For Discussion on
16 January 2017

LC Paper No. CB(2)545/16-17(01)

Legislative Council Panel on Health Services

Proposed Regulatory Framework for Medical Devices

PURPOSE

This paper briefs Members on the results of the consultancy study on the control of use of selected medical devices and the latest legislative proposal on regulation of medical devices.

BACKGROUND

2. The Administration presented an information paper (LC Paper No. CB(2)1754/13-14(04)) and briefed the Legislative Council Panel on Health Services ("the Panel") on 16 June 2014 regarding the proposed regulatory framework for medical devices, which had taken into account the regulatory and business impacts of the proposed regulatory regime on the trade. As indicated in the above paper, there is currently no specific legislation to regulate the manufacture, import, distribution, sale or use of medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionising radiation[1]. There is a need to develop a regulatory framework for medical devices to protect public health while ensuring our community's continued access to the benefits of new technologies. To this end, a voluntary Medical Device Administrative Control System ("MDACS") has been established by the Department of Health ("DH") since 2004 to pave the way for implementing the long-term statutory control. Having examined and evaluated the regulatory and business impacts of the various options for the statutory regulatory regime for medical devices, the Government indicated that the proposed regulatory regime for medical devices would adopt a risk-based approach whereby the level of control would be proportionate to the degree of risk classified for medical devices according to the recommended classification scheme of the International Medical Device Regulators Forum ("IMDRF") (previously known as Global Harmonization Task Force ("GHTF")).

[1] Devices which contain pharmaceutical products or emit ionising radiation are respectively regulated under the Pharmacy and Poisons Ordinance (Cap. 138) and the Radiation Ordinance (Cap. 303).

3. The proposed statutory regulatory regime would comprise three main areas –

(a) pre-market control – to ensure medical devices conform with the requirements on safety, quality, performance, and efficacy before allowing them to be placed on the market;

(b) post-market control – to enable swift control measures against defective or unsafe medical devices; and

(c) use control – to restrict the use of certain high-risk medical devices.

After briefing the Panel on 16 June 2014, the Government has further developed the details of the pre-market control and post-market control of the regulatory regime for medical devices. Moreover, the Government commissioned an external consultant, namely the Emergency Care Research Institute ("the Consultant"), in September 2015 to conduct an in-depth study regarding the control of use in Hong Kong of 20 types of selected medical devices (at **Annex I**) which have been used for cosmetic purposes ("the Study"). Further details of the Study and an update on the latest proposal regarding the regulatory regime for medical devices taking into account the recommendations of the Study are set out below.

THE STUDY

Background

4. Following the adverse incident in October 2012 involving a beauty centre inappropriately offering high-risk medical procedures, the Government established the Working Group on Differentiation between Medical Procedures and Beauty Services under the Steering Committee on Review of Regulation of Private Healthcare Facilities ("the Working Group") to examine and identify cosmetic procedures that should be classified as medical treatment and performed by registered medical practitioners/registered dentists. Among others, the Working Group examined the safety and health risks of devices commonly used for cosmetic purposes, e.g. high-power medical lasers, intense pulsed light ("IPL") equipment and radio frequency devices, etc. The Working Group considered that given the heterogeneity of the devices involved, a more detailed study should be conducted to examine overseas experience and practices and the scope of control on the use of these medical devices. Against this background, the DH thus commissioned the Consultant to conduct the Study from September 2015 to September 2016 during which the Consultant assessed local trends and took into account international

regulatory approaches with the aim of delineating the associated risks in the use of 20 types of selected medical devices for cosmetic purposes and proposing recommendations for the regulatory approach to control the use of the selected medical devices in Hong Kong.

Methodology

5. The Study was divided into two phases, namely Discovery Phase and Analysis Phase. During the Discovery Phase, the Consultant performed extensive information searches on the selected devices, including their uses for cosmetic purposes, associated adverse incidents reported in literature and to regulatory authorities, and complaints made to Consumer Council ; as well as the practices and regulations on the use of the selected medical devices in five major economies, including Australia, the Mainland China, Singapore, the United Kingdom ("UK") and the United States of America ("US"). The Consultant also conducted a multifaceted assessment on the market situation of Hong Kong. In order to gauge local stakeholders' views, the Consultant conducted a total of 38 site visits and interviews (i.e. 14 from beauty sector, 13 from medical sector and 11 from medical device trade sector); and a survey inviting feedback from some 60 additional industry stakeholders through questionnaires and public forums (a total of 32 questionnaires responses received and 27 forum participants). At the Analysis Phase, the Consultant pieced together its expertise in medical device operation and information/findings collected in the Discovery Phase to develop overall and device-specific recommendations over the use control. The Executive Summary of the Final Report of the Study prepared by the Consultant is at **Annex II**. Key findings of the Study are summarised in the ensuing section.

