

立法會
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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 third meeting
held on Tuesday, 26 February 2019 at 2:30 pm
in Conference Room 2 of the Legislative Council Complex**

- Members present** : Hon Tommy CHEUNG Yu-yan, GBS, JP (Chairman)
Dr Hon Elizabeth QUAT, BBS, JP (Deputy Chairman)
Hon Jeffrey LAM Kin-fung, GBS, JP
Hon WONG Ting-kwong, GBS, JP
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
- Members absent** : Prof Hon Joseph LEE Kok-long, SBS, JP
Hon YIU Si-wing, BBS
Dr Hon Pierre CHAN
- 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

Ms Jacko TSANG
Principal Assistant Secretary for Commerce & Economic
Development (Commerce & Industry)SD

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

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

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

Attendance by : Agenda item I
invitation

Hong Kong Doctors Union

Dr Albert KONG Yim-fai
Vice President

International CICA Association of Esthetics

Ms LUK Wai-fong
Chairman

Miss CHAN Yu

The Democratic Party

Mr YUEN Hoi-man
Spokesperson

Federation of Beauty Industry (H.K.)

Ms Angela CHAN Sau-yee
Chairman

Hong Kong Beauty Industry Union

Ms TSANG Yue
主席

黃麗女士

Beauty Industry Standardisation Organisation

Mr Nelson IP
Chairman

The Cosmetic & Perfumery Association of HK

Mr HO Shiu-chung
Chief Supervisor

Association of Private Medical Specialists of Hong Kong

Dr Veronica WAI Yuk-chun
Council Member

Liberal Party

Mr Dominic LEE
黨員

Hong Kong Dental Association

Dr Haston LIU Wai-ming
President

Mr NGAN Tsz-leung

Democratic Alliance for the Betterment and Progress of
Hong Kong

Mr HUI Wah-kit
Commerce & Industry Affairs Vice-Spokesperson

Ms KWOK Man-ha

Grand Aesthetic Academy

Ms Kay WAN
Head of Training & Development

Citi Concept

Ms Jo WONG Choi-lam
Training & Development Manager

Ms LAM Ho-yan

Hong Kong Medical and Healthcare Device Industries
Association

Mr Benjamin CHAN Wai-kit
Deputy Chairman

Medtechnoskorp Ltd

Mr Rupert MOK Kwok-cheung
President

Associated Medical Supplies Company Limited

Mr Henry LAM Kee-wo
Managing Director

Hong Kong Beauty and Fitness Professional General Union

Ms Amy HUI

Starz Tech International Ltd

YIM Wai-ling
Administration Officer

鍾蔚庭先生

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

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

Ms Peggy CHUNG
Council Secretary (4)3

Ms Sandy HAU
Legislative Assistant (4)4

Action

I. Development, regulation and support of the beauty industry

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

Written submissions from deputations/individuals not attending the meeting

(LC Paper No. CB(4)558/18-19(06) -- Submission from the Hong Kong Society of Dermatology & Venereology (*English version only*)

LC Paper No. CB(4)558/18-19(07) -- Submission from the Patients and Healthcare Professionals Rights Association (*Chinese version only*)

LC Paper No. CB(4)558/18-19(08) -- Submission from Hong Kong College of Dermatologists (*English version only*)

LC Paper No. CB(4)558/18-19(09) -- Submission from Dr CHAN Wai-man, Mandy (*English version only*)

LC Paper No. CB(4)576/18-19(01) -- Submission from the Hong Kong Academy of Nursing (*English version only*)

LC Paper No. CB(4)576/18-19(02) -- Submission from the Hong Kong Association of the Pharmaceutical Industry (*English version only*)

LC Paper No. CB(4)576/18-19(03) -- Submission from the Hong Kong College of Physicians (*English version only*)

LC Paper No. CB(4)596/18-19(07) -- Submission from the Federation of Medical Societies of Hong Kong (*English version only*)

Action

LC Paper No. CB(4)596/18-19(08) -- Submission from the Hong Kong Medical Association
(*English version only*)

LC Paper No. CB(4)596/18-19(09) -- Submission from Civic Party (*English version only*)

