

**For Information  
on 16 June 2014**

**Legislative Council Panel on Health Services  
Proposed Regulatory Framework for Medical Devices**

**Purpose**

This paper briefs Members on the latest development of the proposed regulatory framework for medical devices.

**Background**

2. The term “medical devices” generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It covers devices that are used for the purpose of investigation, replacement, modification or support of the anatomy or physiological process of the human body. These range from simple devices like hot/cold pads to sophisticated devices like implantable defibrillator and high power laser machines. Devices used for examination of human specimens are also included under the term.

3. Currently, there is no specific legislation to regulate the import, distribution, sale or use of medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionising radiation<sup>1</sup>. 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. It will also help bring Hong Kong in line with the medical device regulations adopted by other major jurisdictions and raise industrial standards. To this end, the Department of Health (DH) has made reference to the definition of “medical device” as recommended by the Global Harmonization Task Force (GHTF) (now the International Medical Device Regulators Forum (IMDRF)) (Annex I) and established a **voluntary** Medical Device Administrative Control System (MDACS) to raise public awareness of the importance of medical device safety pending the establishment of a long-term statutory control system.

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<sup>1</sup> 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).

4. To prepare for the establishment of a statutory regulatory framework, the Administration examined and evaluated the various options for the statutory regulation of medical devices and assessed the likely regulatory impact of each option. In November 2010, the Administration briefed the Legislative Council (LegCo) Panel on Health Services (the Panel) on the proposed statutory regulatory framework together with the assessment of the regulatory impact on the industry. As requested by the Business Facilitation Advisory Committee, the Administration subsequently conducted another study between 2011 and 2013 to further assess the business impact of the proposed statutory regulatory regime on the trade.

### **Study on the Impact on the Trade**

5. The Administration's study aimed at examining and evaluating the impact of the proposed regulation on the trade, especially on local small and medium-sized enterprises (SMEs). Representatives from 51 stakeholder organisations were interviewed, covering relevant trade associations, manufacturers, importers, distributors, retailers from local medical devices industry, as well as the beauty and optical industry; government departments and other relevant organisations.

6. The Executive Summary of the business impact study is at Annex II. In gist, stakeholders interviewed are supportive of the proposed statutory regulation of medical devices, as the safety and quality of medical devices placed on the market will be ensured through regulation, bringing health benefits to consumers and local community. It will also reduce patients' risk of complications and injuries caused by medical device shortcomings. This may be translated to broader economic benefits in terms of reduced/avoided morbidity and even mortality rates and improved productivity. It will also help bring Hong Kong in line with the medical device regulations adopted by other major jurisdictions and raise industrial standards. The status of local medical device industry will also be upgraded and new job opportunities in regulatory affairs will be created.

7. While traders are in general supportive of the proposed statutory regulation of medical devices, some have also raised concerns on the expected increase in operational costs arising from the statutory obligation to comply with the new legislative requirements.

## **Proposed Regulatory Framework**

8. The proposed regulatory framework is modelled largely on the recommendations made by relevant international organisations, e.g. GHTF and World Health Organization (WHO)<sup>2</sup>. In sum, a risk-based approach is adopted whereby the level of control will be proportional to the degree of risk classified for medical devices according to GHTF's recommended classification scheme.

9. The proposed statutory regulatory regime comprises three main areas: (i) pre-market control – to ensure medical devices conform with the requirements on safety, performance, and quality before allowing them to be placed on the market; (ii) post-market control – to enable swift control measures against defective or unsafe medical devices; and (iii) use control – to restrict the possession and use of certain high-risk medical devices. The DH will be responsible for the administration and enforcement of the statutory regulatory regime.

10. Having considered the findings and recommendations of the study, views of stakeholders, experience of the voluntary MDACS, and relevant international practices, the Administration has refined its proposed regulatory framework for medical devices. Due consideration has been given to safeguard public health on the one hand and avoid overburdening the industry with excessive administrative work and compliance costs on the other hand. The proposed regulatory framework is now set out in ensuing paragraphs.

### ***(I) Pre-market control***

11. The pre-market control is levied on two dimensions, viz, the product and the party that introduces the product into the local market.

#### *Registration of medical devices*

12. The Administration will continue to impose registration requirement for medical devices and in vitro diagnostic medical devices (IVDMDs) with risk levels of Class II or above and Class B or above respectively (the different classification of medical devices is set out at Annex III).

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<sup>2</sup> In 2003, the WHO issued a booklet entitled "Medical Device Regulations: Global Overview and Guiding Principles" providing guidance for different countries in setting up or modifying their regulatory systems for medical devices.

Registration of a medical device will be granted for a period of 3 years, and can be renewed every 3 years. Exemptions will be granted to the supply of unregistered medical devices under certain special circumstances, such as clinical research, on a named-patient due to special needs, or under public health emergencies.

13. The Administration originally proposed to require authorised representatives (ARs) to notify the DH of all Class I medical devices that they intend to supply in Hong Kong. In view of the low risk posed and huge volume of Class I medical devices involved (e.g. bandages, dressings and surgical masks), it might not be cost-effective to impose such requirement. The Administration has revised the proposed regulatory framework by exempting Class I medical devices from registration or notification. Nevertheless, traders of Class I medical devices will still be required to register with the DH (see paragraph 14 below) and maintain a list of Class I medical devices supplied by them in the local market and to provide the list to the DH upon request. In addition, they must fulfil certain requirements, including compliance with product recall notices and record keeping requirements.

#### *Registration of traders*

14. The original proposal of the Administration has required traders who place medical devices on the local market, including local manufacturers, ARs, importers and distributors, to register with the DH and meet the registration requirements stipulated by the DH.

15. Local manufacturers, which are normally large operations, will be required to conform to Quality Management System (QMS) certification requirements. Having considered that ARs, importers and distributors are largely SMEs, the Administration proposes to introduce a set of essential requirements for QMS. The Administration will 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 alternative approach.

16. In line with the validity period of medical device registration (see paragraph 12 above), the validity period of all trader registrations will be aligned to 3 years, which can be renewed every 3 years.

### *Registration of conformity assessment bodies (CABs)*

17. The Administration maintains that the proposed legislation should empower the DH to designate CABs to perform conformity assessment audits on medical devices. CABs provide third party conformity assessment services to traders. This proposal is in line with the global trend. The CABs will be required to register with the DH so that their performance can be periodically monitored.

### *Import / export control*

18. The original regulatory proposal included an import / export licensing system, which aimed at monitoring the supply of medical devices in the local market and tracing imports of unregistered medical devices. However, considering that Hong Kong is a major hub for re-exports of medical devices<sup>2</sup>, the above import / export licensing system may not be cost-effective as majority of the medical devices imported will be re-exported, instead of being sold / used in Hong Kong. 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 Administration now proposes not to introduce any import / export licensing control at this stage.

### *Appeal mechanism*

19. As the Administration originally proposed, an appeal board with members from external parties such as trade associations, medical associations, engineering institutions and academic institutes appointed by the Secretary for Food and Health would be set up to handle appeal cases relating to registration.

### *Control over advertisements*

20. Misleading or fraudulent advertising of medical devices will be prohibited. The promotion of medical devices for use other than their approved use will also be forbidden. Supply for off-label use of a medical device by any person, except by a registered healthcare professional, shall be deemed supplying an unregistered medical device and liable for an offence.

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<sup>2</sup> Imports of medical devices amounted to some HK\$ 10.6 billion, of which HK\$10.06 billion (95%) were re-exports in 2010.

***(II) Post-market control***

21. The DH will establish a post-market surveillance system to monitor the safety, performance and quality of medical devices in the local market, as well as maintain vigilance on medical devices safety alerts issued by overseas authorities and follow-up as appropriate. Both local manufacturers and ARs are required to have in place a tracking system that tracks certain high-risk devices. In addition, it will be a mandatory requirement for the manufacturer and AR concerned to report any adverse incidents of medical devices to the DH and to conduct investigations and implement remedial measures to the satisfaction of the DH.

***(III) Control over the use of specific medical devices***

22. The objective of imposing control over the use and operation of medical devices is to prevent unnecessary harm or complications arising from the improper use of medical devices. In the absence of control arrangements, certain medical device operated by a person without proper training or qualification may pose health risks to the operator and his/her clients.

