立法會
Legislative Council

LC Paper No. CB(2)1754/13-14(05)

Ref : CB2/PL/HS

Panel on Health Services

Updated background brief prepared by the Legislative Council Secretariat for the meeting on 16 June 2014

Proposed regulatory framework of medical devices

Purpose

This paper gives an account of the past discussion by the Panel on Health Services ("the Panel") on the proposed regulatory framework of medical devices.

Background

2. 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 purposes 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 breast implants and high power laser machines. Devices used for examination of human specimens are also regarded as medical devices.

3. At present, 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 ionizing radiation. Pharmaceutical products are regulated under the Pharmacy and Poisons Ordinance (Cap. 138) whereas devices emitting ionizing radiation or contain radioactive substances are regulated under the Radiation Ordinance (Cap. 303).

4. To safeguard the health and safety of patients, users and the public, the Government put forth a risk-based framework for regulating the supply and use of medical devices in the public consultation document entitled "Regulation of Medical Devices" in July 2003 for a three month consultation. The feedback received revealed a general support from different sectors of the community on the proposed principles of regulation, definition and classification of medical devices and the scope of control. As a step forward, the Department of Health ("DH") established a voluntary Medical Device Administration Control System ("MDACS") in 2004 to raise public awareness of the importance of medical device safety and pave the way for implementing the long-term statutory control. MDACS, which was introduced in phases over five years, comprises (a) a listing system for medical devices under which manufacturers and importers of medical devices can voluntarily listed their medical devices with DH; and (b) an adverse incident reporting system through which the manufacturers, importers, users and the general public can report adverse incidents to DH.

5. At the Panel meeting on 8 November 2010, members were briefed on the proposed regulatory framework for medical devices which is modelled largely on the recommendations of the Global Harmonization Task Force ("GHTF")[1] and World Health Organization[2]. A risk-based approach is adopted whereby the level of control will be proportional to the degree of risk. Medical devices other than in-vitro diagnostic medical devices ("IVDMD") are classified into four classes, namely Class I (low risk level), Class II (medium to low risk level), Class III (medium to high risk level) and Class IV (high risk level). IVDMDs are also classified into four classes, namely Class A (low individual risk, low public health risk), Class B (medium individual risk, low public health risk), Class C (high individual risk, medium public health risk) and Class D (high individual risk, high public health risk). The proposed scope of control covers (a) pre-market control through registration of medical devices and traders; (b) post-market control through the putting in place a surveillance system and control measures against defective or unsafe medical devices; and (c) use control to restrict the possession and use of certain high-risk medical devices.

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[1] GHTF was formed in 1992 by a group of representatives from regulatory authorities and medical device industries to harmonize the standards and principles for the regulation of medical devices.

[2] In 2003, the World Health Organization 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.

Deliberations of the Panel

6. The Panel held a number of meetings between June 2002 and November 2010 to discuss the proposal on the regulation of medical devices and received the views of deputations on the proposal at one meeting. The subject was also discussed in the context of regulation of medical beauty treatments/procedures at four Panel meetings held in 2012 and 2013. The deliberations and concerns of members are summarized below.

Definition and classification of medical devices

7. Members noted that the proposed regulatory control over medical devices would be proportional to the level of risk associated with a medical device. Concern was raised about the standard to be adopted in classifying the risk levels of medical devices, in particular that of the Chinese medicine medical devices as no international reference on their classification was available. The Administration advised that for the purpose of the proposed legislation, the definition and the classification of medical device would be based largely on the recommendation of GHTF with a view to ensuring consistency with international practices. Modifications would however be made to suit local circumstances. The principle was that the imposition of regulatory control should not place an unnecessary burden on the regulators, the trade and the industry nor delay the introduction of new products that would benefit patients.

8. Members noted that while both corrective and non-corrective contact lens were intended for use on human body with similar potential adverse effect, the former would be classified as Class II medical device subject to statutory control under the proposed regulatory framework whereas the latter would be included for regulatory control through listing in a Schedule of the proposed legislation. Question was raised about the factors to be taken into account by DH in determining which of those products that did not fall within the definition of medical device should be included in the Schedule for regulatory control.

9. The Administration advised that experience of countries with regulatory control showed that, despite the attempt to provide a clear definition for medical device, a number of products appeared to be borderline cases. It was therefore proposed that the Director of Health ("DoH") should be empowered under the legislation to designate through a form of Schedule those products which were to be included for regulatory control having taken into account factors such as

the sale and use of the product in the local market; the risk of the product in causing adverse effect on human body; the frequency of adverse incidents arising from the use of the product; as well as the views of the sellers and users.

10. Some members considered that such an approach would cause confusion to the public and place unnecessary burden on the trade and industry. There was a view that an independent committee should be set up to advise DoH on which products should be included in the Schedule of the proposed legislation. Members were advised that any amendments to the Schedule would be subject to negative vetting of the Legislative Council. Similar to the arrangements under other legislation, the regulatory authority, rather than another committee, would be empowered to determine the products to be designated in the Schedule.

Pre-market control of medical devices

11. Members noted that registration or listing with DH would be required before a medical device could be placed on the local market. There was a call for the Administration to ensure that DH would have adequate manpower and resources to effectively perform the assessment work, so as to ensure that a medical device was safe and would perform as intended before market entry.

12. According to the Administration, the proposed legislation would empower DH to designate conformity assessment bodies ("CABs") to perform conformity assessment audits on medical devices, so as to provide third party conformity assessment services to manufacturers. In response to members' concern about the requirements to become a CAB, the Administration advised that conformity assessment was one of the requirements under the current MDACS. DH had, based on the quality standard adopted by the European Union in conformity assessment, accredited three CABs which comprised a balanced mix of expertise in the various professional fields.

