

Research Report

Regulation of aesthetic practices in selected places



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Acronyms and abbreviations

ASAPS	American Society for Aesthetic Plastic Surgery
Botox	botulinum toxin
CASE	Consumers Association of Singapore
CEN	European Committee for Standardization
CQC	Care Quality Commission
CSIC	Cosmetic Surgery Inter-specialty Committee
DH	Department of Health of Hong Kong
DH-UK	Department of Health of the United Kingdom
EU	European Union
FBOM	Florida Board of Medicine
FDBPR	Florida Department of Business and Professional Regulation
FDOH	Florida Department of Health
GMC	General Medical Council
Guidelines on AP	<i>Guidelines on Aesthetic Practices for Doctors</i>
HEE	Health Education England

Acronyms and abbreviations (cont'd)

IPL	intense pulsed light
ISAPS	International Society of Aesthetic Plastic Surgery
NHS	National Health Services
RCS	Royal College of Surgeons of England
the Panel	the Panel on Health Services
the Review Report	Report on the Review of the Regulation of Cosmetic Interventions
the Steering Committee	Steering Committee on Review of the Regulation of Private Healthcare Facilities
the UK	the United Kingdom
the US	the United States
the Working Group	the Working Group on Differentiation between Medical Procedures and Beauty Services

Executive summary

1. In recent years, aesthetic practices have grown in prevalence in Hong Kong, as well as in many places around the world. The recent adverse incidents relating to aesthetic procedures provided by beauty service providers in Hong Kong have prompted public calls for tightening the regulatory framework for aesthetic practices. This research study examines the regulatory framework of aesthetic practices in Hong Kong, Florida of the United States ("US"), South Korea, Singapore and the United Kingdom ("UK") in terms of classification of aesthetic procedures, competency requirements for performing aesthetic procedures, regulation of the beauty sector in performing aesthetic procedures, regulation of cosmetic-related medical devices and ambulatory facilities, and protection of persons undergoing aesthetic procedures.
2. All the places studied have defined the types of aesthetic procedures to be performed by medical practitioners only. The inherent risk level and/or invasiveness level are the common criteria adopted in these places for classifying aesthetic procedures. Singapore has taken a step further by requiring that procedures which are supported by low or very low level of scientific evidence should be performed on justifiable grounds only. In the European Standard for Aesthetic Surgery Services, which is a set of voluntary pan-European service standards for surgical aesthetic practices, factors taken into consideration when classifying aesthetic procedures include the required anaesthesia level and facilities in which aesthetic procedures are performed.
3. In order to safeguard the safety of persons undergoing aesthetic procedures, Singapore has specified in the *Guidelines on Aesthetic Practices for Doctors* ("Guidelines on AP") the level of required competency and qualifications of medical practitioners for performing aesthetic procedures. There is also a requirement in Florida that surgical procedures, including aesthetic procedures, must be performed by medical practitioners who have the appropriate training and skills. In response to the recommendations of the review report on the regulatory framework for aesthetic practices, the UK government is developing accredited training standards for practitioners performing surgical and non-surgical aesthetic procedures. Hong Kong and South Korea have not set the related competency requirements for medical practitioners to perform aesthetic procedures.

4. The beauty sector in all the places studied, with the exception of South Korea, may perform some aesthetic procedures which are not defined as medical practices. The regulatory regime for the beauty sector in South Korea precludes it from engaging in aesthetic practices. Florida has also established a dedicated regulatory regime for the beauty sector. Under the regime, cosmetologists are required to meet the training requirements set by the licensing authority and pass the licensing examination prior to practising. In Hong Kong, Singapore and the UK, no mandated qualifications are set for beauticians in general. Yet, beauticians in Singapore and some local areas in the UK are required to have relevant training before they can operate laser or intense pulsed light ("IPL") devices for aesthetic procedures. The UK government is also developing appropriate accredited qualifications for non-surgical aesthetic procedures, as well as examining the need to require the performance of aesthetic procedures by non-healthcare practitioners be supervised by qualified clinical professionals.
5. The use of cosmetic-related medical devices such as high-power lasers and/or IPL devices are subject to registration/licensing requirements in Singapore, Florida and the UK. In these places, there is a requirement for operators of these devices to be medical practitioners or those who possess accredited knowledge and skills. For example, in Singapore, only those persons who have obtained the required training or qualification can apply for a licence to operate Class 3b lasers while only registered medical practitioners and dentists may be granted a licence to operate Class 4 lasers. The Hong Kong Government is planning to introduce a regulatory framework for medical devices and is considering imposing control on the use of cosmetic-related medical devices such as restricting the use of some devices to registered healthcare professionals.
6. All the overseas places studied have imposed mandatory safety standards for ambulatory facilities in which aesthetic procedures are performed. Specifically, for liposuction procedure, Singapore and Florida have set stringent requirements in terms of staffing support and adequacy of equipment and supplies. Some recent adverse incidents in South Korea have prompted public calls for enhancing the safety standards of ambulatory facilities, particularly standards on anaesthesia work and medical equipment for dealing with

emergencies. In the UK, the regulator of healthcare service providers is currently reviewing the inspection scheme and assessment criteria for facilities in which surgical aesthetic procedures are performed. Meanwhile, Hong Kong is planning to revamp the regulatory regime for private healthcare facilities, covering ambulatory facilities in which high-risk aesthetic procedures may be performed.

7. With regard to the protection of persons undergoing aesthetic procedures, some of the overseas places studied have introduced or planned to introduce specific mechanisms or measures to enhance protection of the public. For example, South Korea has recently introduced regulation to restrict aesthetic-related advertisements on public transportation and in areas close to schools. In Singapore, medical practitioners providing liposuction procedures or procedures supported by low evidence are required to obtain informed consent from the clients before performing the procedures. Similarly, the UK is considering tightening control on irresponsible advertising and promotion practices, and the need to introduce a requirement for medical practitioners engaging in surgical aesthetic practices to obtain informed consent from their clients.
8. Singapore is the only place studied in this research that has introduced a mandatory seven-day cooling-off period for persons undergoing liposuction procedures. Some beauty service providers which are accredited under a voluntary accreditation programme are also required to offer a cooling-off period of at least five working days for the service package offered to their clients. A distinctive feature of the redress system in South Korea is the mediation mechanism put in place by the nation for resolving medical disputes, including those relating to aesthetic practices.

Regulation of aesthetic practices in selected places

Chapter 1 – Introduction

1.1 Background

1.1.1 In early October 2012, there were four reported cases of women suffering from septic shock after receiving intravascular infusions at a beauty treatment centre. One woman subsequently died of multiple organ failure while the other three were seriously ill. In June 2014, another woman died after undergoing liposuction procedure in a hair transplant centre. These incidents have aroused public concerns over issues such as differentiation between medical procedures and beauty services, regulation of cosmetic-related medical devices, regulation of ambulatory facilities in which high-risk medical aesthetic procedures are performed, regulation of the beauty sector in performing aesthetic procedures and measures to enhance the safety of persons undergoing aesthetic procedures.

1.1.2 The Panel on Health Services ("the Panel") is deeply concerned about the regulation of medical beauty treatments/procedures. The Panel requested the Research Office of the Information Services Division at its meeting on 28 April 2014 to conduct a research on the regulation of aesthetic practices in overseas places. A research outline was presented to the Panel at its meeting on 16 June 2014, proposing to study the regulation of aesthetic practices in Florida of the US, Singapore and the UK. Taking note of some members' suggestions to include South Korea and Sweden in the study in view of the prevalence of aesthetic practices in these two places, the Research Office undertook to conduct a preliminary study on their regulatory framework for aesthetic practices.

1.2 Scope of research

1.2.1 The Research Office has conducted a preliminary study on the regulation of aesthetic practices in a number of overseas places¹ and observed that different regulatory approaches have been adopted by these places to regulate aesthetic practices. Some places may confine the practices of aesthetic procedures to medical practitioners while other places may allow the beauty sector to perform some non-surgical or non-invasive procedures. This research report studies Florida of the US, South Korea, Singapore and the UK to capture the different regulatory approaches that they have adopted for regulating the medical and beauty sectors in performing aesthetic procedures and compares their approaches with that of Hong Kong.

1.2.2 According to a survey among board-certified plastic surgeons around the world conducted by the International Society of Aesthetic Plastic Surgery ("ISAPS"²) in 2013, more than 23 million surgical and non-surgical aesthetic procedures were performed by board-certified plastic surgeons worldwide in 2013 and the US performed the most surgical and non-surgical aesthetic procedures in the year.³ Each state in the US has its own regulatory framework for governing the medical and beauty sectors in performing aesthetic procedures. Florida is one of the many states in the US which has imposed stringent regulation on the performance of aesthetic procedures. Under its regulatory framework, most aesthetic procedures are required to be performed by medical practitioners or by healthcare practitioners such as physician assistants under the supervision of medical practitioners.

1.2.3 In South Korea, aesthetic procedures involving skin puncture, including tattooing and ear piercing, are considered as medical practices which should be performed by licensed medical practitioners. Under the current medical system governed by the *Medical Service Act*, licensed medical practitioners can perform any medical practice including aesthetic procedures. On the other hand, beauty treatment centres can only provide skin care services set out in the *Public Health Control Act* and they cannot use any medical devices or medicines.

¹ These places include Singapore, Taiwan, the US, the UK, Australia and Canada.

² ISAPS is a professional body for board-certified aesthetic plastic surgeons aiming at providing a forum for the interchange of ideas and knowledge for the advancement of aesthetic plastic surgery. Its membership comprises over 2 400 aesthetic plastic surgeons in 94 countries.

³ International Society of Aesthetic Plastic Surgery (2014).

1.2.4 In Singapore, all invasive and minimally invasive aesthetic procedures such as injections of botulinum toxin ("Botox") and lasers for skin rejuvenation must be performed by medical practitioners who are regulated under the self-regulatory framework of the medical profession. The beauty sector may provide certain non-invasive aesthetic procedures such as laser hair removal and is subject to regulation of the *Penal Code* and other relevant legislation.

1.2.5 Compared to the other places studied, the UK has adopted a less stringent regulatory approach under which the beauty sector is allowed to perform a wider range of non-surgical aesthetic procedures. While surgical aesthetic procedures must be performed in regulated clinical settings by qualified medical practitioners, non-surgical procedures, such as Botox and dermal filler injections and laser treatments, can be performed by both medical and non-medical practitioners in clinics or beauty treatment centres. Recognizing the need to provide for a uniform standard to regulate the provision of aesthetic procedures by the medical and non-medical practitioners, the UK government has recently completed a review on its regulatory framework for aesthetic practices and embarked on improving its framework to better protect the safety and interests of the public.

1.2.6 Similar to the UK, surgical aesthetic procedures in Sweden are mainly performed by medical practitioners while non-surgical procedures can be performed by both medical and non-medical practitioners. A review report released by the National Board of Health and Welfare⁴ in June 2012 indicated that the existing regulatory framework did not provide adequate protection for persons undergoing aesthetic procedures. Following the release of the report, the Swedish government commissioned a consultancy study to determine legislative amendments and other measures in order to enhance the protection of persons undergoing aesthetic procedures. The consultancy study is expected to be completed in 2015.

1.2.7 As the regulatory framework of Sweden is similar to that of the UK and is currently under review, the Research Office will provide in [Appendix I](#) an overview of the Swedish regulatory framework and the recent developments of its regulatory reform for members' reference.

⁴ The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs responsible for duties such as collecting and analyzing information related to health and social care and developing standards and guidelines related to health and medical services.

1.3 Research method

1.3.1 This study adopts a desk research method, which involves literature review, documentation analysis, Internet research and correspondence with relevant authorities, associations and professionals.

Chapter 2 – Hong Kong

2.1 Overview

2.1.1 Aesthetic practices, which are treatments or procedures aiming at changing the appearance or structure of bodily features⁵, have increased in prevalence in Hong Kong in recent years. While surgical and invasive aesthetic procedures are mainly provided by the medical sector, procedures involving the use of medical devices such as laser and IPL devices are provided by both the medical and beauty sectors. The Government does not have a specific regime for regulating the provision of aesthetic procedures. Instead, various service aspects of these procedures such as services of beauty service providers and/or healthcare professionals, premises, drugs, and advertising and sales practices are regulated under different pieces of legislation enforced by different government departments such as the Department of Health ("DH") and the Customs and Excise Department. Nonetheless, the provision of medical aesthetic procedures by some beauty service providers under the cover of "medical beauty services" in recent years has aroused public concerns about the health risks of these procedures.

2.1.2 In October 2012, one woman died and three women became seriously ill after receiving intravascular infusions at a beauty treatment centre. The incident prompted the Government to set up the Working Group on Differentiation between Medical Procedures and Beauty Services ("the Working Group") under the Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee"⁶) in November 2012 to differentiate medical procedures from ordinary beauty services, and make recommendations on procedures that should be performed by registered medical practitioners. The report submitted by the Working Group was endorsed by the Steering Committee in November 2013. The Government has also implemented the recommendations put forward by the Working Group accordingly.

⁵ At present, there is no internationally accepted definition of aesthetic practice. According to the UK Cosmetic Surgery Interspecialty Committee, aesthetic practice is defined as an area of practice involving "operations and other procedures that revise or change the appearance, colour, texture, structure, or position of bodily features, which most would consider otherwise to be within the broad range of 'normal' for that person". This definition is adopted in places such as the UK and Singapore when they consider the regulatory framework for aesthetic practices.

⁶ The Steering Committee was set up in October 2012 by the Food and Health Bureau to review the regulatory regime for private healthcare facilities in Hong Kong. The review aims at strengthening the regulatory control over private health facilities so as to safeguard people's health and consumer rights.

2.2 Classification of and competency requirements for performing aesthetic procedures

2.2.1 According to the recommendations of the Working Group, certain types of aesthetic procedures can be performed only by registered medical practitioners or registered dentists in view of the inherent risks involved in the procedures.⁷ These procedures are: (a) procedures that involve injection of substances into the human body such as injection of Botox or dermal fillers; (b) procedures that involve mechanical/chemical exfoliation of the skin below the epidermis; (c) hyperbaric oxygen therapy; and (d) dental bleaching. However, body tattooing and piercing, which are traditionally deemed non-medical procedures and their associated risks have been well-known by the public, can be performed by non-medical practitioners.

2.2.2 For the classification of aesthetic procedures involving the use of medical devices, particularly energy-emitting devices, the Working Group recommended that they should be deliberated within the regulatory framework for medical devices currently under review by the Government. As such, these procedures can be performed by both the medical and beauty sectors at present. The list of aesthetic procedures considered and the categorization of procedures by the Working Group are given in **Appendix II**.