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

2. The Administration's response to the views expressed by deputations at the meeting:

Deputy Secretary for Food & Health (Health)1, Food and Health Bureau ("DS(H)1, FHB") said that:

- (a) The purpose of the proposed Medical Devices Bill ("the Bill") was to ensure the safety, quality, performance and efficacy of medical devices supplied in Hong Kong under the premise of protecting public health. There were currently some 40 000 types of medical devices in the market. Only about 20 000 higher risk devices were required to make registration under the Bill and beauty devices only formed a small proportion of these 20 000 devices to be regulated. Hence, the Bill was not targeted at the beauty industry;
- (b) some beauty devices in Hong Kong which met the definition of medical device as recommended by the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force) would be regulated under the Bill. Many advanced jurisdictions/regions such as Australia, Canada, the United States of America, South Korea, Mainland China, etc. had also included devices used for cosmetic purposes and met the definition of medical devices under their local regulatory framework for medical devices to protect public health. The Administration had not identified any jurisdictions with a separate regulatory system for beauty devices, and was not aware of jurisdictions with a regulatory regime of medical devices in place which did not regulate beauty devices as part of the regime;
- (c) the beauty industry did not agree that beauty devices meeting the definition of medical device should be regulated as medical devices. It was suggested that medical devices and beauty devices should be delineated by energy output, intended purposes

Action

or intended users, etc. Having critically reviewed the issue, the Administration considered that segregating the regulatory regime for medical devices and beauty devices would not be practical and was inconsistent with the prevailing regulatory practices in other jurisdictions;

- (d) to address some stakeholders' concerns that a number of beauty devices commonly used by the beauty industry at the moment might not be ready to fulfill the registration requirements under the regulatory regime of medical devices, a five-year transitional listing mechanism would be established for beauty devices which could not fulfill the registration requirements for medical devices but complying with basic listing requirements set by the Department of Health ("DH"). As some deputations considered that the transitional period should be shortened to three years, the Administration would continue to communicate with the stakeholders to determine an appropriate transitional period;
- (e) as some traders/manufacturers were worried that the application procedure for listing/registering medical devices might be complicated, the Administration would streamline the application procedure by suitably adjusting the documentary evidence submitted for assessment to facilitate the registration of devices that have acquired marketing approvals from certain jurisdictions (e.g. Mainland China and South Korea) in addition to those approved by the founding members of IMDRF, which otherwise would require third-party conformity assessment to certify safety and performance requirements;
- (f) taking into account the diverse views of stakeholders on whether use control of specified medical devices should be pursued, the current legislative proposal on medical devices would focus on pre-market and post-market control and would not include the use control of specified medical devices. Nevertheless, the Administration would continue to communicate with the stakeholders over the issue;
- (g) there were currently around 250 learning programmes and a Recognition of Prior Learning mechanism for the beauty industry under the Qualifications Framework. The Administration would work with the beauty industry to promote training regarding the proper use of medical devices used in cosmetic procedures with a view to enhancing the competency of beauty practitioners; and

Action

Principal Assistant Secretary for Commerce & Economic Development (Commerce & Industry)SD said that:

- (h) the Administration had met with merchant acquirers such as banks to explain the proposed mandatory cooling-off period and relay the concerns of some in the beauty trade that merchant acquirers might lengthen the time during which funds would be withheld before being released to the trader ("the withholding period") for credit card payment as a result of the introduction of mandatory cooling-off period. According to the merchant acquirers, risk assessment would be conducted on individual merchants to determine the withholding period. The withholding period was therefore a risk management measure adopted by the merchant in order to fulfil the requirements under the credit card chargeback protection mechanism provided by credit card schemes to protect consumer interests. The arrangement has been applicable to all trades and was not introduced in response to the introduction of the cooling-off period. The Administration also explained to the merchant acquirers that the introduction of mandatory cooling-off period might have a positive impact on the development of the trade as there would be less incentive for the deployment of unfair trade practices.