23. The Administration originally proposed to restrict the use and operation of specific medical devices to specified personnel to safeguard public health and to apply for a licence to possess and operate such devices. For example, the operation of Class 3B and Class 4 high-power medical lasers is to be limited to statutorily registered healthcare professionals. As for intense pulsed light (IPL) equipment, those who are not statutorily registered healthcare professionals would be allowed to operate the equipment provided that they have undergone training and passed the IPL trade test run by authorised institutes, such as the Vocational Training Council.

24. Following the adverse incident in October 2012 involving a beauty centre inappropriately offering high-risk medical procedures, the Administration has 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. The Working Group has examined the safety and health risks of devices commonly used in beauty procedures e.g. high-power medical lasers, IPL equipment, radiofrequency devices, etc. The Working Group considers 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.

### *Regulation of medical devices in future legislation*

25. To ensure professional and industrial involvement, the Administration proposes to set up an advisory committee comprising members from relevant stakeholder groups including trade associations, medical associations, engineering institutions and academic institutes to advise the DH on the classification of medical devices and issues relating to the implementation and administration of the future legislation.

### **Cost of Compliance**

26. The table at Annex V sets out the compliance costs between the original proposal and the revised regulatory proposal. The total one-off compliance cost for the trade is estimated to be reduced from HK\$2,289 million to HK\$627 million and the annual recurrent compliance cost from HK\$1,339 million to HK\$599 million. Regarding the impact on individual traders, it is estimated that the average cost of compliance for an AR dealing in one medical device with model life of 10 years may range from HK\$3,765 to HK\$7,740 per year, depending on the frequency of changes that are subject to the approval of the DH. The estimated average costs of compliance for distributors / importers may range from HK\$932 to HK\$1,187 per year and that for manufacturers may range from HK\$16,182 to HK\$54,282 per year, depending on the size of their businesses.

### **Proposed Way Forward**

27. The DH is in the process of engaging an external consultant to conduct a detailed study on the use control of selected medical devices as proposed in paragraphs 24 above. The Administration expects to report to the Panel on the outcome of the consultancy study and the details of the legislative proposal in 2015.

## **Advice Sought**

28. Members are invited to note the content of the paper.

Food and Health Bureau  
June 2014



Global Harmonization Task Force (GHTF) was formed in 1992 to harmonise the standards and principles for the regulation of medical devices. In 2011, GHTF was disbanded, and a new regulator-led group known as International Medical Device Regulators Forum was formed to build on the foundational work of GHTF and aims to accelerate international medical device regulatory harmonization and convergence.

According to GHTF's recommendation, medical device means –

“any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of –

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means”; and

accessory to a medical device means –

“an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use”

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# **Department of Health**

## **Business Impact Assessment on Statutory Regulation of Medical Devices**

### **Executive Summary of Final Report**



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### **Commercial-in-Confidence**

This report has been prepared for, and only for, the Department of Health (DH) of The Government of Hong Kong Special Administrative Region (Government) in accordance with the terms of the DH contract of 21 April 2011, 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 report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.



## Introduction

1. PricewaterhouseCoopers Advisory Services Limited (PwC) has been commissioned by the Department of Health to conduct a consultancy study to assess the business impact of the proposed new statutory regulation for medical devices.
2. The consultancy study started in May 2011, and was completed in January 2013.
3. This executive summary of the Final Report of the consultancy study gives:
  - An overview of the local medical device industry and relevant trades focusing on those business segments that are expected to be impacted by the introduction of the proposed legislation.
  - The key findings from the interviews we conducted with a cross-section of the relevant local stakeholders to collect views and understand concerns.
  - A summary assessment of the business impact of the proposed legislation on the local medical device industry and relevant trades (beauty, and optical), including an estimation of the potential cost of compliance.
  - The key recommendations, including proposed changes to the regulatory proposal, mitigation measures and monitoring/evaluation mechanisms.

## Overview of the Local Medical Device Industry and Relevant Trades

4. Given the broad definition of a ‘medical device’ (and ‘in-vitro diagnostic medical device’ or IVDMD<sup>1</sup>), which includes everything from sophisticated and computerised medical equipment, such as heart valves and orthopaedic implants, to simple instruments, such as wooden tongue depressors and bandages, the proposed legislation is expected to impact a number of local trades:
  - Medical device industry—it also includes local general traders who might be involved in importing/exporting and distributing common Class I devices (e.g. bandages, dressings, surgical masks, etc) either as a ‘side business’ or on a non-regular basis.
  - Beauty trade—some beauty parlours may use or operate medical devices.
  - Optical trade—contact lenses and their disinfectant solutions are considered medical devices.

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<sup>1</sup> Global Harmonisation Task Force ([http://www.ghtf.org/documents/sg1/sg1final\\_n071.pdf](http://www.ghtf.org/documents/sg1/sg1final_n071.pdf)).

## Overview of the Local Medical Device Industry

5. Hong Kong is a major hub for re-export of medical devices. The bulk of imported and locally manufactured medical devices are for export, and only a very small proportion is intended for domestic use. In 2010, Census and Statistics Department (C&SD) estimated that there were approximately 220 to 240 medical devices manufacturers<sup>2</sup> in Hong Kong; however, the figures included approximately 170 dental laboratories, which may be considered 'custom-made-medical-device' manufacturers and fall outside the proposed scope of regulation. According to C&SD, there were also approximately 1,000 establishments<sup>3</sup> involved in trading medical devices in 2010. The C&SD statistics covered only major economic activities within the medical equipment sector. As such, the figures were not meant to represent the overall situation and the entire market.
6. The largest end-user of medical devices in Hong Kong is believed to be the Hospital Authority (HA). It is estimated that the number of medical devices owned by HA alone accounts for approximately 70% to 90%<sup>4</sup> of all the medical devices purchased locally.
7. According to guesstimates collected from local stakeholders we interviewed, it is estimated that there are a total of approximately 80,000<sup>5</sup> medical devices on the local market. Based on their knowledge of overseas markets (e.g. the US, the UK, Australia), local stakeholders estimate that approximately 50% of these are Class I devices.

## Overview of the Local Beauty Trade

8. As DH is proposing to regulate the use of high power (Class 3B and 4<sup>6</sup>) laser equipment and intense pulsed light (IPL) devices by non-healthcare professionals, we also interviewed local stakeholders to collect information about the local beauty trade. Local stakeholders estimate that there are currently a total of approximately 6,000 to 8,000 Class 3B and 4 laser equipment and IPL devices being used by local beauty operators; and approximately 5,000 beauty salons in Hong Kong. Local industry stakeholders believe that at least 90% (about 4,500) of these beauty salons have IPL devices, of which:

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<sup>2</sup> Census and Statistics Department ([http://www.censtatd.gov.hk/products\\_and\\_services/products/individual\\_statistical\\_tables/labour/index\\_cd\\_D525000810E\\_dt\\_latest.jsp](http://www.censtatd.gov.hk/products_and_services/products/individual_statistical_tables/labour/index_cd_D525000810E_dt_latest.jsp)).

<sup>3</sup> Census and Statistics Department ([http://www.censtatd.gov.hk/products\\_and\\_services/products/individual\\_statistical\\_tables/labour/index\\_cd\\_D525000810E\\_dt\\_latest.jsp](http://www.censtatd.gov.hk/products_and_services/products/individual_statistical_tables/labour/index_cd_D525000810E_dt_latest.jsp)).

<sup>4</sup> Espicom (Hong Kong Market Device Market Intelligence Report, First Quarter of 2011); and Synergus AB (<http://www.synergus.com/europe/sidor/hong-kong.aspx>).

<sup>5</sup> While we understand that from the information collected from stakeholders, some of the 80,000 medical devices may be combined into a family, series or systems of devices for device registration purposes, we have assumed that there will be approximately 80,000 device registrations when the proposed legislation is implemented because there is no additional information to allow us to be able to determine/estimate more accurately the exact number of device registrations.

<sup>6</sup> Laser equipment is classified into four classes and a few sub-classes based on wavelength and maximum output power (1, 1M, 2, 2M, 3R, 3B, and 4) according to the standard (60825) published by the International Electrotechnical Commission (IEC) ([http://webstore.iec.ch/preview/info\\_iec60825-1%7Bed2.0%7Db.pdf](http://webstore.iec.ch/preview/info_iec60825-1%7Bed2.0%7Db.pdf)).