Key findings

Market situation of Hong Kong

6. The three groups of stakeholders (medical sector, beauty sector and medical device supplier sector) unanimously supported the development of mandatory standards and qualifications to control the use of selected medical devices in Hong Kong. They also agreed the need for a risk-based and device-specific regulatory approach to ensure that operators of the selected medical devices possess the appropriate qualifications. The medical sector considered that operators of the selected medical devices should be able to make appropriate clinical judgements during treatment for the safety of the consumers whereas the beauty sector reiterated that cosmetic procedures were non-invasive and posed no serious harm to consumers.

International practices and regulations

7. After having studied the practices and regulations on the use of medical devices for cosmetic purposes among the five major economies (please refer to **Annex III** for more details), the Study has concluded that there is no uniform and full-fledged regulatory approach among them. Even for those that have some use-related regulations, they are either on the stringent side in restricting the use of most medical devices for cosmetic purposes to medical practitioners or physician assistants/registered nurses under supervision of medical practitioners (e.g. the US and the Mainland China) or on the very loose side with little or no qualification requirements (i.e. Singapore and the UK).

Recommendations

8. Having regard to local stakeholders' views and international practices and regulations, the Consultant has developed a use control assessment framework for the purpose of determining the use control for medical devices in Hong Kong. The proposed use control assessment framework comprises (a) a selection process for determining whether or not a medical device used for cosmetic purposes should be subject to use control assessment; (b) classification of use control categories; and (c) a three-pronged use control assessment.

Selection of medical devices to be assessed for the need of use control

9. To be included in the use control assessment framework, a medical device should be defined as an "active" device (i.e. source of power other than human power or gravity) or an "invasive" device that penetrates inside the body, either through the surface of the body or a natural orifice ; and be used for cosmetic purposes[2]. Moreover, it should only focus on non-home-use medical devices and be assessed at a sub-classification level, if one exists. This will also form the basis of whether a new-to-the-market medical device should be included in the use control assessment framework in the future.

Use control categories

10. The Consultant has further proposed the following four categories to specify the qualification requirement of the users for medical devices classified into that specific category –

- Category I: User must be a registered healthcare professional

[2] Cosmetic purposes comprise skin resurfacing, hair removal or restoration, body contouring, metabolism improvement, weight reduction and general wellness treatment.

("HCP").

- Category II: User must be a registered HCP or a person supervised by a registered HCP on site.
- Category III: User meets the requirements of either Category I or II, or has completed device-specific training through training programme recognised by the Government
- Category IV: No user restriction

Three-pronged use control assessment

11. To determine the appropriate use control category for a non-home-use medical device which is either active or invasive and used for cosmetic proposes, the Consultant has devised a three-pronged assessment approach whereby separate assessments respectively on clinical risk, regulatory, as well as knowledge and skills would be conducted. The most stringent category of use designation from the three assessments determines which use control category should be designated to the device. With the increase in multi-modality medical devices emerged globally and in Hong Kong, the Consultant has suggested that a use control category based on the modality with the highest use control rating be adopted for the sake of safeguarding public health. More details of the three-pronged use control assessments are set out in paragraphs 12 to 14 below.

(i) Clinical risk assessment

12. The Consultant has recommended four levels of clinical risk for medical devices, namely *"Extreme"*, *"High"*, *"Medium"* and *"Low"* being determined by a proposed Clinical Risk Matrix which has taken into account a combination of factors including potential harms from adverse events, complications or missed contraindications, and the probability of the harms occurring. A medical device which has been rated as "*Extreme*" clinical risk according to the above Matrix will be classified under use control Category I, whereas a medical device rated as "*Low*" clinical risk will be classified as use control Category IV.

(ii) Regulatory assessment

13. Regulatory requirements, such as the use of prescriptive local anaesthetic for particularly painful procedures, may exist for the use of some of the selected medical devices. Use control Category I will be assigned if a medical device is subject to certain regulations that require its use by a registered HCP, and use control Category II will be assigned if supervision of a registered HCP is required. Category IV will be given if the use of the medical device does not involve any such requirements.

(iii) Knowledge and skills assessment

14. As the stakeholders concerned have agreed to adopt a risk-based and device-specific regulatory approach to ensure that operators of the selected medical devices possess the appropriate qualifications, the Consultant proposed a list of guidance questions (at **Annex IV**) to assess the level of knowledge and skills required for proper and safe operation of a medical device. The questions touch on the level of competency required for proper pre-treatment consultation, treatment planning and performance of the procedure. The highest level of knowledge and skills required for the operation of a medical device will render this device classified under use control Category II, whereas the lowest level of knowledge and skills required will render the medical device concerned classified under use control Category IV.

