

立法會
Legislative Council

LC Paper No. CB(2)257/17-18
(These minutes have been
seen by the Administration)

Ref : CB2/PL/HS

Panel on Health Services

**Minutes of special meeting
held on Monday, 13 February 2017, at 8:45 am
in Conference Room 1 of the Legislative Council Complex**

- Members present** : Prof Hon Joseph LEE Kok-long, SBS, JP (Chairman)
Dr Hon Pierre CHAN (Deputy Chairman)
Hon WONG Ting-kwong, SBS, JP
Hon CHAN Kin-por, BBS, JP
Hon Paul TSE Wai-chun, JP
Hon LEUNG Kwok-hung
Hon YIU Si-wing, BBS
Hon Charles Peter MOK, JP
Hon CHAN Chi-chuen
Dr Hon KWOK Ka-ki
Dr Hon Fernando CHEUNG Chiu-hung
Dr Hon Helena WONG Pik-wan
Dr Hon Elizabeth QUAT, JP
Hon POON Siu-ping, BBS, MH
Hon CHU Hoi-dick
Dr Hon Junius HO Kwan-yiu, JP
Hon SHIU Ka-fai
Hon SHIU Ka-chun
Hon YUNG Hoi-yan
Hon Jeremy TAM Man-ho
- Members attending** : Hon Starry LEE Wai-king, SBS, JP
Dr Hon CHIANG Lai-wan, JP
Hon Nathan LAW Kwun-chung
- Members absent** : Hon Tommy CHEUNG Yu-yan, GBS, JP
Hon CHAN Han-pan, JP
Hon Alice MAK Mei-kuen, BBS, JP

[According to the Judgment of the Court of First Instance of the High Court on 14 July 2017, LEUNG Kwok-hung, Nathan LAW Kwun-chung, YIU Chung-yim and LAU Siu-lai have been disqualified from assuming the office of a member of the Legislative Council, and have vacated the same since 12 October 2016, and are not entitled to act as a member of the Legislative Council.]

Public Officers : Professor Sophia CHAN Siu-chee, JP
attending Under Secretary for Food and Health

Ms Fiona CHAU Suet-mui
Principal Assistant Secretary for Food & Health
(Health) 1
Food and Health Bureau

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

Dr WAN Yuen-kong
Principal Medical & Health Officer (5)
Department of Health

Ms Jennifer MAK Kit-shu
Senior Electronics Engineer (Medical Device Control
Office) 1
Department of Health

Attendance : *Session One*
by invitation

CIDESCO SECTION CHINA International CICA
Association of Esthetics

Mrs CHEUNG Soo-kan
Vice President

International Professional Cosmetology Association

Ms CHAN Mei-heung
Honorary President

The Civic Party

Mr LEE Ka-ho
Representative

Federation of Beauty Industry (HK)

Ms Frances CHIU Siu-ling
Chairman

Ms LIT Ming-wai

Dr Grace SZETO Pui-yuk

Hong Kong Physiotherapy Association

Miss Priscilla POON
President

Democratic Party

Mr Raymond YUEN
Spokesman

Miss Anna Bella SUEN Mei-yee

Miss Sally WAN Hoi-wing

Physio Action

Mr MA Wui-leung
Member

Mrs Loretta FUNG Ka-lin

Beauty Industry Reform Research and Development
Committee

Ms YANG Hui-chun
Spokeswoman

Asia Pacific Beauty Group Limited

Ms CHAN Yu
Director

Democratic Alliance for the Betterment and Progress of
Hong Kong

Mr WU Cheuk-him
Deputy Spokesperson on Policy

Neo Derm Group Ltd

Ms LEUNG Yin-shan
Group Public Relations Manager

Ms MAK Man-yu

Mr WONG Chun-ho

The Cosmetic & Perfumery Association of Hong Kong

Mr Joseph HO
President

Zenith Cosmetics Trading Co Ltd

Ms Joanne LI
Business Development Manager

CMM Monita International Group Limited

Ms CHENG Ming-ming
Director

Prof Raymond TONG Kai-yu

HK Beauty & Wellness Association

Ms Joyce TSANG Yue
Chairlady

Ka Man Beauty Group Limited

Mr NG Siu-sun
Director

Association of Doctors in Aesthetic Medicine (Hong Kong) Ltd

Dr LAU Kwan-chark
Chairman

Ms Susanna CHEUNG Ying

Mr LEE Wing-yip

Dentsply Sirona Inc

Mr LUI Ka-him
Quality Assurance and Regulatory Affair Specialist, Asia

Miss Rufina LAU Wing-lum

Hong Kong Medical and Healthcare Device Industries
Association

Prof Andros CHAN
Chairman

Hong Kong Physiotherapy Concern

Miss TONG Sheung-yau
President

Session Two

Hong Kong Academy of Medicine

Dr Gilberto LEUNG Ka-kit
Vice-President (Education & Examinations)