Control over the use and operation of selected high risk medical devices

13. Members were advised that operation of Class 3B and Class 4 high-power medical lasers would be limited to statutorily registered healthcare professionals, and only trained personnel who had passed the IPL trade test run by reputable institutions such as the Vocational Training Council (except for statutorily registered healthcare professionals) would be allowed to operate the intense pulsed light ("IPL") equipment. Members noted that the beauty trade had

grave concern over the restrictive use of lasers and IPL equipment, as the business generated by those procedures involving the use of such equipment was fast becoming its main source of income. On the other hand, representatives from the medical sector considered that the use and operation of high-powered lasers and IPL equipment should be confined to qualified doctors and dentists and other persons authorized by them. Members requested that an impact study of the proposed regulation on the workforce and stakeholders should be conducted. There was a view that over regulation would reduce consumer choice of affordable advanced cosmetic procedures which involved the use of devices which emitted different forms of energy.

14. The Administration stressed that while the regulation of medical devices involved complex issues as devices were heterogeneous by nature, the proposed regulatory framework was not intended to undermine the business and the development of the beauty trade. Members were advised at the meeting on 18 November 2013 that in view of the complexity of the issue and the rapid advances in technology, the Administration would engage an international authority as consultant to conduct more in-depth study into the regulatory framework of cosmetic-related medical devices.

15. Members also sought information on the requirements for non-medical operators to take out liability insurance to cover negligence claims arising from the improper use of medical devices. The Administration advised that non-medical operators would be required to have the necessary skills and training for using and operating Class 3B and Class 4 high-power medical lasers and IPL equipment. It was also proposed that the business operators of this group of medical devices had to apply for a licence to use the devices and undertake to comply with a set of licensing conditions including the requirement to ensure that the device was operated by trained and competent personnel. The Administration had no plan at that stage to mandatorily require them to take out liability insurance against the risk of claims.

16. On the question of whether beauticians having undergone appropriate training would be allowed to operate other cosmetic-related medical devices under the new regulatory regime as long as they were working under the supervision of registered medical practitioners. The Administration explained that the employment of any person trained to perform specialized duties or functions in connection with the medical treatment of a patient was acceptable provided that the registered medical practitioner concerned exercised effective

personal supervision over the persons so employed and retained personal responsibility for the treatment of the patients.

Timetable for introducing the regulatory framework

17. Concern was raised about the slow progress of the Administration in putting in place the regulatory control on the supply and use of medical devices as it had, since unveiled the first proposed framework to regulate medical devices in 2003, taken seven years to work out the latest proposed regulatory framework.

18. The Administration advised that as the first step, a voluntary MDACS had been launched by DH since 2004 in phases to facilitate the transition to long-term legislative control. A Regulatory Impact Assessment was conducted from 2007 to 2008 to examine the implications of the possible options for the proposed statutory regulation of medical devices. The Business Facilitation Advisory Committee was briefed on the latest proposed regulatory framework in March 2010. While expressing support for the proposal, the Committee recommended the Administration to conduct Business Impact Assessment ("BIA") at the detailed design stage. It was expected that the outcome of BIA study would be ready in 2011. The Administration would take into account of the findings to finalize a statutory regulatory proposal. Members strongly called on the Administration to engage the beauty industry in formulating the new regulatory regime for medical devices.

Recent developments

19. Following the adverse incident that took place during the performance of an invasive cosmetic procedure provided by a beauty parlour in October 2012, a Working Group on Differentiation between Medical Procedures and Beauty Services was set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities to examine and identify cosmetic services that should be classified as medical treatment and performed by registered medical practitioners or registered dentists. In its report which was endorsed by the Steering Committee on 1 November 2013, the Working Group supported the Administration's plan to introduce a new medical device ordinance to deal with the issue of control over the use of selected high-risk medical devices, and recommended that cosmetic procedures involving the use of medical devices,

particularly those using energy-emitting devices, should be deliberated within the regulatory framework for medical devices. It also recommended the setting up of an expert panel under the future medical device ordinance to advise on the risk and appropriate controls over new cosmetic procedures involving the application of innovative devices.

20. At the Panel meeting on 20 January 2014 to receive a briefing from the Secretary for Food and Health on the 2014 Policy Address in relation to health matters, members were advised, among others, that DH had commissioned in 2011 a consultant to conduct a BIA of the regulatory proposal. The BIA was completed in January 2013. The Administration will report to the Panel on the BIA findings and the way forward of the legislative exercise for putting in place the statutory regulatory framework for medical devices at the Panel meeting on 16 June 2014.

Relevant papers

21. A list of the relevant papers on the Legislative Council website is in **Appendix**.

Council Business Division 2
Legislative Council Secretariat
10 June 2014

Appendix

Relevant papers on the proposed regulatory framework of medical devices

Committee	Date of meeting	Paper
Panel on Health Services	10.6.2002 (Item IV)	Agenda Minutes
Panel on Health Services	12.5.2003 (Item IV)	Agenda Minutes
Panel on Health Services	22.3.2004 (Item I)	Agenda Minutes
Panel on Health Services	19.7.2005 (Item II)	Agenda Minutes CB(2)1034/06-07(01)
Panel on Health Services	8.11.2010 (Item V)	Agenda Minutes CB(2)625/10-11(01)
Panel on Health Services	26.10.2012 (Item I)	Agenda Minutes
Panel on Health Services	27.11.2012 (Item I)	Agenda Minutes
Panel on Health Services	18.11.2013 (Item IV)	Agenda Minutes
Panel on Health Services	23.12.2013 (Item I)	Agenda
Panel on Health Services	20.1.2014 (Item III)	Agenda Minutes

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