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Panel on Health Services and Panel on Commerce and Industry

Report of the Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry

Purpose

This paper reports on the deliberations of the Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of the Beauty Industry ("the Subcommittee").

Background

2. Beauty industry is one of the key service industries in Hong Kong and has grown significantly in recent years. In the midst of favourable growth, there have been public calls for the Administration to strengthen safeguards for beauty services and promote the industry's development. Incidentally, to protect public health, the Administration has planned to introduce a statutory regime for the regulation of medical devices including those for use in cosmetic procedures. According to the Administration, the statutory regime will help bring Hong Kong on par with other major markets in the regulation of medical devices, thus raising industrial standards and facilitating development of local medical device industry.

The Subcommittee

3. The Panel on Commerce and Industry and the Panel on Health Services, at their respective meetings on 21 and 28 February 2017, agreed to form a joint subcommittee to study the policies and measures relating to the regulation of devices and development of beauty industry. Approval of the House Committee was obtained on 23 November 2018 for the Subcommittee to commence work. The term of reference of the Subcommittee is in **Appendix I**.

4. Hon Tommy CHEUNG Yu-yan and Hon Elizabeth QUAT are Chairman and Deputy Chairman of the Subcommittee respectively. The membership of the Subcommittee is in **Appendix II**. The Subcommittee has held a total of five meetings to meet with the Administration, including one meeting to receive views from various stakeholders. The list of deputations and individuals which/who have given views to the Subcommittee is in **Appendix III**.

5. To facilitate members' discussion, the Subcommittee has requested the Research Office of the Legislative Council Secretariat to provide an overview on the beauty industry in Japan, South Korea, Singapore and Taiwan, including regulation of the beauty treatment devices, qualifications framework for beauty practitioners, and support measures to promote the industry, enhance industry standards and protect consumers.[1]

Deliberations of the Subcommittee

Regulatory framework for medical devices

6. The Subcommittee notes that there is currently no specific legislation that regulates the manufacture, import, distribution, supply and use of medical devices in Hong Kong (including those used for cosmetic procedures). To protect public health, the Administration is working on a regulatory framework for medical devices which comprises pre-market control to ensure medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market[2]; and post-market control to enable swift control measures against defective or unsafe medical devices [3]. According to the Administration, the regulatory framework will cover medical devices used in cosmetic procedures which are used to enhance physical appearance through modification or support of the anatomy or a physiological process. However, these devices only account for a relatively small number of the to-be-regulated medical devices.

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1 The fact sheet on "Beauty industry in selected places" can be found at: https://www.legco.gov.hk/research-publications/english/1819fs03-beauty-industry-in-selected-places-20190123-e.pdf

2 Pre-market control comprises registration or listing of medical devices, and registration and licensing of traders of medical devices in Hong Kong.

3 Post-market control refers to the duties of traders of medical devices in Hong Kong to ensure the safety of medical devices supplied in the market, including maintaining records of supply, reporting adverse incidents associated with the medical devices and its investigation results as well as implementing remedial measures to the satisfaction of the Department of Health.

7. Members attach great importance to public health and consider there is a need to regulate high-risk medical devices to ensure the safety and quality standards of these devices. Nevertheless, as the proposed framework will cover devices commonly used by the beauty industry ("beauty devices"), some members consider it undesirable and will severely impact the development of the beauty industry. The Administration should conduct an up-to-date assessment on how the beauty industry will be affected by the proposed framework.

Definition of medical devices

8. The Administration has informed the Subcommittee that the proposed regulatory framework for medical devices has adopted the comprehensive definition of medical devices formulated by the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force[4] ("GHTF")). The term "medical device" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of disease and injuries. It also covers devices that modify body structures or physiological process. Devices (such as extracorporeal shock wave therapy ("ESWT") device and high intensity focused ultrasound ("HIFU") device) that are used for modifying the anatomy of human bodies in cosmetic procedures will be brought under the proposed regulatory framework.