2.2.3 Medical practitioners or dentists performing aesthetic procedures are required to comply with the code of professional conduct issued by their respective councils⁸, including providing formal medical consultation and keeping proper medical records. Medical practitioners or dentists who commit professional misconduct are subject to disciplinary action imposed by the respective councils. At present, there is no specific requirement on the competency or experience of the medical practitioners in performing specific aesthetic procedures.

⁷ The Working Group had considered 35 aesthetic procedures with potential safety concerns and recommended that 15 of them should be performed by registered medical practitioners or registered dentists because of the risks involved.

⁸ Registered medical practitioners have to comply with the *Code of Professional Conduct for the Guidance of Registered Medical Practitioners* issued by the Medical Council of Hong Kong while registered dentists have to comply with the *Code of Professional Discipline for the Guidance of Dental Practitioners* in Hong Kong issued by the Dental Council of Hong Kong.

2.2.4 On the other hand, the Government has advised practitioners in the beauty sector to refrain from performing aesthetic procedures that are classified as medical procedures if they are not themselves registered medical practitioners or registered dentists. Failure to follow the advice may render oneself liable for offences under the *Medical Registration Ordinance* (Cap. 161) or the *Dentists Registration Ordinance* (Cap. 156).⁹ Beauty service providers are also advised to ensure that they have received appropriate training before performing any procedure that involves skin puncture and they should strictly observe infection control practices.

Concerns of stakeholders

2.2.5 Notwithstanding that the Government has implemented the recommendations of the Working Group under which some specific aesthetic procedures are classified as medical procedures and should be performed by registered medical professionals only, stakeholders across sectors are of the view that the Government should expedite the process of introducing regulatory control on aesthetic procedures involving the use of high-risk medical devices and defining clearly the types of personnel and level of training and competence required for performing these procedures to safeguard the safety of users. Some members of the medical sector are also concerned about the health risks of persons undertaking high-risk surgical aesthetic procedures as there is a lack of control on the specialty or experience of medical professionals performing these procedures.

2.3 Regulation of the beauty sector in performing aesthetic procedures

2.3.1 As at March 2014, there were 9 935 establishments and 39 151 people engaged in the beauty sector. While the beauty sector has been performing aesthetic procedures involving the use of cosmetic-related medical devices, e.g. laser or IPL treatments, and other procedures not classified as medical practices, there are concerns about the lack of specific regulation governing the business operation of the service providers, and the training and competency of beauticians performing aesthetic procedures.

⁹ The *Medical Registration Ordinance* stipulates that any person who practises or publishes his or her name as practising medicine or surgery without registration commits an offence. The *Dentists Registration Ordinance* stipulates that any person, not being a registered dentist, practices dentistry within Hong Kong commits an offence.

2.3.2 Though the beauty sector has developed the Specification of Competency Standards under the Qualifications Framework¹⁰ which lays down the learning pathways and competency requirements for different levels of qualifications for practitioners, it is only a voluntary framework. With regard to certification of the competency level of practitioners operating cosmetic-related medical devices, trade test is only available for operators of IPL devices on a voluntary basis.

Concerns of stakeholders

2.3.3 The adverse incidents in October 2012 and June 2014 aroused the concern about the lack of control on the operation of beauty service providers which offer high-risk aesthetic procedures to the general public. To facilitate the healthy and sustainable development of the beauty sector and enhance public confidence in taking aesthetic procedures offered by the sector, representatives of the beauty sector and some Members of the Legislative Council have urged the Government to set up a steering committee to assist the sector in developing a dedicated regulatory framework. They also call for the establishment of a mandatory qualifications accreditation framework for practitioners under which their competencies for performing aesthetic procedures such as laser treatments are recognized.

2.4 Regulation of the use of cosmetic-related medical devices

2.4.1 In Hong Kong, there is no specific legislation to regulate the import, distribution, sale or use of medical devices¹¹ except for those devices which contain pharmaceutical products or emit ionising radiation.¹² Under the proposal to develop a regulatory framework for medical devices, the Government has proposed to restrict the use and operation of some

¹⁰ The Qualifications Framework is a seven-level hierarchy of qualifications covering the academic, vocational and continuing education sectors. The aims of the Framework are to clearly define the standards of different qualifications, ensure their quality and indicate the articulation ladders between different levels of qualifications.

¹¹ Medical device generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries.

¹² Devices containing pharmaceutical products are regulated under the *Pharmacy and Poisons Ordinance* (Cap. 138). Devices emitting ionising radiation or containing radioactive substances are regulated under the *Radiation Ordinance* (Cap. 303).

cosmetic-related medical devices, such as Class 3B and Class 4 high-power medical lasers¹³ to registered healthcare professionals in order to safeguard public health. As for IPL equipment, non-healthcare practitioners would be allowed to operate the equipment provided that they have undergone training and passed the IPL trade test run by authorized institutes, such as the Vocational Training Council.

2.4.2 Recently, the Government has planned to conduct a consultancy study to examine overseas experiences and practices in the use control of cosmetic-related medical devices before proceeding to the legislative process for establishing the regulatory framework for medical devices. The aim of the consultancy study is to assess the types of devices to be put under control and determine the competencies and qualifications required for operating such devices.

Concerns of stakeholders

2.4.3 Representatives of the beauty sector have expressed grave concern about the Government's proposal to restrict the use of some cosmetic-related medical devices, e.g. high-power laser devices, to registered healthcare professionals as the business generated by aesthetic procedures involving the use of these devices is a major source of their income. In their view, the proposed restriction on the use of those cosmetic-related medical devices would adversely affect the livelihood of practitioners in the beauty sector. Pointing out that many beauticians are currently operating these medical devices in a safe manner as they have received relevant training, the beauty sector urges the Government to allow well-trained and competent practitioners, be they healthcare practitioners or beauticians, to operate such cosmetic-related medical devices under a licensing system.

2.4.4 On the other hand, some representatives of the medical sector consider that the use and operation of high-power lasers and IPL devices should be confined to qualified medical practitioners and dentists, and other persons authorized by them to ensure the safety of patients. In their view, only medical professionals are sufficiently trained to make diagnosis and deliver appropriate treatment, including managing the risks and complications from these procedures.

¹³ According to the standard set by the International Electrotechnical Commission, laser products are grouped into four general classes namely Class 1 (further subdivided into 1 and 1M), Class 2 (further subdivided into 2 and 2M), Class 3 (further subdivided into 3R and 3B) and Class 4 based on wavelength and maximum output power.

2.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

2.5.1 In Hong Kong, the existing legislation governing private healthcare facilities mainly cover private hospitals and non-profit-making medical clinics. The Government is considering extending the regulatory regime to cover ambulatory facilities in which outpatient surgeries or high-risk medical services are performed, and premises processing health products for advanced therapies.

2.5.2 The Steering Committee has recently endorsed the recommendations of the three working groups established under it to study specific areas of regulatory control of private healthcare facilities.¹⁴ Recommendations that are relevant for regulating facilities in which high-risk aesthetic procedures are performed include: (a) regulating ambulatory facilities in which high-risk medical procedures¹⁵ are performed under a statutory registration system; and (b) requiring high-risk procedures to be performed only in regulated ambulatory facilities or hospitals by qualified health professionals. The Government has planned to proceed to legislative procedures to enhance the regulation of private healthcare facilities pending the outcome of a public consultation exercise to be conducted in the second half of 2014.

Concerns of stakeholders

2.5.3 Noting that the Government will only proceed to legislative procedures to revamp the regulatory regime for private healthcare facilities after it has completed the public consultation exercise which is scheduled to be conducted in the second half of 2014, some Members of the Legislative Council have urged the Government to introduce administrative measures during the interim period to protect safety of persons undergoing high-risk aesthetic procedures at ambulatory healthcare facilities such as increasing inspections of those facilities.

¹⁴ The three Working Groups are the Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting, the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies, and the Working Group on Regulation of Private Hospitals.

¹⁵ According to the recommendation of the Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting, any procedure defined as high-risk by any one of the three factors, i.e. risk of procedures, risk of anaesthesia involved and patient's conditions, will be regarded as high-risk medical procedures.

2.6 Protection of persons undergoing aesthetic procedures

2.6.1 According to the Government, interests of persons undergoing aesthetic procedures are protected under the *Trade Descriptions Ordinance* as amended by the *Trade Descriptions (Unfair Trade Practices) (Amendment) Ordinance 2012*, which prohibits false trade description in relation to services and certain unfair trade practices such as misleading omissions, aggressive commercial practices and wrongly accepting payment. Moreover, advertisements related to medical and health matters are regulated under the *Undesirable Medical Advertisements Ordinance* (Cap. 231) which aims to protect public health through prohibiting or restricting advertisements that may induce the seeking of improper management of certain health conditions. According to DH, 492 warning letters were issued between October 2012 and June 2014 to service providers who had breached the *Undesirable Medical Advertisement Ordinance* and there were four prosecution cases during the same period.

2.6.2 DH has also stepped up public education since the adverse incident in late 2012 to raise public awareness on the risks associated with aesthetic procedures and advise the public to get more information about the procedures before making the decisions. Between October 2012 and June 2014, DH had also screened over 16 000 advertisements of beauty services and referred cases of suspect violation of the *Medical Registration Ordinance* or the *Dentists Registration Ordinance* to the Police for follow-up action.

Concerns of stakeholders

2.6.3 According to the Consumer Council, there were 195 complaints about invasive aesthetic procedures and those involving the use of high-power light-based devices in 2013, up from 178 in 2012. Among the complaints received in 2013, 39% were about service quality, 18% were about safety issues and 16% were about sales practices of the service providers. To enhance protection of persons undergoing aesthetic procedures, some Members of the Legislative Council have suggested introducing a seven-day cooling-off period to cover transactions involving aesthetic procedures so that the persons concerned can have time to rethink about the benefits and risks involved. Some Members have also considered that a redress system should be put in place for persons who are dissatisfied with the services provided to seek refund or compensation.

2.6.4 Some representatives of the medical sector have expressed concern about inadequate enforcement action against misleading advertisements of aesthetic procedures by some beauty service providers. They observe that there are only a small number of successful prosecutions against beauty service providers under the *Undesirable Medical Advertisements Ordinance* despite the large volume of beauty service advertisements in the market.

Chapter 3 – Florida of the United States

3.1 Overview

3.1.1 In the US, aesthetic practices are governed under the regulatory framework developed by individual states. According to the American Society for Aesthetic Plastic Surgery ("ASAPS")¹⁶, it was estimated that over 11 million aesthetic procedures were performed by board-certified specialists in 2013, of which 16.5% were surgical procedures and 83.5% were non-surgical procedures. The total spending on aesthetic procedures was estimated to be over US\$12 billion (HK\$93.1 billion), of which 58% was spent on surgical procedures and 42% was spent on non-surgical procedures.¹⁷

3.1.2 Florida is selected for this study as it is one of the seven states in the South Atlantic region of the US where the highest number of aesthetic procedures (17.4% of the total) were performed in 2013. Similar to many other states in the US, Florida imposes stringent control on aesthetic practices by restricting the performance of most aesthetic procedures, including surgical procedures, procedures involving injections, and those involving the use of IPL and high-power laser devices, to medical practitioners or some other healthcare practitioners e.g. nurses or physician assistants under the supervision of a medical practitioner. These procedures are considered as medical practices by the Florida Board of Medicine ("FBOM") which is responsible for the licensing of medical practitioners. The beauty sector, which is regulated under a separate licensing system by the Board of Cosmetology, is mainly involved in providing conventional beauty services such as facials and manicures, or some non-invasive aesthetic procedures such as chemical peels and microdermabrasion.

3.1.3 As at December 2012, there were 48 852 medical practitioners in Florida, of which 867 specialized in dermatology and 613 specialized in plastic surgery. In the 2012-2013 financial year, there were 212 650 licensed cosmetologists in Florida.

¹⁶ ASAPS comprises over 2 600 medical practitioners who engage in aesthetic practices, mostly in the US and Canada. Its mission includes medical education, public education and patient advocacy.

¹⁷ The statistics were compiled based on a survey among 714 plastic surgeons, dermatologists and otolaryngologist. See The American Society for Aesthetic Plastic Surgery (2014).

3.1.4 In recent years, an increasing number of medical spas¹⁸ have been established in Florida to capture the growing demand for medical aesthetic services and to raise income for medical practice which faces cut in third-party reimbursement for traditional practice.¹⁹ These medical spas may be owned by licensed medical practitioners, or owned by non-medical practitioners but supervised by a licensed medical practitioner in the capacity of a medical director. These medical spas are supported by a team of staff comprising licensed healthcare practitioners and/or cosmetologists for performing a range of medical aesthetic procedures and conventional beauty services which are allowed under their respective licensed scope of practice. As such, the line between the practice of medicine and cosmetology has become increasingly blurred and there has been concern that the general public may have become less conscious of the risks involved in the procedures.

3.1.5 At present, Florida does not have an overarching regime governing aesthetic practices. Instead, various aspects of aesthetic practices are regulated under different state laws and administrative rules. The main authorities responsible for regulating aesthetic practices include the Florida Department of Health ("FDOH"), the Florida Department of Business and Professional Regulation ("FDBPR") and the respective professional boards.

3.2 Classification of and competency requirements for performing aesthetic procedures

3.2.1 According to FBOM, surgical aesthetic procedures, procedures involving the use of high-power laser devices (i.e. Class IIIa, IIIb and IV lasers²⁰) and IPL devices, and those involving injections (e.g. injection of Botox and dermal filler) are the practice of medicine. Hence, these procedures can only be performed by licensed medical practitioners, or by some licensed healthcare practitioners such as advanced registered nurse practitioners or physician assistants under the on-site or off-site supervision of a medical practitioner.²¹ In addition, there is

¹⁸ Medical spas offer aesthetic procedures such as laser hair removal, and dermal filler and Botox injections under the supervision of medical practitioners, as well as conventional beauty services such as manicures, pedicures and waxing.

¹⁹ Payments for aesthetic procedures are not covered by third-parties such as insurance companies and charges of these procedures can be set at a higher level.

²⁰ Class IIIa, IIIb and IV lasers correspond to Class 3R, 3B and 4 lasers set by the International Electrotechnical Commission which is the classification adopted in Hong Kong.

²¹ While licensed medical practitioners can perform all the abovementioned aesthetic procedures, other licensed healthcare practitioners are mainly involved in procedures involving injections or the use of laser or IPL devices.

a requirement that surgical procedures, including aesthetic procedures, must be performed by medical practitioners who have the appropriate training and skills.