- Approximately 50% (about 2,250) also have laser equipment.
  - It is estimated that these 2,250 salons that have laser equipment comprise of 425 large operators and 1,825 small operators.
9. According to the information collected from local industry stakeholders, nearly all of the devices used by the local beauty trade are manufactured overseas. It is very common for local beauty operators to buy and then import directly from these overseas manufacturers.
10. While there are no official statistics, local industry stakeholders estimate that there are currently hundreds of overseas manufacturers supplying laser equipment and IPL devices to local beauty operators in Hong Kong. Some of these overseas manufacturers have a local presence, and they import and distribute their own products locally.

### **Overview of the Local Optical Trade**

11. The local manufacturing sector can be described as small (in terms of numbers), and there are only half-a-dozen or so local and overseas (with offices in Hong Kong) manufacturers combined.
12. The local distribution sector is also small. There are only a handful of local distributors who are distributing to smaller local retailers. Larger local manufacturers and overseas manufacturers with local offices typically sell directly to local retailers.
13. According to the information obtained from local traders and trade associations, it is estimated that there are approximately 1,200 to 2,000 optical retail shops in Hong Kong. Most of these are small and medium sized enterprises (SME<sup>7</sup>) with 1 or 2 retail branches, and taken together, they account for about 70% of the total number of shops in Hong Kong. More sizeable retailers with about 9 or 10 optical retail branches account for about 18%. There are 2 major optical retail chain stores with approximately 150 shops combined, which account for less than 13%. Collectively, the two major retail chain stores hold approximately 10% of market share of contact lenses, and less than 10% of disinfectant solutions for contact lenses. The two local major retail chain personal care stores have majority market share of disinfectant solutions in the local market according to the information provided by local stakeholders.

## **Key Findings from Stakeholder Interviews**

14. We conducted interviews with 140 representatives from 51 stakeholder organisations, covering relevant trade associations, importers, manufacturers, distributors, retailers from the local medical device industry and relevant trades (beauty, and optical); and government and other relevant organisations.

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<sup>7</sup> Trade and industry Department, The Government of Hong Kong Special Administrative Region ([http://www.smefund.tid.gov.hk/english/sgs/sgs\\_eligibility.html](http://www.smefund.tid.gov.hk/english/sgs/sgs_eligibility.html)).

15. We summarise the key points made by stakeholders against the key aspects of the proposed regulatory framework.

### 15.1 Need for Regulation and Benefits

- There is a need to regulate medical devices through product registration to ensure devices used and accessed by the public and healthcare practitioners meet certain safety and quality standards (interviewees expected these to be defined clearly by DH). However, it is important that the proposed regulatory framework will not overburden the industry with unnecessary administrative work.
- The proposed legislation will benefit the consumer and local community. It will also help bring Hong Kong into line with other major international markets on medical devices regulation, and raise industry standards further.

### 15.2 Proposed Regulatory Framework

- The proposed blanket (one-size-fits-all) approach to regulating medical devices used for medical purposes and devices used for beauty purposes, and subjecting all devices and relevant businesses to the same stringent requirements, is not appropriate or fair. The practice is also not consistent with those in other countries, which have separate pieces of legislation regulating cosmetic products and devices.
- The proposed legislation should also regulate the prescription of non-corrective contact lenses at the retail level (e.g. mandating prescription by registered optometrists only) so that the contact lenses sold are suitable for their users.
- It will be important for DH to set up an appeal board with representation from the local industry to review and rule on 'borderline' device applications (e.g. devices which do not have a consistent or commonly agreed risk classification across different overseas jurisdictions).
- It will also be important for DH to spell out enforcement measures and penalties clearly, and to communicate these to the local industry so that traders understand the impact of the proposed control measures.

### 15.3 Proposed Pre-Market Control Measures

- The classification of medical devices should be aligned with practices of major international markets (such as the US and the EU) to facilitate import and export of medical devices between markets, and to ensure that Hong Kong will not be sidelined as a result of the introduction of the proposed legislation. Classification of medical devices that is not consistent with other major international markets will mean that overseas manufacturers may not be able to provide the necessary documentation to meet Hong Kong's regulatory requirements. Also, Hong Kong is considered a very small market and overseas manufacturers might not be willing to invest extra effort to commission additional tests or assessments in order to meet Hong Kong's regulatory requirements. Interviewees anticipate that some overseas

manufacturers may limit the types of devices they place on the local market, and that means fewer choices for healthcare professionals and the public.

- The process for registering all 4 classes of medical devices that already come with approvals from regulators in major markets (e.g. the US, the EU, Japan) should be kept simple, or DH can consider putting in place a fast-track process to minimise duplication of administrative work and the lead time required to place these devices on the Hong Kong market. There were also concerns about DH imposing Hong Kong-specific requirements because it could potentially drive a significant number of local traders and medical devices out of the local market.
- There were concerns about subjecting local traders to ISO certification requirements because these are seen as a great burden and significant cost to businesses, and could potentially drive some of the traders and/or devices out of the market. Interviewees from the local beauty trade, in particular, felt that subjecting them to ISO13485 or Good Manufacturing Practice (GMP) certification requirement is not appropriate, practical, or fair. This is because those standards are designed and meant for the medical device industry. This requirement alone could drive many local small and medium sized beauty operators to close their businesses. Interviewees from the local optical trade also had similar concerns citing that compliance will be an issue for many small and medium sized optical companies. This is not only because of the costs and resources involved, but also their small setup (especially those with 1 or 2 staff)—which means that it would be very difficult, if not impossible, for them to obtain the required certification. It is anticipated that many local traders will be driven to close their businesses.
- Labelling and re-labelling activities are commonly undertaken by importers, authorised representatives (AR) or distributors in Hong Kong; and should not be considered as a manufacturing activity and subject local traders to stringent ISO13485 certification requirements. This is because Hong Kong is considered a small market, and overseas manufacturers are generally reluctant to customise labels and packages just for the Hong Kong market.
- Nearly all interviewees questioned the move to place import and export controls on selected medical devices, and were concerned about the impact it will have on the local industry as a whole.
- The process should not take more than 3 months to register Class II, III and IV devices, and preferably take approximately 2 to 4 weeks for devices that have approvals from recognised overseas regulators. Anything over 6 months is considered unacceptable from a business point of view as it seriously affects the lead time to place devices on the local market, and being able to launch products quickly is considered essential to the competitiveness and survival of their businesses. There were also concerns about the time that DH will take to process changes because it will also affect the lead time to place say upgraded/improved/etc devices on the local market.
- It will be important for DH to publish clear performance pledges for their registration processes so that traders can take this into consideration when planning for product launches.



#### 15.4 Proposed Labelling Requirements, and Controls on Advertisements

- Medical devices that are sold directly to the public (over-the-counter or OTC products) should have both Chinese and English labels and instructions for use. For medical devices (and their spare parts) that are used and operated by medical professionals, English label and instructions for use would be sufficient.
- Both Traditional and Simplified Chinese should be accepted.
- There were concerns about the requirement of having to certify Chinese translations because it will be difficult and costly to produce certified translations, in addition to having to bear potential legal responsibilities/liabilities associated with any errors and inaccuracies in translations.
- All the requirements in relation to advertisements should be included in the current Undesirable Medical Advertisements Ordinance (Cap 231) instead of in separate pieces of legislation.

#### 15.5 Regulation of Class I Medical Devices (and Class A IVDMDs)

- DH should adopt a more light-handed approach towards regulating Class I (and A) devices because:
  - There are a large number of Class I (and A) devices, and the level of risk to the public and individual users is considered low.
  - Inevitably, regulatory compliance costs will eventually be transferred to the end consumer.
  - There is a potential of driving up 'unauthorised' (or even illegal) import as a way of circumventing the legislation and minimising business and compliance costs. And because these are relatively low risk items, consumers might be more inclined to purchase un-registered products since they tend to be cheaper.
  - This is in line with the regulatory approach adopted by other key international markets such as the US, the EU and Canada.
- A simple process involving trader registration plus product notification or declaration (providing information on make and model) should be sufficient.
- Class I (and A) devices that already have US Food and Drug Administration (USFDA) approval and/or European Conformity (CE) mark should be exempted from registration, and only require listing.

#### 15.6 Estimated Fees for Registrations and Licences

- The estimated fee levels for the 3 types of trader registration (AR, importers, and distributors) look reasonable, but the estimated fee level for the 'local manufacturer' role is too high, especially if simple activities like re-labelling and re-packaging will be considered manufacturing activities, and local

traders undertaking these activities will be required to register as local manufacturers.

