not classified as a medical device in other countries, most likely it would not be considered a medical device in Hong Kong and would not be required to register as medical device. DH would issue guidance notes setting out the general principles and advices to facilitate the trade to decide if devices were "medical device" under the law when the Bill was enacted.

14. Mr SHIU Ka-fai requested the Administration to provide the procedures and criteria for defining a medical device, as well as the procedures for obtaining approval for marketing a medical device in the five GHTF founding countries, South Korea and Mainland China.

(*Post-meeting note*: The Administration's written information was issued to members vide LC Paper No. CB(4)803/18-19(01) on 24 April 2019.)

15. The Chairman enquired about DH's performance pledge on the processing time for approving applications for registering new-to-the-market medical devices. He considered that the registration process should be kept simple with a view to minimizing the lead time required to place these devices on the market. PMO(5), DH remarked that the vetting and approval of an application for listing/registering a device would normally be completed within 12 weeks following the submission of the application and all the required supporting documents.

Use control of medical devices

16. Dr KWOK Ka-ki considered that consumer interests would not be protected if the Bill did not include use control and enquired when the Bill would be introduced. DS(H)1, FHB advised that there was currently no specific regime to regulate medical devices. The Administration planned to introduce the Bill into the Legislative Council in the 2018-2019 legislative session, with a view to ensuring the safety and performance of medical devices including beauty devices which met the definition of medical device. This would be a

Action

positive step forward in protecting public health.

17. Prof Joseph LEE and Dr Pierre CHAN were concerned that the general public could purchase registered medical/beauty devices for home use. If use control was not imposed, there might be adverse incidents arising from improper use of the devices and nobody would be held responsible. DS(H)1, FHB advised that as there were diverse views on use control and consensus over use control might not be reached soon, the Bill would not include use control of specified medical devices 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 the beauty industry.

18. Ms Alice MAK suggested that before use control was imposed, the Administration should consider requiring a registered trader of medical devices to provide users with training and manuals for operating the supplied medical devices as one of the registration requirements. In addition, the Administration should ensure all beauty practitioners receive the necessary training for operating the beauty devices from the traders.

19. The Chairman noted that medical devices would be classified into Class I to Class IV based on their risks and asked whether the Administration would adopt the same risk-based approach to require traders to provide the level of training in proportionate to the degree of risk of the medical devices. Mr SHIU Ka-fai urged the Administration to differentiate between high-risk medical devices and non-invasive beauty devices and specify what devices could be operated by beauty practitioners and what training should be provided for these practitioners for operating the devices. Mr WONG Ting-kwong shared similar views with Mr SHIU and urged the Administration to impose use control through legislation in the long run.

20. AD(SHS), DH responded that at present, medical devices for home use might be provided with operation manuals. For beauty devices, traders would commonly provide training regarding the proper use of the devices to beauty practitioners. Given the diversity of medical devices, it would be difficult to determine a standardized level of training for all the medical devices in a particular Class. On the contrary, the level of training for each device should take reference to its potential risks and users. DS(H)1, FHB supplemented that DH would require traders to provide sufficient training regarding the proper use of the medical devices as a registration requirement.

Items for discussion at the next meeting

21. The Chairman proposed and members agreed that the Subcommittee would continue to discuss regulation and use of beauty devices at the next meeting.

Action

II. Any other business

22. There being no other business, the meeting ended at 4:16pm.

Council Business Division 4
Legislative Council Secretariat
25 May 2020

Annex

Panel on Health Services and Panel on Commerce and Industry

Proceedings of the fourth meeting of the Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry on Monday, 25 Match 2019 at 2:15 pm in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s)	Action required
Agenda Item I – Regulation and use of beauty devices			
000439-002416	Chairman The Administration	Opening remarks Administration's briefing on the regulation of medical devices including those for use in cosmetic procedures	
002417-003614	Chairman Dr KWOK Ka-ki Administration	Documentary evidence for medical device registration under the Medical Devices Bill ("the Bill") Legislative timeline for the Bill	
003615-005729	Chairman Ms Alice MAK Administration	Registration of traders Delisting criteria under the transitional listing system Inclusion of user training as a medical device registration requirement	
005730-012047	Chairman Mr SHIU Ka-fai Administration	Regulation of beauty devices sold by electric appliance shops Registration requirements for medical devices Definition of the term medical device under the Bill Application procedures for listing beauty devices and renewing listing status	
012048-014818	Chairman Prof Joseph LEE Administration	The Administration was requested to provide a matrix showing classification of medical devices by risk level, energy output level, intended purposes and intended users Use control of medical devices	
014819-015116	Chairman Dr Pierre CHAN Administration	Use control of medical devices	

Time marker	Speaker(s)	Subject(s)	Action required
015117-015830	Mr WONG Ting-kwong Administration	Definition of the term medical devices under the Bill Regulation and development of the beauty industry	
015831-020344	Dr Helena WONG Administration	Renewal of listing status of medical devices under the transitional listing system Estimated number and types of listed devices under the transitional listing system	
Agenda Item II – Any other business			
020345-020513	Chairman Mr SHIU Ka-fai	The Administration was requested to provide the procedures and criteria for defining a medical device, as well as the procedures for obtaining approval for marketing a device in the founding members of the Global Harmonization Task Force, South Korea and Mainland China Closing remarks	

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