DEPARTMENT OF HEALTH

Report of the Working Group on Differentiation between Medical Procedures and Beauty Services

for submission to the Steering Committee on Review of Regulation of Private Healthcare Facilities

2013

CONTENTS

1 BACKGROUND

1.1. The Administration announced in October 2012 the establishment of the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) to conduct a review on the regulatory regime for private healthcare facilities in Hong Kong. The aim of the review is to strengthen regulatory control of private healthcare facilities in order to safeguard people's health.

1.2 At its first meeting on 2 November 2012, the Steering Committee set up four working groups to carry out focused study on four priority areas of concern regarding the provision of private healthcare facilities and to work out options on the way forward. Following the adverse incident in October 2012 resulting from invasive medical procedures provided by a beauty service company, it became evident that one of the priorities was to address the health risk brought by beauty parlours improperly performing medical procedures under the cover of "medical beauty services" through clearly differentiating ordinary beauty services from medical treatments.

1.3 The Working Group on Differentiation between Medical Procedures and Beauty Services (Working Group) was thus formed and tasked to differentiate between medical treatments and ordinary beauty services and to make recommendations on the regulatory approach.

2 THE WORKING GROUP

Membership

2.1 The Working Group, chaired by the Director of Health, comprised 22

members, including 7 Steering Committee members and 15 co-opted members from the relevant medical specialties, beauty industry and consumer representatives. A membership list of the Working Group is at Annex I. The Working Group held a total of three meetings during the period from December 2012 to July 2013.

Terms of Reference

2.2 At the first Working Group meeting, Members agreed that the Chinese translation of the term "medical treatments" in the Terms of Reference (TOR) endorsed by the Steering Committee should read "醫藥治療" instead of "醫療程序" to tally with the Chinese version of the term "medical treatment" adopted in Section 28(2)(b) of the Medical Registration Ordinance (Cap. 161). The revised TOR is set out below –

(a) to differentiate between medical treatments and ordinary beauty services currently available in the market (區分市場上現有的醫藥治療及一般美容服務)

(b) to make recommendations on procedures which should be performed by registered medical practitioners (就應由註冊醫生施行的程序，提出建議)

3 REGULATION OF BEAUTY SERVICES IN JURISDICTIONS OUTSIDE HONG KONG

3.1 Based on the papers prepared by the Secretariat, Members were introduced to the regulatory regimes on beauty services in China (including Taiwan), selected States in the United States of America (USA), Singapore, the United Kingdom (UK) and

Australia. A summary is provided in Annex II.

3.2 The Working Group noted that the type and level of control on beauty services varied greatly in different jurisdictions. In Mainland China and Singapore, medical cosmetic services or invasive cosmetic procedures were regulated by the Ministry of Health. In general, they required all invasive cosmetic procedures to be performed by medical practitioners.

3.3 In the USA, some States have their own State laws on the regulation of beauticians which were administered by their respective beauticians/ cosmetologists boards and they prohibited their licensees from performing certain specified cosmetic procedures. On the other hand, the medical boards in some states defined certain procedures as "cosmetic medical procedures" which had to be performed by licensed physicians.

3.4 In the UK, there was no overarching regulation for beauty services but in response to the adverse incidents related to breast implants in 2011/12, the UK Department of Health has carried out a review on the regulation of cosmetic interventions. The recommendations of the Review Committee were published in its final report released on 24 April 2013. In gist, the Review Committee considered that people choosing to undergo cosmetic interventions are both patients and consumers, as they were making purchasing decisions on procedures and products that might have a significant impact on their health and wellbeing. Noting the lack of standards for non-surgical cosmetic procedures and the failure of the sector to self-regulate, the Review Committee called for the strengthening of training and regulation of non-surgical practitioners. The UK Government was considering the

report and it was expected that a response would be provided in the summer. The report can be accessed from –

https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions

3.5 With regard to the regulation of laser devices, it was noted that some jurisdictions applied controls over the use of laser products through their radiation safety legislation. For example, in Singapore and certain states in Australia, use and possession licences were required for all Class 3B and/or 4 lasers under their radiation safety legislation. In other jurisdictions (e.g. certain states in the USA), control over the cosmetic use of lasers was applied through the laws regulating medical practitioners such that procedures involving their use were defined as "medical practice".

