Proposed research outline

Regulation of aesthetic practices in selected places

1. Background

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. The incident has aroused public concerns over the need for the Government to tighten up regulation of the beauty sector and provide a clear definition to differentiate beauty services from medical procedures.

1.2 In November 2012, the Government set up a working group, 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[1]") to differentiate high-risk medical procedures from low-risk, non-invasive beauty services, and make recommendations on procedures that should be performed by registered medical practitioners.

1.3 In November 2013, the Steering Committee endorsed the report submitted by the Working Group which recommends, among other things, (a) that procedures involving injections or the mechanical/chemical exfoliation of the skin below the epidermis and hyperbaric oxygen therapy should be performed by registered medical practitioners; and (b) that dental bleaching should be performed by registered dentists in view of the inherent risks of the procedure. The Steering Committee also noted that the Working Group supported the Government's plan to implement control over the use of energy-emitting medical devices such as laser devices through legislation.

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

1.4 In response to the above, the Government has implemented the recommendations put forward by the Working Group through issuing an advisory note to beauty service providers reminding them to refrain from those procedures that should only be performed by registered medical practitioners or registered dentists. It has also sent letters to all medical practitioners reminding them to strictly observe the Code of Professional Conduct issued by the Medical Council of Hong Kong when they provide cosmetic procedures in their medical practice. In addition, the Government will report on the way forward for the regulation of medical devices at the meeting to be held by the Panel on Health Services ("the Panel") on 16 June 2014.

1.5 The Panel has discussed the regulation of medical beauty treatments/procedures at four meetings since October 2012. During these meetings, members expressed their concerns over issues including differentiation between medical procedures and beauty services; regulation of cosmetic-related medical devices and private healthcare facilities for conducting high-risk medical procedures; regulation of the beauty sector in conducting medical aesthetic procedures; and measures to enhance safety of beauty services. To facilitate the discussion of the issue at future meetings, the Panel requested the Research Office to conduct a research on the regulation of aesthetic practices in overseas places at its meeting held on 28 April 2014. The scope of study should cover, among other things, the regulation of the provision of aesthetic procedures by the beauty sector which includes the qualification requirements and accreditation framework governing the practitioners involved in the operation of cosmetic-related medical devices.

2. Proposed places to be studied

2.1 The Research Office has conducted a preliminary study on the regulation of aesthetic practices in Singapore, Taiwan, the United States ("US"), the United Kingdom ("UK"), Australia and Canada. It is observed that these places adopt different approaches in regulating aesthetic practices, particularly imposing different levels of regulatory control on the beauty sector in performing aesthetic practices. Taiwan and many US states (e.g. Florida)[2] are governed by the most stringent regulatory framework which requires the performance of most of the aesthetic procedures by medical practitioners or by health practitioner(s) under the supervision of a medical practitioner.

[2] In the US, each state has developed its own regulatory framework regulating beauty service providers and the use of cosmetic-related medical devices for aesthetic procedures.

2.2 In contrast, Singapore as well as some Australian states and Canadian provinces allow the beauty sector to perform some non-surgical, non-invasive aesthetic procedures such as laser hair removal, while requiring higher-risk, invasive medical aesthetic procedures to be performed by medical practitioners. The UK has adopted a relatively less stringent regulatory approach under which the beauty sector can perform a wider range of non-surgical aesthetic procedures which include botulinum toxin (commonly known as "Botox") and dermal filler injections. Hong Kong is similar to the above places as some aesthetic procedures can be performed by both medical practitioners and beauty therapists.

2.3 The Research Office proposes to study Florida of the US, Singapore and the UK to capture the different regulatory approaches that have been adopted for regulating the medical and beauty sectors in conducting aesthetic practices. The salient features of their regulatory framework also warrant the inclusion of these places in the research study.

2.4 In Florida, medical aesthetic procedures are required to be performed by medical practitioners or health practitioners such as nurses under the supervision of a medical practitioner. In Singapore, all invasive and minimally invasive aesthetic procedures such as Botox injections and lasers for skin rejuvenation must be performed by medical practitioners. The beauty sector is allowed to provide some non-invasive aesthetic procedures such as laser hair removal. The UK has recently completed a review of its regulatory framework on medical aesthetic procedures and embarked on improving its framework to better protect the safety and interests of consumers.