3.2.2 In Florida, hair removal treatments using laser or light-based devices may be performed by electrologists (i.e. healthcare practitioners specializing in hair removal treatments) who are licensed under the Electrolysis Council²² and under the on-site supervision of a medical practitioner. Licensing requirements of electrologists include having at least 120 hours of academic training and at least 200 hours of practical experience, attending a two-hour course on prevention of medical errors and passing an examination. Prior to starting his or her practice, an electrologist is also required to complete a 30-hour continuing education course approved by the Electrolysis Council, be certified in the use of laser and light-based devices for hair removal by an approved certification organization, and develop written protocols with regard to the practice of hair removal treatments with the supervising medical practitioner. The electrologist licence is renewed on a biennial basis, conditioned upon completion of 20 hours of continuing education.

Delegation and supervision arrangements

3.2.3 Under the existing regulatory regime, the operators of medical spas or general medical offices providing aesthetic procedures have to ensure that healthcare practitioners delegated to perform medical aesthetic procedures are practising within their licensed scope of practice and are under proper supervision by medical practitioners if so required. According to the state law on medical practice, medical spas must be supervised by a board-certified dermatologist or plastic surgeon. For medical offices offering both primary care services and aesthetic procedures, supervision can be provided by any licensed medical practitioner.

3.3 Regulation of the beauty sector in performing aesthetic procedures

3.3.1 In Florida, the practice of cosmetology, i.e. the mechanical or chemical treatment of the head, face and scalp for aesthetic rather than medical purposes, is regulated under a licensing system administered by the Board of

²² The Electrolysis Council is an advisory council under the supervision of FBOM with the responsibilities to ensure that the electrologists and electrolysis facilities meet the minimum requirements for safe practice.

Cosmetology.²³ Meanwhile, licensed practice of cosmetology covers conventional beauty services as well as some non-invasive aesthetic procedures such as chemical peels and microdermabrasion which are not restricted to be performed by medical or healthcare practitioners.

Licensing requirements

3.3.2 Under the current licensing system, a person is required to attend a minimum of 1 200 hours of training in a licensed school of cosmetology or a public education institution offering cosmetology programme, and pass the licensing examination in order to obtain a licence. A person may also register with the Board of Cosmetology as a specialist in one or more specialty practices e.g. facials or manicuring, after completing the relevant specialty training programme. The licensees are required to renew the licence every two years, conditioned upon the completion of at least 16 hours of continuing education.

3.3.3 Training programmes for cosmetologists are developed based on the minimum competency requirements set by the Board of Cosmetology. The competency requirements are mainly set for broad areas of cosmetology practice e.g. facials, hair styling and manicuring instead of specific aesthetic procedures. The Board also determines areas of competency to be tested in the licensing examinations.

3.4 Regulation of the use of cosmetic-related medical devices

3.4.1 In the US, companies that design, manufacture and/or import medical devices are regulated by the US Food and Drug Administration at the federal level. On the other hand, use control of medical devices such as high-power lasers is subject to the regulation of individual states.

3.4.2 In Florida, any person manufacturing, acquiring or possessing laser device that emits laser radiation is required to register with FDOH. With regard to the use control on laser devices, FBOM considers the use of high-power laser devices to be the practice of medicine. As mentioned in paragraph 3.2.1, performance of aesthetic procedures using such devices is restricted to medical

²³ The Board of Cosmetology regulates cosmetologists, nail specialists, facial specialists, full specialists, hair braiders, hair wrappers, body wrappers and cosmetology salons. It is created within FDBPR under Chapter 477 of the *Florida Statutes* and Rule 61G5 of the *Florida Administrative Code*.

practitioners or some other healthcare practitioners under the supervision of a medical practitioner. The use of such devices is subject to the regulation governing the practices of the relevant groups of medical and healthcare practitioners. For example, the Florida state law provides that electrologists may operate high-power lasers to perform laser hair removal treatment provided that they have received relevant training, obtained certification for their competence and are under the supervision of a medical practitioner when practising.

3.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

3.5.1 In Florida, facilities in which aesthetic procedures are performed such as hospitals, ambulatory surgical centres, medical practitioners' offices where surgeries are conducted, electrology facilities and cosmetology salons are subject to the state laws and administrative rules. For example, hospitals and ambulatory surgical centres are regulated by the Agency for Health Care Administration under a licensing system which governs various aspects of the facilities including their services, staffing and management, equipment, infection control, and quality improvement system. The licensed facilities are subject to routine inspection by the Agency unless they are accredited by a recognized accrediting agency.

3.5.2 FDOH administers the Florida Office Surgery Registration and Inspection Programme for regulating medical practitioners' offices where surgeries are performed. Prior to 2013, the programme only required registration of medical practitioners' offices where Level II surgical procedures lasting more than five minutes and all Level III surgical procedures were performed.²⁴ The Programme was enhanced in early 2013 to cover all facilities in which liposuction procedures²⁵ which aimed to remove more than 1 000 cubic centimetres of supernatant fat were performed. This enhancement was introduced as there had been a number of adverse incidents causing the death of persons undergoing liposuction procedures in an unregulated ambulatory setting.²⁶

²⁴ Level II procedures involve the use of peri-operative medication and sedation intravenously, intramuscularly or rectally, thus making intra and post-operative monitoring necessary. Level III procedures involve the use of a general anaesthesia or major conduction anaesthesia and pre-operative sedation.

²⁵ According to ASAPS, liposuction was the most popular surgical aesthetic procedure in the US in 2013.

²⁶ Prior to the introduction of the new regulation, medical practitioners could perform liposuction procedures in unregulated offices if they only used local sedatives for the procedures.

3.5.3 In order to register an office for surgical procedures, the medical practitioner has to comply with requirements on surgery training, equipment and supplies, assistance of other personnel such as nurses or anaesthetists during the procedures, and emergency procedures related to serious anaesthesia complication. FDOH will inspect the registered offices annually unless they are accredited by a nationally recognized accrediting agency or an accrediting organization approved by FBOM. The list of equipment and supplies required is provided in **Appendix III**.

3.5.4 Electrology facilities and cosmetology salons are subject to regulation under the licensing systems administered by FDOH and FDBPR respectively.²⁷ The facilities are required to comply with safety and sanitary requirements and subject to inspection by the respective licensing authorities.

3.6 Protection of persons undergoing aesthetic procedures

3.6.1 Protection of the public against false, deceptive or misleading advertising of the medical sector is provided under the administrative rules of FBOM. According to the relevant rules, medical practitioners cannot disseminate or cause the dissemination of any advertising which contains a misrepresentation of facts, makes only a partial disclosure of relevant facts or contains any statement or claim which misleads or deceives.

3.6.2 FDOH and FDBPR, which are responsible for regulating healthcare practitioners and cosmetologists respectively, put in place a complaint handling mechanism to receive and investigate complaints lodged by the public against practitioners who may have violated the relevant laws and rules in their practices. Such complaints may be related to malpractice or unlicensed practice of practitioners. The two departments also handle complaints against facilities regulated under their remit. The total number of complaints against medical practitioners was 4 269 in 2012-2013, down from 4 652 in 2011-2012. According to FDBPR, the total number of complaints against cosmetologists has decreased from 4 964 in 2008-2009 to 3 187 in 2012-2013.

²⁷ There is no specific provision regulating the use of title of these facilities under the relevant legislation.

3.6.3 Moreover, persons undergoing aesthetic procedures are protected under the *Florida Deceptive and Unfair Trade Practices Act* enforced by the Consumer Protection Division of the Office of Attorney General. The *Act* protects the public against individuals and entities that engage in unfair methods of competition or deceptive and unfair practices in any trade or commerce.

3.7 Recent developments

3.7.1 In view of the growing demand for aesthetic procedures and a decline in reimbursements for traditional insurance-based medicine, a growing number of medical practitioners, regardless of their specialties, have engaged in medical aesthetic practices such as providing aesthetic procedures in their offices or practising in medical spas. There have been public concerns about potential health risks of persons undergoing aesthetic procedures in medical spas since they are not covered by the existing regulatory regime unless surgical procedures requiring specified types of anaesthesia or electrolysis are performed on the premises. Besides, there is no specific requirement for the specialty and experience of medical practitioners practising or supervising non-surgical aesthetic procedures e.g. Botox injections or laser treatments in their offices.

3.7.2 The recent implementation of the rule requiring the registration and inspection of offices of medical practitioners where liposuction procedures removing more than 1 000 cubic centimetres of supernatant fat are performed has been supported by the public and medical sector as a move to enhance public safety. Under the current regulation, the surgeon may be assisted by an anaesthetist, a qualified nurse or physician assistant (anaesthesia) to assist with or administer the anaesthesia during the surgical procedures. However, some medical practitioners have called for further tightening of the regulation by requiring medical practitioners to engage an anaesthetist for aesthetic procedures requiring anaesthesia, including all liposuction procedures, as anaesthesia complications during such procedures can be life-threatening.

3.7.3 In order to strengthen the regulation on medical spas and clinics providing advance therapies on a cash basis²⁸, a Florida Senator introduced two legislative proposals to the Florida Senate in 2011 and early 2014 respectively to amend the *Health Care Clinic Act* such that medical spas and medical clinics would be subject to regulation of the Agency for Health Care Administration. The legislative proposal regarding medical spas was subsequently withdrawn due to the lack of support in the Senate while the legislative proposal regarding medical clinics providing advance therapies on a cash basis is currently under consideration by the Senate.

²⁸ At present, the *Health Care Clinic Act* provides for the licensing and enforcement of basic standards for those medical clinics which receive reimbursements for services provided from third-parties such as insurance companies but does not cover those clinics receiving cash payments.

Chapter 4 – South Korea

4.1 Overview

4.1.1 In South Korea, aesthetic practices have been growing in popularity in recent years. According to a survey conducted by ISAPS²⁹, about 650 000 aesthetic procedures were performed by board-certified plastic surgeons in South Korea in 2011, the highest rate of aesthetic activities per capita among the surveyed countries. Surgical and non-surgical procedures accounted for 40% and 60% respectively.³⁰ South Korea is a popular destination for plastic surgery. It was reported that the revenue of the plastic surgery industry in 2013 amounted to 267 billion Korean won (HK\$1.9 billion), more than double the revenue generated in 2010. The market of filler and Botox injections was worth an estimated 104 billion Korean won (HK\$718 million) in 2012, up from 66 billion Korean won (HK\$442 million) in 2010.

4.1.2 Aesthetic procedures, including those involving skin puncture and use of medical devices, are considered as medical procedures in South Korea, and they must be performed by medical practitioners in licensed hospitals or medical clinics. As at 2012, there were 107 221 licensed medical practitioners in South Korea, of which 1 851 were certified plastic surgeons and 1 994 dermatologists. Any licensed medical practitioner, regardless of whether he or she is a general practitioner or specialist, can perform aesthetic procedures. Currently, there are no clear regulatory requirements on the adequacy of the facilities used for performing aesthetic procedures at medical clinics. The reported incidents of death in recent years have led to public calls for corrective measures.

4.1.3 As aesthetic procedures are considered as medical procedures in South Korea, non-medical personnel such as beauticians are not allowed to provide such services. The law governing the beauty sector also prohibits beauticians from utilizing any medical device or medicine in the provision of beauty services.

²⁹ The survey results were compiled based on data collected from 996 board-certified plastic surgeons around the world in 2011.

³⁰ The Research Office has sent an enquiry to ISAPS for updated figures for South Korea in 2013. As at publication of this report, it has not yet given a reply.

4.1.4 Since 2011, the South Korean government has started to impose the value added tax of 10% on the most common aesthetic procedures.³¹ Beginning in 2014, the tax has been extended to cover other non-surgical procedures, for the purposes of broadening the tax base and suppressing aesthetic activities.

4.2 Classification of and competency requirements for performing aesthetic procedures

4.2.1 In South Korea, private medical institutions and medical practitioners are regulated by the Ministry of Health and Welfare and are subject to licensing under the *Medical Service Act*. Any aesthetic procedure that involves skin puncture is considered as medical practice and should be performed by licensed medical practitioners. Hence, procedures such as Botox injection and filler injection can only be administered by medical practitioners. Tattooing and ear piercing, which are typically performed by non-medical practitioners in Hong Kong, are determined as medical procedures in South Korea.³²

4.2.2 In South Korea, the right to practise aesthetic procedures is not exclusively conferred to medical specialists such as certified plastic surgeons and dermatologists. Any licensed medical practitioner can legally perform surgical or non-surgical aesthetic procedures, but he or she must perform the procedures in licensed hospitals or medical clinics. According to news reports, over 4 000 out of 28 000 clinics in Seoul provide aesthetic surgery services.

4.3 Regulation of the beauty sector in performing aesthetic procedures

4.3.1 Beauty treatment centres in South Korea can only provide conventional beauty services set out in the *Public Health Control Act*, which include analysis of skin condition, skin care, hair removal, eyebrow care and other hairdressing services. In addition, they cannot use any medical device or medicine. A beauty business is termed as a "beauty art business" in the *Public Health*

³¹ The most common procedures were nose jobs, liposuction, wrinkle removal, breast augmentation and blepharoplasty.

³² While both tattooing and ear piercing are considered as medical practices in South Korea, according to some news reports, there are instances of such services rendered by non-medical practitioners.

Control Act.³³ Both business owners and beauticians working in the sector should be licensed by the local government. To be eligible for a licence, a person has to obtain the required training or qualifications specified by the Ministry of Education.

4.4 Regulation of the use of cosmetic-related medical devices

4.4.1 In South Korea, medical devices are subject to legislation. Medical devices cover those that can be used for cosmetic treatment, such as IPL devices and high-power lasers. Under the *Medical Service Act*, where a hospital or clinic possesses and operates radiation-emitting diagnostic devices, it should appoint a person to take care of the safety matters, and comply with the standards and guidelines stipulated by the Ministry of Health and Welfare.³⁴

4.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

4.5.1 Medical clinics in South Korea are required to comply with the general facility standards and safety requirements prescribed by the Ministry of Health and Welfare. It is however noted that they are not required to put in place medical equipment dealing with emergencies that may arise in the course of an aesthetic procedure. According to an assessment made by the Health Insurance Review and Assessment Service³⁵, about 77% of cosmetic surgery clinics nationwide lacked proper emergency medical equipment such as defibrillators and ventilators. Besides, there is no regulation requiring anaesthesia work be performed by anaesthetists at medical clinics. It was reported that some clinics had undertaken surgery in the absence of anaesthetists or trained professionals in order to save costs.