Discussion

3. Mr SHIU Ka-fai said that the definition of medical devices under the Bill would cast the net too wide to cover also low-risk cosmetic devices. It would be difficult for traders to ascertain whether a cosmetic device fell within the definition of medical device. He asked the Administration to list out the devices commonly used by the beauty industry that would fall outside/within the scope of regulation. Moreover, Mr SHIU was worried that only medical practitioners would be allowed to operate the medical devices regulated under the Bill in the long run, hindering the development of the beauty industry. He urged the Administration to develop a set of criteria to assess the competencies and qualifications required for operating the medical devices so that beauty practitioners could operate some of the devices commonly used in beauty industry.

4. Principal Medical & Health Officer (5), DH ("PMO(5), DH") advised that 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. If the devices used in cosmetic procedures altered the skin's physiological processes by means of medical technology whereby achieving the effect of modifying skin

Action

structures, such as Extracorporeal Shockwave Therapy (ESWT) device and High Intensity Focused Ultrasound (HIFU) device, they would fall within the definition of medical device and would be regulated under the Bill. For operators of medical devices, they would not necessarily be medical practitioners. For instance, bandages could be used by the general public. On use control, DS(H)1, FHB supplemented that the Bill would not include use control of specific medical devices. The Administration would revisit the issue of use control and related matters at a later stage and would maintain close communication with the stakeholders in mapping out the way forward.

5. Mr SHIU Ka-fai requested the Administration to provide information on countries where beauty devices were regulated under the medical device legislation and the beauty devices under regulation, countries with a separate regulatory regime for beauty devices and the devices under regulation, and countries where there was no regulatory legislation for beauty devices.

(Post-meeting note: The Administration's written information was issued to members vide LC Paper No. CB(4)677/18-19(01) on 22 March 2019.)

6. Dr KWOK Ka-ki expressed disappointment at the shelving of use control of specified medical devices under the Bill. In his view, the Bill would not be able to protect the consumers if the use of medical devices was not restricted to operators with certain qualifications. He enquired how the Administration could ensure that the operators of medical devices used in cosmetic procedures acquire the necessary training for operating these devices and when the Administration would impose use control of medical devices through legislation.

7. DS(H)1, FHB responded that there was currently no specific legislation regulating medical devices and beauty devices in Hong Kong. The Bill was introduced as the first step to regulate the medical devices including devices used for cosmetic purposes, with a view to ensuring safety of all these devices. In fact, medical device suppliers had all along been providing operators of the medical devices training regarding the proper use of the devices. This arrangement would continue before use control was imposed.

8. The Deputy Chairman opined that the regulation of beauty devices should be of two-fold; first to protect consumer interests and second to support the development of enterprises in the beauty industry. The Administration should join hands with the beauty sector to develop the industry in the long run. In addition, the Deputy Chairman expressed concern that the development of the industry would be stifled if the Administration would not allow new applications for medical devices to be listed beyond the five-year transitional window. In fact, to her understanding, the model of a beauty device used by the medical

Action

practitioners and beauty practitioners would be different. Hence, she urged for separate regimes for regulating medical devices and beauty devices.

9. Dr Helena WONG enquired whether injectable cosmetic products such as hyaluronic acid, Botox, etc. and their promoting and marketing practices would be regulated under the Bill. PMO(5), DH explained that "Botox" (botulinum toxin) as a pharmaceutical product was regulated under the Pharmacy and Poisons Ordinance (Cap. 138). Hyaluronic acid, as tissue filler, would be regulated under the Bill. Such products must have fulfilled the requirements in terms of safety, quality, performance and efficacy in order to gain registration. Relevant regulatory authorities would conduct spot checks on the products in the market. The Medical Devices Bill would also cover false or misleading statements made in advertisements.