Florida of the United States

2.5 In Florida, invasive aesthetic procedures are performed by medical practitioners, while minimally invasive and non-invasive aesthetic procedures (such as laser hair removal and Botox injection) can be performed by health practitioners (e.g. nurses) under the supervision of a medical practitioner. Among the non-invasive procedures, laser hair removal can also be performed by licensed electrologists (i.e. health practitioners specializing in hair removal treatments) who have completed the required training and obtained certification in the use of laser device for hair removal. They are allowed to perform laser hair removal under the supervision of a medical practitioner. The Florida Board of Medicine, which is responsible for the registration and regulation of medical practitioners, has specified the delegation arrangements for performing specific types of aesthetic procedures by different categories of health practitioners.

Singapore

2.6 In Singapore, all invasive and minimally invasive procedures, such as Botox injections and lasers for skin rejuvenation, must be performed by medical practitioners who are required to register with the Singapore Medical Council ("SMC").[3] For better professional self-regulation of aesthetic practices, the Academy of Medicine Singapore[4], the College of Family Physicians Singapore[5] and SMC jointly implemented the Guidelines on Aesthetic Practices for Doctors ("the Guidelines") on 1 November 2008. Medical practitioners who perform any aesthetic procedures not in accordance with the Guidelines may be liable for disciplinary action by SMC.

2.7 The beauty sector, which is allowed to provide non-invasive aesthetic procedures such as laser hair removal, is not governed by the Guidelines. Instead, the *Penal Code* applies to regulate the beauty service providers and the beauty therapists who could be sued for negligence in a civil suit. Besides, operators of high-power medical lasers[6] are required to hold a licence and have training and special knowledge on the safe use of lasers.

The United Kingdom

2.8 In the UK, surgical aesthetic procedures must be conducted in regulated clinical settings by qualified medical practitioners regulated by the General Medical Council. On the other hand, non-surgical procedures, such as Botox and dermal filler injections, chemical skin peels and laser treatments, can be performed by both medical and non-medical practitioners in clinics or beauty treatment centres. However, there is a lack of mandatory standards regulating the provision of these procedures by non-medical practitioners.

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[3] SMC is responsible for regulating the professional conduct and ethics of registered medical practitioners in Singapore.

[4] The Academy of Medicine Singapore was founded in 1957 as a professional institution of medical and dental specialists.

[5] The College of Family Physicians Singapore was formed in 1971 by a group of family physicians in Singapore to promote the values and ideals of family medicine.

[6] High-power medical laser devices refer to Class 3B and Class 4 medical laser devices. A licence to use Class 4 medical laser devices may be granted only to registered medical practitioners and registered dentists.

2.9 In 2012, the outbreak of the breast implant incident[7] prompted the UK Department of Health to conduct a review on the regulation of aesthetic procedures, as a response to public concerns about the safety of these procedures. A review report was published in April 2013, containing 40 recommendations to enhance the regulation of aesthetic procedures. These recommendations focus on three key areas, namely (a) providing high quality care with safe products, skilled practitioners and responsible providers; (b) ensuring that consumers can get accurate advice on aesthetic procedures and the vulnerable are protected; and (c) establishing accessible redress and resolution system in case things go wrong.

2.10 In February 2013, 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 overall standards of aesthetic procedures. These steps include (a) improving standards for surgical aesthetic procedures; (b) improving training for providers of some non-surgical aesthetic procedures; (c) strengthening the involvement of medical professionals in non-surgical aesthetic procedures; and (d) extending the remit of the Health Service Ombudsman to cover patients who receive inadequate medical aesthetic procedures.

3. Proposed research outline

3.1 The Research Office proposes the following outline for the research:

Chapter 1 – Introduction

Chapter 2 – Hong Kong

Chapter 3 – Florida of the United States

Chapter 4 – Singapore

Chapter 5 – the United Kingdom

Chapter 6 – Analysis

[7] In 2010, the silicone breast implants supplied by a French company, Poly Implant Prothese ("PIP"), were reported to have quality problems. The incident has aroused concerns about the safety and well-being of women who have used PIP products.

3.2 Chapter 1 depicts the background, scope and methodology of the research.

3.3 Chapters 2 to 5 examine the regulation of aesthetic practices in selected overseas places and Hong Kong in terms of the following areas:

(a) overview of aesthetic practices, including classification of aesthetic procedures and practitioners involved in performing the procedures;

(b) regulation of the medical and beauty sectors in conducting aesthetic procedures;

(c) regulation of the use of cosmetic-related medical devices;

(d) regulation of healthcare facilities for providing aesthetic procedures; and

(e) review of the regulatory framework (if any).

3.4 Based on the findings in Chapters 2-5, Chapter 6 compares the salient features of the regulatory framework of aesthetic practices in the places studied and highlights the major observations of the research.

4. Proposed completion date

4.1 The Research Office proposes to complete the research in September 2014.

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