4 REGULATION OF MEDICAL DEVICES IN HONG KONG

4.1 As certain medical devices could also be used in beauty procedures, Members were also briefed on the progress of the proposed statutory control of medical devices in Hong Kong. In view of the safety and health risks that certain devices might pose to users or patients especially if they were operated by unqualified / untrained personnel, Members were informed that the proposed medical device regulatory framework would consider applying restrictions on the use and operation of certain high-risk medical devices. Members noted that the Administration has plans to report to the Legislative Council Panel on Health Services on the outcomes of its Business Impact Assessment on the regulation of medical devices together with details of the legislative proposal in 2013.

5 COMMON COSMETIC PROCEDURES THAT MAY POSE SAFETY CONCERNS OFFERED BY BEAUTY CENTRES IN HONG KONG

5.1 To facilitate the differentiation of medical procedures from beauty services, the Secretariat conducted a review to identify cosmetic procedures available in local beauty centres which might fall within the boundaries of medical practice and pose safety concerns. As the focus of the Working Group was on the types of procedures lying "borderline" between medical and beauty practice, conventional cosmetic procedures such as hairdressing, manicuring and nail sculpting etc. were excluded. On the other hand, surgical operations which were clearly considered as "medical" procedures were also excluded from the review. In addition, the review focused on safety rather than efficacy of such procedures in attaining their non-medical claims.

5.2 Based on information obtained via monitoring of advertisements and site visits to beauty centres, the Secretariat attempted to map the types of beauty procedures identified to the actual technology behind. Members of the Working Group also provided information on other procedures known to them. A total of 35 cosmetic procedures were identified (Annex III). Literature search was carried out on the purported mechanism of action and the potential risks involved for the identified cosmetic procedures. Based on the mechanisms of action and invasiveness of the procedures, they were classified into four categories to facilitate systematic risk assessment –

(a) Procedures that involve skin puncture;

(b) Procedures that involve external application of energy;

(c) Procedures that involve mechanical or chemical exfoliation of skin; and

(d) Other procedures that may pose safety concerns.

5.3 Based on the above information, the Working Group discussed on the guiding principles for differentiating between medical treatment and beauty service and deliberated on the potential risks associated with the cosmetic procedures identified. The relevant discussions are summarized in the following paragraphs.

Guiding principles for differentiating between medical treatment and beauty service

5.4 Taking into account the potential risks of the cosmetic procedures and regulation of these procedures in other jurisdictions, the following guiding principles for differentiating between medical treatment and ordinary beauty service were proposed –

(a) All procedures that involve skin puncture to inject, deliver, implant, or anchor any substances or objects into the body; or to withdraw or remove blood/ body fluids/ tissues should be regarded as medical procedures.

(b) All procedures that involve the penetration of the body orifices to deliver substances into or remove substances from the body should be regarded as medical procedures.

(c) All procedures that involve the external application of energy which is capable of causing severe or irreversible injury should be regarded as medical procedures.

(d) All procedures that involve mechanical/ chemical exfoliation of the skin

below the level of epidermis should be regarded as medical procedures.

5.5 Discussion was made on the appropriateness of the above principles. Some Members agreed to adopt the principles and emphasized that any procedure which caused damage to human tissues should be considered as "medical treatment" to be performed only by medical practitioners who were qualified to handle the complications caused by the procedures. They also opined that many cosmetic procedures involved the diagnosis of medical conditions which had to be done by medical practitioners. On the other hand, some Members opined that the basis for suggesting these "principles" were absent and they disagreed to classify a procedure as "medical" or "non-medical" based on its risk level. They opined that since cosmetic procedures were by nature performed for beauty purposes and not for treatment of diseases, they should not be regarded as "medical treatment" and clients should not be regarded as "patients". Nevertheless, they agreed that high risk procedures should be regulated.

5.6 Although there was no consensus on whether to adopt the above principles as the criteria for differentiating medical treatment from beauty services, these principles served as the basis for Members' further deliberation of the level of risks of the individual procedures.