II. Any other business

10. Members agreed that the Joint Subcommittee would discuss the regulation of beauty devices in the next meeting.

11. There being no other business, the meeting ended at 4:31 pm.

Council Business Division 4
Legislative Council Secretariat
25 May 2020

Panel on Health Services and Panel on Commerce and Industry

**Proceedings of the third meeting of the
Joint Subcommittee on Issues Relating to the Regulation of Devices and
Development of the Beauty Industry
on Tuesday, 26 February 2019 at 2:30 pm
in Conference Room 2 of the Legislative Council Complex**

Time marker	Speaker(s)	Subject(s)	Action required
<i>Agenda Item I – Development, regulation and support of the beauty industry</i>			
000436-001046	Chairman Mr SHIU Ka-fai	Opening remarks Items to be discussed at the next meeting	
001047-001401	Hong Kong Doctors Union	Presentation of views [LC Paper No. CB(4)596/18-19(02)] Expressed support for the regulation of medical devices through pre-market control and post-market control. Use control should be imposed in the long run, a clearer definition of medical device with detailed explanation should be provided, and the five-year transitional period should be shortened to three years.	
001402-001649	International CICA Association of Esthetics	Presentation of views [LC Paper No. CB(4)610/18-19(01)] Urged for separate regulatory regimes for medical devices and beauty devices.	
001650-001956	The Democratic Party	Presentation of views Expressed concerns over the regulation of injectable cosmetic products. Expressed support for the development of the beauty industry and the regulation of medical and beauty devices, but considered that the use control of these devices should be imposed.	
001957-002322	Federation of Beauty Industry (H.K.)	Presentation of views [LC Paper No. CB(4)558/18-19(02)] Expressed concerns that the legislative proposals for regulating medical devices and implementing cooling-off period would wipe out the whole beauty industry. Licensing, appraisal and training systems for beauty practitioners should be developed.	

Time marker	Speaker(s)	Subject(s)	Action required
002323-022645	Beauty Industry Standardisation Organisation	<p>Presentation of views [LC Paper No. CB(4)558/18-19(03)]</p> <p>Urged for separate regulatory regimes for medical devices and beauty devices, and professionalization of the beauty industry.</p>	
002646-003005	The Cosmetic & Perfumery Association of HK	<p>Presentation of views</p> <p>Expressed objection to the regulation of medical devices including those used in cosmetic procedures. A set of criteria to determine the level of competence required of the beauty practitioners to operate beauty devices should be developed to facilitate healthy development of the industry.</p>	
003006-003254	Chairman Mr SHIU Ka-fai Dr Helena WONG Mr CHAN Chi-chuen Deputy Chairman	<p>Late requests for oral representations at the meeting</p>	
003255-003606	Association of Private Medical Specialists of Hong Kong	<p>Presentation of views [LC Paper No. CB(4)596/18-19(03)]</p> <p>Expressed support for the regulation of medical devices including those used in cosmetic procedures. Certification and training should be provided to beauty practitioners for operating beauty devices and the transitional period should be shortened.</p>	
003607-003903	Liberal Party	<p>Presentation of views</p> <p>Expressed concerns over the five-year transitional listing system which would hinder the development of the beauty industry. Separate regulatory regimes for medical and beauty devices should be established and the Administration should support industry development.</p>	
003904-004058	Hong Kong Dental Association	<p>Presentation of views [LC Paper No. CB(4)558/18-19(04)]</p> <p>Expressed support for the introduction of five-year transitional listing mechanism and regulation of medical devices through pre-market control and post-market control. Use control should be introduced in the long run.</p>	
004059-004239	Mr NGAN Tsz-leung	<p>Presentation of views [LC Paper No. CB(4)583/18-19(01)]</p> <p>Expressed objection to the five-year transitional</p>	