9. Given the broad definition of medical devices which ranges from simple instruments like bandages to sophisticated equipment such as implantable defibrillator, some members consider there will be grey areas in distinguishing whether a device falls within the definition of medical devices. They relayed the beauty industry's worries that the Administration will include all beauty devices in the scope of regulation, leading to excessive regulation of the beauty industry. To avoid confusion, there is a suggestion that the Administration should provide a clear definition of medical devices by using a matrix system to demonstrate the classification of medical devices including those used for cosmetic procedures by risk level, energy output, intended purposes and intended users.

10. The Administration has explained that the proposed statutory regulatory regime adopts a risk-based approach whereby the level of control will be

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[4] GHTF was formed in 1992 by regulatory authorities and trade representatives of the United States of America, Canada, Australia, Japan and the European Union to harmonize the standards and principles of regulating medical devices. In 2011, GHTF was disbanded, and a new regulator-led group known as IMDRF was formed to build on the foundational work of GHTF and aims to accelerate international medical device regulatory harmonization and convergence.

proportional to the degree of risk associated with the medical devices according to the recommended IMDRF classification scheme.[5] Under the scheme, general medical devices are classified into four classes I, II, III and IV, where Class I is the lowest and Class IV is the highest level of risk. A simple matrix system is incapable to map the risk to different levels due to the large number and wide variety of medical devices. In addition, the Administration is not aware of any jurisdiction that has adopted a classification system for medical devices that is based on energy output level, intended purposes or intended users.

11. Some members have pointed out that the beauty industry attaches great importance to the safety of customers and does not object to the introduction of a regulatory regime for beauty devices. However, the industry considers devices solely used for cosmetic procedures are not medical devices and should not be regulated as such. These members have also pointed out that many adverse events related to cosmetic procedures involved the use of invasive devices by medical practitioners. In their view, beauty devices are non-invasive and pose no harm to consumers. Subjecting all these devices to the same stringent requirements is not appropriate or fair. These members urge the Administration to make distinction between medical devices and beauty devices; make reference to the international approaches for regulating beauty devices; and put in place separate regulatory regimes for medical and beauty devices.

12. The Administration has advised that only devices that meet the definition of medical devices will be subject to the regulation of the regime. It is not practical to segregate the regulatory regime for medical devices and devices used for cosmetic procedures since the latter, as the case may be, is invariably a subset of the former. The technology deployed, energy output, theory in producing effects, and risks used on human body of the latter are similar to those of the medical devices intended for treatment or rehabilitation. Moreover, there is currently no statutory definition for such devices used for cosmetic procedures internationally. Many advanced jurisdictions/regions such as the United States of America ("USA"), Canada, Australia, Japan, the Mainland China and Singapore, etc. have included devices used for cosmetic procedures which meet the definition of medical devices under the local regulatory framework for medical devices to protect public health. The Administration has not identified any jurisdictions with a separate regulatory system for medical devices used for cosmetic procedures and is not aware of jurisdictions with a regulatory regime of medical devices in place which does not regulate devices used for cosmetic procedures as part of the regime.

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[5] The IMDRF classification scheme is a rule-based system that uses a set of criteria that can be combined in various ways in order to determine the risk class of the devices, for example, duration of contact with the body, degree of invasiveness, and local versus systemic effect, etc.

Registration and listing mechanism

13. According to the Administration, the proposed regulatory framework for medical devices will impose registration requirement on Class II-IV general medical devices before they can be supplied to the local market. To facilitate the registration of devices, the Department of Health ("DH") will accept marketing approvals obtained from the Mainland China and South Korea, in addition to those five GHTF founding members (i.e. Australia, Canada, European Union, Japan and USA), as documentary evidence of safety, quality, performance and efficacy of the related medical device, sparing the requirement for third-party conformity assessment.

14. Some members consider that conformity assessment is important for ensuring the safety and effectiveness of medical devices, and should not be exempted for registration. They also cast doubt over the credibility of the marketing approvals issued by the aforesaid jurisdictions and enquired about the criteria for accepting a jurisdiction's marketing approval.