5.7 The Working Group went on to deliberate on the potential risks of the 35 cosmetic procedures and attempted to classify them into either medical treatment or non-medical treatment. However, no consensus could be reached because there was fundamental difference in opinions regarding the meaning of "medical treatment".

The agreed views

5.8 Although there was no consensus reached for the classification of individual procedures, the following recurrent themes emerged throughout the discussions, which appeared to be generally agreed by Members –

(a) Some cosmetic procedures carried high risks and should be regulated.

(b) Procedures involving injections were of high risk of causing infections and complications. As such, all these procedures should be performed by medical practitioners, regardless of the purpose of the procedure. Examples of such procedures include items 1 to 8 and item 33 of Annex III.

(c) Procedures that involve the mechanical/ chemical exfoliation of the skin below the epidermis should be performed by medical practitioners (items 27 to 30 of Annex III).

(d) Traditional body tattooing and piercing (items 10 and 11 of Annex III) should be exempted from being considered as a "medical procedure" as their risks were already well known to the general public and these procedures were traditionally deemed as non-medical procedures. However, it was also noted that tattooing and body piercing on certain body parts (e.g. near the eyes, tongue etc.) might be of higher risk of complications.

(e) Hyperbaric oxygen therapy (item 32 of Annex III) should only be performed by medical practitioners.

(f) Dental bleaching (item 34 of Annex III) should only be performed by dentists.

The discrepant views

5.9 During the discussion, procedures that created the widest split in opinions were those involving the use of devices which emit different forms of energy. Some Members opined that only medical professionals were trained in making diagnosis and delivering appropriate treatment, including managing the risks and complications from invasive/ high risk procedures. In contrast, some Members considered that the risk of certain cosmetic procedures could be managed by any person with appropriate training and not just medical practitioners. They suggested that beauticians should be allowed to perform high risk cosmetic procedures after undergoing appropriate training and had their skill competencies proven through tests or examination.

5.10 In addition, some Members questioned whether the subject of colon hydrotherapy (item 31 of Annex III) should be handled by the Working Group as it was a procedure known to be practised as a form of alternative medicine which was outside the Working Group's purview. It was known that such procedure commonly involved the use of "Colonic Irrigation Systems" which were medical devices intended for bowel preparation before radiological or endoscopic procedures.

5.11 Regarding microneedle therapy, some Members considered that the risk associated with the procedure was high because numerous tiny wounds would be created on the skin after the procedure. Moreover, there was also a possible risk of spread of infection, including blood borne infections if the device was reused on different clients. In contrast, some Members opined that the risk associated with the procedure could be managed by persons who have undergone appropriate training.

6 CONCLUSION

6.1 Members reached the consensus that high risk cosmetic procedures should be regulated and some procedures such as those involving injections, should be performed by medical practitioners. However, there was no consensus as to the means of enforcing the requirement; i.e. whether the procedure should be regarded as "medical treatment" under Cap. 161.

6.2 Given that besides having to "differentiate between medical treatments and ordinary beauty services", the TOR of the Working Group also included "to make recommendations on procedures which should be performed by registered medical practitioners", Members decided to focus on making recommendations under this second TOR instead of dwelling on whether the procedures were "medical treatments", so that the Working Group could move a step forward in protecting public health by making it clear to the public that only medical practitioners should be allowed to perform certain cosmetic procedures. It was considered that whether the recommendations would be implemented via legal, administrative or other means would then be a matter for the Steering Committee and the Administration to decide, possibly after wider public consultation.

6.3 On the other hand, procedures that created the widest split in opinions were those involving the use of medical devices which emitted different forms of energy. Indeed, the regulation of medical devices involved complex issues as devices were heterogeneous by nature. The Working Group noted that the Administration was separately planning on introducing a new piece of legislation to regulate medical devices. It was thus considered appropriate that the regulation of the use of specific

medical devices be dealt with under the future medical device ordinance. This would include items 12 to 26; and item 31 of Annex III.

6.4 Likewise, as microneedle therapy (item 9 of Annex III) involved the application of an apparatus which might also be regarded as a medical device, Members supported the notion that the control over its use be further deliberated under the future medical device ordinance.