- It would be more acceptable if the fee level for trader registration is kept to several hundred dollars. Also, DH should not be charging the trader registration fee on a per-role basis because it does not incur additional work on the part of the Department when reviewing and vetting applications.
- The estimated fee levels for device registration (first-time, and changes per submission) are too high, even when compared to the registration of pharmaceutical products. This is because, based on experience, there will be a larger number of device registrations and more changes per device when compared to pharmaceutical products. Several hundred (not thousand) dollars would be more reasonable.
- It is unfair for DH to charge hundreds of dollars for Class I (and A) product notification on a per-product basis. It should be free of charge.
- While there are only a few larger beauty parlour chains in Hong Kong, charging fees for the Business Operator's Licence on a per-shop/branch basis will pose a financial burden on traders. It would be more acceptable if the fee was kept to several hundred dollars.
- A 3-year validity period is more reasonable for all 3 types of trader registrations (AR, importers, and distributors) because renewing them on an annual basis is just too frequent.
- A 5-year validity period would be a sensible period for device registrations given that:
  - Class II and III devices typically have a 5- to 7-year life span, and IVDMDs generally have an even longer life span;
  - Global Harmonisation Task Force (GHTF) suggests a 5-year validity period for product registrations;
  - typical tenders issued by HA are usually for a period of 5 years, and generally require suppliers to provide guarantees of at least 7 years; and
  - the currently proposed 1-year validity period for Class I devices is simply too short given that these devices are relatively low risk.

### **15.7 Proposed Control Measures on Use and Operation (of Selected Medical Devices)**

- In principle, there should be some form of regulatory control placed on the use and operation of Class 3B and 4 laser equipment and IPL devices, including requirements on operating environment, and the level of knowledge and competency of their operators (e.g. recognised certification or accreditation), but it should be done separately from the proposed medical devices legislation.
- There were strong views about the proposed idea of limiting the use and operation of Class 3B and 4 laser equipment to the 12 groups of statutorily registered healthcare professionals.

- There were questions from nearly all interviewees, including healthcare professionals interviewed, about the idea of not requiring the 12 groups of statutorily registered healthcare professionals to receive relevant training before using and operating Class 3B and 4 laser equipment. None of those professionals receive any relevant training as part of their professional education and training, and are therefore just as likely to cause injuries to patients and consumers as untrained beauticians. All operators, healthcare professionals or not, should be required to undergo relevant training, trade test and device specific training.
- Equipment that emits radiation should also be controlled (e.g. x-ray machines, ultrasound devices), and devices that are based on high power radio frequency radiation technology should also be regulated as these devices are used for invasive treatments, and could potentially cause serious and irreparable damages to patients if used in incorrect ways by untrained personnel. However, distinction should be made between devices used for medical and cosmetic applications.
- There were serious concerns about DH including other devices that might be used by the beauty trade in the scope of regulation in the future, in addition to Class 3B and 4 laser equipment and IPL devices.

### 15.8 Proposed Post-Market Control Measures

- In terms of the record retention period, a maximum of 7 years is considered to be reasonable assuming that the information requirements are similar to those for tax filing purposes. However, not all medical devices have unique serial numbers, and this presents some challenges around the traceability of the products sold. Also, most of the medical devices do not have an expected life span, and manufacturers are generally reluctant to give one because such a claim carries legal implications for product liability. Only consumables and devices that contain chemicals, sterilised components, or reagents have a limited shelf life; and some parts and accessories of devices have a limited number of uses. For higher risk devices (e.g. implants), the current practice is to keep relevant records for as long as these devices remain functional and in use.
- It might be more practical to base the retention period on the period that a manufacturer plans to service and maintain (and provide relevant parts and accessories) a device that has an expected life span longer than 7 years. That said, in some cases, even when parts or accessories are no longer available from original manufacturers, some devices can still remain in use if operators are able to find similar parts or accessories from other sources (e.g. second-hand dealers, other manufacturers).
- Large local operators already follow international practices. Some local small and medium sized companies engaged in import/export and distribution of Class III and/or IV medical devices also follow robust practices.
- Small and medium sized general traders interviewed believed that most of the businesses carrying Class I and II devices will not be able to comply with the requirement for very detailed information. To meet the requirement, all the relevant traders involved in the local supply chain (importers, distributors, logistics and storage providers) will need to set up integrated systems and

processes that link their internal operations such as sales, distribution, finance, etc, and with those of their business partners. This involves significant costs and resources.

- There were concerns that there might be difficulties in tracing/tracking devices in cases where there is a change of local AR. Newly appointed local AR will unlikely have records kept by their predecessors, and are unlikely to be willing to take up the responsibility (and liability) for tracing/tracking devices that were previously sold by predecessors. Also, previous local AR or overseas manufacturers are unlikely to be willing to share this information because customer information is considered commercially sensitive.
- DH should provide clear guidelines (e.g. definition of an adverse incident).

### **15.9 Proposed Transition Arrangements**

- There was an expectation that current listings under the Medical Device Administrative Control System (MDACS) will be transferred to the new regulatory 'system' easily, and that local traders will not have to re-submit applications and supporting documentation for their devices that are already listed.
- There should be an adequate grace period (some suggested not less than 4 or 5 years) from the time when the legislation is enacted to full compliance given the large number of local traders and devices involved. Also, sufficient time should be given to local traders to comply with regulatory requirements. Clear guidelines (e.g. guidance notes) and communications (e.g. regular briefings) should be provided to them. Implementation period should reflect actual experience, and should be adjusted as needed.
- There were concerns that currently there is not enough people in the local market with relevant regulatory experience to support the implementation of the proposed legislation. There is also the concern about whether the 3 Conformity Assessment Bodies (CAB) in Hong Kong will be able to handle the increase in certification and audit work.
- DH should publish a clear implementation timetable early so that local traders can start planning for the implementation.
- DH should conduct another round of wider consultation with the local industry before finalising the detailed regulatory requirements. DH should also conduct regular communications (through a number of channels) with the local business community to brief and explain the 'finalised' legislation and specific requirements. In addition, once the proposed legislation comes into effect, it would be helpful to have clear guidelines (including hotlines and helpdesks that can help answer questions) to assist local traders through different processes.

## Estimated Cost of Compliance

16. We have estimated the impact of the proposed legislation in terms of approximate total cost to the relevant trades for complying with the proposed regulatory requirements (the cost of compliance). These are broad estimates; and are based on 1) DH's proposed regulatory framework and requirements (not the recommended changes given in the Final Report of this consultancy study), and 2) a set of key assumptions.
17. The 3 main categories of compliance cost are:
- **Administrative Costs**—These are marginal internal staff costs associated with preparing the paperwork and submitting them to Government, keeping records (for inspection by DH), trying to understand and clarify regulatory requirements, and liaising with Government during registration, renewal and updating processes.
  - **Substantive Costs**—These are marginal costs associated with commissioning professional or non-professional services, conducting staff training, recruiting staff, purchasing new equipment, carrying out building works and renovations, and paying relevant fees and expenses to third parties (other than Government) for services/goods needed.
  - **Financial Costs**—These are marginal costs associated with paying relevant fees to Government or other regulatory body(ies) involved if any, and costs that are directly related to such activities or transactions.
18. Our estimates indicate that the total cost of compliance to relevant local trades (medical device, beauty, and optical) for complying with the proposed requirements is approximately HK\$2,289.1 million (for the one-off cost) and HK\$1,339.2 million (for the recurrent cost on an annualised basis).
19. In terms of estimated 'one-off costs', the estimated cost of registering Class II, III and IV devices (and Class B, C and D IVDMDs) by AR is the largest contributor (HK\$1,086.1 million, which accounts for approximately 47.45% of the estimated total 'one-off' cost of compliance) followed by the estimated cost of obtaining ISO certification and re-certification to meet the requirements for trader registration for AR, importer, and distributor (HK\$1,050.3 million, which accounts for approximately 45.88% of the estimated total 'one-off' cost of compliance). The HK\$1,086.1 million includes approximately HK\$819.7 million of substantive cost and HK\$266.4 million financial cost, while the HK\$1,050.3 million are all substantive costs.
20. In terms of estimated 'recurrent costs', the estimated cost of attending to annual audits associated with ISO re-certification (also to meet the requirements for trader registration for AR, importer, and distributor) is the largest contributor (HK\$622.15 million, which accounts for approximately 46.46% of the estimated total 'recurrent' cost of compliance) followed by the estimated cost of employing healthcare professionals to operate Class 3B and 4 laser equipment by beauty parlours (HK\$508.04 million, which accounts for approximately 37.94% of the estimated total 'recurrent' cost of compliance), and then the estimated cost

associated with traders having to notify the Department about changes and updates to devices (HK\$171.85 million, which accounts for approximately 12.83% of the estimated total 'recurrent' cost of compliance). The HK\$622.15 million and HK\$508.04 million are both substantive costs, while the HK\$171.85 million includes approximately HK\$71.44 million of administrative cost and HK\$100.41 million of financial cost.