15. The Administration has explained that marketing approval meant that the safety and performance of these devices had been assessed and cleared for marketing. To be selected for acceptance, marketing approvals should be issued by a regulatory authority of places where regulations for medical devices are well established. Having due regard to the fact that many traders of medical devices are small and medium-sized enterprises, the arrangement is proposed to reduce the costs for placing medical devices in the local market without compromising the quality of conformity assessment.

16. While the beauty industry does not object to regulate beauty devices through product registration, some members consider that these devices should not be subject to the medical device registration requirements. They have expressed concern that traders will not be able to present valid marketing approvals if the devices are not classified as medical devices in the aforesaid seven jurisdictions. Moreover, a majority of the traders are small and medium-sized enterprises which cannot afford the high costs for conformity assessment. As a result, many devices of latest technology cannot be imported to Hong Kong for use by the industry. That means, the choice of beauty devices in the market will be limited, depriving the beauty industry of room for survival. Consequently, many traders and beauty operators will be driven out of the market.

17. The Administration has explained that DH has adopted IMDRF's definition of medical device which is widely adopted internationally. If a device is not classified as medical device in the aforesaid jurisdictions, most likely it

will not be regulated under the proposed regulatory framework for medical devices. Furthermore, noting some stakeholders' concerns that a number of beauty devices will not be able to fulfill the proposed medical device registration requirements, a five-year transitional listing mechanism for devices[6] which cannot fulfill the registration requirements for medical devices will be established so that these devices can still be supplied for a period of time. Devices that meet the listing requirement may qualify for a permit to be granted and/or renewed once every five years. Beyond the five-year transitional window period, no new listing applications will be accepted.

18. Some members consider the effectiveness of the transitional listing mechanism in helping the beauty industry doubtful. They pointed out that according to the industry's guesstimates, a majority of the new beauty devices will not be able to meet the medical device registration requirements because these devices are not designed for medical purposes. If no new listing applications will be accepted upon expiry of the transitional period, new devices which fall short of the registration requirements but are deemed to be safe for use by the beauty industry can no longer be introduced to the market. There are suggestions that the Administration should consider lengthening the transitional period, establishing a non-time-defined listing mechanism or imposing separate and less stringent registration requirements on beauty devices.

19. On the other hand, some other members have raised concerns about the potential safety risks associated with the use of beauty devices which fall short of medical device registration requirements. They have shared some deputations' concerns that the transitional arrangement will become a dumping ground for unscrupulous devices and have suggested shortening it to three years.

20. The Administration has explained that only those aforesaid medical devices which comply with the basic listing requirements set by DH (for example general requirements for household and electrical appliance) will be qualified for listing. Also, traders of concerned devices have to comply with requirements such as furnishing the required documents, undertaking post-market surveillance and reporting adverse events, which will greatly facilitate the Administration in tracking these devices and enabling product recalls when necessary. In fact, the ultimate target of the transitional arrangement is for all medical devices including those for use in cosmetics procedures in Hong Kong to fully meet all registration requirements.

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[6] Listing mechanism is proposed for those Class II or III non-invasive electrical medical devices for skin related purpose which may be used by the beauty industry or the public for the purpose of modifying the anatomy or physiological process of skin of a person to preserve, restore or enhance physical appearance.

21. Some members consider it necessary to put in place a delisting mechanism under the transitional listing mechanism to ensure a high level of protection for public health. The Administration has advised that DH will investigate upon receiving reports of listed device adverse events. If a medical device model is found to have potential risks on public health, DH will require traders to take remedial actions and conduct product recalls whenever necessary. For more serious cases, the device will be delisted.

22. There are also concerns about the time DH will take to approve applications for listing/registration of new-to-the-market beauty devices. Members consider that the Administration should keep application procedures simple and process an application expeditiously, with a view to minimizing the lead time required to place these devices on the market. It is important for the Administration to make practical performance pledges for the listing/registration processes so that traders can take this into consideration when planning for product launches.

23. The Administration has advised that taking reference from the current Medical Device Administrative Control System, the vetting and approval of a listing application will normally be completed within 12 weeks following the submission of the application and all the required supporting documents. Information on the listed devices and listed traders will then be uploaded on the website of DH for public access.