7 RECOMMENDATIONS

7.1 The following recommendations are put forward for consideration of the Steering Committee -

(a) Invasive cosmetic procedures in general may cause complications including infection, bleeding, haematoma formation, bruising, and scarring. While there is no doubt that surgical operation is a form of "medical" procedure, there is a need to clearly define cosmetic procedures involving injections as a "medical" procedure to be performed only by registered medical practitioners.

Recommendation (1): Cosmetic procedures that involve injections should be performed by registered medical practitioners.

(b) Procedures that involve the mechanical/ chemical exfoliation of the skin aim to achieve skin rejuvenation through the removal of old, dead skin cells. The complications associated with these procedures may include hyperpigmentation, infection and scarring, especially if performed on the

deeper layers of the skin.

Recommendation (2): Procedures that involve the mechanical/ chemical exfoliation of the skin below the epidermis should be performed by registered medical practitioners.

(c) Although tattooing and body piercing are procedures which involve skin puncture with injection of pigment or insertion of objects into the skin, they are traditionally deemed as non-medical procedures and their associated risks were already well known to the general public. However, the risks are relatively higher when performed in close proximity to organs or body parts which are prone to severe complications, such as the eyes and tongue.

Recommendation (3): Traditional body tattooing and piercing should be exempted from being considered as a "medical procedure", but special care should be taken for those performed on body parts which are of higher risk of complications (e.g. near the eyes, tongue etc.). All practitioners should be well-trained and adopt infection control measures when performing the procedures. Practitioners should ensure that consumers are made aware of the inherent risks involved and allowed to make informed decisions before undergoing the procedure.

(d) Hyperbaric oxygen therapy has been utilized for the treatment of medical conditions such as decompression sickness or acute carbon monoxide poisoning. The procedure is known to be associated with serious complications including barotrauma and oxygen toxicity.

Recommendation (4): Hyperbaric oxygen therapy should not be performed as a form of beauty procedure. In view of its risks of complications, it should be performed by registered medical practitioners on patients with clinical indications.

(e) Dental bleaching is a procedure involving the use of bleaching agents to achieve teeth whitening. Tooth bleaching materials which are based primarily on hydrogen peroxide may cause irritation of mucous membranes and the gastric tract if the product is swallowed accidentally. Tooth dentine hypersensitivity, pulpal pain caused by bleaching on undetected caries and defective dental fillings are also common complications of tooth bleaching procedures carried out by non-dental professionals.

Recommendation (5): Dental bleaching may lead to complications, especially if performed inappropriately or performed on inappropriate clients, such as those suffering from pre-existing dental conditions. The procedure should be performed by registered dentists.

(f) Given the heterogeneity of the energy-emitting devices, some of which may be used in beauty procedures, the control over their use may be best dealt with separately under the medical device ordinance. It is noted that the proposal on restricting the use of Class 3B and 4 lasers to registered healthcare professionals only has been discussed at the Legislative Council Panel on Health Services as early as 2004 and that the Administration has plans to report back to the Panel on the outcomes of its Business Impact Assessment

study together with the details of the legislative proposal in 2013.

Recommendation (6): The Working Group supports the Administration's plan to introduce a new medical device ordinance to deal with the issue of control over the use of selected high-risk medical devices.

(g) With continuous advancement in science and innovative technology, the Working Group believed that there should be a mechanism for dealing with new procedures and devices that may arise in the future. As most of the new cosmetic procedures which may pose safety risks are likely to involve the application of devices, consideration may be given to form an expert panel under the future medical device regulatory framework to deal with the new devices.

Recommendation (7): The Working Group recommends the setting up of an expert panel under the future medical device ordinance to advise on the risk and appropriate controls over new cosmetic procedures based on innovative technology.