21. In addition, it is estimated that the 'one-off' substantive cost associated with beauty parlours having to ensure that their staff have undergone the required pre-requisite training needed for the trade test for operating IPL devices and passed the trade test is approximately HK\$73.31 million (about HK\$31.33 million for completing the pre-requisite training, and HK\$41.98 million for taking and passing the trade test).

## Assessment of Business Impact

22. In this section, we give an assessment of the overall impact in terms of anticipated key changes that could potentially take place in the local market when the proposed legislation is implemented.
23. Unlike compliance costs, which are comparatively easier to estimate, impacts such as the anticipated growth or reduction in business, changes to the local market structure (e.g. number of players consolidating and leaving the local market, increase or decrease in the number of devices being placed on the local market), are difficult to estimate or quantify. This is especially true in this case because of a general lack of information. Also, there are too many factors at play that could influence the outcome. It is, therefore, only possible to provide a qualitative assessment.

### Impact on Market Structure

24. The current local market is very diverse and the industry is made up of mostly small and medium sized players. This is in contrast to its closely related counterpart—the pharmaceutical industry, which is dominated by large corporations. We expect this to change with regulation mainly because of cost considerations as it will be more expensive to place devices on the local market in the future regulated environment.
25. Smaller players are likely to either: 1) consolidate in order to be able to continue to operate their medical device businesses in a more cost effective way by exploiting greater economies of scale; or 2) choose to exit the market because it might no longer make business sense to continue—this is especially likely for players whose medical device business accounts for only a small portion of their overall business. Larger players will likely dominate the competition much like they already do in certain areas, e.g. Class III and IV devices.
26. This means that there is likely to be more vertical integration (as in fewer layers of distribution) within the supply chain. While this is likely to drive some of the current players out of the market and might even affect business livelihood, it is not without benefits when considered from a macro point of view. Having fewer

parties involved in the supply chain makes it less difficult to trace/track devices. Also, those who remain in the market are likely to be larger businesses, who:

- Often operate to higher standards—the potential monopoly issue aside, this will nonetheless help raise industry standards in general.
- Tend to have more robust management systems and processes, and access to more resources, which facilitate better compliance with the proposed regulatory requirements.

27. There will be new local market opportunities. Demand for local capability to assess the conformity of ‘quality management systems’ of local (or locally based) traders and quality standards of locally manufactured devices, and assistance with registration and regulatory compliance (e.g. people with regulatory compliance background and experience, and are familiar with the registration processes and regulatory requirements) are likely to see an increase.

28. Regulation will also help improve the status of the local medical device industry; and bring benefits to the community at large through improved safety and quality of medical devices, and from a potentially reduced number of repeat or corrective procedures that need to be undertaken as a result of adverse incidents arising from medical device failures and shortcomings. That said, Hong Kong currently enjoys quick and easy access to new and latest technologies because of the unregulated environment, though some might be ‘unproven’ and Hong Kong might be used as a testing ground for these new devices. With regulation, this might change and companies will likely be a lot more selective in terms of the devices they bring to and place on the local market because of cost considerations, but the exact impact remains to be seen.

### **Impact on Businesses (and Government)**

29. From our discussions with local industry stakeholders, no one disputes that medical devices should be designed, manufactured and supplied in such a way that, when operated and used for the purposes intended by the manufacturer, will provide the expected clinical benefits and harm neither the patient nor the user. While voluntary controls may help achieve this objective to some extent, many developed countries believe that statutory controls are needed. However, such a regulatory system is costly to set up and maintain, and is likely to place a heavy burden on the local business community:

- Compliance costs from changes to business practices and procedures (including resource increase to handle regulatory affairs) in order to comply with regulatory requirements. These, in some cases, could be significant to individual companies or their business units/divisions that focus on the Hong Kong market. Our estimates of the potential cost of compliance (see section on ‘Estimated Cost of Compliance’), which cover only key compliance activities and cost components and as such represents only a lower estimate of the potential cost of compliance, indicate that this is likely the case. Some companies or their business units/divisions might be forced to exit the medical device business in Hong Kong. The compliance cost to the overall business community is also significant when looked at in totality

because the proposed legislation is expected to impact a number of trades (medical device, beauty, and optical) and a large number of stakeholders, including general traders who might be involved in importing/exporting/re-exporting and distributing common Class I devices either as a 'side business' or on a non-regular basis. However, the distribution of the cost of compliance across the companies, business units or divisions in the medical device, beauty and optical industries is anticipated to be uneven (and not in proportion to the turnover of their businesses), with those who manufacture, import and distribute medical devices in the Hong Kong market to bear more of the total cost of compliance (because the proposed regulatory requirements are more stringent for businesses which place medical devices on the Hong Kong market), and companies or business units or divisions which import medical devices for re-export only will incur considerably less cost when complying with the proposed regulatory requirements.

- Costs associated with the establishment and ongoing administration of the regulatory system by Government.

30. Because of the higher costs associated with placing products on the local market, local companies, large or small, will be much more selective in terms of the medical devices they carry. This will change their overall product portfolio, and local traders are likely to carry only the more profitable typical (or mainstream) devices. This means:

- Potentially, fewer choices (not just devices, but also relevant services), higher prices, and longer waiting times for consumers.
- A potential reduction of income/revenue for local traders. This may or may not happen depending on factors like any changes in the buying behaviour of local consumers, pricing strategy of the remaining local traders, etc as a result of market changes.
- A potential reduction of tax income for Government because of a reduction of income/revenue for local traders, local companies leaving the business as a result of regulation, and overall contraction of the local market.

### **Impact on 'Unauthorised' Imports (for Some Medical Devices)**

31. There might be an increase in 'unauthorised' imports, an unintended but likely consequence of regulation—even though it might be an offence to supply un-registered devices (or non-listed ones in the case of Class I devices) in the future regulated environment for some medical devices. These are likely the more common, lower risk and lower cost Class I devices such as bandages, dressings, etc because local consumers tend to be less discerning about these products.

32. These 'unauthorised' products are likely to appeal to the more price-sensitive group of local consumers because these products can be sold at lower than market prices since they do not have the 'added' cost of compliance that registered traders need to carry.



### **Impact on Hong Kong as a Major Re-export Hub**

33. Hong Kong is a major hub for re-export of medical devices. The bulk of imported and locally manufactured medical devices are for export, and only a very small proportion is intended for domestic use. We anticipate that re-exports will also be affected (but the extent of the impact remains to be seen) because while devices not intended for domestic use will be exempted from device registration, locally based traders who import selected medical devices for re-export only will still be required to:

- Register with DH and meet the proposed ISO certification requirements for importer. This requirement alone, as pointed out by stakeholders we spoke with, will be seen as a great burden and significant cost to businesses, and could potentially drive some of the local traders out of the local market because it might no longer make business sense, or be sufficiently attractive, for them to continue if the economics—costs versus income and profit—do not work for them.
- Obtain an import/export licence for each consignment.

### **Impact on Hong Kong as a Distribution Location**

34. Hong Kong is also a hub for distribution of some medical devices. There are a number of trade shows, fairs and exhibitions held in Hong Kong each year. These events attract a significant number of local and overseas traders to promote, test and distribute new devices (traders sell and distribute locally and to neighbouring locations) because there are essentially no restrictions (unregulated) and devices can come in and out of Hong Kong freely.

35. This is likely to change with regulation. While there will be exemptions for devices intended for exhibition, traders are expected to incur administrative costs when preparing applications for exemption from device registration even though, according to the information provided by DH, the application process is expected to be simple.

36. There is also a condition that these devices cannot be used for demonstration. This is likely to drive some traders away from these trade shows because it will be difficult for them to showcase their products without being able to perform demonstrations; and might drive some foreign businesses away from the Hong Kong market who are looking to test/market/sell their products to other neighbouring locations through Hong Kong.