Device-specific control recommendations

15. Based on the proposed use control assessment framework, the Consultant has assessed the clinical risk, regulatory as well as knowledge and skills requirements for the 20 types of selected medical devices and recommended use control categories for these devices. A summary of these assessments is provided in **Annex V**. With device sub-classifications included, seven types of medical devices have been assessed as use control Category II; ten types of medical devices have been assessed as use control Category III; and eight types of medical devices have been assessed as use control Category IV. No medical device researched in the Study requires that the user must be a registered HCP. However, the Consultant has recommended that a user, regardless of his/her background, of a medical device should receive basic training regarding the proper and safe operation of the medical device concerned provided by its manufacturers / suppliers / authorised persons of the manufacturers.

Public Registry of Recognised Training Programmes

16. The Consultant has also recommended that the Government, for the purpose of implementing the use control regime for the selected types of medical devices, should publish a list of recognised training programmes which offer recognised training for operating specified types of medical device. The published list will on one hand facilitate a service provider who wishes to operate the selected medical devices to obtain the necessary training, and on the other hand will provide handy reference for consumers to verify the qualifications of service providers.

LATEST PROPOSED REGULATORY FRAMEWORK

17. Taking into account the need to ensure safety of all medical devices and the recommendations made by the Consultant on the use control for selected medical devices, the Government is now in the process of finalising the regulatory framework for medical devices. As mentioned in paragraph 2 above, a risk-based approach is adopted whereby the level of control will be proportional to the degree of risk associated with the medical devices according to IMDRF's recommended classification rules. The latest proposed regulatory framework largely follows the previous proposal reported to the Panel in June 2014 (please refer to paragraph 3 above), and the latest details are set out in the following paragraphs.

Pre-market control

18. Pre-market control is levied on two dimensions, viz, the medical devices and the traders that introduce the medical devices into the local market. It also includes other ancillary issues such as labelling and advertisement associated with the medical devices.

Registration of medical devices

19. Following the risk-based approach, the Government will not impose registration requirement on Class I general medical devices / Class A in vitro diagnostic medical devices ("IVDMDs") due the low risk posed (the different classification of medical devices is set out at **Annex VI**). For Class II-IV general medical devices and Class B-D IVDMDs, they are required to be registered with the DH before they can be supplied to the market. Registration of a medical device will be granted for a period of three years, and can be renewed every three years. Moreover, a registered medical device can only be supplied for the purpose(s) as approved by the DH.

20. Without compromising public health, the proposed regulatory framework will allow the supply of unregistered medical devices under special circumstances and must be with prior approval granted by the DH as required. Examples of special circumstances include the medical devices are supplied for the purpose of clinical trial; for non-clinical purpose like exhibition; on a named-patient due to special needs; or under public health emergencies.

Registration and licensing of traders

21. Traders including authorised representatives ("ARs"), local manufacturers, importers and distributors of medical devices must be registered with or have obtained a licence from the DH before they can

supply medical devices in Hong Kong, regardless of whether the medical devices concerned are subject to registration requirement. They will be subject to respective registration requirements or licensing conditions, which include holding a valid business registration certificate; maintaining a recognised quality management system for the supply of medical devices; and fulfilling any criteria as specified by the DH. They are also required to maintain a list of medical devices supplied by them in the local market and provide to DH upon request, as well as comply with the post-market requirements.

22. Local manufacturers will be required to conform to Quality Management System ("QMS") certification requirements. Having considered that ARs, importers and distributors are largely small and medium enterprises ("SMEs"), the Government plans to introduce a set of essential requirements for QMS for them to adhere to. The Government will further provide assistance to the traders (especially the SMEs) with support packages to fulfil the essential requirements. It is anticipated that the compliance cost can be substantially reduced by using this approach.

23. In line with the validity period of medical device registration (see paragraph 19 above), the validity period of all trader registrations will be aligned to three years, which can also be renewed every three years.

Recognition of conformity assessment bodies ("CABs")

24. The proposed legislation will empower the DH to recognise CABs to perform conformity assessment on medical devices, as well as to provide third party conformity assessment services to traders. DH will monitor the performance of the recognised CABs regularly.

Import / export control

25. As reported to the Panel in 2014, in view of the concerns about the amount of administrative work involved, and the overall lead-time required for importing products, especially for fast moving consumer goods, the Government proposes not to introduce any import / export licensing control for medical devices.