³³ A "beauty art business" is defined as the business of making customers' appearance beautiful with respect to their faces, hair, and skin, etc. There is no specific provision regulating the use of title of these business establishments under the *Public Health Control Act*.

³⁴ The Research Office has sent enquiries to the Ministry of Health and Welfare, and the Ministry of Food and Drug Safety requesting information on the standards and guidelines for the operation of high-power laser devices, including the respective licensing and training requirements. As at publication of this report, the two Ministries have not given a reply.

³⁵ The Health Insurance Review and Assessment Service is responsible for, among others, carrying out reviews and assessments of healthcare costs and healthcare service quality provided by medical institutions in South Korea.

4.6 Protection of persons undergoing aesthetic procedures

4.6.1 In South Korea, advertisements featuring before-and-after differences of the aesthetic procedures, especially plastic surgery, are abundant on streets. It was also reported that one in five women from ages 19 to 49 in Seoul had undergone some sort of aesthetic treatments.³⁶ In a bid to contain the unhealthy trend, the South Korean government announced in early 2014 new regulations to restrict aesthetic-related advertisements on public transportation and in areas close to schools. Meanwhile, the Ministry of Education distributed booklets on "plastic surgery syndrome" to educate students about the negative effects and unhealthy obsession associated with cosmetic surgery.³⁷

4.6.2 Since 2012, persons suffering from medical malpractice have been able to seek remedies from the mediation organization, Korea Medical Dispute Mediation and Arbitration Agency established by the nation. The Agency may come up with a legally binding mediation result within 90 days, if the medical practitioner concerned agrees to participate in the mediation. As compared with the traditional litigation process, this channel provides a more timely resolution of medical disputes. Since its establishment, over 2 200 mediation requests involving different kinds of medical matters have been received, of which 42% have been settled successfully, involving compensation claims of 123 billion Korean won (HK\$873 million). Yet, information on the number of mediation cases in relation to the malpractice of aesthetic procedures is not available. Apart from the Korea Medical Dispute Mediation and Arbitration Agency, the persons concerned may seek redress through other civil mediation channels such as the Korea Consumer Agency, or through civil proceedings before the court.

4.7 Recent developments

4.7.1 The popularity of aesthetic procedures in South Korea has prompted not only medical specialists but also general practitioners to enter the lucrative market. According to a news report, about 90% of the medical practitioners engaging in aesthetic practices in South Korea are not specialists in plastic

³⁶ The New York Times (2011).

³⁷ The Research Office has sent a request to the Ministry of Education for a copy of the booklet. As at publication of this report, it has not yet given a reply.

surgery.³⁸ However, there were reported incidents of complications or death following the aesthetic procedures. For instance, earlier in 2014, a woman was having respiratory difficulty when undergoing rhinoplasty at a plastic surgery clinic and was dead on the way to the hospital. In 2013, another woman lost consciousness when undergoing an aesthetic procedure at a clinic and died after one month. Another girl was reported dead in the same year after being administered anaesthesia at a clinic for an aesthetic procedure.

4.7.2 These incidents were considered to be related to the lack of relevant training of general practitioners and inadequate regulation on emergency facilities and anaesthesia procedure at medical clinics. According to the Korea Consumer Agency, it received 130 and 110 complaints on side effects from plastic surgery in 2012 and 2013 respectively. The figures were up from 87 in 2011. There are concerns about the lack of an information disclosure process in which medical practitioners explain to clients about the inherent risks and potential side effects before carrying out the procedure for them. To enable clients to make an informed decision, some interests groups have called for the introduction of a mandatory risk disclosure process for plastic surgery.³⁹

³⁸ 新報 (2014 年)。

³⁹ the hankyoreh (2014).

Chapter 5 – Singapore

5.1 Overview

5.1.1 Similar to Hong Kong, Singapore has seen growing popularity in aesthetic procedures in recent years. The aesthetic market is estimated to be S\$200 million (HK\$1.24 billion) a year. In view of a large number of medical practitioners and specialists performing a range of unproven aesthetic procedures at their clinics⁴⁰, the Singapore Medical Council, a statutory board of the Ministry of Health, jointly with the Academy of Medicine, Singapore, and the College of Family Physicians, Singapore, issued the Guidelines on AP in 2008, spelling out the procedures supported by different levels of scientific evidence and the requirements for performing these procedures.

5.1.2 The Guidelines on AP are applicable only to registered medical practitioners for better self-regulation of aesthetic practices. In Singapore, non-medical personnel are prohibited from performing procedures that are invasive in nature. It follows that beauticians may only carry out non-invasive aesthetic services. Currently, there is no specific law regulating such practices in the beauty sector, except that where high-power lasers are engaged, a licence for the possession and operation is needed. It is estimated that there are about 19 000 businesses in Singapore providing services on beauty and skin care, spa and massage, and/or slimming treatment.⁴¹

5.1.3 Liposuction, considered as a highly invasive procedure, is regulated as a special care service in Singapore. Prior to engaging in liposuction practice, medical clinics and medical practitioners must seek approval from the Ministry of Health. They must also meet the requirements with respect to facilities and equipment, and staffing support.

⁴⁰ According to the Strait Times, over 1 000 medical practitioners and specialists had performed a range of unproven aesthetic procedures at their clinics.

⁴¹ The 19 000 businesses may include those providing only spa or massage services. The exact number of beauty treatment centres providing beauty and skin care services is not known, as there is no specific regulation governing the sector.

5.2 Classification of and competency requirements for performing aesthetic procedures

5.2.1 Implemented on 1 November 2008, the Guidelines on AP classify aesthetic practices into List A and List B based on currently available scientific evidence. List A procedures, supported by moderate to high level of scientific evidence, are further grouped into (a) non-invasive procedures, (b) minimally invasive procedures and (c) invasive procedures. Non-invasive and minimally invasive procedures can be carried out by any registered medical practitioner with the necessary experience or required competence. For invasive procedures, they must be performed by medical practitioners with appropriate surgical training.

5.2.2 The required competence for List A aesthetic procedures can be achieved through attending the accredited specialized courses approved and recognized by the Singapore Medical Council. Medical practitioners should submit the relevant information to the Singapore Medical Council for verification of the acquired competence. The need to submit such information could be exempted if medical practitioners had already been performing the procedures before the introduction of the Guidelines on AP and fulfilled the requisite number of procedures performed from 1 October 2006 to 30 September 2008. In other words, medical practitioners could continue to practise the procedures if they had enough relevant experience.

5.2.3 List B procedures, e.g. mesotherapy and carboxytherapy, are supported by low or very low level of scientific evidence. In fact, these unproven procedures had been totally banned in early 2008 when the Guidelines on AP were under development. At that time, there was criticism from the medical profession that the Ministry of Health had not consulted the medical sector and not evaluated the relevant documentation before putting an outright ban. The Guidelines on AP, issued subsequently, were considered less stringent, as the performance of such procedures is allowed on justifiable grounds⁴² and provided that medical practitioners list themselves with the Singapore Medical Council beforehand. (The aesthetic procedures in List A and List B are given in **Appendix IV**).

⁴² The justifiable grounds are that all other conventional and sound-evidence based treatments or procedures have been attempted on the patient and have not been shown to produce the desired outcomes, and the low-evidence procedure has not been shown to carry any risk of significant adverse effects of harm to any patient based on the available evidence. In addition, the person undergoing the low-evidence procedure should be aware of the circumstances and the procedure should be performed under highly monitored conditions.

5.3 Regulation of the beauty sector in performing aesthetic procedures

5.3.1 Beauty service providers in Singapore are not subject to licensing unless they provide specified services such as massage and spa services.⁴³ When the Guidelines on AP were introduced in 2008, the Ministry of Health specifically pointed out that it did not regulate aesthetic practices in the beauty sector, on the ground that most of the products used by the beauty sector were generally not intended for medical purpose.

5.3.2 Notwithstanding the above, minimally invasive and invasive aesthetic procedures, as well as List B procedures specified in the Guidelines on AP can only be performed by medical personnel. Any person who is not a registered medical practitioner or dentist but engages in these practices may be liable to an offence under the *Medical Registration Act*.

5.3.3 Beauticians in the beauty sector may only provide non-invasive aesthetic services, for example, skin tightening and hair removal with the use of certain medical devices, and chemical peeling. In the absence of relevant regulation governing aesthetic practices in the beauty sector, in the event of injuries or physical harm caused by an aesthetic procedure, a person may file a civil suit against the beauty treatment centre or its beautician for negligence to recover damages under the *Penal Code*. A person may also take civil action against unfair practices of a beauty treatment centre such as making a false claim under the *Consumer Protection (Fair Trading) Act* to seek civil remedies before the court.

5.4 Regulation of the use of cosmetic-related medical devices

5.4.1 In Singapore, cosmetic-related equipment such as IPL devices and high-power lasers are medical devices regulated by the Singapore Health Authority. Due to the potential danger to human body, high-power medical lasers are subject to licensing by the National Environment Agency for the possession and operation under the *Radiation Protection (Non-Ionising Radiation) Regulations*.

⁴³ Under the *Massage Establishment Act*, if a beauty treatment centre provides treatments requiring massage, manicure, or spa related services, it is required to obtain a massage establishment licence issued by the Singapore Police Force. The purpose of licensing is to control any illegal activities in these establishments.

5.4.2 Higher-power medical lasers refer to Class 3b and Class 4 lasers as defined by law.⁴⁴ Therapeutic and acupuncture lasers usually belong to Class 3b lasers. Class 4 lasers are commonly used in plastic surgery, ophthalmic, obstetrics and gynaecology applications. For these high-power lasers, only the trained and qualified persons are granted licence for the operation. In making a licence application to the National Environment Agency, the applicant is required to provide the necessary documents to support that he or she has obtained the relevant training or qualification, e.g. certificate on laser safety course or certificate of training in using medical lasers. He or she may also be required to sit a qualifying test to demonstrate the knowledge in laser safety. For Class 4 medical lasers, a licence may only be granted to registered medical practitioners and dentists for operation.

5.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

5.5.1 Generally, aesthetic procedures requiring local anaesthesia and sterile conditions may be performed at a clinic with appropriate facilities and staff, while those requiring intravenous sedation or general anaesthesia should be performed in hospitals or ambulatory surgery centres (see **Appendix IV**). Medical clinics are required to have in place functional and effective facilities and equipment for medical and surgical purpose, and maintain resuscitation facilities for emergency use (details are provided in **Appendix V**). Where the anaesthesia work is required, there should be adequate and proper facilities for recovery from anaesthesia. Specified types of anaesthesia work must be performed by either (a) an anaesthetist or (b) a medical practitioner or a dentist under the supervision of an anaesthetist.

5.5.2 Since 1 November 2008, the Ministry of Health has imposed specific requirements on medical clinics to regulate the practice of liposuction. Both medical clinics and licensed medical practitioners wishing to engage in liposuction practice should obtain prior approval from the Ministry of Health.⁴⁵ Among others, medical clinics should have the equipment for ventilation, suction, resuscitation and monitoring, including pulse oximetry and defibrillator. The

⁴⁴ Class 3b lasers gives a power output from 5mW up to 500mW, whereas Class 4 lasers produce a power output of 500mW or more.

⁴⁵ Approval of medical practitioners for performing liposuction procedures is made through the Accreditation Committee on Liposuction of the Ministry of Health.

procedure room or operating theatre shall be equipped with emergency lighting, water and power supply (further details are provided in **Appendix V**). There are also requirements on the training of the medical practitioners performing the procedure and staffing support. In addition, medical clinics are required to report to the Ministry of Health within 24 hours on cases of patients who suffer major complications.⁴⁶

5.5.3 Considering that liposuction is a highly invasive procedure and has been known to cause severe complications including death in Singapore, earlier in October 2014, the Ministry of Health imposed further requirements to enhance the safety of liposuction procedure. Under the new requirements, liposuction practice shall only be allowed in hospitals or medical clinics that are approved to provide ambulatory surgery, namely ambulatory surgical centres.⁴⁷ Medical clinics that intend to engage in liposuction practice must first apply for approval to become ambulatory surgical centres and then seek additional approval to engage in liposuction practice. For existing clinics that are engaging in liposuction practice, the revised licensing terms and conditions reflecting the new requirements will be enforced from 1 March 2015.⁴⁸

5.6 Protection of persons undergoing aesthetic procedures

Cooling-off period

5.6.1 As part of the licensing conditions, medical clinics which engage in liposuction practice are required to provide clients with a seven-day cooling-off period before the liposuction procedures are performed on them. During the cooling-off period, no financial transaction, contract or any inappropriate constraint may be carried out or effected by the medical practitioners.⁴⁹

⁴⁶ Major complications refer to those cases that require the patient to undergo remedial treatment or be referred to another medical practitioner for remedial treatment; and/or requiring the patient to be medically managed in a hospital.

⁴⁷ Liposuction shall only be performed in hospital on an inpatient basis under the following circumstances: (a) involving the removal of more than 1 litre of supernatant fat per session or repeating removal/injection of fat over the same region of the body, (b) requiring patients to be under general anaesthesia or deep sedation, or (c) performing on patients with Body Mass Index of more than 28.

⁴⁸ Ministry of Health (2014a).

⁴⁹ Clinics are exempted from imposing the seven-day cooling-off period for foreigners who come to Singapore specifically for liposuction.

5.6.2 In order to raise the professional standards of the businesses providing beauty, spa and/or massage services, an accreditation programme was implemented in 2008 by CaseTrust, the accreditation arm of the Consumers Association of Singapore ("CASE").⁵⁰ Under the accreditation programme, CaseTrust will certify the related businesses which have put in place clear fee policies, ethical business practices and well-trained personnel. In August 2014, there were over 480 accredited businesses, of which about 15% indicated on their website that they were offering aesthetic procedures with the use of medical apparatus. As part of the accreditation requirements, these businesses shall accord a cooling-off period of at least five working days to allow clients including tourists to seek full refund of payments made if they do not wish to proceed with the service package offered.

Information disclosure to persons undergoing certain aesthetic procedures

5.6.3 Given the low level of scientific evidence of the List B procedures, medical practitioners wishing to undertake such procedures should make sure that the persons undergoing the procedures are aware of the low-evidence in nature and that they are offered only in the light of the lack of efficacy of conventional and sound-evidence based treatments. A written consent from the person concerned should be obtained prior to the performance of the procedure. Likewise, medical clinics and ambulatory surgery centres engaging in liposuction practice are obliged to obtain a written consent from patients. The signed consent form should contain the following information:

- (a) name and description of the liposuction procedure being provided;
- (b) possible risk and complications;
- (c) type of anaesthesia and whether sedation is to be used;
- (d) anticipated costs, benefits and outcomes of the procedure;
- (e) any alternative procedure or treatment other than liposuction; and
- (f) name, designation and signature of the treating medical practitioner.