Regulation of the beauty industry

24. Members have pointed out that the beauty industry does not object to a regulatory regime for the industry. While some members consider it appropriate to impose strict regulation on the beauty industry, some others think that the industry should have room for survival. Nonetheless, members in general consider that the Administration should strike a proper balance between safeguarding consumer interests and sustaining the long-term development of the industry.

Use and operation of beauty devices

25. In members' view, safe and effective application of devices requires a safe device as well as appropriate and proficient use. In the absence of control arrangements, the operation of a medical/beauty device by a person without proper training or qualification may pose health risks to the operator and the customers. They therefore are disappointed that the Administration has yet mapped out how use control of specific medical devices including those for use

in cosmetic procedures (i.e. to restrict the use of specific types of medical devices to users with certain qualifications) should be taken forward.

26. While supporting there should be some form of regulatory control placed on the use and operation of beauty devices, some members consider it should be done separately from medical devices. These members are worried that if beauty devices are broadly defined as medical devices, these devices will only be operated by medical practitioners or with their supervision on site in future. As most beauty salons are small and medium-sized enterprises, they do not have the resources to employ medical practitioners. Many services currently provided by beauty practitioners can no longer be provided in future, particularly those using laser and IPL equipment to provide relatively low-risk beauty services which are a main source of income for the beauty industry. As a result, many beauty salons may no longer be able to remain in business, causing unemployment to a large number of beauty practitioners.

27. The Administration has advised that taking into account the feedback from stakeholders, use control for specific medical devices will not be pursued as part of the current legislative exercise for the regulation of medical devices. The Administration will revisit the issue of use control of specific medical devices separately and will maintain communication with the stakeholders in mapping out the way forward. Meanwhile, operators of medical devices including those devices used for cosmetic procedures will be encouraged to acquire the necessary training regarding the proper use of devices. The Administration further stressed that some medical devices are not necessarily required to be operated by medical practitioners.

28. As many beauty devices are used by trained beauty practitioners at present, some members consider that beauty practitioners fulfilling a set of skills and competency requirements should be allowed to continue to operate these devices. There are suggestions that the Administration should better understand international approaches for ensuring the safe and effective operation of beauty devices; conduct a detailed study on the devices commonly used by the local beauty industry; clearly differentiate between medical devices and general beauty devices; identify the devices that should be operated by medical practitioners and those that can also be operated by beauty practitioners; and specify the competencies and qualifications required for operating the devices. In the course of taking forward the suggestions, the beauty industry should be fully consulted.

29. To enhance service quality of and consumers' confidence in the beauty industry, members consider there is a need to require beauty practitioners to acquire the appropriate qualifications and training for operating the devices.

Members have put forward suggestions including setting the level of training for a device according to the degree of risk associated with the device, introducing a transitional period of, for example, five years to allow beauty practitioners sufficient time to undertake necessary training, and requiring traders of beauty devices to provide training courses and manuals for operating the supplied devices as one of the registration requirements before use control is imposed.

30. According to the Administration, the authorized representatives of a medical device are responsible for providing necessary operation and safety training on the devices for their clients. It will not be viable for DH to set a standardized training level for all the medical devices in a particular Class. Nevertheless, the Administration has taken note of members' suggestions.

Trade and sales practices

31. The Subcommittee notes that the Administration has planned to impose a statutory cooling-off period for beauty services consumer contracts. Deputations from the beauty industry have expressed their views over the possible impact of the practical arrangements of cooling-off period, such as the arrangements for consumers to exercise the right of cancellation, the refund arrangement, the possible extension of withholding period by banks or other merchant acquirers, etc. They are worried about that the imposition of cooling-off period will affect business operation and many beauty salons may close down. While some members have supported the implementation of cooling-off period to prohibit unfair trade practices of public concern, some others have shared the deputations' concern that it may harm the industry, particularly when Hong Kong is facing uncertain economic prospects. Members urge the Administration to conduct an impact assessment of the cooling-off regime on the beauty industry, take into account the operational difficulties that will be faced by the industry and provide support measures to assist the industry where necessary. There is also a suggestion that the Administration should consider developing licensing system and demerit point system to deter unscrupulous acts of beauty operators.