Appeal mechanism

26. An appeal board with members comprising representatives from the medical devices industry, medical associations, engineering institutions and academic institutes appointed by the Secretary for Food and Health ("SFH") would be set up to handle appeals relating to registration of medical devices, licence issuance and CAB recognition.

Labelling requirements and control over advertisements

27. To provide users with essential information for the proper and safe use of medical devices and to identify the traders which have been engaged in the supply of the medical devices concerned, medical devices will also be required to meet the corresponding labelling requirement. As for advertisement, misleading or fraudulent advertising of medical devices will be prohibited. Promotion of medical devices for use other than their approved use is also forbidden.

Post-market control

28. As the responsibility of the trader for the safety of a medical device does not end when it is put on the market, there will be a post-market surveillance system to monitor the performance of devices and reporting of problems associated with the use of devices. It is a general duty of ARs, local manufacturers, importers and distributors of medical devices, as well as suppliers of unregistered medical devices in accordance with the specified exemption conditions, to maintain records of supply and produce such records to the DH for inspection upon request. As for certain high-risk medical devices, ARs are also required to put in place a system to track these devices down to patient level or down to a level stipulated by the DH. Traders are also subject to mandatory requirements for reporting adverse incidents associated with the medical devices and investigation results, as well as implementing remedial measures to the satisfaction of the DH.

29. It should be noted that the pre-market control and post-market control outlined in paragraphs 18 to 28 above only largely apply to manufacture, import, distribution and sale of medical devices. They do not regulate the use of medical devices generally. Use control is only proposed for specific medical devices being also used for cosmetic purposes. Such control will be covered in the ensuing paragraphs.

Use control of specific medical devices

30. The Government will adopt a risk-based approach to impose use control on specific medical devices. In this regard, we will not impose use control on medical devices associated with low risk in their use. In addition, the proposed regulatory framework will not impose control on use of medical devices by the registered HCPs as their practice will be subject to the respective professional code of conduct. The proposed regulatory framework will focus on the use control on specific medical devices which are often used by persons other than registered HCPs, and the use of these devices may pose a high risk of serious injury or harm to the public if the users have not undergone proper training and acquired appropriate

qualifications. Based on the recommendations of the Study, the proposed regulatory framework will adopt the following two levels of use control –

(a) users must be supervised on site by a registered medical practitioner (similar to use control Category II of the Study) ; and
(b) users must be supervised on site by a registered medical practitioner or be a personnel who has successfully completed the relevant training programme as recognised by the Government (similar to use control Category III of the Study).

While the above use control will be imposed on specific medical devices, the proposed regulatory framework will not restrict the use of any medical devices by a registered HCP for purposes within the scope of his professional practice.

31. In future, SFH will be empowered to specify the types of medical devices which shall be subject to the proposed use control and their respective use control categories in the legislation, having regard to the public health interests. For this purpose, a statutory Advisory Committee comprises members from relevant stakeholder groups including trade associations, medical associations, engineering institutions and academic institutions will be set up to advise SFH on various implementation and administration of the future legislation. As far as use control is concerned, the use control assessment framework proposed by the Consultant will form the basis on selection of medical devices to be subject to use control and corresponding use control categories.

PROPOSED WAY FORWARD

32. The Government plans to introduce a new bill setting up the above proposed regulatory framework on medical devices into the LegCo in the latter half of 2016-17 legislative session.

ADVICE SOUGHT

33. Members are invited to note and comment on the content of this paper.

Food and Health Bureau
January 2017

Annex I

List of 20 types of selected medical devices studied

1. Laser (Class 3B and 4) device
2. Radiofrequency device
3. Intense pulsed light device
4. Extracorporeal shock wave therapy device
5. Ultrasound device for skin tightening and lipolysis (including focused ultrasound, high intensity focused ultrasound and nonthermal ultrasound)
6. Device for cryotherapy including cryolipolysis
7. Device emitting high voltage pulsed current
8. Device emitting micro-current
9. Plasma device
10. Light emitting diode device
11. Infrared device
12. Device for cryo electrophoresis
13. Device for electroporation
14. Device for iontophoresis
15. Device creating pulsed magnetic field
16. Microwave device
17. Microneedle & other device involving needle insertion
18. Colon hydrotherapy device
19. Short wave hair removing device
20. Robotic hair restoration device

Annex II

Department of Health

The Government of the Hong Kong Special Administrative Region

STUDY ON THE CONTROL OF USE OF SELECTED MEDICAL DEVICES IN HONG KONG

EXECUTIVE SUMMARY

21 September 2016

ECRI Institute
The Discipline of Science. The Integrity of Independence.

