立法會
Legislative Council

LC Paper No. CB(2)183/10-11(06)

Ref : CB2/PL/HS

Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 8 November 2010

Regulation of medical devices

Purpose

This paper gives an account of the past discussions by the Panel on Health Services ("the Panel") on the regulation of medical devices.

Background

2. A medical device generally refers to any instrument, apparatus, appliance, material or other article, excluding drugs, used for human being for diagnosis, prevention, treatment or monitoring of diseases or injuries; or for rehabilitation purposes; or for the purposes of investigation, replacement or modification of body structure or function; or for examination of human specimens. There are now more than 20 000 types of medical devices in the local market, including highly complex and sophisticated products such as Magnetic Resonance Imaging System to simple products such as bandages and thermometers. Many of them are readily accessible to the public.

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 are regulated under the Radiation Ordinance (Cap. 303). In the Consultation Document on Health Care Reform released by the then Health and Welfare Bureau in December 2000, the Administration proposed to carry out a comprehensive review of the statutory regulations in relation to, among other things, the use of medical devices. In this connection, the Department of Health ("DH") had worked with the Electrical and Mechanical Services Department ("EMSD") to review the situation and propose an appropriate regulatory system for medical devices in Hong Kong.

Deliberations of the Panel

4. The Panel held four meetings on 10 June 2002, 12 May 2003, 22 March 2004 and 19 July 2005 respectively to discuss the proposal on the regulation of medical devices and received the views of deputations on the proposal at one meeting. The deliberations and concerns of members on the proposal are summarized below.

Principle and scope of the regulatory framework

5. Following a review by DH and EMSD, the Panel was briefed on the proposal on the regulation of medical devices on 10 June 2002. Members were advised that the proposed regulatory control would be proportional to the level of risk associated with a medical device. 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. The scope of control would include pre-market control through registration of products and traders; control on the use and operation of selected medical devices; and post-market control through establishing an adverse incident reporting system.

6. Members were of the view that the definition of medical devices, including that of Chinese medical devices, should be clear. Noting that a risk-based approach was proposed to be adopted for the regulation of medical devices, concern was raised about the standard to be adopted in classifying the risk levels of the medical devices.

7. The Administration advised that the proposed regulatory framework was largely in line with the recommendations made by the Global Harmonisation Task Force, a voluntary consortium with representatives from the trade and regulatory authorities from the United States, Canada, Australia, Japan and the European Union. This included definition and classification of medical devices, essential principles of safety and performance, quality system requirements, vigilance system requirements, and the use of international standards. Modifications would be made to suit local circumstances.

Proposed control arrangements

8. At the meeting on 12 May 2003, the Administration briefed the Panel on the proposed control arrangements, the salient points of which are as follows -

(a) medical devices would be classified into four classes based on their risk to patients, users and other persons: Class I (low risk level), Class II (medium-low risk level), Class III (medium-high risk level) and Class IV (high risk level). Examples of Class I devices were tongue depressor and walking aid. Examples of Class IV devices were heart valve and implantable pacemaker;

(b) while devices of all classes would be required to meet labelling requirements before sale, registration would only be required for devices

of Class II and above. On the trade side, registration would be required for all local manufacturers of medical devices who sold medical devices in Hong Kong, local representatives of overseas manufacturers of medical devices of Class II and above, and all importers of medical devices;

(c) the use or operation of selected high risk medical devices would be restricted to trained personnel; and

(d) the manufacturers would be required to collect data on the performance and safety of selected high-risk medical devices in the market so that precautionary measures could be taken to minimize any potential public health hazards associated with their use. In addition, the manufacturers of all devices and their local representatives would be required to report any adverse incidents that had led to death or serious injury of the user, patient or other persons.

9. Members noted that the scope of medical devices covered a very wide range of equipment, apparatus and articles. The scope would include non-orthodox devices such as those having the effect of changing the human anatomy based on non-orthodox medicine theory, or those carrying unsubstantiated health or medical claims. Although most of these items fell into the low risk category and would not be subject to control under the proposed regulatory system, the Administration advised that for those non-orthodox devices that emitted energy or were invasive to human body, i.e. devices meeting Class II or above definition, registration would be required.

10. Members were advised that an administrative control system based on the same principles as the proposed statutory control would be implemented in stages. The administrative control system would start with the listing of high-risk (Class IV) medical devices, their importers, manufacturers and authorized representatives in 2004. After review and evaluation, listing of Class III devices, Class II devices and their importers, manufacturers and authorized representatives would follow in stages.