Chairperson,
Working Group on Differentiation between
Medical Procedures and Beauty Services

8 ANNEX I - Composition of the Working Group

Chairperson –

Dr Constance CHAN Hon-yee, Director of Health

Members –

Steering Committee members
Ms Connie LAU Yin-hing
Dr Sigmund LEUNG Sai-man
Dr Susie LUM Shun-sui
Dr TSE Hung-hing
Ms Sandy WONG Hang-yee
Dr YEUNG Chiu-fat
Head of Healthcare Planning and Development Office, Food and Health Bureau/Representative

Co-opted members
Professor Henry CHAN Hin-lee
Ms Rinbo CHAN
Dr HO Chiu-ming
Dr HO King-man
Dr Michael HO Ming-tai
Ms Amy HUI
Mr Nelson IP Sai-hung
Dr Walter KING Wing-keung
Ms Cecilia KUK
Ms Maggie LEUNG
Dr NG Yin-kwok
Ms Quby TANG Mei-yee
Ms Sandra TSOI Lai-ha
Dr David WONG Sau-yan
Dr Hunter YUEN Kwok-lai

9 ANNEX II – A summary on the regulation of beauty services in jurisdictions outside Hong Kong

The following is a summary prepared based on WG1 Paper No. 02/2012, Paper No. 01/2013 and Paper No. 02/2013.

China

1. In Mainland China, hairdressing and cosmetic services are regulated under "商務部令 2004 年第 19 號《美容美髮業管理暫行辦法》"while medical cosmetic services are regulated under "中華人民共和國衛生部令（第 19 號）醫療美容服務管理辦法". According to the latter, "medical cosmetic procedures" refer to procedures that use surgical operations, medicines, medical devices and other traumatic or invasive medical technologies to restore or remodel human facial appearance or bodily features.
2. Premises that offer "medical cosmetic services" must be licensed with the health department according to the 《醫療機構管理條例》 before starting their business. The person delivering these procedures must be a registered medical practitioner under the 《執業醫師法》and must also satisfy a specified set of criteria including working experience in the relevant field. Furthermore, nursing staff involved in providing medical cosmetic care services should be qualified nurses registered by the health department according to the《護士管理辦法》. They should have undergone training in medical cosmetics and possess relevant working experience. Violations of the 《醫療機構管理條例》,《執業醫師法》 and 《護士管理辦法》may lead to penalties.
3. In Taiwan, beauticians can obtain a Technician Certificate issued by the Council of Labour Affairs through examination according to the "Skills Certification Standards" for beauty technicians. The published document on these Standards explicitly stated that procedures which are deemed to be "medical practice" that should be performed by healthcare personnel are outside the scope of the Standards. Examples of such procedures include blepharoplasty, rhytidectomy, microneedle therapy, skin resurfacing, breast augmentation, nose augmentation or selling of drugs etc. On the other hand, the Department of Health has developed the 《瘦身美容業管理規範》 which states that beauty salons should employ practitioners who are certified beauty technicians.

The United States of America (USA)

1. In USA, there is no federal regulation on beauty services but each State may have their own State law on the regulation of beauty services. In some States, such as California, New Jersey and Maryland, the relevant State law is administered by the respective professional board. In these States, both beauty practitioners and the establishments are required to be licensed with the State Board. Moreover, a person is required to attend a licensed school and complete a minimum required training hours and take the Board examination in order to obtain a

licence from the relevant State Board. In addition, the Board also prohibits licensed practitioner to perform certain procedures as summarized in the following paragraphs.

2. The relevant legislation that governs medical practice in these States is administered by the State Medical Board. Under specified conditions, the Medical Board allows a physician to delegate certain medical procedures to other trained personnel.

The State of New Jersey

3. For the regulation of beauty services, the New Jersey State Board of Cosmetology and Hairstyling requires that a licensed practitioner shall not –
    - perform or offer to perform massaging, cleansing or stimulating of the skin, with or without cosmetic preparations, by hand, mechanical or electrical appliance, below the stratum corneum, thereby affecting the living cells of the epidermis
    - perform or offer to perform any service that claims to cure or remedy any disease or illness
    - perform or offer to perform any service that has been determined by the New Jersey State Board of Medical Examiners to be a medical service. Such services shall include laser hair removal and injections of Botox, Restylane or other similar medications for purpose of skin enhancement or collagen production
    - utilize any medical device to perform services within the definition of cosmetology and hairstyling, manicuring or skin care specialty, other than Class I medical devices approved by United States Food and Drug Administration
4. A practitioner who engages in the above practices shall be deemed to be engaged in unlawful practice and may be subject to penalty. Besides, a holder of a shop licence at which such unlawful practices occur shall also be deemed to have engaged in unlawful practice and may be subject to penalty if he or she aids, abets, or permits a practitioner to engage in any prohibited practices.
5. Concerning the regulation of medical practice, the New Jersey State Board of Medical Examiners states that a physician may direct a certified medical assistant employed in the medical practice in which the physician practices medicine, to administer to the physician's patients an intradermal, intramuscular or subcutaneous injection where certain conditions such as proper qualification of the medical assistant are satisfied.