The College of Surgeons of Hong Kong

Dr WONG Sau-yan
Representative

Miss CHEUNG Sze-nga

Hong Kong Physiotherapists' Union

Ms Eleanor CHAN
President

Association of Private Medical Specialists of Hong Kong

Dr Ricky CHAN Wai-keung
Council Member

Hong Kong College of Physicians

Dr HO King-man
Representative

Hong Kong College of Dermatologists

Prof Henry CHAN Hin-lee
Vice President

The Hong Kong Society of Dermatology & Venereology

Dr YEUNG Chi-keung
Representative

Miss HO Lai-chu

Dr Alan FUNG Ho-wang

Mr LEUNG Yu-wing

Miss FUNG Wan-sze

Miss CHEUNG Yuk-ying

Miss Candy CHAN Nga-lam

Miss LAM Ho-yan

Beauty Industry Standardisation Organisation

Mr Nelson IP
Chairman

郭敏霞小姐

Spa Collection Group

Miss WAN Wing-yin
Training Manager

Miss WONG Mei-ying

Mr FOK Man-kit

Miss KWOK Mei-mei

Ms CHAN Wing-mui

The Hong Kong Society of Professional Optometrists

Miss Victoria LAW
President

Miss Manki CHAN

Hong Kong Beauty and Fitness Professionals General
Union

Ms Amy HUI Wai-fung
Chairman

NUDERMA

Miss CHAN Suet-yu
董事

Full Moral Technology Cosmetic

Mr PUN Sho-hoi
Managing Director

Mrs Teresa TSOI

The Hong Kong Medical Association

Dr LAM Tzit-yuen
Honorary Secretary

Hong Kong Hair & Beauty Merchants Association

Mrs PANG Yuk-ling
President

Session Three

The Hong Kong Association of the Pharmaceutical
Industry

Ms Karen YUEN Pui-shan
Lead, Regulatory Affairs Task Force

Modern Beauty Salon

Miss HO Siu-man
Training Manager

The Hong Kong Society of Plastic, Reconstructive and
Aesthetic Surgeons

Dr HO Chiu-ming
Representative

Medical Aesthetic Professionals Group

Ms Maggie LEUNG Mei-ying
Convenor

Miss TO Po-chu

Miss LAU Wing-sum

Starz Tech International Ltd.

Miss YIM Wai-ling
Administrative Officer

Miss Gobby CHAN Ching-ting

Grand Aesthetic Academy

Ms Fanny LEE
Principal

Ms MA Wing-sheung

Ms Carmen SIN Ka-man

Ms CHAN Kai-hung

Miss WOO Ka-ki

Miss Audrey CHIU Man-ying

Ms TSOI Lee-lee

Ms NG Yin-san

Dr CHAN Ka-yin

Miss WU Po-po

HK Association of Professional Aestheticians
International

Ms Andie MOK
Honorary President

Clerk in attendance : Ms Maisie LAM
Chief Council Secretary (2) 5

Staff in attendance : Ms Janet SHUM
Senior Council Secretary (2) 5

Ms Priscilla LAU
Council Secretary (2) 5

Miss Maggie CHIU
Legislative Assistant (2) 5

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I. Proposed regulatory framework for medical devices
[LC Paper Nos. CB(2)545/16-17(01) and CB(2)751/16-17(01)]

Presentation of views by deputations

The Chairman reminded the organizations and individuals attending the meeting that they were not covered by the protection and immunity provided under the Legislative Council (Powers and Privileges) Ordinance (Cap. 382) when addressing the Panel. At the invitation of the Chairman, a total of 80 organizations and individuals presented their views on the proposed regulatory framework for medical devices. A summary of their views is in the **Appendix**. Members also noted the 10 written submissions from organizations and individuals not attending the meeting.

2. Members noted the updated background brief on the subject prepared by the Legislative Council ("LegCo") Secretariat (LC Paper No. CB(2)751/16-17(01)).

Discussion

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Definition of medical devices

3. Mr SHIU Ka-fai enquired about the criteria adopted in defining and classifying medical devices under the proposed regulatory framework for medical devices. Under Secretary for Food and Health ("USFH") and Assistant Director of Health (Special Health Services), Department of Health ("ADH(SHS))" advised that the comprehensive definition of medical devices adopted by the International Medical Device Regulators Forum ("IMDRF"), which was formulated by its predecessor known as Global Harmonization Task Force, would be adopted. IMDRF was a voluntary group of medical device regulators from different places such as European Union and the United States of America. Under the definition, medical devices ranged from simple devices like thermometers to sophisticated devices like high-power laser equipment. These devices were used by both registered healthcare professionals and persons other than registered healthcare professionals for medical or non-medical purposes.

Medical devices to be subject to regulation

4. Mr CHAN Chi-chuen was concerned that the physiotherapy academia and profession had not been properly consulted on the proposed use control of selected medical devices. He shared the concern raised by the deputations concerned that some types of medical devices which were of high risk of serious injury or harm if used improperly, such as those extracorporeal shock wave therapy devices that emitted strong energy output, would be classified into use control category IV whereby no user restriction would be imposed. At the invitation of Mr CHAN Chi-chuen, Miss Priscilla POON of the Hong Kong Physiotherapy Association said that while they agreed to the direction of and the adoption of a risk-based approach for the proposed regulatory regime for medical devices, they were of the view that separate use control should respectively be imposed on medical devices designed for medical use, therapeutic use, cosmetic use and home use which could be delineated according to, among others, the level of energy output of the devices.