32. The Administration has advised that the Commerce and Economic Development Bureau ("CEDB") is studying and consolidating the submissions received during the public consultation on the mandatory cooling-off proposal. Members' views and concerns will be taken into consideration. On the concerns that merchant acquirers might lengthen the withholding period for releasing funds to the traders, CEDB had met with merchant acquirers such as banks to explain the proposed statutory cooling-off period and relay the concerns from the beauty industry. According to the merchant acquirers, the withholding period was a risk management measure adopted by the merchant acquirers to

fulfill the requirements under the credit card chargeback protection mechanism to protect consumer interests. The arrangement has been applicable to all trades and was not introduced in response to the proposed cooling-off period.

Development of the beauty industry

33. Members in general consider professionalization of beauty practitioners conducive to healthy development of the beauty industry. Some members have pointed out that the beauty industry has been making active efforts to upgrade the skill levels of its practitioners. However, they consider that the Administration does not attach importance to enhancing the qualifications and competency of beauty practitioners. No mandatory training/qualifications framework has been developed for beauty practitioners. Members and deputations from the beauty industry have called for a standardized training regime to enhance competitiveness of the industry, with a view to fostering sustainable long-term development.

Qualifications Framework

34. As beauty practitioners' participation in Qualifications Framework[7] ("QF") is voluntary, some members have questioned the effectiveness of QF in upgrading beauty services. They consider there should be a wider implementation of QF to enhance the capability and competitiveness of beauty practitioners. Some members have suggested that the Administration should build upon QF platform to develop a set of competency requirements to enable beauty practitioners to operate certain devices such as HIFU device after receiving mandatory training.

35. According to the Administration, it has all along encouraged beauty practitioners to receive training regarding proper use of devices and there are currently learning programmes regarding the operation of beauty devices under QF. Moreover, as the beauty industry has attached great importance to the safety operation of cosmetic light equipment, six new clusters of Units of Competency related to the operation of these equipment will be introduced in 2020 for beauty practitioners to apply for assessments under the Recognition of Prior Learning ("RPL") mechanism[8].

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[7] QF is a voluntary system that defines clear and objective standards applicable to qualifications in the academic, vocational, professional, as well as continuing education sectors.

[8] RPL mechanism provides an alternative route for beauty practitioners to obtain QF recognised qualifications without undergoing a training programme.

36. Some members enquired about the measures adopted to ensure that beauty practitioners have the appropriate qualifications for safe use of devices upon completion of the relevant learning programmes, and that such programmes have caught up with the rapid development of the devices and met the evolving needs of the industry. As there are over 60 operators operating more than 200 beauty-related learning programmes under QF, concerns have also been raised as to whether monitoring measures are in place to ensure the quality of the courses, standard of the operators and qualifications of the instructors; and whether there is transparency of course contents, course fees and qualifications of teachers.

37. The Administration has advised that the Beauty and Hairdressing Industry Training Advisory Committee ("B&H ITAC") set up under QF comprises representatives[9] who have a good understanding of the industry. It draws up Specification of Competency Standards for the industry, which set out the skills, knowledge and outcome standards required of the beauty practitioners to facilitate the formulation of learning programmes for recognition under QF. QF-recognized learning programmes and operators offering such programmes must be accredited by the Hong Kong Council for Accreditation of Academic and Vocational Qualifications which will continue to monitor the quality and standards of these programmes through re-accreditation. Information on QF-recognized learning programmes including their respective operators and other programme details is available on Qualifications Register, a web-based database, for public access free of charge.