The State of California

6. Regarding regulation of beauty services, the California Board of Barbering and Cosmetology requires that no licensee may perform any act which affects the structure or function of living tissue of the face or body. Any such act shall be considered an invasive procedure. The Board also defines invasive procedures to include, but are not limited to the following:
    - Application of electricity which contracts the muscle
    - Application of topical lotions, creams, or other substances which affect

living tissue
- Penetration of the skin by metal needles, except electrolysis needles
- Abrasion of the skin below the non-living, epidermal layers
- Removal of skin by means of a razor-edged instrument

7. For skin peeling, the Board requires that only the non-living, uppermost layers of facial skin, known as the epidermis, may, by any method or means, be removed, and then only for the purpose of beautification. Skin removal techniques and practices which affect the living layers of facial skin, known as the dermis, are prohibited and constitute the practice of medicine.
8. Any licensee who violated the regulation is subject to an administrative fine and may be subject to a misdemeanor. In addition, it is also specifically mentioned that any licensee who uses a laser in the treatment of any human being is guilty of a misdemeanor.
9. On the front of physicians' regulation, the Medical Board of California states that physician assistants and registered nurses may perform laser or intense pulsed light treatments under a physician's supervision. Concerning Botox injection, a physician may direct registered nurses or physician assistants to perform the injection under their supervision. Besides, the Board also states that microdermabrasion for cosmetic treatment which only affects the outermost layer of the skin or the stratum corneum may be performed by a licensed cosmetician or esthetician. If the treatment penetrates to deeper levels of the epidermis, it must be performed by a physician, or by a registered nurse or physician assistant under supervision. Treatments to remove scars, blemishes, or wrinkles would be considered medical treatments.

<u>The State of Maryland</u>

10. In terms of the regulation of beauty services, the Maryland Board of Cosmetologists prohibits the following activities to be performed in beauty salons:
    - The removal of corns, calluses, or other growths of the skin, such as warts, by cutting
    - The use of electrical muscle stimulator devices purported to produce nonsurgical face or body lifts
    - Cosmetic tattooing
    - The use or possession of a Credo blade or a similar razor-type implement used to cut growths on the skin
    - The use of lasers, microdermabrasion equipment, or any other mechanical device used to remove one or more layers of skin unless an individual possesses a valid and appropriate health occupation licence issued by the Department of Health and Mental Hygiene e.g. nurse or physician assistant
    - The use of any product or method that causes tissue destruction or penetrates the blood fluid barrier, including chemical peels; and glycolic acids unless an individual possesses a valid and appropriate health occupation licence issued by the Department of Health and Mental Hygiene e.g. nurse or physician assistant

11. A licensee who is found to perform unauthorized or prohibited services is

subject to a fine or may be subject to formal hearing.

12. As per the regulation of physicians, the Maryland Board of Physicians states that an individual using a "cosmetic medical device" or performing a "cosmetic medical procedure" who is not a licensed physician and is not authorized to perform the cosmetic medical procedure, or under regulations promulgated by another licensing board is guilty of the practice of medicine without a license and may be subject to a fine.
13. The Board has provided a definition of "cosmetic medical device" and "cosmetic medical procedure" in its regulation which are listed below:
    - Cosmetic medical device means a device that alters or damages living tissue. It includes any of the following items, when the item is used for cosmetic purposes -
        - Laser
        - Device emitting light or intense pulsed light
        - Device emitting radiofrequency, electric pulses, or sound waves
        - Microdermabrasion device
        - Devices used for the injection or insertion of foreign or natural substances into the skin, fat, facial tissue, muscle, or bone
    - Cosmetic medical procedure means a procedure using a cosmetic medical device or medical product to improve an individual's appearance. It includes the following:
        - Skin treatments using lasers
        - Skin treatments using intense pulsed light
        - Skin treatments using radio frequencies, microwave or electric pulse
        - Deep skin peels
        - Skin treatments with phototherapy
        - Microdermabrasion
        - Subcutaneous, intradermal or intramuscular injections of medical products
        - Treatments intended to remove or cause destruction of fat and any treatment using a cosmetic medical device for the purpose of improving an individual's appearance
14. Moreover, the Board also states that cosmetic medical procedures may be delegated to a physician assistant or assigned to any other health care provider whose licensing board has determined that the procedure falls within the provider's scope of service.
15. Regarding tooth whitening, the Maryland State Board of Dental Examiners considers it as a dental procedure.