Executive Summary

1. This executive summary has been prepared by ECRI Institute for the Department of Health (DH) of the Government of the Hong Kong Special Administrative Region (the Government) for the study of the control of use in Hong Kong (HK) of 20 types of specified medical devices for cosmetic purposes.

2. The Government has commissioned the ECRI Institute (with the Hong Kong Productivity Council and ECRI Institute's Asia Pacific Regional Office as subcontractors) to better understand local and international approaches for ensuring the safe and effective operation of specified medical devices for cosmetic purposes. Medical devices extend an operator's ability to provide diagnostic or therapeutic support to a patient. In the cosmetic sector, medical devices may also be used to enhance a client's physical condition or appearance. In either case, the safe and effective application of medical devices requires a safe device, appropriate and proficient use, and an appropriate and safe environment for use. The objectives of this study include conducting an assessment of the local trends in the use of specified medical devices for cosmetic purposes; delineating the risk of the use of specified medical devices for cosmetic purposes; studying and summarising international regulatory approaches including consideration of practices of Australia, the People's Republic of China (PRC), Singapore, the United Kingdom (UK), and the United States of America (US); and proposing recommendations for a new regulatory approach to control the use of specified medical devices for cosmetic purposes in HK.

3. The methodology for this study consisted of Discovery and Analysis Phases, which included researching trends, adverse events, and regulations to build the foundation for recommendations. During the Discovery Phase of this study, the consultancy team performed extensive information searches on the practices and regulations on the use of the specified medical devices for cosmetic purpose in Australia, the PRC, Singapore, the UK, and the US, and conducted a multifaceted assessment of specified medical devices used for cosmetic purposes in the HK market. The HK market assessment provided an excellent benchmark for comparison with other researched countries, which included site visits and interviews with 38 representatives of the beauty, medical, and medical device trader sectors (total of 47 device-specific interviews), and a survey of more than 60 additional industry stakeholders through questionnaires and public forums (32 questionnaires responses received and 27 forum participants). During the Analysis Phase, the consultancy team drew heavily from its expertise in medical device operation, safety, regulation, and risk assessment, understanding of the local HK environment, and findings from the HK market assessment to develop overall and device-specific findings and recommendations.

Findings

4. The majority of the 20 types of specified medical devices researched in this study are used to perform skin resurfacing, hair removal, body contouring, and/or improved metabolism and general wellness procedures. Microwave and robotic hair restoration devices represented exceptions. Also, most of these devices were considered to be established or emerging in the HK market. Exceptions included micro-current (MENS), high voltage pulsed current (HVPC), extracorporeal shockwave therapy (ESWT) and shortwave hair removal devices that appear to be waning in popularity.

5. All five of the researched countries have medical device classification systems that are based on intended use and the level of risk posed to the client and user. Risk is categorised into three or four risk classes ranging from low to high. Furthermore, under the device classifications systems in Australia, Singapore and the UK, which are very similar, 19 types of the researched medical devices are classified as active devices (e.g., source of power other than human power or gravity); some micro-needle devices are not powered and therefore would not be considered active.

6. The HK market assessment revealed differences of opinion amongst beauty, medical and supplier stakeholders about what specific regulatory steps should be taken to control the use of specified medical devices for cosmetic purposes. A common concern from the medical sector was the ability of a medical device user to make good clinical judgements during treatment by drawing knowledge from a more formal clinical educational background. Beauty sector representatives stressed that cosmetic procedures are non-invasive and do not pose serious harm to clients. From the market assessment, strong support existed from all three stakeholder groups for the development of mandatory standards and qualifications in HK to promote professionalism and safety across the industry. Also, stakeholders uniformly stressed the need for a risk-based and device-specific regulatory approach to ensure that users have the appropriate qualifications.

7. The consultancy team's analysis found that medical device use regulations for cosmetic purposes vary broadly across the countries researched in this study. Currently, Australia, the UK, and the US do not have national regulations for medical device use for cosmetic purposes and oversight is delegated at the state/province level. For example, in the US, the states of California, Florida and New York take a common regulatory approach by broadly defining procedures that are considered medical practice. This restricts the use of most medical devices for cosmetic purposes to a medical practitioner or a healthcare professional (HCP) under a medical practitioner's supervision.

8. In general, some states in Australia and regions in the UK have broad device use regulations and/or licensing requirements. Additionally, there are no supervision requirements by law in either of these countries. Inconsistent user qualification requirements and regulation enforcement coupled with high profile client injuries and deaths have led Australia and the UK to actively investigate their regulation policies at a national level. Government reports in both these countries highlight the challenges of regulating the beauty industry. The goal of these preliminary frameworks appears to be to develop a standardised training and credentialing pathway for HCPs and non-healthcare professionals (non-HCPs) to acquire the necessary theoretical knowledge and practical skills to provide quality and safe cosmetic treatments.