⁵⁰ CASE is a non-profit and non-governmental organization providing assistance, advice and mediation services to consumers aggrieved by unfair practices.

In addition, persons undergoing liposuction procedures should be given a feedback form for completion after the procedure.

Restrictions on advertising

5.6.4 Medical practitioners are prohibited from advertising that they are performing the aesthetic procedures classified as low-evidence in nature in the Guidelines on AP. Besides, CASE has issued the *Singapore Code of Advertising Practice*, imposing restrictions on unacceptable claims on beauty advertisements. For instance, advertisements are not allowed to contain any claim to provide rejuvenation, that is to prevent, retard or reverse the physiological changes and degenerative conditions brought about by, or associated with, increasing age.

5.7 Recent developments

5.7.1 In Singapore, there is no specific regulation governing the services provided by beauty treatment centres, although they are prohibited from performing aesthetic treatments that are invasive in nature. There are concerns that in the absence of relevant legislation, no enforcement can be taken against the irregularity or inadequacy of beauty businesses, only until and when customers have suffered.

5.7.2 Similar to Hong Kong, there is yet an accepted standard of education or training in the beauty sector. Despite plenty of training courses in the market place, attaining the relevant qualification is not compulsory. To create more transparent and accountable industry practices, the Spa & Wellness Association of Singapore, a trade association representing the spa, beauty and massage establishments, is planning to develop an online registry to let the public know the qualifications and experience of the industry practitioners including beauticians and spa therapists. Registration of practitioners is voluntary. According to a news report, the Association has been discussing with CASE and other government agencies to seek their support and it is expected that the registry will be launched in early 2015.⁵¹

⁵¹ The Straits Times (2014).

Chapter 6 – The United Kingdom

6.1 Overview

6.1.1 In the UK, the aesthetic practice market has experienced substantial growth recently. A survey conducted by ISAPS indicated that about 211 406 aesthetic procedures were performed by board-certified plastic surgeons in the UK in 2011, up from 183 618 in 2010. According to the UK Department of Health ("DH-UK"), the total value of the aesthetic practice market was estimated to be £2.3 billion (HK\$27.6 billion) in 2010 and was forecast to grow to £3.6 billion (HK\$47.7 billion) by 2015. It was also estimated that about 75% of the market value was contributed by non-surgical procedures such as Botox injections, chemical peels, and laser and IPL treatments. Most aesthetic procedures are performed outside the National Health Services ("NHS"), the publicly funded health services in the UK, and the costs of procedures are usually assumed by the persons undergoing the procedures.

6.1.2 According to DH-UK, the existing regulatory framework for aesthetic practices in the UK is fragmented and legislation has been developed in a piecemeal manner to regulate different aspects of aesthetic practices. The UK also follows the European Union ("EU") directives with regard to the regulation of medical devices and medicines, including items that may be used in aesthetic procedures.

6.1.3 Meanwhile, surgical aesthetic procedures such as breast implantation and face-lifts must be performed in regulated clinical settings by qualified medical practitioners regulated by the General Medical Council ("GMC").⁵² On the other hand, non-surgical procedures can be performed by both medical and non-medical practitioners in clinics or beauty treatment centres. At present, there is no standard regulating the provision of these procedures by non-medical practitioners.

⁵² GMC is a statutory body responsible for administering the registration and licensing systems for medical practitioners, setting standards for professional practice (i.e. the Good Medical Practice), and disciplining medical practitioners who fail to comply with the standards.

6.1.4 In 2012, the outbreak of the breast implant incident⁵³ prompted DH-UK to conduct a review on the regulation of aesthetic procedures, as a response to public concerns about the safety of these procedures. DH-UK published the Report on the Review of the Regulation of Cosmetic Interventions ("the Review Report") in April 2013 which contained 40 recommendations to enhance the regulation of aesthetic practices. These recommendations focus on three key areas, namely (a) providing high quality care with skilled practitioners, safe products, and responsible providers; (b) ensuring that the public can get accurate advice on aesthetic procedures and the vulnerable are protected; and (c) establishing an accessible redress and resolution system in case things go wrong.

6.1.5 In February 2014, the UK government published its response to formally set out the steps to be taken to address the current lack of effective regulatory framework to safeguard the safety and interests of people undergoing aesthetic procedures. The recommendations of the Review Report and the actions taken by the UK government in response to the Review Report are summarized in the ensuing sections.

6.2 Classification of and competency requirements for performing aesthetic procedures

6.2.1 In the Review Report published by DH-UK, aesthetic procedures are generally classified into surgical procedures (e.g. breast implantation and face-lifts) and non-surgical procedures (e.g. Botox and dermal filler injections, and laser and IPL treatments) depending on whether surgery is involved. At present, only medical practitioners with surgery training can perform surgical aesthetic procedures but there is no requirement for them to have specialized training or experience in aesthetic surgery. As for non-surgical procedures, they can be performed by any licensed medical practitioners, or non-medical practitioners such as beauticians.

⁵³ In 2010, the silicone breast implants supplied by a French company, Poly Implant Prothese, were reported to have quality problems. The incident has exposed weaknesses of the regulatory system for aesthetic practices such as the lack of regulation of non-surgical practices, and inadequate control on product quality and after-care services for users.

Competencies of practitioners performing aesthetic procedures

6.2.2 The Review Report published by DH-UK in April 2013 reveals that the current professional regulatory oversight on aesthetic practices is weak due to factors including that aesthetic practice is not a discrete defined specialty, procedures are mainly provided in the private sector, and data about the procedures performed are lacking. The Review Report recommends the development of accredited training standards, approved training schemes, and associated registers of practitioners for both surgical and non-surgical aesthetic procedures so that the public would be assured that the person performing an aesthetic procedure has the appropriate training. The Review Report also proposes that only medical practitioners on a GMC specialist register should perform aesthetic surgery, and these medical practitioners should work within the scope of their specialty training.

6.2.3 In response to the recommendations of the Review Report, the Cosmetic Surgery Inter-specialty Committee ("CSIC")⁵⁴ under the auspices of the Royal College of Surgeons of England ("RCS")⁵⁵ was formed in late 2013 to set clinical standards for the training and practice of aesthetic surgery, develop measures to help improve clinical outcomes, and provide evidence-based standardized information to better inform persons undergoing the procedures about what they can expect from their surgery. The clinical standards developed by CSIC will be submitted to GMC for approval as part of a new framework that GMC is working on for regulating the credentialing of practitioners who practise aesthetic surgery.⁵⁶ GMC will also work with CSIC to develop a code of ethical practice for aesthetic surgery.

6.2.4 Regarding the performance of non-surgical procedures, the Review Report suggests that (a) all non-surgical procedures must be performed under the responsibility of clinical professionals who have obtained the accredited qualifications to prescribe, administer and supervise aesthetic procedures; (b) non-healthcare practitioners who have achieved the required accredited qualifications may perform these procedures under the supervision of a qualified clinical professional; and (c) all practitioners must be registered centrally.

⁵⁴ CSIC comprises representatives from key stakeholder groups in the medical sector including RCS, GMC and other medical professional bodies.

⁵⁵ RCS is a professional organization of about 20 000 surgeons in the UK and overseas. Its missions are to promote surgical standards and improve patient care.

⁵⁶ Credentialing is a system which will enable medical practitioners to demonstrate competencies in a particular field of practice and have those competencies publicly recognized by the regulator.

Recent progress regarding the implementation of these recommendations is covered in the next section when the regulation of the beauty sector in performing aesthetic procedures is discussed.

European Standard for Aesthetic Surgery Services

6.2.5 In June 2014, the European Standard for Aesthetic Surgery Services developed by the European Committee for Standardization ("CEN")⁵⁷ was approved by its member countries. It was subsequently put on hold pending the resolution of an appeal from one of the member countries. The European Standard is a set of voluntary pan-European service standards for surgical aesthetic practices developed with the aim of promoting consistently high standards for service providers across Europe in order to reduce the risk of complications and enhance client satisfaction and safety. Another set of standards on non-surgical aesthetic practices is currently under development by CEN.

6.2.6 According to the European Standard for Aesthetic Surgery Services, medical aesthetic procedures are classified into three categories based on factors including risk level, anaesthesia level and facilities in which the procedures are performed. The three categories are: (a) Category 1 – non-surgical procedures undertaken with/without anaesthesia (e.g. Botox injections and laser treatments); (b) Category 2 – intermediate/minor minimally invasive procedures undertaken under local anaesthesia in clinic or facility providing minor surgery (e.g. blepharoplasty and brachioplasty); and (c) Category 3 – major surgical procedures undertaken under local/general anaesthesia in hospital or clinic (e.g. most aesthetic facial or nasal surgery, and most aesthetic breast and body contouring). There is also a set of essential requirements on the various service aspects of surgical aesthetic practices such as consultation and assessment before treatment, obtaining consent from clients, documentation, cooling-off period, care of clients before and after treatment, insurance and facilities.

⁵⁷ CEN is one of the three European Standardization Organizations that have been officially recognized by EU and the European Free Trade Association as being responsible for developing and defining voluntary standards at European level. CEN's national members are the national standardization bodies of 33 European countries, including the EU member countries.

6.2.7 The European Standard for Aesthetic Surgery Services suggests that medical aesthetic procedures have to be performed by medical practitioners and those performing Category 2 and Category 3 procedures must have aesthetic surgery training. It also suggests establishing a registration scheme for all practitioners performing medical aesthetic procedures.

6.3 Regulation of the beauty sector in performing aesthetic procedures

6.3.1 At present, the beauty sector in the UK is involved in the provision of non-surgical aesthetic procedures such as Botox and dermal filler injections, chemical peel, and laser and IPL treatments. Nonetheless, no mandatory licensing and training requirement is imposed on beauticians performing non-surgical aesthetic procedures at the national level.

6.3.2 In response to the recommendation of the Review Report to develop appropriate accredited qualifications for prescribers and providers of non-surgical aesthetic procedures, Health Education England ("HEE")⁵⁸ has conducted a review on the related qualifications requirements and is currently working on the qualifications framework. During the review, stakeholders agreed on the principles underlying the development of the qualifications framework, such as: (a) providing an opportunity for every practitioner, whether clinically trained or not, to attain the necessary skills and expertise to safely deliver non-surgical aesthetic procedures; and (b) recognizing a range of entry points to training for different groups of practitioners and the accreditation of prior learning mechanism will be used to assist in determining specific entry levels and modules to be completed.

6.3.3 On the other hand, the UK government will not consider establishing a central register for all practitioners of non-surgical aesthetic procedures since many practitioners such as medical practitioners, dentists and nurses are already on professional registers. The UK government believes that the involvement of clinical professionals in certain non-surgical aesthetic procedures will lead to the improvement of service standards amongst practitioners who are not on any professional register.

⁵⁸ HEE is a special health authority under NHS responsible for managing the education and training system for the healthcare workforce in the UK.

6.4 Regulation of the use of cosmetic-related medical devices

6.4.1 In the UK, the manufacture, marketing and distribution of cosmetic-related medical devices, including laser devices and breast implants are regulated under the provisions of the EU directives to ensure their quality and safety. With regard to the use control of laser and IPL devices, there is a requirement for facilities in which surgical laser treatments are performed to register with the Care Quality Commission ("CQC"). CQC is responsible for administering a registration and inspection system for health and adult care service providers to ensure that they comply with a set of essential quality and safety standards. For the use of laser or IPL devices for non-surgical procedures, e.g. hair removal, some local authorities may require the establishment owners and the operators of the devices to apply for a special treatment licence. Under the licensing system, licensees may be required to comply with a code of conduct which covers staffing, qualifications, access to expert advice and maintenance of equipment.

6.4.2 The Review Report indicates that the existing EU regulatory regime for medical devices has a loophole as it does not cover some devices such as IPL devices, some dermal fillers and implants which do not serve a medical purpose but are commonly used in aesthetic procedures. In 2012, the European Commission published the proposals to revise the medical devices directives to keep pace with technological advancement in the medical device sector and changing needs of users. Under the proposals, the scope of medical devices to be regulated will be extended to cover certain invasive or implantable devices without a medical purpose, i.e. IPL devices and dermal fillers. Meanwhile, the proposals are under negotiation in the EU.

6.4.3 Regarding the use control of laser and IPL devices for non-surgical aesthetic treatments, the UK government is considering the recommendation of the Review Report to impose requirements for non-surgical laser and IPL treatments to be prescribed and supervised by clinical professionals as part of its effort to strengthen the regulation of non-surgical aesthetic practices. The qualifications and training requirements for prescribers and providers of these procedures will be reviewed and specified under the qualifications framework for non-surgical aesthetic procedures to be developed by HEE as mentioned in paragraph 6.3.2.

6.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

6.5.1 At present, facilities in which surgical aesthetic procedures including surgical laser treatments are performed are subject to registration and regular inspection by CQC.⁵⁹ However, the Review Report comments that CQC lacks a set of specific standards and data on clinical outcome for effective assessment of the quality of these service providers. The Review Report recommends that CQC should work with the related professional organizations to produce inspection guidelines for providers of surgical aesthetic procedures and perform risk-based and unannounced inspections of the providers.

6.5.2 Facilities in which non-surgical aesthetic procedures are performed are generally required to comply with the health and safety at work legislation which provides that facility owners have to protect the safety of their employees and customers by assessing, preventing and controlling risks.

6.5.3 To enhance safety of facilities in which non-surgical aesthetic procedures are performed, the Review Report suggests that the training curriculum for non-surgical practitioners should include topics such as infection control, treatment room safety and adverse incident reporting. The code of conduct for practitioners subject to registration should include an obligation to meet certain clearly defined minimum standards for such facilities.

6.5.4 The UK government basically accepts the principle of the above-mentioned recommendations of the Review Report. Meanwhile, the UK government is working with the responsible authorities such as CQC and HEE in implementing the recommendations.

⁵⁹ The regulated facilities are required to meet a set of essential standards covering six key areas i.e. involvement and information; personalized care, treatment and support; safeguarding and safety; suitability of staffing; quality and management; and suitability of management. Specific requirements on equipment and supplies and personnel performing anaesthesia work in these facilities are not specified in the relevant legislation.