### **Impact on Registered Healthcare Professionals**

37. The proposed move to restrict the use and operation of Class 3B and 4 laser equipment to registered healthcare professionals only is anticipated to increase the demand for these professionals, and trigger a 're-distribution' of these professional resources between the local medical field and the local beauty trade.

## Impact on Operator and Consumer

38. According to the local stakeholders we interviewed, the Hong Kong market is characterised as having a great variety of medical devices (driven by consumer demand for new and latest technology) but in very small quantities (dictated by the small size of the local market). This is made possible by an unregulated environment, which means that the cost to place devices on the local market is lower. We expect to see notable changes when the proposed legislation is implemented.
39. In general, there will be fewer choices in terms of devices and relevant services, higher prices, and longer waiting times for local operators (e.g. hospitals, clinics, beauty salons) and consumers. This is because companies, large or small, are likely to be more selective in terms of the medical devices they carry and place on the local market since it will be more costly to do so. The additional cost will likely be passed on to the local consumer. Local operators and consumers will also likely need to pay a premium for devices that are considered less profitable from a business point of view to supply to the Hong Kong market. But even if local consumers were willing to pay a premium, local operators might still not be keen to import and place those devices on the local market simply because they might be able to reap even greater rewards if they were to focus on other more profitable devices and opportunities. In addition, local operators and consumers can expect to wait longer for their devices, especially for new and 'less typical' (or non-mainstream) ones. This is mainly due to longer lead times to place products on the market as a result of all the registration processes.
40. That said, regulation will bring health benefits to patients who are less likely to be subject to complications and injuries caused by medical device shortcomings. This might be translated to broader economic benefits in terms of reduced/avoided morbidity and even mortality rates, improved productivity (because of lower 'downtimes'), etc.

## Recommendations

41. Based on our findings and assessment, we recommend some changes to the proposed regulatory requirements with a view to making the regulatory requirements as business friendly as possible while ensuring public safety and health.
42. We have recommended changes to areas where we think adjustments are needed. For other areas, we agree, in principle, with DH's current proposal (knowing that in some cases fuller details have yet to be developed by DH).

## Definition and Classification of Medical Devices

43. DH proposes to adopt the definition and classification system suggested by GHTF. The proposed legislation will also empower the Director of Health to include certain products that do not fall squarely under the proposed definition to

be within the scope of regulation and classify/re-classify products according to local conditions and considerations. We recommend DH:

- Where possible, to try and align with international practices (e.g. GHTF member countries) when defining and classifying medical devices, unless there is no consistent practice, or there are other more important factors to consider.
- For safety purpose, to adopt the highest risk classification for devices that do not have a consistent risk classification across key markets.
- To consider setting up an advisory committee (ideally, with representation from relevant stakeholder groups) to discuss and provide inputs on borderline cases by considering all the relevant factors and different perspectives.

### Trader Registration

44. DH proposes to register all traders (importers, distributors, and AR) involved in importing (or re-exporting) and distributing medical devices. Traders will be required to conform with relevant ISO or equivalent standards. We recommend DH:

- Not to subject traders involved in importing and distributing Class I devices (and Class A IVDMDs) to the same stringent trader registration requirements (e.g. ISO certification).
- Not to require importers involved in re-exports only to register as a trader with DH, or subject them to trader registration requirements (e.g. ISO certification). This is because DH's main focus is on devices placed on the local market.

45. DH is also considering: 1) whether to allow a single or multiple AR when it comes to representing the same brand or product; and 2) ways of delineating the responsibilities and legal obligations more clearly between AR. We recommend DH:

- To allow the market to decide the number of local AR present, and permit multiple local AR to represent the same brand or product so as not to interfere with market dynamics.
- To consider issuing relevant guidelines around things for potential local AR so that they are aware of their responsibilities and potential liabilities.

46. DH proposes to register all local manufacturers of all classes of devices and IVDMDs, except those who manufacture custom-made devices. All 'brand owners' will require ISO 13485 certification. Refurbishing of medical devices, re-labelling and re-packaging will also be considered as manufacturing activities and subject to ISO 13485 certification requirements. We recommend DH:

- To require only local manufacturers and local OEM who manufacture and place devices on the local market to conform with ISO 13485 certification requirements.

- Not to require local 'private label manufacturers' to conform with ISO 13485 certification requirements, but require them to conform with other relevant ISO standards for import and/or distribution of medical devices depending on the role(s) they undertake. For those who make use of manufacturing services from overseas instead of local OEM, they should also ask their overseas OEM to provide documentation proof that they meet ISO13485 certification requirements, and submit relevant documents to DH during the device registration process.
- Not to classify simple refitting and simple relabeling (to affix labels with registration numbers and details about AR) of medical devices as manufacturing activities. These traders should not be required to register as manufacturers and subject to ISO 13485 certification requirements. Instead, these traders should only be required to declare to DH that they agree to be held responsible and liable for these devices.

### Device Registration

47. DH proposes to use own in-house resources to review and approve pre-market registrations; and to set up an appeal board to handle appeals, which will be made up of independent members selected from a cross-section of relevant parties. We recommend DH:
- To consider using a board that is ideally made up of independent members selected from a cross-section of relevant and interested parties, including representatives from the relevant trades to review and approve 'exceptional' cases.
  - To publish clear performance pledges for different registration and licensing processes, and where appropriate, different activities within each process.
48. DH proposes a simple device-based notification system for Class I (and A) devices. We recommend DH:
- To consider requiring Class I (and A) device notification to be trader-based as opposed to device-based to reduce the cost of compliance and minimise the impact on the business community.
49. DH proposes Class II, III and IV (and B, C and D) devices to be registered before they can be placed on the local market. Refurbished medical devices will be regulated in the same way. We recommend DH:
- To consider putting in place a fast-track device registration process for medical devices that already come with approvals from overseas regulators with recognised quality standards (e.g. the US, the EU, Japan). This process will involve only a simple validation process and the issuing of a registration number.

### Import/Export Licence

50. DH proposes to implement an import/export licensing system for selected medical devices. A trader must be registered as an 'importer', and will need to

obtain an import/export licence for each consignment they import into Hong Kong. We recommend DH:

- Not to introduce an import/export licensing system, but to only include relevant provisions in the proposed legislation to allow DH to implement such a licensing system for selected medical devices, when needed.
- To review the local situation and conditions from time to time, and determine the need to implement an import and export licensing system that targets those un-registered devices intended for export/re-export.

51. If DH sees a genuine need to implement such a licensing system when enacting the proposed legislation, we recommend DH:

- To either exempt registered medical devices from needing/obtaining a licence (i.e. only target those un-registered devices intended for export/re-export, as opposed to burdening registered traders and devices with an additional import/export control); or to allow registered traders to apply for a licence for registered devices that is valid for certain period of time as a way of minimising the administrative burden on both traders and DH.

### **Use and Operation of Medical Devices**

52. DH proposes to license business operators of Class 3B and 4 laser equipment and IPL devices, and require them to meet certain safety requirements. The proposal also proposes to restrict the use and operation of Class 3B and 4 laser equipment to the 12 groups of registered healthcare professionals. IPL devices can be used and operated by non-medical personnel who have undergone recognised general training (and passed a trade test) and device-specific training. We recommend DH:

- To examine using other more appropriate means of regulating the use and operation of medical devices, as opposed to using the proposed medical devices legislation to do so.
- To consider allowing all persons (registered healthcare professionals or not) who fulfil a set of skills and competency requirements to operate and use Class 3B and 4 laser equipment and IPL devices; and requiring all operators to have adequate recognised training before operating Class 3B and 4 laser equipment and IPL devices.

### **Fees for Trader Registration and Device Registration**

53. DH proposes to charge:

- local manufacturers HK\$13,000 for first-time registration (valid for 3 years), and HK\$6,500 for renewal.
- AR, importers, and distributors HK\$600 per role undertaken for first-time registration (valid for 1 year), and HK\$300 per role undertaken for renewal.
- Class I and A device notifications HK\$500 for first-time notification (valid for 1 year), and HK\$250 for renewal.

- Class II to IV and B to D device registrations HK\$6,500 for first-time registration (valid for 3 years), HK\$600 for renewal, and HK\$3,500 for changes per submission.