38. Some members are concerned that only a small number of beauty practitioners have sought assessment of their qualifications under the RPL mechanism. In members' views, more promotion activities should be organized to enable more employers in the beauty industry to recognize the importance of QF and adopt in their recruitment, training and promotion. Education and training providers should be encouraged to accept RPL qualifications so as to enhance the recognition of RPL qualifications and boost the confidence and incentives for beauty practitioners to participate in QF or submit applications under the RPL mechanism. Moreover, the Administration should step up its publicity and promotion efforts on QF in enhancing the general public's awareness of QF so as to boost consumers' confidence in the beauty industry.

39. The Administration has advised that since the introduction of the RPL in the beauty industry in 2014, over 4 000 applications from practitioners for the assessment of RPL have been processed. Besides, riding on B&H ITAC

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[9] Representatives include employers, employees, trade associations, professional bodies and trade unions of the beauty and hairdressing industries.

networks, various promotion and publicity campaigns have been conducted to introduce QF in the beauty industry. The Education Bureau will continue to explore effective ways to promote QF to the industry and the general public.

40. Some members have pointed out that there are still a number of private beauty training organizations in the industry. They urge the Administration to explore effective measures to assist them in seeking accreditation for their training courses to be recognised under QF, with a view to supporting their survival. Some members also call for the establishment of more financial supporting schemes to encourage training providers and beauty practitioners to participate in QF and training courses offered by the Employees Retraining Board and private beauty training organizations.

Training and accreditation

41. Members take the view that mandatory standards and qualifications should be developed to promote professionalism and safety across the beauty industry. They urge the Administration to join hands with the beauty industry including frontline staff to design recognized training courses, formulate a certification mechanism, and provide a well-structured training ladder for beauty practitioners. In the long run, the Administration should establish training, appraisal and registration systems for beauty practitioners, with a view to regulating their skill levels and protecting consumers in a more effective manner.

42. Apart from the provision of training support, there is a suggestion that the Administration 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. According to the Administration, AR Scheme aims to enhance the society-based registration arrangements for healthcare professionals which are 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 decisions. As beauty practitioners do not perform medical procedures, AR Scheme is not an option for beauty practitioners. Nonetheless, the Food and Health Bureau and DH will be pleased to share their experience with relevant bureaux, departments or organizations if they wish to apply the spirit of AR Scheme to establish an accreditation mechanism for beauty practitioners, with a view to ensuring their professional competency.

Funding support

43. The Administration has informed the Subcommittee that the Government has, through various bureaux and departments, introduced more

than 40 funding schemes[10] to support business enterprises and organizations in such areas as exploring export markets, obtaining financing, enhancing overall competitiveness, increasing productivity or upgrading or transforming business processes through adoption of technological services or solutions, and conducting research and development work, etc. While there are no detailed breakdown of statistics on the number of companies in the beauty industry which have received funding support under the funding schemes, some members have pointed out that many small and medium-sized beauty salons do not meet the eligibility criteria of those funding or financing schemes. They urge the Administration to undertake specific support measures to help develop the beauty industry.

Industrialization of the beauty industry

44. Members considered that the beauty industry is a promising industry with good development potential. A flourishing beauty industry can create employment opportunities and wealth for Hong Kong. In the long run, the Administration should promote industrialization of the beauty industry, with a view to achieving a pre-eminent position in Asia's beauty industry. Some members have expressed disappointment that the Administration has failed to take heed of the calls of the industry.

45. As regulatory and support measures relevant to the beauty industry straddle across various policy areas, members strongly urge the Administration to set up a steering committee comprising relevant bureaux/departments and formulate a holistic policy to assist the industry in sustainable development and competitiveness enhancement. Some members have pointed out that the key to facilitate industrialization of the beauty industry is to have a good understanding of the uniqueness of the industry and to obtain the consensus and support of different stakeholders. There is a need for the Administration to collaborate with various stakeholders of the beauty industry in long-term development of the industry. A communication platform should also be established to collect the views of the frontline staff in the industry.