6.6 Protection of persons undergoing aesthetic procedures

6.6.1 The Review Report indicates that the number of complaints about beauty treatments received by the Office of Fair Trading⁶⁰ had increased from less than 1 000 in 2006-2007 to about 3 500 in 2011-2012. To enhance protection of persons undergoing aesthetic procedures, the Review Report calls for the government to enhance access to independent and evidence-based information about the potential risks and outcome of aesthetic procedures to enable the public to make informed decisions. The Review Report also suggests that a transparent and accessible redress system should be established to handle disputes relating to aesthetic procedures. Irresponsible advertising and promotion practices such as time-limited deals, financial inducement and package deals should be prohibited.

6.6.2 The UK government agrees with the Review Report's recommendations regarding protection of persons undergoing aesthetic procedures and has been working with the responsible regulatory authorities to implement the specific recommendations. In July 2014, the UK government introduced new legislation requiring all regulated healthcare professionals, including medical practitioners and nurses to have relevant insurance or indemnity cover for their practices, including aesthetic practices, to provide patients with redress after adverse clinical incidents.⁶¹ It has also considered extending the remit of the Parliamentary and Health Service Ombudsman, which is responsible for investigating complaints against services provided by NHS and other public organizations, to cover services provided in the private medical sector, including aesthetic procedures.⁶² GMC will consider including a consent process in the code of ethical practice for aesthetic surgery to ensure that the person undergoing the procedure and the medical practitioner concerned have a shared understanding of the desired outcome, limitations and risks of the procedure.

⁶⁰ The Office of Fair Trading was responsible for protecting consumer interests in the UK. It was closed in April 2014, with its responsibilities being passed to a number of different organizations.

⁶¹ Prior to the new legislation, some healthcare professionals such as self-employed nurses are not subject to mandatory requirement to have insurance or indemnity cover for their practices.

⁶² At present, patients do not have access to an independent ombudsman service for complaints against private healthcare services. Instead, they may complain to the service providers concerned or the regulators of the healthcare professionals concerned.

6.6.3 In addition, a new set of guidance note on the marketing of aesthetic practices for the Advertising Codes has been published to address issues of concern highlighted in the Review Report, including responsible advertising claims and sales promotion. The Advertising Codes guide advertising practices in the UK which are regulated by the Advertising Standards Authority.⁶³

⁶³ The Advertising Standards Authority is an independent authority responsible for regulating non-broadcast advertising under a self-regulatory system, and regulating broadcast advertising under a co-regulatory system with the involvement of Ofcom, the statutory regulator of the communications sector.

Chapter 7 – Analysis

7.1 Introduction

7.1.1 Based on the findings in the previous chapters, this chapter analyzes the regulatory framework of aesthetic practices in Florida of the US, South Korea, Singapore and the UK against that of Hong Kong in terms of (a) classification of and competency requirements for performing aesthetic procedures, (b) regulation of cosmetic-related medical devices, (c) regulation of the beauty sector in performing aesthetic procedures, (d) regulation of ambulatory facilities in which aesthetic procedures are performed, and (e) protection of persons undergoing aesthetic procedures. A summary table comparing the salient features of the regulatory framework in the places studied is provided in **Appendix VI**.

7.2 Classification of and competency requirements for performing aesthetic procedures

Classification of aesthetic procedures

7.2.1 All the places studied have defined the types of aesthetic procedures to be performed by medical practitioners. The inherent risk level and/or invasiveness level are the common criteria adopted in these places for classifying aesthetic procedures. Apart from the above criteria, Singapore has taken a step further by requiring that procedures which are supported by low or very low level of scientific evidence should be performed on justifiable grounds only. In the European Standard for Aesthetic Surgery Services, factors taken into consideration when classifying the procedures into Category 1, (i.e. non-surgical procedures undertaken with/without anaesthesia), Category 2 (i.e. minor minimally invasive procedures) and Category 3 (i.e. major surgical procedures) include the required anaesthesia level and facilities in which aesthetic procedures are performed.

7.2.2 Among the places studied, Hong Kong, Florida, Singapore and the UK do not preclude non-medical practitioners such as beauticians from performing certain types of non-invasive or non-surgical aesthetic procedures. Only South Korea requires all aesthetic procedures, including tattooing and ear piercing⁶⁴, to be performed by medical practitioners. While the findings thus far have not shown any consistent link between the risk and complaints associated with non-invasive or non-surgical aesthetic procedures performed by medical practitioners or those performed by non-medical practitioners, there are reported adverse incidents in the places studied associated with invasive aesthetic procedures. Some of these incidents had caused death or serious injury, which were believed to be attributable to the lack of relevant training of medical practitioners, inadequate equipment or inadequate facilities. Hence, there are calls for strengthening the regulatory regime and introducing corrective measures.

Competency requirements for performing aesthetic procedures

7.2.3 The level of required competency and qualifications of medical practitioners for performing aesthetic procedures vary among the places studied. Singapore has developed detailed guidelines on aesthetic practices for medical practitioners. The guidelines specify the competency requirements for performing each aesthetic procedure and the appropriate premises at which the procedure may be performed. Under the guidelines, some invasive procedures have to be performed by relevant medical specialists such as plastic surgeons and dermatologists. In fact, similar competency requirements are suggested in the European Standard for Aesthetic Surgery Services which specifies that medical practitioners performing procedures in Category 2 and Category 3 must have appropriate aesthetic surgery training.

7.2.4 There is also a requirement in Florida that surgical procedures, including aesthetic procedures, must be performed by medical practitioners who have the appropriate training and skills. The related requirements on medical practitioners in Hong Kong, South Korea and the UK have yet been set. However, it is noted that the UK is revamping the regulatory regime for aesthetic practices and is developing accredited training standards for practitioners performing surgical and non-surgical aesthetic procedures, in response to the

⁶⁴ While both tattooing and ear piercing are considered as medical practices in South Korea, there are news reports about the provision of such services by non-medical practitioners.

recommendations of the Review Report. The adverse incidents in recent years in South Korea and the high participation of non-specialized medical practitioners in aesthetic practices have prompted public calls for the establishment of competency requirements for aesthetic procedures in respect of the training and specialty of medical practitioners. Seemingly, there is a tendency towards setting out the competency requirements for medical practitioners performing surgical aesthetic procedures in the overseas places studied.

7.3 Regulation of the use of cosmetic-related medical devices

7.3.1 All the overseas places studied have put in place a regulatory regime for the manufacture, import and distribution of medical devices including those commonly used for aesthetic procedures. The use of certain cosmetic-related medical devices such as high-power lasers are also subject to registration/licensing requirements in most of the overseas places studied.

7.3.2 The control over the operation of cosmetic-related medical devices is seen to be the most stringent in Singapore as compared with the other overseas places studied. In Singapore, a licence is needed for the use of cosmetic high-power lasers. To be eligible for a licence, the applicant should obtain the necessary training on laser safety. For example, for Class 4 lasers which are commonly used in plastic surgery, a licence will only be granted to registered medical practitioners or dentists. In Florida, the use of high-power laser devices is considered a practice of medicine, and hence the use of such devices should be confined to medical practitioners or some other healthcare practitioners under the supervision of a medical practitioner. For example, the law provides that electrologists with the relevant training and certification of competence may perform hair removal treatment using high-power lasers under the supervision of a medical practitioner.

7.3.3 The control on the use of cosmetic lasers in the UK is less rigorous than the other overseas places studied. In the UK, only the facilities in which surgical laser treatments are provided are required to register with CQC, the regulator of health and adult care service providers. For those offering non-surgical laser or IPL treatments, there are no uniform registration requirements at the national level but some local authorities may require the operators to hold a special treatment licence. In response to the recommendations of the Review Report, the UK government is considering imposing more control on non-surgical

aesthetic procedures by requiring them to be performed under the prescription and supervision of clinical professionals. Meanwhile, it is proposed that non-healthcare personnel performing non-surgical procedures be properly trained.

7.3.4 The above findings show that the operators of cosmetic-related medical devices, particularly high-power lasers, in the overseas places studied must be either medical practitioners or those who possess accredited knowledge and skills. Hong Kong has yet a regulatory framework for medical devices but it is noted that the Government will soon commission a consultancy study to assess the types of cosmetic-related medical devices to be put under control and determine the competencies and qualifications required for operating such devices.

7.4 Regulation of the beauty sector in performing aesthetic procedures

7.4.1 Among the places studied, only South Korea and Florida regulate the beauty sector through a dedicated licensing scheme. South Korea requires all aesthetic procedures to be performed by medical practitioners. The beauty sector can only perform basic skin care or beauty treatments without the use of any medical device or medicine. Under the licensing scheme implemented in Florida, cosmetologists are required to meet the training requirements set by the licensing authority, the Board of Cosmetology, and pass the licensing examination prior to practising. Yet, cosmetologists are allowed to perform some non-invasive aesthetic treatments only.

7.4.2 In contrast, there is no specific regulation governing aesthetic procedures performed by the beauty sector in Singapore. Except for the operation of high-power lasers, no mandatory training requirements are set for the performance of non-invasive procedures. The situation of Hong Kong is somewhat similar to Singapore in that there are no mandated qualifications required of beauticians. The Ministry of Health of Singapore indicated in 2008 that it did not regulate aesthetic practices in the beauty sector as most of the products used by beauticians were not intended for medical purpose. Nevertheless, the beauty sector itself is looking for ways to improve its services. As a means to enhance public confidence, the Spa & Wellness Association of Singapore, a trade association representing the related businesses, is developing a voluntary online registry to share with the public the qualifications and experience of its member beauticians.

7.4.3 Compared with Hong Kong and other places studied, the beauty sector in the UK can perform a wider range of non-surgical aesthetic procedures including Botox injection and laser treatments. While no mandatory training is required of beauticians at present, the UK government is currently developing appropriate accredited qualifications for practitioners performing non-surgical aesthetic procedures as well as considering the need to require the performance of these procedures by non-healthcare practitioners be supervised by qualified clinical professionals. The underlying principle of the qualifications framework is to enable the related non-healthcare practitioners to be equipped with the necessary knowledge and qualifications to safely deliver non-surgical aesthetic procedures.

7.4.4 In short, it is observed that practitioners in the beauty sector, particularly those subject to a statutory licensing scheme such as Florida and South Korea or a voluntary accreditation programme such as Singapore, are only allowed to perform a limited range of aesthetic procedures or related services. It is also observed that most overseas places studied have developed or will develop accredited training standards for practitioners in the sector to raise the quality of aesthetic services provided and instil public confidence.

7.5 Regulation of ambulatory facilities in which aesthetic procedures are performed

7.5.1 All the overseas places studied have imposed statutory requirements on the safety standards of ambulatory facilities in which medical and/or aesthetic procedures are performed. In Hong Kong, there are concerns about the lack of statutory control on the safety standards of private medical clinics and beauty treatment centres where high-risk aesthetic procedures may be performed. The Government is planning to revamp the regulatory regime for private healthcare facilities, including ambulatory facilities in which high-risk aesthetic procedures are performed, to safeguard public health.

7.5.2 Florida and Singapore have introduced regulatory control on various types of ambulatory facilities in which medical and/or aesthetic procedures are performed. In Florida, the premises allowed for performing aesthetic procedures, e.g. ambulatory surgical centres, electrology facilities and cosmetology salons, are subject to regulation under the respective licensing or registration systems. These facilities are required to meet the specified

standards on safety, infection control and sanitary conditions. Singapore has laid down in the guidelines for aesthetic practices the appropriate facilities in which the various types of aesthetic procedures are performed. In addition, all medical clinics in Singapore are required to have functional and effective equipment including those for resuscitation and emergency use.

7.5.3 It is noteworthy that both Florida and Singapore have introduced stringent control on ambulatory facilities in which liposuction procedures are performed. There are statutory requirements on the competence of medical practitioners, adequacy of equipment and supplies, and staffing support. Moreover, in Singapore, medical clinics that intend to engage in liposuction practice must first apply for approval from the Ministry of Health to become ambulatory surgical centres and then seek additional approval to engage in liposuction practice. Licensed medical practitioners should also obtain approval from the Ministry prior to engaging in liposuction practice.

7.5.4 Medical clinics in South Korea are not mandated to put in place medical equipment to deal with emergencies arising from aesthetic procedures. There is also no clear regulation requiring anaesthesia work to be performed by anaesthetists at medical clinics. In fact, these inadequacies are believed to be the possible causes of the adverse incidents in the past few years in the country which have prompted the public to call for corrective measures.

7.5.5 In short, the safety standards of ambulatory facilities in which invasive aesthetic procedures are performed are recognized as important in protecting the health and safety of the persons undergoing those procedures. Of particular concerns are standards on anaesthesia work, equipment and supplies for handling emergencies, and the competence of the practitioners in dealing with emergencies.

7.6 Protection of persons undergoing aesthetic procedures

7.6.1 All the places studied have put in place legislation or guidelines to protect the public from misleading medical-related advertising and/or unfair trade practices of businesses including aesthetic service providers. The respective consumer protection agency or regulators of practitioners in the medical and/or beauty sectors in these places also receive and resolve consumer complaints, including those related to aesthetic practices. Some places have further introduced or planned to introduce specific mechanisms or measures to enhance protection of the public.

Advertising

7.6.2 Heavy advertising and promotion offers are seen as factors prompting people to take up aesthetic procedures without seriously considering the risks and outcome involved. There have been calls for regulating irresponsible advertising and promotion practices related to aesthetic procedures to protect the interests of the public. For example, South Korea has recently introduced new regulations to restrict aesthetic-related advertisements on public transportation and in areas close to schools. Education booklets about the negative effects associated with cosmetic surgery have also been distributed by the Ministry of Education to students. In the UK, the Review Report recommends prohibiting undesirable promotion practices such as time-limited deals and financial inducement. In response to the recommendation, the responsible authority in the UK has published a new set of guidance note on the marketing of aesthetic practices to guide the relevant advertising practices.

Information disclosure

7.6.3 Clear information disclosure is an integral part of protection for persons undergoing aesthetic procedures. In this regard, Singapore is at the forefront among the places studied. It has put in place the requirements that medical clinics should adequately provide information to persons undergoing liposuction procedures about the inherent risk and possible complications and obtain a written consent from them prior to the performance of the procedures. Furthermore, persons undergoing liposuction procedures should be given an opportunity to provide written feedback after the procedures. Meanwhile, for the procedures that are low evidence in nature, medical practitioners have a duty to ensure that the persons undergoing the procedures are aware of the low-evidence in nature and obtain a specific written consent from them before performing the procedure.

7.6.4 In South Korea, the reported side-effects of aesthetic procedures and adverse incidents have also invited calls for a mandatory process of information disclosure. As part of the revamp, the UK is currently considering measures to enhance public access to independent and evidence-based information about the potential risks and outcome of aesthetic procedures, and the need to stipulate a requirement to obtain informed consent from the clients before performing surgical aesthetic procedures.