54. We recommend DH to consider reducing the cost of compliance and minimising the impact on the business community by:

- Charging traders who play multiple roles (AR, importers, and/or distributors) a single fee only (and not on a per-role basis).
- Charging Class I notifications on a trader basis as opposed to charging on a per-device basis.
- Standardising the validity period at 3 years for all types of trader registration (including Class I trader notification), and adjusting the proposed fee level downwards for Class II to IV devices and Class B to D IVDMD registrations.
- Allowing companies that qualify as small and medium sized enterprises (SME) to pay discounted fee rates for device registration for Class II, III and IV devices as a measure to help small business.
- Standardising the validity period at 5 years for all Class II to IV device and Class B to D IVDMD registrations.

### **Fees for Business Operator's Licence**

55. DH proposes to charge HK\$2,000 for first-time registration (valid for 3 years), and HK\$1,000 for the renewal of Business Operator's Licence. We recommend DH:

- To consider whether there is room for adjusting the proposed fee level downwards to reduce the cost of compliance and minimise the impact on the business community. However, our main recommendation is for DH to examine using other more appropriate means of regulating the use and operation of medical devices, as opposed to using the proposed medical devices legislation to do so.

### **Labelling Requirements**

56. DH proposes to require Class I devices to have bilingual (English and Chinese) labels and instructions for use. Manufacturers will be the one responsible for undertaking translations. The Department is also considering whether or not to require certified translations if the translations are undertaken by importers, AR, or distributors (as opposed to manufacturers). We recommend DH:

- To require 'self-use' devices to have bilingual labels and instructions for use.
- To issue guidelines to encourage overseas manufacturers to undertake the translation work, but allow local importers, AR and/or distributors to do so.
- Not to require certified translations if translations are undertaken by local importers, AR, or distributors (as opposed to overseas manufacturers).

## Control on Advertisements

57. DH proposes to regulate the advertising of medical devices to prevent misrepresentation. Traders will need to meet the proposed requirements, and any other relevant requirements under other Ordinances (e.g. Undesirable Medical Advertisements Ordinance (Cap 231), Trade Descriptions Ordinance (Cap 362), etc). The idea of placing controls on advertisements for medical devices is considered, in principle, appropriate. We recommend DH:

- To include the controls under one of the existing relevant pieces of legislation as opposed to spreading the regulatory requirements in separate pieces of legislation.

## Post-market Control

58. DH proposes to require traders to put in place adequate mechanisms for monitoring device performance and recalls (when needed) in Hong Kong. In addition to proactive surveillance and trending, the proposal also requires:

- AR or local manufacturers to report adverse incidents of all classes of medical devices. When needed, an investigation of an incident should be conducted by the AR or local manufacturer(s) and DH.
- AR or local manufacturers to put in place a tracing/tracking system and maintain a proper distribution records for a period of 7 years or longer.
- ‘One step backward, one step forward’ approach to device traceability, which requires traders to be able to identify at least the immediate supplier(s) and the immediate buyer(s) of their devices. In addition, traders will be required to have systems and processes in place that allow this information to be made available to the Government when requested.

59. In principle we agree with DH’s proposal, and we recommend DH:

- To issue guidelines to ask traders to report an adverse incident within a reasonable period of time of them knowing about the incident, and then give traders time to investigate and come back to DH with relevant details.
- To adopt a standardised 2-category approach to determining the record retention period for easier implementation:
  - A period of time equivalent to the design and expected life of the device (as determined by the manufacturer), but not less than 7 years (based on the minimum requirement of the Inland Revenue Ordinance) from the date of release for commercial distribution by the manufacturer—mainly for Class I, II and III devices (and A, B and C IVDMDs).
  - 99 years—mainly for Class IV devices (and D IVDMDs), unless it can be proven that a device can/should be subject to a shorter retention period (a period of time equivalent to the design and expected life of the device, or a minimum of 7 years).
- To do away the word ‘proactive’ (in ‘Proactive Surveillance and Trending’).

- To consider issuing guidelines to encourage traders to keep detailed information (e.g. lot numbers, serial numbers, where these exist) explaining that this will help target recalls.

### **Implementation Considerations**

60. DH proposes to undertake registration by phases. The current voluntary listing system, MDACS, will be transitioned to the new regulatory environment. Traders and products who are currently listed in MDACS will not be required to re-submit their 'registrations', but may be asked to provide additional information. Pre-existing devices which are imported, procured and put into service before the date when the proposed legislation comes into effect will be exempted from registration. In view of the large number of traders and medical devices involved, we recommend DH:

- To make provisions for a longer implementation period, at least for the first 2 phases—trader registration, and device registration. We anticipate that the first 2 phases of implementation will likely take 2 to 3 years each to complete. DH should review progress regularly, and make adjustments to reflect actual experience and changing circumstances.
- To communicate with relevant stakeholders through different channels.
- To consider setting up an industry advisory committee (ideally, with representation from relevant stakeholder groups) to discuss and provide inputs to issues encountered during implementation.
- To consider exempting pre-existing devices from the proposed record-keeping requirement so as to minimise the impact on the business community.



**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 –

<b>Class</b>	<b>Risk Level</b>	<b>Examples</b>
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 –

<b>Class</b>	<b>Risk Level</b>	<b>Examples</b>
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

<b>Class</b>	<b>Risk Level</b>	<b>Examples</b>
C	High individual risk, Medium public health risk	Blood glucose self testing, HLA typing, PSA screening, rubella
D	High individual risk, High public health risk	HIV blood donor screening, HIV blood diagnostic

Summary of Regulatory Proposal

<u>Scope and Definition</u>		
	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Scope of coverage</b>	<ul style="list-style-type: none"> <li>• Covers products defined as “medical devices”</li> <li>• “Borderline products” will be included into the regulatory control framework through a Schedule. These include products that do not fall squarely within the medical device definition, but are intended for use on human and carry the potential of causing adverse effect on human body in a similar way to a medical device (e.g. non-corrective contact lenses).</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Definition of Medical Device</b>	<ul style="list-style-type: none"> <li>• Based on the Global Harmonisation Task Force’s (GHTF) recommendations.</li> <li>• “Medical device” generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It covers devices that are used for the purpose of investigation, replacement, modification or support of the anatomy or physiological process of the human body. Devices used for examination of human specimens are also included under the term.</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Classification of Medical Device</b>	<ul style="list-style-type: none"> <li>• <b>General medical devices</b> are classified into four classes according to the risk-based classification rules recommended by GHTF, with Class I being the class with the lowest risk and Class IV with the highest risk.</li> <li>• <b>In vitro diagnostic medical devices</b> are classified into four classes according to the risk-based classification rules recommended by GHTF, with Class A being the class with the lowest risk and Class D with the highest risk.</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>

<b><u>Pre-market control</u></b>		
	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Local manufacturer</b>	<ul style="list-style-type: none"> <li>• Registration with the Department of Health (DH) and renewal every 3 years</li> <li>• Compliance with quality management system (QMS) requirements and obtain certification</li> <li>• Local manufacturer of custom-made devices exempted from registration</li> <li>• Refurbishing, re-labelling and re-packaging of medical devices are considered manufacturing activities</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Authorised representatives (ARs)</b>	<ul style="list-style-type: none"> <li>• Registration with DH and annual renewal</li> <li>• Designated by the manufacturer to register the medical devices and hold the certification of registration of medical devices</li> <li>• Compliance with relevant quality management system (QMS) requirements and obtain certification</li> <li>• Responsible for product recall, adverse events reporting and investigation</li> </ul>	<ul style="list-style-type: none"> <li>• Extending the registration validity period from 1 year to 3 years</li> <li>• Requiring specific standard operating procedures (SOPs) in QMS, but certification for QMS not required</li> </ul>
<b>Importers / Exporters</b>	<ul style="list-style-type: none"> <li>• Registration with the DH and annual renewal</li> <li>• Compliance with relevant quality management system (QMS) requirements and obtain certification</li> </ul>	<ul style="list-style-type: none"> <li>• Extending the registration validity period from 1 year to 3 years</li> <li>• Requiring specific standard operating procedures (SOPs) in QMS, but certification for QMS not required</li> </ul>
<b>Distributors (Wholesalers)</b>	<ul style="list-style-type: none"> <li>• Registration with the DH and annual renewal</li> <li>• Compliance with relevant quality management system (QMS) requirements and obtain certification</li> </ul>	<ul style="list-style-type: none"> <li>• Extending the registration validity period from 1 year to 3 years</li> <li>• Requiring specific standard operating procedures (SOPs) in QMS, but certification for QMS not required</li> </ul>