Time marker	Speaker(s)	Subject(s)	Action required
		listing mechanism. A separate regulatory regime for medical devices used for cosmetic purpose should be developed.	
004240-004558	Democratic Alliance for the Betterment and Progress of Hong Kong	<p>Presentation of views [LC Paper No. CB(4)596/18-19(04)]</p> <p>Urged for a separate regulatory regime for beauty industry with a view to developing the industry. A set of criteria to determine the level of competence required of the beauty practitioners to operate beauty devices should be developed.</p>	
004559-004815	Ms KWOK Man-ha	<p>Presentation of views</p> <p>Expressed objection to the five-year transitional listing mechanism. Certification and training should be provided to beauty practitioners to enhance their professionalism.</p>	
004816-005020	Grand Aesthetic Academy	<p>Presentation of views</p> <p>Urged for separate regulatory regimes for medical and beauty devices, and the provision of training and licencing systems to facilitate healthy development of the beauty industry.</p>	
005021-005340	Citi Concept	<p>Presentation of views [LC Paper No. CB(4)583/18-19(02)] <i>(Restricted to members only)</i></p> <p>Expressed dissatisfaction over the legislative proposal for regulating medical devices which would hinder the development of the beauty industry. The Administration should assist beauty practitioners in enhancing their competencies to ensure public health and safety.</p>	
005341-005659	Ms LAM Ho-yan	<p>Presentation of views [LC Paper No. CB(4)596/18-19(05)]</p> <p>Expressed concerns that the legislative proposal for regulating medical devices would affect the livelihood of beauty practitioners; expressed objection to the five-year transitional listing mechanism; and suggested of a beauty industry authority to monitor the industry.</p>	
005700-010031	Hong Kong Medical and Healthcare Device Industries Association	<p>Presentation of views [LC Paper No. CB(4)558/18-19(05)]</p> <p>Expressed no objection to the enactment of legislation for regulating medical devices but worried that some devices might not fall within</p>	

Time marker	Speaker(s)	Subject(s)	Action required
		the regulatory framework. Use control should be imposed in the long run.	
010032-010225	Medtechnoskorp Ltd	<p>Presentation of views</p> <p>Expressed support for regulatory framework on medical devices but the application procedures for listing/registering devices should be streamlined and the application processing time should be shortened.</p>	
010226-010334	Associated Medical Supplies Company Limited	<p>Presentation of views</p> <p>Suggested the development of a quality standard system to replace the transitional listing mechanism.</p>	
010335-010511	Hong Kong Beauty and Fitness Professional General Union	<p>Presentation of views</p> <p>Expressed support for pre-market control of medical devices. Separate regulatory regimes for medical and beauty devices should be established and certification of beauty practitioners should be developed by the Administration.</p>	
010512-010838	Starz Tech International Ltd	<p>Presentation of views [LC Paper No. CB(4)596/18-19(06)]</p> <p>Expressed objection to the implementation of cooling-off period, regulation of beauty devices as medical devices, introduction of five-year transitional listing mechanism, and restriction of the use of beauty devices to medical practitioners. The Administration should establish a set of criteria to determine the level of competence required of the beauty practitioners to operate beauty devices and plans to develop the beauty industry.</p>	
010839-011143	Miss CHAN Yu	<p>Presentation of views [LC Paper No. CB(4)558/18-19(01)]</p> <p>Expressed concerns that the five-year transitional listing mechanism would greatly hinder the development of the beauty industry and the regulation of beauty devices as medical devices had not taken into account the needs and long-term development of the industry.</p>	
011144-011510	Hong Kong Beauty Industry Union	<p>Presentation of views</p> <p>Expressed dissatisfaction to legislative proposals on regulation of medical devices and cooling-off period which would wipe out the whole beauty industry. Expressed objection to</p>	

Time marker	Speaker(s)	Subject(s)	Action required
		the transitional listing mechanism and urged the Administration to communicate with and take into account the feedback of the industry.	
011511-011732	黃麗女士	Presentation of views Expressed dissatisfaction to legislative proposals on regulation of medical devices and cooling-off period which would wipe out the whole beauty industry.	
011733-012026	鍾蔚庭先生	Presentation of views Urged the Administration to take into account the views of the beauty industry to provide appropriate regulatory framework for beauty devices	
012027-013537	Chairman Administration	Administration's consolidated response to the views expressed by deputations	
013538-014210	Chairman Dr KWOK Ka-ki Administration	Use control of medical devices Provision of training to operators of medical devices	
014211-015225	Chairman Mr SHIU Ka-fai Administration	Definition of medical devices under the Medical Devices Bill	
015226-015756	Chairman Dr Helena WONG Administration	Regulation of injectable cosmetic products	
015757-020515	Chairman Deputy Chairman Administration	Regulation and development of beauty industry	
<i>Agenda Item II – Any other business</i>			
020516 020555	Chairman	Closing remarks	