Recommendations

9. The DH should establish a selection process for determining whether or not a medical device that is used for cosmetic purposes needs to have a control of use assessment. To be selected for assessment, the consultancy team recommends that a medical device should be an "active" device or an "invasive" device that penetrates inside the body, either through a body orifice or through the surface of the body for cosmetic purposes; and be indicated for non-home-use. Any skin resurfacing, hair removal or restoration, body contouring, metabolism improvement, weight reduction, or general wellness treatment should be considered cosmetic purposes.

10. The selection process should also identify and independently consider any sub-classifications of device types, when applicable. In the ultrasound device category, high-intensity focused ultrasound (HIFU) was found to be the only ultrasound type used for cosmetic purposes. For the researched medical devices, the following sub-classifications are proposed:

    - Laser: Class 3B and Class 4
    - Radiofrequency (RF): Monopolar, Bipolar and Unipolar
    - Cryotherapy: Whole Body Cryotherapy and Cryolipolysis
    - Microneedle: Microneedle >0.3 mm and ≤ 1.0 mm and Microneedle >1.0 mm and ≤ 3.0 mm*

    (*It is recommended that microneedle devices with lengths ≤0.3 mm should be excluded from the future regulatory framework for use control in view of its significantly low risk of harm.)

11. Regardless of a device user's background, basic training on performing an intended cosmetic procedure and a device's principles of operation and safety should be obtained. Most commonly this training is provided by the supplier, but could also be obtained from vocational training centres, peer proctoring, or internal beauty centre training programmes.

12. Multi-tiered use control categories are proposed for medical devices used for cosmetic purposes as follows:

    - ***Category I:*** User must be a registered HCP
    - ***Category II:*** User must be supervised by a registered HCP, or be a registered HCP
    - ***Category III:*** User meets Category I or II requirements, or has received device-specific training through a government recognised training programme
    - ***Category IV:*** No user restrictions

13. In HK, the most common registered HCP that were found to use medical devices for cosmetic purposes were medical practitioners. For medical devices that require Category I and II use controls, the consultancy team recommends that the specific registered HCPs be determined on a device-by-device basis related to the intended use. However, in most situations, a Category I or II medical device that provides cosmetic treatment will likely be performed by or supervised by a medical practitioner. Oral cosmetic treatments would be appropriate for dentist use or supervision.

14. Requirements for supervision vary internationally. Therefore, the consultancy team recommends that registered HCPs be required to be within the treatment facility for Category II use control to allow for direct intervention if a complication arises, and to provide oversight for treatment planning and post-procedure examination.

15. A framework that considers the *clinical risk, regulatory requirements, and knowledge and skills* is proposed for the control of use of non-home-used medical devices for cosmetic procedures. Under this framework, assessments and use determinations are made upon recommendations by a Government appointed Advisory Committee that is comprised of experts from all relevant stakeholder fields. Clinical risk, regulatory, and knowledge and skills assessments are conducted and each provides a category of use recommendation (e.g., Category I – IV). The most stringent category of use designation (e.g., I is more stringent than II) from the three assessments, determines the overall control of use categorisation for a device type. A detailed assessment process is outlined for each of the following three assessment areas:

    - ***Clinical Risk Assessment.*** The safe use of a medical device is predicated on mitigating preventable risks. Thus, a clinical risk level of Extreme, High, Medium or Low is determined for a medical device based on a combination of *potential harm* from adverse events, complications or missed contraindications; and the *probability* of this harm occurring. This determination is derived from a proposed Clinical Risk Matrix. Control

of use is assigned based on the clinical risk level (e.g., Extreme = Category I, High = Category II, Medium = Category III, Low = Category IV). The consultancy team's clinical risk assessment and use control category for each of the researched medical devices is provided in Table 1 below.

Table 1 Clinical Risk Levels of Medical Devices and Assigned Control of Use Category

Clinical Risk Level (Use Control Category)	**Medical Devices**
Extreme (Category I)	None
High (Category II)	Laser Class 3B, Laser Class 4, and Colon Hydrotherapy
Medium (Category III)	Cryolipolysis, HIFU, Infrared (IR), Intense pulsed light (IPL), Light-emitting diode (LED), Microwave, Microneedle (>0.3 mm and ≤ 3.0 mm), Plasma, Radiofrequency (RF; Monopolar, Bipolar, or Unipolar), Robotic Hair Restoration, and Whole Body Cryotherapy
Low (Category IV)	Cryo-electrophoresis, Electroporation, Extracorporeal shock wave therapy (ESWT), High Voltage Pulsed Current (HVPC), Iontophoresis, Micro-current electrical neuromuscular stimulation (MENS), Pulsed Electromagnetic Field (PEMF), and Short-wave Hair Removal