46. In formulating the policy for industry development, members consider it necessary to refer to the practices of individual jurisdictions/regions and take into account the actual situation of Hong Kong. In view of the booming beauty

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[10] Examples are the Dedicated Fund on Branding, Upgrading and Domestic Sales, the Small and Medium Enterprises Export Marketing Fund, the SME Loan Guarantee Scheme, the SME Financing Guarantee Scheme, the Retail Technology Adoption Assistance Scheme for Manpower Demand and Management, the Trade and Industrial Organization Support Fund, and the Technology Voucher Programme and the Enterprise Support Scheme under the Innovation and Technology Fund, etc.

industry in Korea and Japan, some members urge 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 local beauty industry. Some other members have suggested that the Administration should conduct more researches and studies on the existing situation and development potential of the industry.

47. Members in general consider that there is still considerable room for development in local beauty industry. If the Administration introduces effective measures to help industrialization of the industry, it can lead to the development of Hong Kong as a pre-eminent international beauty centre and create new tourist spots, hence promoting the development of the tourist industry. In order to be successful, members have suggested that the Administration should assess Hong Kong's strengths and weaknesses, as well as the competitive edge and opportunities for development.

48. The Administration has assured members that it will review the existing measures and policies in supporting the development of beauty industry by making reference to the Subcommittee's recommendations.

Recommendations

49. The Subcommittee urges the Administration to take into account the views and concerns expressed by members on various issues relating to the regulation of devices and development of the beauty industry. The Subcommittee recommends that the Administration should:

Regulatory framework for medical devices

(a) make distinction between medical devices and beauty devices, and put in place separate regulatory regimes for these two types of devices;

(b) better understand international approaches for regulating devices used for cosmetic procedures, conduct a study to acquire information on the number and types of devices commonly used by the beauty industry, and conduct an up-to-date impact assessment of the regulatory framework for medical devices on the beauty industry;

(c) conduct communications with the beauty industry stakeholders to brief and explain the regulatory framework for medical devices

and make adjustments if necessary;

(d) put in place a performance pledge on the processing time of a device registration/listing application since a protracted assessment process may result in a loss of business opportunity, and publish clear performance pledge so that traders can take this into consideration when planning for device launches;

(e) take into account the views of the relevant stakeholders including the beauty industry and re-consider whether there should be a cut-off date of the listing mechanism;

(f) establish a delisting mechanism with clear delisting criteria under the regulatory framework for medical devices, and require traders to put in place adequate mechanisms for monitoring device performance and recalls;

(g) issue clear guidelines and provide sufficient assistance to traders in registration of devices;

Regulation of the beauty industry

(h) before imposition of use control to restrict the use of beauty devices to users with certain qualifications:

(i) perform extensive information searches on practices and regulations on the use control of beauty devices in other countries;

(ii) discuss with relevant stakeholders in detail the items and types of beauty devices and assess the health and safety risks of them, so as to determine the list of devices to be included under use control;

(iii) identify the devices that can be operated by beauty practitioners, and specify the competencies and qualifications required for operating the devices;

(iv) require traders to provide user training and manual for operating the devices as an additional traders registration requirements;

(i) publish a clear implementation timetable early if use control to restrict the use of beauty devices to users with certain qualifications is imposed, so that relevant stakeholders can start planning for the implementation;

(j) take into account the present situation of the beauty industry and re-consider whether the statutory cooling-off period should be implemented for the industry;

(k) regulate cosmetic injections and their advertising to prevent misrepresentation;

(l) maintain a close communication with relevant stakeholders, including beauty practitioners, traders, manufacturers, etc. over the implementation of regulations on beauty industry in future;

Development of the beauty industry

(m) conduct a comprehensive review on the qualification structure of the beauty industry and collect feedback from relevant stakeholders with a view to further refining QF for the industry;

(n) maintain ongoing communication and establish partnerships with different stakeholders, including employers, employees, professional bodies, education and training providers, in the promotion and development of QF for the beauty industry;

(o) consult extensive consultation with members of the beauty industry on the practical skills and knowledge required of beauty practitioners in the workplace, with a view to developing a standardized training and credentialing pathway for beauty practitioners to acquire the necessary knowledge and skills to provide quality and safe beauty treatments;