5. While considering that Hong Kong had lagged far behind the global practices in respect of the regulation of the sale and use of medical devices and supporting the broad direction of the legislative proposals, Dr Fernando CHEUNG expressed concern that the current legislative proposals were prepared without sufficient consultation with the stakeholders. He shared the view of the Hong Kong Physiotherapy Association that home-use medical devices, medical devices used for medical purposes and medical devices used for cosmetic purposes should be subject to different regulatory regimes. Dr CHIANG Lai-wan

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considered that the Administration could restrict the purchase of those medical devices manufactured for medical purposes. In response to Mr SHIU Ka-fai's view that devices solely used for cosmetic purposes should be subject to separate regulation, Professor Henry CHAN of the Hong Kong College of Dermatologists pointed out that there were media reports whereby the medical devices used in beauty parlours were copycat devices not properly registered in their countries of origin and the safety and effectiveness of which were in question.

6. Dr Pierre CHAN noted that the Working Group on Differentiation between Medical Procedures and Beauty Services ("the Working Group") set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities had, among others, examined the safety and health risks of devices commonly used for cosmetic purposes and recommended that a more detailed study should be conducted in this regard. He noted that the Working Group comprised representatives from the beauty sector. In response to Dr Pierre CHAN's enquiry, Ms YANG Hui-chun of the Beauty Industry Reform Research and Development Committee said that while the Working Group comprised six members from the beauty sector, their views that devices used for medical purposes and devices used for cosmetic purposes should be subject to separate regulation were not properly addressed in the discussion as the majority of members of the Working Group were registered medical practitioners. At the invitation of Mr SHIU Ka-fai and Dr Elizabeth QUAT, Mr Nelson IP of the Beauty Industry Standardisation Organisation said that being a member of the Working Group, he considered that views of the beauty sector had not been taken heed of due to the fact that representatives from the beauty sector only accounted for one-fourth of the membership of the Working Group. He stressed that the devices commonly used for cosmetic purposes were heterogeneous. This was a reason why the Administration had sought to commission an external consultant to conduct a detailed study on the scope of control on the use of these devices.

7. Mr Nelson IP of the Beauty Industry Standardisation Organisation further said that he had strong views against the proposed device-specific use control as recommended in the consultancy study. In his view, whether a laser device and an intense pulse light ("IPL") device should be regarded as a medical device or a cosmetic device depended on their design purposes and application. Those devices widely used in the beauty industry solely for cosmetic purposes should not be classified as medical devices. While such devices were currently used by beauty practitioners in the absence of on-site supervision by medical practitioners, there had been no reported fatal cases in relation to such beauty treatments. Expressing a similar view, Miss HO Lai-chu urged the Administration to consult not only the medical

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sector but also the beauty sector in assessing and classifying the risks of the devices used for cosmetic purposes. Mr SHIU Ka-fai considered that the proposed use control of specific medical devices for cosmetic purposes would stifle the development of the beauty industry. He called on the Administration to engage the beauty sector in mapping out the way forward.

8. Dr Pierre CHAN remarked that most complaint cases on beauty services did not involve registered medical practitioners. According to the statistics of the Consumer Council, 144 out of the 1 000-odd complaints about beauty services it received in 2013 were related to optical treatment. He stressed that there was a need to regulate the use of high-risk medical devices for cosmetic purposes in order to safeguard public health, albeit that this might affect the interest and development of the beauty industry. He also expressed concern that there was an increasing number of adverse incidents involving alternative therapy with the use of medical devices in recent years. For instance, an adverse incident took place in June 2015 whereby a woman died when receiving meridian treatment provided by a non-healthcare personnel using an electrical device.

9. At the invitation of the Chairman, Professor Henry CHAN of the Hong Kong College of Dermatologists stressed that all devices meeting the definition of medical devices should be regulated as medical devices, albeit that they might be used for cosmetic purposes. Mr SHIU Ka-fai pointed out that removal of moles for beauty purpose was currently commonly performed by beauty practitioners. In response to Mr SHIU Ka-fai, Dr LAU Kwan-chark of the Association of Doctors in Aesthetic Medicine (Hong Kong) Ltd said that clinical examination should be conducted to identify whether a mole involved any skin diseases before its removal.

10. Mr POON Siu-ping was concerned that while the external consultant commissioned by the Administration had conducted a total of 38 site visits and interviews to gauge views from the medical sector, beauty sector and medical device trade sector on the use of medical devices, the views so expressed had not been fully taken heed of. He did not consider it appropriate for the Administration to take forward its current legislative proposals in the absence of support from LegCo Members and the stakeholders. Mr SHIU Ka-fai held similar views. At the invitation of Mr POON Siu-ping, Ms Joyce TSANG of HK Beauty & Wellness Association said that the Administration should engage the beauty sector in formulating the regulatory framework for cosmetic-related devices. Miss Priscilla POON of the Hong Kong Physiotherapy Association advised that the Association, which had been invited to give views on the use of medical devices, had indicated to the external consultant that more details, such as the energy output level concerned, other than the names of the 20

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types of selected medical devices were required for giving any feedback. Site visit to a clinic was subsequently arranged to explain to the consultant that certain medical devices under study were of high risk of serious injury or harm. However, these views had not been reflected in the key findings of the study. In response to Mr SHIU Ka-fai, she agreed that the Administration should consult the stakeholders, including the physiotherapy profession, again and refine its legislative proposals. Mr Joseph HO of the Cosmetic & Perfumery Association of Hong Kong was of the view that the current legislative proposals were prepared in a slipshod manner. He expressed concern that about 90% of the devices used by the beauty sector would be classified as medical devices under the proposed definition.