Singapore

1. In Singapore, there is no specific regulation for the beauty industry. The Singapore Medical Council (SMC) has issued guidelines on the practice of aesthetic procedures for medical practitioners in Singapore. However, the guidelines are only intended for medical practitioners.
2. The SMC administratively classified aesthetic treatment and procedures into List A and List B based on currently available scientific evidence. List A procedures are supported by moderate to high level of evidence and/or with local medical

expert consensus that the procedures are well-established and acceptable. They are further categorized by their invasiveness into non-invasive, minimally invasive, and invasive procedures.

3. List B procedures have low or very low level of evidence support and/or with local medical expert consensus that the procedure is neither well-established nor acceptable. Examples of these procedures include mesotherapy, skin whitening injection or stem cell activator protein for skin rejuvenation etc.
4. According to the Ministry of Health, List A "minimally-invasive" and "invasive" as well as List B invasive procedures are required to be performed by registered medical practitioners. Any person who is not a registered medical practitioner and engages in the practice of these procedures may be liable for an offence under the Medical Registration Act.
5. Some examples of invasive and non-invasive procedures are given below:
    - Invasive: use of laser for the treatment of vascular lesions, skin pigmentation and skin rejuvenation/ resurfacing; and microneedle therapy
    - Non-invasive: IPL treatment, radiofrequency/ infrared light/ ultrasound for skin tightening, extracorporeal shock wave/ ultrasound for lipolysis
6. In addition, an operator of high power medical laser (Class 3B and 4) shall hold a licence under the Radiation Protection Act 2007. The operator shall be at least 18 years old and shall have been adequately trained and have special knowledge on the safe use of lasers. A licence to use Class 4 medical lasers may be granted only to registered medical practitioners and registered dentists.
7. The Ministry of Health also states that non-dental professionals could perform tooth whitening if the tooth whitening products contain less than or equal to 0.1% hydrogen peroxide.

The United Kingdom (UK)

1. In UK, there is no overarching regulation for beauty services. Currently, depending on the nature of the cosmetic procedure, some are regulated by relevant regulations. For cosmetic surgery such as breast augmentation, it can only be conducted by a doctor. In addition, all independent clinics and hospitals in the UK that provide cosmetic surgery must be licensed with the Care Quality Commission.
2. As a prescription-only medicine, botulinum toxin A injection needs to be prescribed by a healthcare professional who is registered as an independent prescriber. The injection can be administered by a physician; or by anyone acting in accordance with the directions of an appropriate practitioner. An appropriate practitioner can be a doctor, a dentist, or subject to certain limitations, a nurse or pharmacist independent prescriber or supplementary prescriber. If the individual administering the product is a doctor, nurse, dentist or pharmacist, then they need to follow their appropriate professional standards.
3. Dermal filler injection, chemical peel and hair removal treatment using laser or intense pulsed light, can be administered by non-healthcare professionals. However, for deep peels, the UK Department of Health recommends that the procedure should be administered by a surgeon or dermatologist with relevant skills and experience in an establishment registered with the Care Quality Commission.
4. Certain local authorities, including most London authorities, also regulate the

nonsurgical uses of class 3B and 4 laser and intense pulsed light, which require the provider to apply for a Special Treatment Licence issued by the borough council. Providers must comply with a code of conduct, covering access to expert advice, staffing, maintaining a register, safety, qualifications and maintenance of equipment. For example, the licence holder shall employ the services of an expert medical practitioner to produce a treatment protocol in relation to the licence holder's equipment or premises and to provide ongoing support and advice. The borough council may revoke a licence held by a person for any of the grounds as mentioned in the legislation e.g. The borough council is not satisfied as to the safety of the special treatment to be given.