Cooling-off period

7.6.5 There are suggestions that Hong Kong should mandate the provision of cooling-off period by service providers to allow persons wishing to undergo aesthetic procedures to think twice. It is noted that Singapore is the only place studied in this research that has introduced a mandatory cooling-off period of seven days for persons undergoing liposuction procedures. On the beauty sector front, CaseTrust, the accreditation arm of CASE, administers a voluntary accreditation programme in Singapore to accredit beauty, spa and massage businesses with good business practices. Under the programme, accredited businesses have to provide a cooling-off period of at least five working days to allow clients to seek refund of payments made if they do not wish to proceed with the service package.

Redress system

7.6.6 A distinctive feature of the redress system in South Korea is the mediation mechanism put in place to resolve medical disputes including those relating to aesthetic procedures. Persons seeking remedies for medical malpractice can lodge their disputes to the Korea Medical Dispute Mediation and Arbitration Agency, the mediation organization established by the nation in 2012. If the medical practitioner concerned agrees to participate in the mediation, the Agency claims that it is able to make a legally binding decision within 90 days. This provides a more timely resolution of medical disputes as compared with the traditional litigation process.

Overview of the regulatory framework of aesthetic practices in Sweden

A.I.1 According to Statistics Sweden, the number of establishments that might engage in aesthetic practices, including clinics with plastic surgery practice, dental clinics and beauty salons, was estimated to be about 4 552 in 2011. According to a survey among 167 establishments which had performed aesthetic procedures in 2011, about 63 850 procedures were performed, of which 62.8% were performed in clinics with plastic surgery practice or dental clinics and 37.2% were performed in beauty salons.

A.I.2 At present, there is no specific regulatory regime governing aesthetic practice in Sweden. Existing legislation that regulates the practice of medical professionals, and the standards of medical services and facilities does not apply to aesthetic practices as they are not considered as medical practices. There are no specific qualifications and competency requirements for practitioners in the medical and beauty sectors to perform aesthetic procedures except for some laser or IPL treatments.

A.I.3 Sweden basically follows the EU directives with regard to the regulation of the manufacture, marketing and distribution of medical devices, including cosmetic-related medical devices. With regard to use control on laser and IPL devices, there are requirements for treatments on or around the eyes using Class 3B or 4 laser devices or IPL devices to be performed under the responsibility of licensed medical practitioners. Owners and operators of laser and IPL devices are required under the radiation safety legislation to be familiar with the operation of the devices and the risks involved, and take the necessary precautions to prevent or combat damage. However, training requirements on the use of those devices are not specified.

A.I.4 According to the same survey mentioned in A.I.1, among providers of aesthetic procedures, 59% of clinics with plastic surgery practice, 39% of dental clinics and 22% of beauty salons had received complaints from their clients in 2011. Some of these providers had paid financial compensation to the clients concerned in resolving the complaints. The regulator of healthcare service providers does not handle complaints from persons suffering from injury induced by aesthetic procedures, as aesthetic practices are not within its regulatory scope. Nevertheless, compensation may be sought from the service providers who may

have patient insurance cover (for medical professionals) and/or liability insurance cover, or it may be sought in accordance with the terms of the service agreement or under the tort law.

A.I.5 In June 2012, the National Board of Health and Welfare⁶⁵ published a review report on the regulation of aesthetic practices in Sweden. The report indicated that the safety of persons undergoing aesthetic procedures, which might be risky in nature, was not adequately protected under the current regulatory regime. The report further suggested strengthening regulatory control on aesthetic practices to enhance protection of public interests.

A.I.6 In response to the report, the National Board of Health and Welfare proposed in 2013 changes to the current regulatory regime. These changes included: (a) aesthetic procedures involving surgery, injections and penetration of the skin should be regarded as medical practices and be regulated under the healthcare laws; (b) high-risk aesthetic procedures should be performed by licensed healthcare practitioners such as medical practitioners with plastic surgery expertise; (c) persons suffering from injuries due to undergoing aesthetic procedures could seek redress through the regulatory authority supervising healthcare service providers and get compensation through the patient insurance cover of the providers; and (d) banning aesthetic procedures aiming at improving the appearance of children or adolescents under 18 years old.

A.I.7 The Swedish government considers that further investigation is required before it would proceed to introduce legislative changes to the regulatory regime on aesthetic practices. It commissioned in April 2014 a consultancy study to determine the legislative changes and other measures required to strengthen safety and protection of persons undergoing aesthetic procedures. The consultancy study aims at determining, among other things: (a) aesthetic procedures which may be required to be performed by medical professionals; (b) information to be provided to and forms of consent to be obtained from persons undergoing aesthetic procedures; (c) whether a specific insurance scheme should be introduced to cover injuries induced by aesthetic procedures; and (d) whether an age limit is required to be set for certain aesthetic procedures. The consultancy study is expected to be completed by November 2015.

⁶⁵ The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs responsible for duties such as collecting and analyzing information related to health and social care and developing standards and guidelines related to health and medical services.

**Categorization of aesthetic procedures with potential safety concerns
by the Working Group on Differentiation between
Medical Procedures and Beauty Services in Hong Kong**

Procedure	Performed by medical practitioners/ dentists	Deliberate within the regulatory framework for medical devices
I. Procedures involving skin puncture		
(a) Dermal filler injection	✓	
(b) Botulinum toxin A injection	✓	
(c) Autologous platelet-rich plasma	✓	
(d) Autologous cellular therapy	✓	
(e) Cryo-crystalised Growth Factor	✓	
(f) Skin whitening injection	✓	
(g) Injection lipolysis	✓	
(h) Mesotherapy	✓	
(i) Microneedle therapy		✓
(j) Tattooing	Exempted	
(k) Body piercing	Exempted	
II. Procedures involving mechanical/chemical exfoliation of the skin below the epidermis		
(a) Microdermabrasion	✓	
(b) Chemical peel	✓	
(c) JETPEEL	✓	
(d) Water microjet plus vacuum	✓	
III. Procedures involving external application of energy		
(a) Laser (Class 3B and 4)		✓
(b) Radiofrequency		✓
(c) Intense pulsed light		✓
(d) Extracorporeal shock wave		✓
(e) Ultrasound for lipolysis (high intensity focused ultrasound and nonthermal ultrasound)		✓

**Categorization of aesthetic procedures with potential safety concerns
by the Working Group on Differentiation between
Medical Procedures and Beauty Services in Hong Kong**

Procedure	Performed by medical practitioners/ dentists	Deliberate within the regulatory framework for medical devices
III. Procedures involving external application of energy (cont'd)		
(f) Cryolipolysis		✓
(g) High voltage pulsed current		✓
(h) Plasma		✓
(i) Lighting emitting diode phototherapy		✓
(j) Infrared light		✓
(k) Micro-current therapy		✓
(l) Cryoelectrophoresis		✓
(m) Electroporation/ Iontophoresis		✓
(n) Pulsed magnetic field therapy		✓
(o) Microwave application		✓
IV. Other procedures that may pose safety concerns		
(a) Colon hydrotherapy		✓
(b) Hyperbaric oxygen therapy	✓	
(c) Jet injector	✓	
(d) Dental bleaching	✓	
(e) Suction massage ⁽¹⁾	Not required	

Note: (1) The risk involved in this procedure is considered to be relatively low. This is not a medical treatment if not performed together with other energy applications such as light energy or radiofrequency.

Source: Food and Health Bureau and Department of Health (2014).

**Equipment and supplies required for medical practitioners' offices
where surgeries are performed in Florida of the US**

Equipment and supplies required for medical practitioners' offices where Level II and Level III surgical procedures are conducted⁽¹⁾

- (a) Full and current crash cart at the location where anaesthesia work is being carried out with the inclusion of specified resuscitative medications;
- (b) a Benzodiazepine must be stocked, but not on the crash cart;
- (c) positive pressure ventilation device (e.g. Ambu) plus oxygen supply;
- (d) end tidal CO₂ detection device;
- (e) monitors for blood pressure/EKG/Oxygen saturation;
- (f) emergency intubation equipment including suction devices, endotracheal tubes, laryngoscopes;
- (g) defibrillator or an Automated External Defibrillator unit;
- (h) emergency power source able to produce adequate power to run required equipment for a minimum of two hours;
- (i) appropriate sterilization equipment; and
- (j) intravenous solution and equipment.

Note: (1) Level II procedures involve the use of peri-operative medication and sedation intravenously, intramuscularly or rectally, thus making intra and post-operative monitoring necessary. Level III procedures involve the use of a general anaesthesia or major conduction anaesthesia and pre-operative sedation.

**Equipment and supplies required for medical practitioners' offices
where surgeries are performed in Florida of the US**

Additional requirements for medical practitioners' offices where Level III surgical procedures are conducted

- (a) Equipment, medication, including at least 36 ampules of dantrolene on site, and monitored post-anesthesia recovery must be available in the office;
- (b) the office, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical centre, including, but not limited to, recovery capability;
- (c) pulse oximeter, precordial or esophageal stethoscope, and a temperature monitoring device; and
- (d) a table capable of trendelenburg and other positions necessary to facilitate the surgical procedure.

Source: Florida Department of Health (2014c).

**List A and List B procedures under the
Guidelines on Aesthetic Practices for Doctors in Singapore**

Types of treatment and procedure in List A	Minimum level of competence required⁽¹⁾	Appropriate premises at which procedure can be done	Requisite no. of procedures performed⁽²⁾
Non-invasive			
(a) Chemical or pressurized gas/liquid peels	MBBS ⁽³⁾ (COC) ⁽⁴⁾	Clinic ⁽⁵⁾	30
(b) Microdermabrasion	MBBS (COC)	Clinic	30
(c) Intense pulsed light (IPL)	MBBS (COC)	Clinic	30
(d) Radiofrequency, Infrared and other light-based devices e.g. for skin tightening or hair removal	MBBS (COC)	Clinic	30
(e) Lasers (non-ablative) for hair removal	MBBS (COC)	Clinic	30
(f) Photodynamic/ photopneumatic therapy	MBBS (COC)	Clinic	30
(g) External lipolysis (heat/ultrasound)	MBBS (COC)	Clinic	30
Minimally invasive			
(a) Botulinum toxin injection	MBBS (COC)	Clinic	30
(b) Filler injection	Plastic surgeon, MBBS (COC)	Clinic	30
(c) Phlebectomy	Plastic surgeon, General/vascular surgeon	OT ⁽⁶⁾	20

Appendix IV (cont'd)

**List A and List B procedures under the
Guidelines on Aesthetic Practices for Doctors in Singapore**

Types of treatment and procedure in List A	Minimum level of competence required	Appropriate premises at which procedure can be done	Requisite no. of procedures performed
Minimally invasive (cont'd)			
(d) Sclerotherapy	Plastic surgeon/ Dermatologist, MBBS (COC)	OT/Clinic	20
(e) Thread lifts	Plastic surgeon, MBBS (COC)	OT/Clinic	20
(f) Lasers for <ul style="list-style-type: none"> • treating vascular lesions and skin pigmentation • skin rejuvenation (e.g. fractional lasers) 	MBBS (COC)	OT/Clinic	30
Invasive			
(a) Abdominoplasty	Plastic surgeon/ General surgeon/ Gynaecologist (COC)	OT	10
(b) Blepharoplasty (including double eyelid)	Plastic surgeon/ Ophthalmologist trained in oculoplastic surgery	OT/Clinic	20
(c) Breast enhancement or reduction	Plastic surgeon	OT	10
(d) Brow lift	Plastic surgeon	OT	10
(e) Free fat grafting	Plastic surgeon/ Dermatologist, MBBS (COC)	OT/Clinic	10

Appendix IV (cont'd)

List A and List B procedures under the *Guidelines on Aesthetic Practices for Doctors in Singapore*

Types of treatment and procedure in List A	Minimum level of competence required	Appropriate premises at which procedure can be done	Requisite no. of procedures performed
Invasive (cont'd)			
(f) Hair transplantation	Plastic surgeon/ Dermatologist, MBBS (COC)	OT/Clinic	10
(g) Implants (excluding breast implants)	Plastic surgeon	OT/Clinic	10
(h) Lasers (ablative e.g. CO ₂ /YAG) for skin resurfacing	MBBS (COC)	OT/Clinic	20
(i) Liposuction (traditional/water assisted/VASER/ laser)	As per Ministry of Health special licensing conditions for liposuction	As per Ministry of Health special licensing conditions for liposuction	N.A.
(j) Rhinoplasty	Plastic surgeon/ENT (ear, nose, throat) surgeon	OT/Clinic	10
(k) Rhytidectomy (facelift)	Plastic surgeon	OT	10
(l) Dermabrasion (mechanical)	Plastic surgeon/ Dermatologist, MBBS (COC)	OT/Clinic	10

- Notes: (1) Minimum level of competence means competence necessary to carry out the procedure and manage the anticipated serious complications.
- (2) Medical practitioners must have fulfilled the requisite numbers during 1 October 2006 to 30 September 2008.
- (3) MBBS stands for bachelor of medicine and bachelor of surgery.
- (4) COC refers to Certificate of Competence achieved through attending accredited specialized courses in the respective area of interest, approved and recognized by the Singapore Medical Council.
- (5) Clinic refers to clinics with appropriate facilities and staff. This means that the clinic must be equipped and staffed to a level commensurate with the procedure performed.
- (6) OT refers to operating theatres in hospitals and ambulatory surgery centres.

**List A and List B procedures under the
*Guidelines on Aesthetic Practices for Doctors in Singapore***

List B procedures

- (a) Mesotherapy;
- (b) Carboxytherapy;
- (c) Microneedling dermaroller;
- (d) Skin whitening injections;
- (e) Stem cell activator protein for skin rejuvenation;
- (f) Negative pressure procedures (e.g. Vacustyler); and
- (g) Mechanised massage (e.g. "slidestyler", "endermologie" for cellulite treatment).

Source: Ministry of Health (2008).

Equipment and supplies required for medical clinics in Singapore

Equipment and resuscitation facilities

Medical clinics should, among others, meet the following requirements:

- (a) adequate sterilization of surgical instruments used for invasive procedures after each use by means of steam autoclaving (alternatively, sterile disposable sets are used);
- (b) post anaesthesia monitoring facilities at the recovery area;
- (c) resuscitation facilities for emergencies and adverse reactions to any form of treatment provided, e.g. resuscitative drugs which include Injection Adrenaline, Injection Hydrocortisone, or their equivalent; and
- (d) possessing means to set up an intravenous infusion (including intravenous drip sets, intravenous cannulas and intravenous infusion solutions); and maintenance of a clear airway (including air-viva and airways of various sizes).