11. Pointing out that the subject was first discussed in 2004, Dr KWOK Ka-ki considered that the regulatory regime for medical devices, including those devices used for cosmetic purposes, should be put in place as early as practicable to protect public health. He urged the Administration to expeditiously address the concerns of the various professions, in particular that of the physiotherapy profession, over the use control of medical devices in order to take forward the legislative proposals. He sought the views of deputations on whether the use of certain types of medical devices should be restricted to prescribed healthcare professions. Dr Grace SZETO said that the physiotherapy profession welcomed the suggestion. However, there was a need to ensure that the relevant legislation could be amended efficiently in the future to cater for advancement in medical technologies. Dr WONG Sau-yan of the College of Surgeons of Hong Kong pointed out that it was not uncommon that the level of energy output and the associated risks of different models of each type of medical devices, such as IPL device, varied. Hence, whether the use of a single model of a particular type of medical device should be subject to on-site supervision by a registered healthcare professional needed to be assessed individually. Subject to the passage of the relevant legislation, a working group should be set up to review the use control of each medical device based on a risk-based approach.

12. Dr Junius HO supported the broad direction of regulating the use of medical devices. He called on the Administration to clearly explain the classification of general medical devices and the use control categories of selected medical devices for cosmetic purposes to avoid misunderstanding. He then sought the views of deputations on how the use control of electrotherapy devices could be classified. Miss Priscilla POON of the Hong Kong Physiotherapy Association said that those medical devices commonly used in physiotherapy which involved identified risks and contraindications should not be classified under use control category IV

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with no user restriction, details of which were set out in Annex I to the submission from Dr Grace SZETO (LC Paper No. CB(2)782/16-17(02)). Ms YANG Hui-chun of the Beauty Industry Reform Research and Development Committee considered that devices used for medical purposes and cosmetic purposes should be subject to separate regulatory regime. The Administration should engage the relevant stakeholders to map out the way forward. Mr MA Wui-leung of Physio Action urged the Food and Health Bureau to join hands with the physiotherapy profession, the Electrical and Mechanical Services Department and the Radiation Board of Hong Kong in ironing out the details of the regulation of laser devices and devices emitting ionizing radiation or containing radioactive substances. With reference to the practice in Singapore, he suggested that any parties intended to purchase high-risk medical devices should be required to make applications to the regulatory authority in the future. Dr LAU Kwan-chark of the Association of Doctors in Aesthetic Medicine (Hong Kong) Ltd said that the medical profession in general was not interested to be engaged in the provision of beauty treatment. However, it was necessary to ensure the safety in the use of medical devices for cosmetic purposes.

13. Dr Elizabeth QUAT declared that her family members were involved in beauty business but she had no pecuniary interest in the business. She expressed concern that those cosmetic-related devices commonly used by the beauty sector would be classified under use control category II whereby user of which had to be a registered healthcare professional or a person supervised by a registered healthcare professional on site. She considered it impracticable to require the thousands beauty companies in Hong Kong, in particular those of small or medium size, to employ registered healthcare professionals to supervise the use of these devices. In her view, devices used for medical purposes and devices solely used for cosmetic purposes should be subject to separate regulation. She agreed to regulate devices used for medical purposes under the proposed regulatory framework. However, the regulation of devices solely used for cosmetic purposes could not be singled out from the overall regulatory regime for the beauty sector. She expressed her intention to move a motion urging the Government to set up a deliberation platform to clearly define medical devices and cosmetic devices, and formulate an independent regulatory regime for the beauty sector.

14. In response to the views expressed by members and deputations, USFH advised that a voluntary Medical Device Administrative Control System had been established by the Department of Health ("DH") since 2004 to pave the way for implementing the long-term statutory control. The proposed regulatory regime put forth by the Administration covered all devices meeting the definition of "medical devices", the draft of which had

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been made reference to the definition of medical devices adopted by IMDRF, and comprised three main areas, namely pre-market control, post-market control and use control of medical devices. The level of control under each area would be proportionate to the degree of risk of the medical devices. As far as use control was concerned, it should be noted that the use of medical devices by registered healthcare professionals would be subject to the code of conduct of respective professions. Hence, it was proposed that only those specific medical devices which were often used by persons other than registered healthcare professionals, and might pose a high risk of serious injury or harm to the public if users had not undergone proper training would be subject to regulation. A reason why it was proposed that users of specific medical devices for cosmetic purposes had to be supervised on site by a registered medical practitioner was for overseeing treatment planning and providing intervention in case any complications arose. USFH further advised that given the concerns expressed by members and deputations on the part of use control, the plan of the Administration was to set up a multi-party platform to invite participation from different stakeholders to exchange views in this regard. As regards the suggestion of differentiating devices used for cosmetic purposes from devices used for medical purposes by level of energy output of the devices, ADH(SHS) advised that it might not be practicable to do so as there could be overlap in the range of energy output of these devices or the parameter might be similar.