- ***Regulatory Assessment.*** For cosmetic treatments with some medical devices, the use of prescriptive local anaesthetic (drugs or creams) is required and is usually a universally recognised standard of practice. Thus, regulatory requirements may exist for the use of these medical devices for cosmetic purposes (e.g., use only by a prescribing authority or under the supervision of a prescribing authority), and depending upon the regulatory requirements, use control may be of Categories I and II. For example, the consultancy team's regulatory assessment identified RF-monopolar, microwave and robotic hair restoration devices as Category II use control devices. According to the above regulatory assessment, the researched medical devices have been assigned to use control Categories II or IV.

- ***Knowledge and Skills Assessment.*** Common levels of knowledge, understanding and critical thinking were consistent concerns from beauty, medical, and supplier stakeholders for discerning between simple and complex procedures. The knowledge and skills assessment is designed to assess the most reasonable category of users for the device in terms of the competency required for proper pre-treatment consultation (e.g.,

exclusion of major contraindications), treatment planning and performance of the procedure so as to prevent or minimise the risk of harm (e.g. due to missed contraindication, inappropriate treatment plan and faulty operation of device). For example, the consultancy team's knowledge and skills assessments found colon hydrotherapy, HIFU, and robotic hair restoration devices to be Category II use control devices since they require an advanced understanding of clinical sciences and pathophysiology to develop individualised treatment plans. According to the above knowledge and skills assessment, the researched medical devices have been assigned to use control Categories II, III or IV.

16. Using the proposed Control of Use framework, the consultancy team recommends control of use restrictions for the researched medical devices as outlined in Table 2 below.

Table 2 Recommended Medical Device Use Control Categories

Use Control Category	Medical Devices
I	None
II	Colon Hydrotherapy, Laser Class 3B, Laser Class 4, HIFU, Microwave, RF-Monopolar, and Robotic Hair Restoration
III	Cryolipolysis, IR, IPL, LED, Microneedle (>0.3 mm and ≤ 3.0mm), Plasma, RF-Bipolar, RF-Unipolar, and Whole body cryotherapy
IV	Cryo-electrophoresis, Electroporation, ESWT, HVPC, Iontophoresis, MENS, PEMF, and Short-wave Hair Removal

17. In addition to the use control recommendations above, the consultancy team recommends the Government to develop a voluntary Public Registry of Recognised Training Programmes. This listing would provide potential operators of specified medical devices with a central listing of training options in HK, and provide local consumers with information to verify the qualifications of service providers.

Disclaimer

This executive summary has been prepared for, and only for, the Department of Health (DH) of The Government of Hong Kong Special Administrative Region in accordance with the terms of the DH contract of 21 September 2015, and for no other purpose. We do not accept or assume any liability or duty of care for any other purpose or to any other person to whom this executive summary is shown or provided to. In addition, we do not accept or assume any liability or duty of care if modifications are made, by a third party, to the content in this executive summary. The information herein is time sensitive and may not be accurate or complete at a future date and we assume no liability for the accuracy of the information herein at a future date. This executive summary may include non-public or proprietary information about specific equipment or products that has been provided to ECRI Institute by manufacturers or other sources. This executive summary should not be transmitted to third parties without adequate disclaimers and protections. We are not responsible for any disclaimers or protections added/modified by a third party.

Annex III

Summary of regulations and practices on the use of medical devices for cosmetic purposes among the five major economies

	US	Australia	UK	Mainland China	Singapore
Applicable use-related regulations	● Use of most medical devices researched in the Study in certain states of the US (i.e. California, Florida and New York) is considered as medical practice and has been restricted to physicians and physician assistants/ registered nurses under physician's supervision	● The national government does not regulate medical devices used for cosmetic purposes ● Only some states have regulations on the use of certain medical devices (e.g. Class 3B and Class 4 lasers) for cosmetic purposes	● Majority of the selected medical devices researched in the Study can be used by both medical practitioners and non-medical practitioners ● However, the UK Department of Health carried out a review in 2012 on the regulation of cosmetic interventions	● Whenever a technology is registered as a medical device, the beauty sector is not allowed to use it for any purposes	● Device use is highly regulated in the medical sector ● Does not regulate the beauty sector except that licences for possession and operation are required when high-power lasers (Class 3B and 4) are involved