5. Concerning tooth whitening, the General Dental Council, United Kingdom considers it as practice of dentistry.

Review of the regulation of cosmetic interventions

6. In response to the adverse incidents related to breast implants in late 2011, the UK Department of Health has launched a review on the regulation of cosmetic procedures. The final report with 40 recommendations was published in April 2013.
7. The report highlighted three key areas in which changes were needed: **high quality care** with safe products, skilled practitioners and responsible providers; an **informed and empowered public** to ensure people get accurate advice and that the vulnerable are protected; and, **accessible redress and resolution** in case things go wrong. Of particular note was that the Review Committee considered that people choosing to undergo cosmetic interventions are **both patients and consumers**. This is because they are making purchasing decisions on procedures and products that may have a significant impact on their health and wellbeing.
8. Noting the lack of standards for non-surgical cosmetic procedures and the failure of the sector to self-regulate, the Review Committee called for the strengthening of training and regulation of non-surgical practitioners.
9. According to the Health Minister Dr Dan Poulter, the Government will consider the report carefully and respond in detail in the summer.

Australia

1. In Australia, there is also no specific regulation on beauty services. However, individuals who use Class 3B or 4 laser systems and/or premises providing these laser services require licensing or registration according to individual state laws on radiation safety.
2. For example, in Western Australia, individuals who operate Class 3B or 4 laser must possess a licence under the Radiation Safety Act 1975 or be acting under supervision of a licensee. The applicants for the licence must attend a laser safety course approved by the Radiation Council of the Western Australia and pass an examination conducted by the Council and achieve a minimum of 65%. Registered medical or dental practitioners are not required to take the examination.
3. In addition, the owner of any premises that possesses Class 3B or 4 laser services requires registration by the Radiological Council of Western Australia. A laser

safety officer must be appointed by the registrant who oversees and is responsible for the safe use of the laser. The registrant shall ensure that the safety requirements stipulated in the Radiation Safety (General) Regulation 1983 are complied. If a person contravenes or fails to comply with any condition, restriction or limitation imposed, the Council may revoke the licence or registration.

10 ANNEX III - List of 35 cosmetic procedures with potential safety concerns

Item	Procedure
Procedures involving skin puncture	
1.	Dermal filler injection
2.	Botulinum toxin A injection
3.	Autologous platelet-rich plasma
4.	Autologous cellular therapy
5.	Cryo-crystalised Growth Factor
6.	Skin whitening injection
7.	Injection lipolysis
8.	Mesotherapy
9.	Microneedle therapy
10.	Tattooing
11.	Body piercing
Procedures involving external application of energy	
12.	Laser (Class 3B and 4)
13.	Radiofrequency
14.	Intense pulsed light
15.	Extracorporeal shock wave
16.	Ultrasound for lipolysis (high intensity focused ultrasound and nonthermal ultrasound)
17.	Cryolipolysis
18.	High voltage pulsed current
19.	Plasma
20.	Lighting emitting diode phototherapy
21.	Infrared light
22.	Micro-current therapy
23.	Cryoelectrophoresis
24.	Electroporation/ Iontophoresis
25.	Pulsed magnetic field therapy
26.	Microwave application
Procedures involving mechanical/ chemical exfoliation of the skin	
27.	Microdermabrasion
28.	Chemical peel
29.	JETPEEL
30.	Water microjet plus vacuum
Other procedures that may pose safety concerns	
31.	Colon hydrotherapy
32.	Hyperbaric oxygen therapy
33.	Jet injector
34.	Dental bleaching
35.	Suction massage

11 References

The Working Group papers were prepared by making reference to the following documents and published literature –

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2. 中華人民共和國商務部令 2004 年第 19 號《美容美髮業管理暫行辦法》
3. 中華人民共和國主席令第 5 號《執業醫師法》
4. 中華人民共和國衛生部令第 31 號《護士管理辦法》
5. 中華人民共和國國務院令第 149 號《醫療機構管理條例》
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