Qualification requirements of users for specific medical devices

15. Dr CHIANG Lai-wan considered that the current legislative proposals would stifle the development of the beauty industry. In her view, trained beauty practitioners meeting specified competency requirements, such as that developed under the Qualifications Framework, should be allowed to operate those devices for cosmetic purposes. It was impracticable to require registered healthcare professionals, including registered medical practitioners, to supervise the use of these devices by beauty practitioners. At her invitation, Ms Joyce TSANG of the HK Beauty & Wellness Association said that it was not feasible to require the thousands beauty companies to employ registered medical practitioners to supervise the use of these devices. Dr Elizabeth QUAT was of the view that all users of devices for cosmetic purposes, regardless of their background, should be required to undergo training before operating the devices concerned.

16. In response to Dr Fernando CHEUNG, Ms YANG Hui-chun of the Beauty Industry Reform Research and Development Committee considered it necessary to differentiate between medical devices and cosmetic-related devices. The Administration should build upon the Qualifications

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Framework to develop a set of training and competency requirements for beauty practitioners in operating cosmetic-related devices. Expressing support to regulate the beauty industry and to clearly differentiate between devices for medical and cosmetic purposes, Dr Pierre CHAN remarked that the medical profession in general had no intention to be involved in the use of devices for cosmetic purposes.

17. USFH advised that the external consultant had recommended that for the purpose of implementing the use control regime for the selected types of medical device, a user of a medical device should receive basic training regarding the proper and safe operation of the medical device concerned. DH would, on the basis of the Qualifications Framework, work out a list of recognized training programmes which offered training for operating specified types of medical device.

[At this juncture, the Chairman suggested and members agreed that the three motions respectively proposed by Dr Elizabeth QUAT, Dr Fernando CHEUNG and Mr SHIU Ka-fai, which were directly related to the agenda item under discussion and the wording of which had been tabled at the meeting, be dealt with towards the end of the discussion of this agenda item.]

Legislative timetable

18. Ms Starry LEE sought the assurance of the Administration that it would not take forward the legislative proposals given the strong views of the stakeholders and the absence of consensus views of the public on the proposed regulatory framework for medical devices. Dr Fernando CHEUNG sought elaboration from the Administration on the legislative timetable for the proposed regulatory framework for medical devices. Dr KWOK Ka-ki was concerned that the introduction of a regulatory regime for medical devices had been dragged on for some 13 years. He sought views from deputations from the medical sector on possible further procrastination in this regard due to the strong views on the proposed use control of selected medical devices. Professor Henry CHAN of the Hong Kong College of Dermatologists said that there was an imminent need for Hong Kong to introduce a regulatory framework for medical devices to protect public health in order to bring Hong Kong in line with the medical device regulations adopted by other major jurisdictions and raise industrial standards. Dr WONG Sau-yan of the College of Surgeons of Hong Kong said that he did not receive any views from the medical sector that the legislative exercise in this regard should be further postponed. Dr KWOK Ka-ki asked whether the Administration would expeditiously refine its legislative proposals to address the various concerns of the

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stakeholders and introduce the relevant Bill into LegCo in the 2016-2017 legislative session.

19. USFH advised that given that it took time to reach consensus over the use control of specific medical devices, the Administration would adopt a phased approach in taking forward the legislative proposals on regulation of medical devices. Taking into account that the general public expected that the pre-market control and the post-market control for medical devices could be introduced as soon as practicable, the Administration would first focus efforts to take forward the legislative work on the pre-market control and post-market control for medical devices, which largely applied to the manufacture, import, distribution and sale of medical devices with a view to ensuring the safety, quality and efficacy of medical devices before allowing them to be placed in the market and enabling swift control measures against defective or unsafe medical devices. In response to Dr Fernando CHEUNG's follow-up enquiry, USFH advised that the plan of the Administration was to introduce a bill focusing on the above two areas of the regulatory regime for medical devices into LegCo in the 2016-2017 legislative session.

[At this juncture, the Chairman informed members of his decision to extend the meeting for 15 minutes beyond its appointed ending time at 2:45 pm to allow more time for discussion on the subject matter and to deal with the three motions proposed by members. He then sought members' views on whether to further extend the above period of extension of meeting for 15 minutes. Dr Elizabeth QUAT objected to the proposal, as she had to chair the meeting of the Panel on Information Technology and Broadcasting. The Chairman said that the meeting would end at 3:00 pm.]

Regulation and development of the beauty industry

20. Dr KWOK Ka-ki was of the view that the Commerce and Economic Development Bureau should take the lead to regulate the practices of the beauty industry. Dr Pierre CHAN was concerned that no mechanism was currently put in place for the reporting of adverse beauty incidents. He pointed out that while it was a consensus view of the community that a regulatory framework should be introduced to regulate the practices of the beauty sector to safeguard consumers, the Administration had repeatedly indicated that it had no intention to regulate the beauty industry but shrunk the responsibility to medical practitioners.