11. Concern was raised as to the implementation of the proposed control arrangements, particularly with regard to the use of certain medical devices in beauty parlours. The Administration agreed that it was important to define clearly what constituted the use of a medical device for beauty therapy or for medical treatment. Particular attention would be paid to the use of devices such as medical lasers which could have serious adverse effect if used improperly.

<u>Control on use and operation of selected high risk medical devices</u>

12. Members shared the concern of many deputations about the proposal of limiting the use of high risk medical devices, such as Class 3B and 4 lasers intended for medical or beauty therapy and intense pulsed light ("IPL") devices, to trained personnel. Members noted that the beauty trade in general supported the regulation

of medical devices for safeguarding public health, but it had grave concern over the restrictive use of lasers and equipment, as the beauty trade generated by 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. Meanwhile, the Administration should consider setting up an appeal system in case of disputes arising from the regulatory system.

13. The Administration assured members that the proposed regulation of medical devices was not intended to undermine the business and the development of the beauty trade. Indeed, the Administration had proposed to allow non-medical personnel to continue to use high-powered medical devices, provided that they had received recognized training to use and operate such devices.

14. At the meeting on 19 July 2005, members were advised that a Working Group had been set up by DH in June 2004 to devise measures to strengthen the control on the use of selected high-risk medical devices. The Working Group, comprising representatives from DH, the then Education and Manpower Bureau, the Vocational Training Council ("VTC"), the Consumer Council, medical practitioners and beauticians, agreed that an examination should be developed by VTC to provide an avenue for IPL operators, including beauticians, to obtain accreditation and certification as trained practitioners to operate IPL devices. The first examination was expected to be held within 2005.

15. Members were concerned about the assistance given to the industry in meeting the accreditation and certification requirements. The Administration advised that some beauticians had already received training provided by the supplier of the IPL device. VTC would also publish the syllabus of the examination for reference of the candidates. It was also expected that some training institutions would be interested in organizing training programmes for the examination.

16. Members sought information on the requirements for practitioners to take out insurance to cover claims arising from mishandling of medical devices. The Administration advised that most medical practitioners had taken out professional indemnity insurance. As regards non-medical operators, the certification system would ensure that they had the necessary skills and training for the operation of the devices. The Administration had no plan at that stage to require them to take out insurance against the risk of claims.

Implementation of the voluntary Medical Device Administrative Control System

17. Members were advised that a voluntary Medical Device Administrative Control System ("MDACS") had commenced operation in November 2004. Manufacturers and importers of medical devices were invited to apply for listing in a register for their products, starting with Class IV devices, that met specific safety,

efficacy and quality standards. A post-market Safety Alert and Recall System and an Adverse Incident Reporting System had also been launched as part of MDACS. DH would draw up guidance notes and hold briefing sessions on the listing of Class II and III devices which should take place from early 2006 onwards.

Recent developments

18. Subsequent to the meeting on 19 July 2005, the Administration advised the Panel in writing on 2 February 2007 that DH was consulting the relevant parties on the listing of local manufacturers and intended to launch the listing scheme in the first quarter of 2007. Separately, DH would begin the consultation on the listing system for importers of medical devices in due course. In addition, DH was working with the Efficiency Unit and the Economic Analysis and Business Facilitation Unit on the preparatory work for a regulatory impact assessment ("RIA") to examine the direct and indirect impact that the proposed regulatory model would have on various stakeholders. The assessment would commence upon selection of the consultant. The Administration further advised that the first trial written and practical tests for operators of IPL devices were conducted in September and November 2006 respectively. VTC would launch the comprehensive trade tests in March 2007.

19. At the special meeting of the Panel on 15 October 2010 to receive a briefing from the Secretary for Food and Health on the 2010-2011 Policy Agenda in relation to health matters, members were advised, amongst others, that on the basis of the RIA completed in 2008, DH was reviewing the RIA recommendations and experience gained from the operation of MDACS. The Administration planned to consult the Panel on the statutory regulatory proposal in 2010.

Relevant papers

20. Members are invited to access the Legislative Council website (http://www.legco.gov.hk) for details of the relevant papers and minutes of the meetings.

Council Business Division 2
Legislative Council Secretariat
2 November 2010