Source: Ministry of Health (undated).

Equipment and supplies required for medical clinics in Singapore

Further requirements for liposuction procedure

- (a) Possession of necessary facilities including proper operating table or procedure couch, lighting, ventilation, suction, resuscitation and monitoring equipment including pulse oximetry and any other special equipment in the procedure room or operating theatre;
- (b) possession of emergency lighting, water and power supply in the procedure room or operating theatre;
- (c) continued monitoring of patients after liposuction procedure with respect to their vital signs (including level of consciousness, pulse rate, respiratory rate, oxygen saturation, blood pressure and temperature) for a period commensurate with the sedation and/or anaesthesia given and the procedure performed;
- (d) possession of a patient's couch and necessary resuscitative equipment such as oxygen apparatus, suction, pulse oximetry and other monitoring facilities in the recovery area; and
- (e) adequate resuscitative and monitoring facilities including the requirement of defibrillator to deal with any emergencies or complications arising from the liposuction procedure.

Source: Ministry of Health (2014b).

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Background information					
Population	• 7.2 million as at end-2013.	• 19.6 million in 2013 (6.2% of the total population in the US).	• 51.2 million as at April 2014.	• 5.4 million as at June 2013.	• 64.1 million as at mid-2013.
Number of registered/ licensed medical practitioners and relevant specialists	• 13 006 general practitioners, 84 specialists in dermatology and venereology and 53 specialists in plastic surgery as at December 2012.	• 48 852 medical practitioners as at December 2012, of which 867 were dermatologists and 613 plastic surgeons.	• 107 221 medical practitioners as at December 2012, of which 1 994 were dermatologists and 1 851 plastic surgeons.	• 11 433 medical practitioners as at December 2013, of which 100 were dermatologists and 55 plastic surgeons.	• 233 373 medical practitioners as at July 2014.
Number of beauty service providers and practitioners	• 9 935 establishments and 39 151 practitioners as at March 2014.	• 212 650 licensed cosmetologists in the 2012-2013 financial year.	• Information not available.	• Information not available.	• About 80 000 beauticians.
Number of aesthetic procedures conducted	• Information not available.	• Estimated to be over 11 million of which 16.5% were surgical procedures and 83.5% were non-surgical procedures in 2013 (for the US in total).	• About 650 000 procedures performed by board-certified plastic surgeons in 2011.	• Information not available.	• About 211 406 procedures performed by board-certified plastic surgeons in 2011.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Background information (cont'd)					
Revenue generated from aesthetic practices	<ul style="list-style-type: none"> Information not available. 	<ul style="list-style-type: none"> Estimated to be about US\$12 billion (HK\$93.1 billion) in 2013 (for the US in total). 	<ul style="list-style-type: none"> About 267 billion Korean won (HK\$1.9 billion) in plastic surgery industry in 2013. 	<ul style="list-style-type: none"> Estimated to be S\$200 million (HK\$1.24 billion) a year. 	<ul style="list-style-type: none"> £2.3 billion (HK\$27.6 billion) in 2010.
Regulatory authorities of aesthetic practices	<ul style="list-style-type: none"> DH; Customs and Excise Department; and the respective statutory councils regulating medical professionals. 	<ul style="list-style-type: none"> FDOH; FDBPR; and the respective professional boards such as FBOM and the Board of Cosmetology. 	<ul style="list-style-type: none"> Ministry of Health and Welfare. 	<ul style="list-style-type: none"> Ministry of Health; and the respective statutory councils regulating medical professionals. 	<ul style="list-style-type: none"> DH-UK; CQC; the respective statutory councils regulating healthcare professionals; and the local authorities.
Classification of aesthetic procedures					
Classification of aesthetic procedures	<ul style="list-style-type: none"> Specifying certain procedures to be medical procedures and regulating them under the self-regulatory regime of medical professionals. 	<ul style="list-style-type: none"> Specifying certain aesthetic procedures to be medical practices and regulating them under the regulatory framework of respective groups of medical and healthcare professionals. 	<ul style="list-style-type: none"> Specifying aesthetic procedures to be medical practices and regulating them under the regulatory framework of the medical professionals. 	<ul style="list-style-type: none"> Specifying aesthetic procedures that are (a) non-invasive, (b) minimally invasive, (c) invasive, and (d) supported by low or very low scientific evidence; and regulating them by way of guidelines for self-regulation of medical practitioners. 	<ul style="list-style-type: none"> Procedures are generally classified into surgical and non-surgical procedures.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Classification of aesthetic procedures (cont'd)					
Procedures specified to be medical practices or allowed to be performed by medical and/or healthcare professionals only	<ul style="list-style-type: none"> Aesthetic procedures such as those involving injections and mechanical/chemical exfoliation of the skin below the epidermis, hyperbaric oxygen therapy, and dental bleaching. 	<ul style="list-style-type: none"> Most aesthetic procedures including surgical procedures, and procedures involving injections and usage of IPL and high-power laser devices. Some procedures e.g. injections or laser treatments can be performed by healthcare practitioners under the supervision of medical practitioners. 	<ul style="list-style-type: none"> Aesthetic procedures involving skin puncture (including tattooing and ear piercing) and those requiring the use of medical devices. 	<ul style="list-style-type: none"> Minimally invasive and invasive procedures, as well as procedures supported by low or very low level of scientific evidence. 	<ul style="list-style-type: none"> Surgical procedures.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Classification of aesthetic procedures (cont'd)					
Requirement for medical practitioners to be registered/board-certified specialists e.g. plastic surgeon to perform aesthetic procedures	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> Yes. Certain invasive procedures such as breast enhancement and facelift have to be performed by plastic surgeons. 	<ul style="list-style-type: none"> No. The UK government is considering the need to impose a requirement that only medical practitioners on a GMC specialist register can perform aesthetic surgery and these medical practitioners should work within the scope of their specialty training.
Requirement for medical practitioners to have relevant training to perform aesthetic procedures	<ul style="list-style-type: none"> No specific requirement on the competency or experience of the medical practitioners in performing specific aesthetic procedures. 	<ul style="list-style-type: none"> Medical practitioners performing surgical procedures are required to have the appropriate training and skills. 	<ul style="list-style-type: none"> No specific requirement on the competency or experience of the medical practitioners in performing specific aesthetic procedures. 	<ul style="list-style-type: none"> There are specific requirements on the competency of medical practitioners performing List A aesthetic procedures. 	<ul style="list-style-type: none"> Medical practitioners are required to have surgery training to perform surgical procedures. Accredited training standards for practitioners performing surgical and non-surgical procedures are under development in response to the recommendations of the Review Report.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Regulation of the beauty sector in performing aesthetic procedures					
Aesthetic procedures may be/ allowed to be performed by beauticians	<ul style="list-style-type: none"> Procedures not specified as medical procedures e.g. body tattooing and those involving the use of cosmetic-related medical devices. 	<ul style="list-style-type: none"> Some non-invasive procedures not specified as medical practices such as chemical peels and microdermabrasion. 	<ul style="list-style-type: none"> Beauticians are not allowed to take part in aesthetic practices. They can only perform conventional skin care treatments. 	<ul style="list-style-type: none"> Non-invasive procedures such as chemical peels and laser hair removal treatments. 	<ul style="list-style-type: none"> Non-surgical procedures e.g. Botox injections, chemical peels and laser treatments.
Any dedicated regime for regulating the beauty sector	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> Yes. Cosmetologists are regulated under a licensing system administered by the Board of Cosmetology. 	<ul style="list-style-type: none"> Yes. Business owners and beauticians are required to be licensed by the local government. 	<ul style="list-style-type: none"> No licence is required unless the beauty treatment centre provides specified services such as spa or massage services. 	<ul style="list-style-type: none"> No dedicated regime at the national level.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Regulation of the beauty sector in performing aesthetic procedures (cont'd)					
Training requirements/ accreditation framework relating to aesthetic procedures	<ul style="list-style-type: none"> No mandatory framework for accrediting qualifications of beauticians. Voluntary trade test is organized for certifying the competence level of IPL device operators. 	<ul style="list-style-type: none"> Cosmetologists are required to attend at least 1 200 hours of training and pass the licensing examination in order to obtain a licence. The Board of Cosmetology has set minimum competency requirements for broad areas of cosmetology practice but not on specific aesthetic procedures. 	<ul style="list-style-type: none"> Both business owners and beauticians shall obtain the required training or qualifications in order to obtain a licence. 	<ul style="list-style-type: none"> No mandatory framework for training or accrediting qualifications of beauticians. 	<ul style="list-style-type: none"> No mandatory framework for accrediting qualifications of beauticians for performing aesthetic procedures. A qualifications framework for prescribers and providers of non-surgical aesthetic procedures is under development in response to the Review Report.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Regulation of the use of cosmetic-related medical devices					
Licensing/ registration requirement for use of cosmetic-related medical devices e.g. high-power lasers and IPL devices	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> Medical or healthcare practitioners are allowed to operate the devices under their professional licences and the related delegation arrangements. 	<ul style="list-style-type: none"> Information is not available, pending the advice of the Ministry of Food and Drug Safety. 	<ul style="list-style-type: none"> Operators of high-power laser devices are required to obtain a licence from the National Environment Agency. 	<ul style="list-style-type: none"> Facilities providing surgical laser treatments are required to register with CQC. Some local authorities may require providers and operators of non-surgical laser and IPL treatments to acquire a special treatment licence.
Training requirements for use of cosmetic-related medical devices	<ul style="list-style-type: none"> No mandatory training requirements are set. 	<ul style="list-style-type: none"> Mandatory training requirement is set for electrologists who can perform laser hair removal treatments under the on-site supervision of a medical practitioner. 	<ul style="list-style-type: none"> Information is not available, pending the advice of the Ministry of Food and Drug Safety. 	<ul style="list-style-type: none"> Obtaining the relevant training or qualification is required in order to obtain a licence to operate high-power laser devices. 	<ul style="list-style-type: none"> Some local authorities may set training requirements on users under the licensing system. The UK government is considering requiring non-surgical procedures, including laser and IPL treatments, to be prescribed and supervised by clinical professionals. The qualifications framework for prescribers and providers of the procedures is under development.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Regulation of the use of cosmetic-related medical devices (cont'd)					
Whether beauticians can perform aesthetic procedures using cosmetic-related medical devices e.g. high-power lasers and IPL devices	• Yes.	• No.	• No.	• Yes.	• Yes.
Whether beauticians can perform aesthetic procedures using cosmetic-related medical devices independently	• Yes.	• No.	• No.	• Yes.	• Yes. However, the UK government is considering requiring the performance of laser and IPL treatments to be supervised by clinical professionals.
Mandatory requirement for beauticians to have relevant training for using cosmetic-related medical devices	• No.	• Not relevant.	• Not relevant.	• Yes.	• Some local authorities may set training requirements under the licensing system.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Regulation of ambulatory facilities in which aesthetic procedures are performed					
Regulatory framework	<ul style="list-style-type: none"> The existing legislation governing private healthcare facilities mainly cover private hospitals and non-profit-making medical clinics. The Government is planning to revamp the regulatory framework for private healthcare facilities to cover ambulatory facilities in which high-risk aesthetic procedures are performed. 	<ul style="list-style-type: none"> Except for some medical spas, most types of ambulatory facilities are regulated under the respective registration or licensing systems. The facilities concerned are required to comply with a set of mandatory standards which may include services, staffing, equipment and supplies, and safety and sanitary conditions. 	<ul style="list-style-type: none"> Medical clinics shall comply with the general facility standards and safety requirements prescribed by the Ministry of Health and Welfare. However, there are no specific requirements on equipment for dealing with emergencies and anaesthesia work. 	<ul style="list-style-type: none"> Medical clinics should have in place functional and effective facilities and equipment for medical and surgical purpose, and maintain resuscitation facilities for emergency use. Clinics should be equipped and staffed to a level commensurate with the procedure performed. 	<ul style="list-style-type: none"> Facilities providing surgical aesthetic procedures are regulated by CQC. In response to the Review Report, CQC will review the existing inspection scheme and assessment criteria used. Facilities providing certain non-surgical aesthetic procedures e.g. laser treatments may be subject to regulatory control of the local authorities. The qualifications framework for service providers which is under development may cover relevant topics to ensure their safety standards.
Requirements on personnel performing anaesthesia for surgical procedures in medical clinics	<ul style="list-style-type: none"> No mandatory requirements are set. 	<ul style="list-style-type: none"> Specified types of anaesthesia such as peri-operative medication and sedation, and general anaesthesia must be assisted or administered by an anaesthetist, or a qualified nurse or physician assistant. 	<ul style="list-style-type: none"> No mandatory requirements are set. 	<ul style="list-style-type: none"> Specified types of anaesthesia such as general anaesthesia must be performed by an anaesthetist, or a medical practitioner or a dentist under the supervision of an anaesthetist. 	<ul style="list-style-type: none"> No mandatory requirements are set.

Salient features of the regulatory framework of aesthetic practices in selected places

	Hong Kong	Florida of the United States	South Korea	Singapore	The United Kingdom
Protection of persons undergoing aesthetic procedures					
Specific mechanisms/ measures to enhance protection of persons undergoing aesthetic procedures	<ul style="list-style-type: none"> Raising public awareness on the risks associated with aesthetic procedures through various media channels; and screening of advertisements related to aesthetic procedures to detect if there is any suspected breach of the relevant legislation. 	<ul style="list-style-type: none"> Mainly putting in place general protection or redress mechanisms, such as the complaint mechanisms set by the respective regulatory authorities to handle complaints against malpractice of licensed practitioners in the medical and beauty sectors. 	<ul style="list-style-type: none"> Imposing restrictions on aesthetic-related advertisements in public transportation and in areas close to schools; issuing booklets to educate students about the negative effects of and unhealthy obsession with cosmetic surgery; and having established the Korea Medical Dispute Mediation and Arbitration Agency for resolving medical disputes, including those relating to aesthetic procedures. 	<ul style="list-style-type: none"> Prohibiting medical doctors from advertising on procedures supported by low level of scientific evidence; mandating the provision of cooling-off period and information disclosure to persons undergoing liposuction procedures, and requiring written consent from them; and requiring medical practitioners to obtain written consent from persons undergoing procedures that are supported by low level of scientific evidence. 	<ul style="list-style-type: none"> The relevant authorities have been working on the recommendations of the Review Report to provide evidence-based information to persons undergoing aesthetic procedures, and to include a consent process in the future code of ethical practice for aesthetic surgery; and the guidance note for the Advertising Codes has been updated to address issues related to the advertising and promotion of aesthetic practices.

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