21. Ms Starry LEE remarked that the beauty industry was a growing industry in Hong Kong which had provided many career prospects and business opportunities for frontline beauty practitioners. The Democratic

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Alliance for the Betterment and Progress of Hong Kong was of the view that instead of requiring registered healthcare professionals to supervise the use of those devices for cosmetic purposes, a licensing system should be introduced for beauty practitioners to foster the development of the beauty industry. Dr Elizabeth QUAT urged the Administration to establish a regulatory regime for the beauty industry and formulate policy to promote the development of the industry. Holding the view that the Administration should promote the development of the beauty industry where Hong Kong enjoyed clear advantages and involved the livelihood of some 60 000 practitioners, Mr YIU Si-wing suggested that the Administration could, by making reference to the establishment of the Insurance Authority and the Travel Industry Authority for the insurance sector and the tourism sector respectively, set up an independent statutory body comprising representatives from the Government, professional bodies and the beauty sector to carry out regulatory and licensing functions for the beauty industry.

22. In response to Mr SHIU Ka-fai, Mr Joseph HO of the Cosmetic & Perfumery Association of Hong Kong said that since 2006 when the beauty industry joined hands with the Consumer Council to prepare a Code of Trade Practices for the beauty industry to encourage self-regulation by the industry, the beauty sector had repeatedly called for the introduction of a licensing system to regulate the beauty industry. In response to Mr YIU Si-wing, Mrs PANG Yuk-ling of the Hong Kong Hair & Beauty Merchants Association advised that the beauty sector was in support of introducing a regulatory framework to facilitate the development of the beauty industry. At the invitation of Dr Elizabeth QUAT, Mr Nelson IP of the Beauty Industry Standardisation Organisation expressed disappointment that the Administration had turned a deaf ear to the repeated call from the beauty industry for introducing a regulatory framework, including a licensing and disciplinary system, for the beauty sector. At Dr Junius HO's invitation, Ms YANG Hui-chun of the Beauty Industry Reform Research and Development Committee said that the beauty industry had called on the Administration to set up a steering committee on regulation of beauty industry since 2015 to steer the development of the industry.

23. In response, USFH advised that issues relating to the development of the beauty industry fell outside the policy purview of the Food and Health Bureau. The Bureau had no intention of imposing regulation over the practices of the beauty industry.

Motions

24. Dr Elizabeth QUAT proposed to move the following motion:

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"本會要求政府設立包括政府、美容業界、儀器生產商及醫療業界組成的商議平台，並在美容業界佔不少於半數代表名額的前提下，重新將醫療儀器及美容儀器明確界定，在保障市民安全的同時，必須避免扼殺美容業界的生存空間。

此外，本會要求政府須為美容業界訂立獨立的監管制度及全面的產業發展政策，如規管美容儀器、推動美容師專業化、監管營商及銷售手法等，讓香港美容業可持續發展、及市民在使用美容服務時有最佳的保障。"

(Translation)

"This Panel requests the Government to, on the premise that at least half of the representatives are from the beauty sector, establish a deliberation platform comprising representatives from the Government, the beauty sector, manufacturers of devices and the medical sector to clearly define medical devices and cosmetic devices afresh so as to protect public safety without throttling the development of the beauty sector.

In addition, this Panel requests the Government to establish an independent regulatory regime for the beauty sector and formulate a comprehensive strategy for the industry's development, including, among others, the regulation of cosmetic devices, promoting the professionalization of beauticians, and the monitoring of trade and sales practices, so as to facilitate sustainable development of the beauty industry in Hong Kong and enhance the protection for the public in the use of beauty services."

25. Dr Fernando CHEUNG proposed to move the following motion:

"本委員會贊同應盡快立法規管醫療儀器。目前本港對於醫療儀器的銷售和使用方面的規管相當落後，可是政府提出的立法文件非常粗疏，諮詢不足。本委員會促請政府重新設立規管醫療儀器立法的工作小組，成員應包括物理治療師、學者、醫生、以及其他相關專業人員等，清楚將儀器分類為醫療用途、美容，以及家用等，並盡快立法全面規管，以保障市民安全。"

(Translation)

"This Panel agrees that legislation for regulating medical devices should be expeditiously introduced. At present, while Hong Kong

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falls far behind in respect of its regulation of the sale and use of medical devices, the paper provided by the Government on the relevant legislative proposals was prepared in a slipshod manner and without sufficient consultation. This Panel therefore urges the Government to establish afresh a working group to provide legislation for the regulation of medical devices, with particular emphasis on differentiation between medical devices and cosmetic devices. Members of the working group should comprise physiotherapists, academics, medical practitioners, and other relevant professionals, etc. The working group so set up should clearly categorize such devices into those for medical purposes, cosmetic purposes and for domestic use, so that legislation can be expeditiously introduced to put such devices under a comprehensive regulatory regime to protect public safety."

26. Mr SHIU Ka-fai proposed to move the following motion:

"鑒於政府當局現時提交的《規管醫療儀器的建議架構》極為粗疏，尤其會扼殺美容行業，本委員會要求當局暫停現時的有關立法計劃，並重新進行全面諮詢，及在保障公眾安全和不傾斜於任何一個業界的前提下，詳細研究將醫療用途和美容用途的儀器徹底分開規管，然後分別提交新的規管建議予本委員會審議。"

(Translation)

"Given that the proposed regulatory framework for medical devices currently provided by the Administration was prepared in an extremely slipshod manner, which, in particular, will stifle the development of the beauty industry, this Panel requests the Administration to withhold its current legislative plan, launch afresh a comprehensive consultation exercise, and, on the premise of protecting public safety without tilting in favour of any single sector, study in detail the adoption of two separate regulatory regimes for medical devices and cosmetic devices for the submission of new regulatory proposals respectively for these two types of devices for consideration by this Panel."