(p) continue to encourage training providers to offer more suitable programmes for the beauty practitioners to pursue continuous learning after attaining different levels of qualifications;

(q) communicate with relevant stakeholders through different channels to explore ways to facilitate the beauty practitioners in receiving training to raise their professional standards;

(r) work closely with the beauty industry so as to enable the industry to keep abreast of the development of devices/services and move towards professionalization, thereby further protecting the interests of consumers;

(s) develop a comprehensive training, appraisal and licensing system for all beauty practitioners to enhance their competence so as to professionalize the beauty industry;

(t) explore the feasibility of applying the spirit of AR Scheme to establish an accreditation mechanism for beauty practitioners;

(u) allocate resources such as setting up designated funding schemes to assist the development of the beauty industry;

(v) set up a steering committee comprising relevant bureaux/departments and beauty industry stakeholders to conduct a thorough review on the beauty industry, and formulate a holistic policy for the healthy development of the industry;

(w) conduct a detailed study to examine the experience and practices in overseas jurisdictions with booming beauty industry, such as South Korea and Japan, for Hong Kong to make reference with; and

(x) undertake effective measures to help industrialization of the beauty industry, and explore the feasibility of developing Hong Kong as a pre-eminent international beauty centre.

Advice sought

50. Members are invited to note the deliberations and recommendations of the Subcommittee.

Council Business Division 4
Legislative Council Secretariat
11 December 2019

Appendix I

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

Terms of reference

To study issues relating to the regulation of devices and development of the beauty industry and make timely recommendations.

Appendix II

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

Membership list*

Chairman	Hon Tommy CHEUNG Yu-yan, GBS, JP
Deputy Chairman	Hon Elizabeth QUAT, BBS, JP
Members	Prof Hon Joseph LEE Kok-long, SBS, JP Hon Jeffrey LAM Kin-fung, GBS, JP Hon WONG Ting-kwong, GBS, JP 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, JP Dr Hon Pierre CHAN (Total : 11 members)
Clerk	Ms Angel WONG
Legal Adviser	Ms Wendy KAN
Date	5 November 2019

* Changes in membership are shown in Annex to Appendix II.

Annex to Appendix II

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

Changes in membership

Member	**Relevant date**
Dr Hon CHIANG Lai-wan, SBS, JP	Up to 23 January 2019
Hon YIU Si-wing, BBS	Up to 30 October 2019
Hon CHAN Chi-chuen	Up to 30 October 2019

Appendix III

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

List of deputations/individuals which/who have given oral representation to the Subcommittee

Deputations

1. Associated Medical Supplies Company Limited
2. Association of Private Medical Specialists of Hong Kong
3. Beauty Industry Standardisation Organisation
4. Citi Concept
5. Democratic Alliance for the Betterment and Progress of Hong Kong
6. Federation of Beauty Industry (H.K.)
7. Grand Aesthetic Academy
8. Hong Kong Beauty and Fitness Professional General Union
9. Hong Kong Beauty Industry Union
10. Hong Kong Dental Association
11. Hong Kong Doctors Union
12. Hong Kong Medical and Healthcare Device Industries Association
13. International CICA Association of Esthetics
14. Liberal Party
15. Medtechnoskorp Ltd
16. Starz Tech International Ltd
17. The Cosmetic & Perfumery Association of HK
18. The Democratic Party

Individuals

19. Miss CHAN Yu
20. Ms KWOK Man-ha
21. Ms LAM Ho-yan
22. Mr NGAN Tsz-leung
23. 黃麗女士
24. 鍾蔚庭先生

List of deputations/individuals which/who have provided written views to the Subcommittee

1. Civic Party
2. Dr CHAN Wai-man, Mandy
3. Hong Kong College of Dermatologists
4. Hong Kong College of Physicians
5. The Federation of Medical Societies of Hong Kong
6. The Hong Kong Academy of Nursing
7. The Hong Kong Association of the Pharmaceutical Industry
8. The Hong Kong Medical Association
9. The Hong Kong Society of Dermatology & Venereology
10. The Patients and Healthcare Professionals Rights Association