<b><u>Pre-market control</u></b>		
	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Conformity Assessment Bodies (CABs)</b>	<ul style="list-style-type: none"> <li>• CABs are required to register with the DH</li> <li>• CABs provide third party conformity assessment services to traders</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Medical device registration</b>	<ul style="list-style-type: none"> <li>• Using the DH’s own “in-house” resources to review and approve pre-market registration</li> <li>• An appeal board that is made up of members from external parties such as trade associations, medical associations, engineering institutions and academic institutes be appointed by the Secretary for Food and Health to handle appeal cases relating to licensing and registration</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> <li>• In addition to the appeal board, to set up an expert group comprising members from relevant stakeholder groups to provide inputs on “borderline cases” and any special issues in connection with the administration of the legislation</li> </ul>
<b>Low-risk medical devices (Class I MD/ Class A IVDMD)</b>	<ul style="list-style-type: none"> <li>• Notification to the DH and annual renewal</li> </ul>	<ul style="list-style-type: none"> <li>• Exempting low-risk medical devices from product registration and notification</li> </ul>
<b>Medium to high-risk medical devices (Class II-IV MD/ Class B-D IVDMD)</b>	<ul style="list-style-type: none"> <li>• Registration with the DH and renewal every 3 years</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Exemptions from medical device registration</b>	<ul style="list-style-type: none"> <li>• Exemptions from medical device registration in specific situations (e.g. devices for re-export only, clinical trials, non-clinical use, public health emergencies, and for use on a named-patient)</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Import / export licence</b>	<ul style="list-style-type: none"> <li>• Requiring selected medical devices to apply for import/export licence for each consignment</li> </ul>	<ul style="list-style-type: none"> <li>• Not to introduce import / export control at this stage</li> </ul>
<b>Labelling requirements</b>	<ul style="list-style-type: none"> <li>• Bilingual labels and instructions of for use required for Class I devices</li> </ul>	<ul style="list-style-type: none"> <li>• Requiring “self-use” devices to have bilingual label and instructions for use</li> </ul>

<b><u>Pre-market control</u></b>		
	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Control on advertisements</b>	<ul style="list-style-type: none"> <li>• Advertising of medical devices to be regulated to prevent misrepresentation and false claims</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>

<b><u>Post-market control</u></b>		
	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Adverse incident reporting</b>	<ul style="list-style-type: none"> <li>• Requiring ARs / local manufacturers to report adverse incidents of all classes of medical devices to the DH and conduct investigation</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>
<b>Device tracing / tracking (and record-keeping)</b>	<ul style="list-style-type: none"> <li>• Requiring ARs / local manufacturers to put in place a tracing / tracking system for selected high-risk medical devices, e.g. implantable pacemakers</li> <li>• Requiring all traders to maintain proper distribution records for a period of 7 years or longer</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> <li>• Distribution records to be maintained for the projected useful life of the medical devices, or 2 years after the medical devices has been shipped, whichever is the longer</li> </ul>
<b>Surveillance and trending, and device recall</b>	<ul style="list-style-type: none"> <li>• Requiring ARs / local manufacturers to keep track of adverse incidents and complaints, including their trends, to keep track of their products' performance and to take remedial action when needed</li> <li>• Requiring ARs / local manufacturers to issue safety notices and instigate product recalls for unsafe medical devices</li> <li>• The DH has the power to order a ban on the supply or a recall of unsafe devices</li> </ul>	<ul style="list-style-type: none"> <li>• No change</li> </ul>

**Control on use and operation**

	<b>Original proposal</b>	<b>Revised proposal</b>
<b>Control on use of certain medical devices</b>	<ul style="list-style-type: none"><li>• Use of specified devices to be restricted to –<ol style="list-style-type: none"><li>1. Registered healthcare professionals only - e.g. Class 3B and 4 medical lasers</li><li>2. Non registered healthcare professionals who have undergone recognised training and passed the relevant trade test - e.g. intense pulsed light devices</li></ol></li><li>• Business operators of specified medical devices (e.g. laser and IPL) to obtain a licence from the DH and renewal of the registration every 3 years</li></ul>	<ul style="list-style-type: none"><li>• No change, but the list of devices to be included under “use control” will be further examined through a consultancy study which would aim to develop a set of criteria for determining the type of personnel and the level of competence required to operate specified types of devices</li><li>• No licence required</li></ul>

### Revised cost of compliance based on the revised proposal

Key Area of Regulation		Total Cost of Compliance (in HK\$ million)			
		One-off		Annual Recurrent	
		Original	Revised	Original	Revised
<b>Pre- market</b>	Registration of local manufacturers	4.36	4.36	2.27	2.27
	Traders registration (AR, importer, distributor)	1,079.99	25.29	635.16	0.31
	# Device notification	31.20	0	10.80	0
	@ Device registration	1,086.10	530.00	180.21	87.94
	Import / Export licence	-	-	0.41	0
<b>Post-market</b>	Surveillance and adverse incident reporting	-	-	-	-
<b>Sub-Total (Medical device industry)</b>		<b>2,201.65</b>	<b>559.65</b>	<b>828.85</b>	<b>90.52</b>

Key Area of Regulation		Total Cost of Compliance (in HK\$ million)			
		One-off		Annual Recurrent	
		Original	Revised	Original	Revised
<b>Use and Operation</b>	Business operator licence - Class 3B and 4 Laser & IPL	14.15	0	2.31	0
	Employ healthcare professional (Class 3B & 4 Laser)	-	-	508.04*	508.04*
	Training and trade test (IPL)	73.31^	73.31^	-	-
<b>Sub-Total (Beauty industry)</b>		<b>87.46</b>	<b>73.31</b>	<b>510.35</b>	<b>508.04</b>

<b>Total (Medical device + Beauty industry)</b>	<b>2,289.11</b>	<b>626.96 (-73%)</b>	<b>1,339.20</b>	<b>598.56 (-55%)</b>
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# Class I medical devices and Class A in-vitro diagnostic medical devices

@ Class II, III, and IV medical devices and Class B, C, and D in vitro diagnostic medical devices

\* Based on the assumption that 45% of beauty salons (i.e. 2,250) are operating Class 3B and 4 lasers and all of them will choose to continue providing the service by employing registered healthcare professionals

^ Based on the assumption that 90% of beauty salons (i.e. 4,500) are with IPL device and all staff involved in the operation of IPL devices (i.e. about 9,300) will take the trade test with 38.28% of them attended the training course (estimate did not account for any changes in the workforce)

The cost of compliance was re-calculated based on the following changes -

1. Refined proposal and adoption of mitigation measures –
  - Extending the validity period of traders' registration from 1 year to 3 years
  - Removing the ISO certification requirements
  - Removing the requirement for import / export licence
  - Removing the requirement for notification or registration of Class I medical devices
  - Removing the requirement for business operator licence for specified medical devices
2. Revised background assumptions -
  - The number of medical devices adjusted from the guesstimated 80,000 to an estimate of 40,000, by making reference to Singapore, which has a market structure similar to Hong Kong and has newly established legislative control over medical devices.
  - The number of medical device traders is adjusted from some 14,000 to an estimate of 3000, by making reference to Singapore.



**Average Annual Cost of Compliance for an Authorised Representative  
dealing with a model of medical device which  
has a model life of 10 years**

<b>Annual Cost of compliance over first 10 years (HK\$)</b>				
<b>Scenarios with different changes in device particulars during the 10 years*</b>				
<b>No change</b>	<b>1 Minor change</b>	<b>1 Major change</b>	<b>1 Major change + 2 Minor changes</b>	<b>3 Major changes</b>
<b>3,765</b>	<b>4,122</b>	<b>5,090</b>	<b>5,804</b>	<b>7,740</b>

\* Scenarios prepared were based on the Medical Device Administrative Control System, where the vast majority of the devices listed 8 years and over did not have any application for change in device particulars and the maximum number of application for change was 3 in one device.

**Average Annual Cost of Compliance for a Local Manufacturer**

<b>Annual Cost of compliance over first 10 years (HK\$)</b>			
<b>Already attained QMS Certificate</b>		<b>Not yet attained QMS Certificate</b>	
<b>Class I MD</b>	<b>Class II-IV MD</b>	<b>Class I MD</b>	<b>Class II-IV MD</b>
<b>16,182</b>	<b>34,782</b>	<b>23,432</b>	<b>54,282</b>

**Average Annual Cost of Compliance for an Importer / a Distributor**

<b>Annual Cost of compliance over first 10 years (HK\$)</b>	
<b>SME</b>	<b>Large Corporation</b>
<b>932</b>	<b>1,187</b>