27. The Chairman invited members to consider whether the above three motions should be proceeded with at this meeting. He reminded members that there was about 20 minutes left before the extended closing time of the meeting. Dr Elizabeth QUAT sought clarification as to whether the Chairman could extend the meeting for 15 minutes beyond its appointed

Action

ending time if there was objection from members. Dr Pierre CHAN remarked that the Chairman had the power to do so according to rule 24A(a) of the House Rules.

28. At the invitation of the Chairman, the Clerk advised that subject to the availability of the meeting venue, the chairman of a committee might, with or without making an announcement, extend a meeting of the committee, or allow a meeting of the committee to continue, for not more than 15 minutes beyond the appointed ending time of the meeting under rule 24A(a) of the House Rules. Under rule 24A(b) of the House Rules, a committee might extend a meeting for more than 15 minutes beyond the appointed ending time of the meeting or the period of extension or continuation of meeting referred to in rule 24A(a), provided that, among others, there was no dissenting voice to the proposal.

29. Dr Elizabeth QUAT considered that in view of the limited time left for members to give views on the three motions, the motions should be dealt with at the next regular meeting of the Panel. Mr SHIU Ka-fai and Mr WONG Ting-kwong were of the same view. Dr KWOK Ka-ki, Dr Helena WONG and Mr LEUNG Kwok-hung considered that the Panel should proceed with the motions at this meeting.

30. The Chairman suggested that given the divergent views expressed by members and that the remaining time might not be sufficient for members to express views on the three motions, the motions be carried forward to be dealt with at the next regular meeting of the Panel on 28 February 2017. Members raised no objection. The Chairman said that under the relevant agenda item of the said meeting, he would call upon Dr Elizabeth QUAT, Dr Fernando CHEUNG and Mr SHIU Ka-fai to move and speak on their respective motion. Members would then be invited to express their views on the motions, if any. Thereafter, he would direct that a vote be taken on each of the motions.

II. Any other business

31. There being no other business, the meeting ended at 2:47 pm.

Panel on Health Services

**Special meeting on Monday, 13 February 2017, at 8:45 am
in Conference Room 1 of the Legislative Council Complex**

Summary of views and concerns expressed by organizations/individuals on the proposed regulatory framework for medical devices

No.	Name of deputation/individual	Submission / Major views and concerns
<i>Session One</i>		
1.	CIDESCO SECTION CHINA International CICA Association of Esthetics	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(02)
2.	International Professional Cosmetology Association	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(03)
3.	The Civic Party	<ul style="list-style-type: none"> • LC Paper No. CB(2)809/16-17(01)
4.	Federation of Beauty Industry (HK)	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(01)
5.	Ms LIT Ming-wai	<ul style="list-style-type: none"> • Supported the regulation of medical devices, but had strong views against the proposed use control assessment framework under which certain medical devices involving high risk of serious injury or harm (such as those for extracorporeal shock wave therapy) were classified into use control category IV whereby no user restriction would be imposed; and • The Administration should fully consult the physiotherapy profession on the proposed regulatory framework for medical devices.
6.	Dr Grace SZETO Pui-yuk	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(02)
7.	Hong Kong Physiotherapy Association	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(05)
8.	Democratic Party	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(03)
9.	Miss Anna Bella SUEN Mei- yee	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(06)
10.	Miss Sally WAN Hoi-wing	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(01)
11.	Physio Action	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(08)
12.	Mrs Loretta FUNG Ka-lin	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(02)
13.	Beauty Industry Reform Research and Development Committee	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(03)

No.	Name of deputation/individual	Submission / Major views and concerns
14.	Asia Pacific Beauty Group Limited	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(09)
15.	Democratic Alliance for the Betterment and Progress of Hong Kong	<ul style="list-style-type: none"> Devices used solely for cosmetic purposes should be subject to separate regulation; and The Administration should set up an accreditation system, so that beauticians fulfilling a set of skills and competency requirements would be allowed to operate cosmetic-related devices.
16.	Neo Derm Group Ltd	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(04)
17.	Ms MAK Man-yu	<ul style="list-style-type: none"> LC Paper No. CB(2)809/16-17(02)
18.	Mr WONG Chun-ho	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(12)
19.	The Cosmetic & Perfumery Association of Hong Kong	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(10)
20.	Zenith Cosmetics Trading Co Ltd	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(05)
21.	CMM Monita International Group Limited	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(11)
22.	Prof Raymond TONG Kai-yu	<ul style="list-style-type: none"> LC Paper No. CB(2)782/16-17(04)
23.	HK Beauty & Wellness Association	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(13)
24.	Ka Man Beauty Group Limited	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(15)
25.	Association of Doctors in Aesthetic Medicine (Hong Kong) Ltd	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(14) LC Paper No. CB(2)782/16-17(05)
26.	Ms Susanna CHEUNG Ying	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(06)
27.	Mr LEE Wing-yip	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(16)
28.	Dentsply Sirona Inc	<ul style="list-style-type: none"> Expressed support for the proposed regulatory framework for medical devices.
29.	Miss Rufina LAU Wing-lum	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(07)
30.	Hong Kong Medical and Healthcare Device Industries Association	<ul style="list-style-type: none"> LC Paper No. CB(2)809/16-17(03)
31.	Hong Kong Physiotherapy Concern	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(17)