	US	Australia	UK	Mainland China	Singapore
Training and education	● Restricts the use of many medical devices to healthcare professionals ("HCPs"), and medical devices (e.g. low-level electrical stimulation devices) which can be operated by beauticians are usually controlled by strict training and certification policies	● No mandatory national training and education requirements for either the medical sector or beauty sector	● A report recently published by the Health Education England provides guidance on the level of training and clinical oversight requirements for users who perform a number of nonsurgical, cosmetic procedures	● Does not allow a beautician to use any medical devices and enforces strict training and certification policies for HCPs ● However, the Mainland China is currently revising its government-mandated vocational and certification requirements, including those for beauticians	● Strict training and certification policies for HCPs ● No mandatory training requirements for beauticians

Annex IV

List of guidance questions for knowledge and skills assessment

Use Category	Assessment Questions
II	**Level II Questions** 1. Is an advanced understanding of clinical sciences and pathophysiology required to identify or rule out a contraindication that may have a serious health consequence if missed? 2. Is an advanced understanding of clinical science and pathophysiology required to develop individualised treatment plans for the use of this device for cosmetic purposes? *If the answer is **Yes** to any Level II question, then the Knowledge and Skills Assessment level is Level II.*
III	**Level III Questions** 1. Does a user need to develop individualised treatment protocols for the use of this device for cosmetic purposes? 2. Does the user need to develop individualised post-treatment discharge and follow-up instructions for clients after the use of this device for cosmetic purposes? 3. Is training beyond that provided to users by the supplier required to prepare a user to adequately discuss potential treatment risks, including contraindications, to obtain a proper informed consent? 4. Is training beyond that provided to users by the supplier required to prepare a user to adequately screen a client for contraindications? *If the answer is Yes to any Level III question, then the Knowledge and Skills Assessment level is Level III.*

Use Category	Assessment Questions
IV	*If the answer is No to all questions above, then the Knowledge and Skills Assessment level is Level IV.*

Annex V

Summary of Recommendations for Control of Use of Selected Medical Devices

Device	Assessment			Control Of Use Recommendation
	Clinical Risk	Regulatory	Knowledge and Skills	
Laser – Class 3B device	II	IV	III	II
Laser – Class 4 device	II	IV	III	II
Radiofrequency (RF) device – monopolar	III	II	III	II
High-intensity focused ultrasound (HIFU) device	III	IV	II	II
Microwave device	III	II	III	II
Colon hydrotherapy device	II	IV	II	II
Robotic hair restoration device	III	II	II	II
RF device – bipolar	III	IV	III	III
RF device – unipolar	III	IV	III	III
Intense pulsed light (IPL) device	III	IV	III	III
Whole body cryotherapy device	III	IV	IV	III
Cryolipolysis device	III	IV	III	III
Plasma device	III	IV	III	III
Light-emitting diode (LED) device	III	IV	IV	III
Infrared (IR) device	III	IV	IV	III
Microneedle >0.3 mm and ≤1.0 mm	III	IV	IV	III
Microneedle >1.0 mm and ≤3.0 mm	III	IV	III	III
Extracorporeal shock	IV	IV	IV	IV

	Assessment			Control Of Use
wave therapy (ESWT) device				
Device emitting high-voltage pulsed current (HVPC)	IV	IV	IV	IV
Micro-current electrical neuromuscular stimulation (MENS) device	IV	IV	IV	IV
Device for cryo electrophoresis	IV	IV	IV	IV
Device for electroporation	IV	IV	IV	IV
Device for iontophoresis	IV	IV	IV	IV
Device creating pulsed electromagnetic field (PEMF)	IV	IV	IV	IV
Shortwave hair removing device	IV	IV	IV	IV

Annex VI

Classification of medical devices

1. According to the rules of the Global Harmonization Task Force, general medical devices are classified into four classes based on their risks (e.g. invasiveness, length of retention in body, location of implant, etc.). Examples of respective classes of medical devices are shown as follows –

Class	Risk Level	Examples
I	Low	Tongue depressor, bandage, dressing, walking aid
II	Medium - Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator, acupuncture needle, corrective contact lens
III	Medium - High	External defibrillator, lung ventilator, contact lens disinfectant, orthopaedic implant, laser
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter

2. For *in vitro* diagnostic medical devices (IVDMDs), they are also classified into four classes according to another set of classification rules with respect to their risks to individual user and the public as follows –

Class	Risk Level	Examples
A	Low individual risk, Low public health risk	Clinical chemistry analyser, prepared selective culture media
B	Medium individual risk, Low public health risk	Pregnancy self-testing, anti-nuclear antibody, urine test strips
C	High individual risk, Medium public health risk	Blood glucose self testing, HLA typing, PSA screening, rubella

Class	Risk Level	Examples
D	High individual risk, High public health risk	HIV blood donor screening, HIV blood diagnostic