No.	Name of deputation/individual	Submission / Major views and concerns
<i>Session Two</i>		
32.	Hong Kong Academy of Medicine	<ul style="list-style-type: none"> LC Paper No. CB(2)782/16-17(06)
33.	The College of Surgeons of Hong Kong	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(19)
34.	Miss CHEUNG Sze-nga	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(18)
35.	Hong Kong Physiotherapists' Union	<ul style="list-style-type: none"> LC Paper No. CB(2)809/16-17(04)
36.	Association of Private Medical Specialists of Hong Kong	<ul style="list-style-type: none"> LC Paper No. CB(2)782/16-17(07)
37.	Hong Kong College of Physicians	<ul style="list-style-type: none"> LC Paper No. CB(2)782/16-17(08)
38.	Hong Kong College of Dermatologists	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(22)
39.	The Hong Kong Society of Dermatology & Venereology	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(23)
40.	Miss HO Lai-chu	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(08)
41.	Dr Alan FUNG Ho-wang	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(25)
42.	Mr LEUNG Yu-wing	<ul style="list-style-type: none"> Expressed grave concern about the proposed restrictive use of devices for cosmetic purposes under the proposed regulatory framework for medical devices.
43.	Miss FUNG Wan-sze	<ul style="list-style-type: none"> Expressed concern about whether the skills and competency acquired by beauty practitioners would be recognized under the proposed regulatory framework for medical devices.
44.	Miss CHEUNG Yuk-ying	<ul style="list-style-type: none"> (No views presented)
45.	Miss Candy CHAN Nga-lam	<ul style="list-style-type: none"> LC Paper No. CB(2)844/16-17(09)
46.	Miss LAM Ho-yan	<ul style="list-style-type: none"> Those devices used solely for cosmetic purposes should be differentiated from medical devices. Both healthcare professionals and beauty practitioners should be required to undergo proper training and meet the competency requirements for operating cosmetic-related devices.
47.	Beauty Industry Standardisation Organisation	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(26)
48.	郭敏霞小姐	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(27)
49.	Spa Collection Group	<ul style="list-style-type: none"> LC Paper No. CB(2)751/16-17(28)

No.	Name of deputation/individual	Submission / Major views and concerns
50.	Miss WONG Mei-ying	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(29)
51.	Mr FOK Man-kit	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(10)
52.	Miss KWOK Mei-mei	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(11)
53.	Ms CHAN Wing-mui	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(30)
54.	The Hong Kong Society of Professional Optometrists	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(09) • LC Paper No. CB(2)809/16-17(05)
55.	Miss Manki CHAN	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(09) • LC Paper No. CB(2)809/16-17(05)
56.	Hong Kong Beauty and Fitness Professionals General Union	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(33)
57.	NUDERMA	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(34)
58.	Full Moral Technology Cosmetic	<ul style="list-style-type: none"> • LC Paper No. CB(2)844/16-17(12)
59.	Mrs Teresa TSOI	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(36)
60.	The Hong Kong Medical Association	<ul style="list-style-type: none"> • LC Paper No. CB(2)809/16-17(10)
61.	Hong Kong Hair & Beauty Merchants Association	<ul style="list-style-type: none"> • LC Paper No. CB(2)782/16-17(10)
<i>Session Three</i>		
62.	The Hong Kong Association of the Pharmaceutical Industry	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(38)
63.	Modern Beauty Salon	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(39)
64.	The Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons	<ul style="list-style-type: none"> • LC Paper No. CB(2)809/16-17(06)
65.	Medical Aesthetic Professionals Group	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(40)
66.	Miss TO Po-chu	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(42)
67.	Miss LAU Wing-sum	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(43)
68.	Starz Tech International Ltd.	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(44)
69.	Miss Gobby CHAN Ching-ting	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(45)
70.	Grand Aesthetic Academy	<ul style="list-style-type: none"> • LC Paper No. CB(2)751/16-17(46)

No.	Name of deputation/individual	Submission / Major views and concerns
71.	Ms MA Wing-sheung	• LC Paper No. CB(2)751/16-17(47)
72.	Ms Carmen SIN Ka-man	• LC Paper No. CB(2)751/16-17(48)
73.	Ms CHAN Kai-hung	• LC Paper No. CB(2)751/16-17(50)
74.	Miss WOO Ka-ki	• LC Paper No. CB(2)751/16-17(51)
75.	Miss Audrey CHIU Man-ying	• LC Paper No. CB(2)751/16-17(52)
76.	Ms TSOI Lee-lee	• LC Paper No. CB(2)751/16-17(53)
77.	Ms NG Yin-san	• LC Paper No. CB(2)782/16-17(09) • LC Paper No. CB(2)809/16-17(05)
78.	Dr CHAN Ka-yin	• LC Paper No. CB(2)782/16-17(09) • LC Paper No. CB(2)809/16-17(05)
79.	Miss WU Po-po	• LC Paper No. CB(2)751/16-17(54)
80.	HK Association of Professional Aestheticians International	• LC Paper No. CB(2)751/16-17(55)

Council Business Division 2
Legislative Council Secretariat
7 November 2017