For Information LC Paper No. CB(2)2087/04-05(01)
28 June 2005

Legislative Council Panel on Health Services

Regulation of Medical Devices in Hong Kong
Recent Progress

This paper aims to inform Members of the recent progress on regulatory control of medical devices.

Background

2. 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[1]. In early 2003, the Administration announced that a regulatory framework on the supply and use of medical devices would be developed. The objective was to protect public health while ensuring our community's continued access to the benefits of new technologies.

3. Following a public consultation exercise in 2003, and having consulted the Panel on Health Services in 2004 (a copy of the relevant paper at **Annex**), the Administration developed a voluntary Medical Device Administrative Control System (MDACS).

Progress

4. The MDACS, which operates on the basis of the guideline developed in consultation with the relevant stakeholders, formally commenced in November 2004. Following the recommendations of the Global Harmonisation Task Force (GHTF)[2], control for the medical devices will be classified into four classes based on their risk levels. The scope of control will consist of three parts: pre-market control through listing of products and traders, post-market control through establishing an adverse incident reporting system, and control on the use and operation of selected medical devices. To introduce pre-market control, manufacturers and importers of medical devices are invited to list their

[1] Devices which contain pharmaceutical products or emit ionising radiation are respectively regulated under the Pharmacy and Poisons Ordinance (Cap. 138) and the Radiation Ordinance (Cap. 303).
[2] This is an international taskforce formed by representatives from regulatory authorities and medical devices industries from around the world.

products, starting with Class IV devices, i.e. those with highest risks[3]. The listing arrangement is a transparency measure allowing consumers to make reference to the list where necessary. Guidance notes and briefing sessions have been provided to relevant traders to familiarize them with the scheme.

5. As at end May 2005, DH has received some 110 enquiries about the MDACS and seven applications for listing of medical devices. Of the latter, two devices have already been listed, while the remaining five are being processed. With the System launched only in late last year, many of the stakeholders are still learning the operation of the System, and we expect the number of listed devices would increase gradually after the trade becomes more familiarized with the System. DH will continue to organize workshops to brief traders on the System and to assist them in preparing listing applications. The list of listed medical devices has been uploaded onto a designated website for public's reference.

6. The DH has also set up a Working Group in June 2004 to devise measures to strengthen the control on the use of selected high-risk medical devices like Intense Pulsed-Light (IPL) and to facilitate the continued use of such devices by operators with no medical training. The Working Group comprises representatives from the DH, Education and Manpower Bureau, Consumer Council, Vocational Training Centre (VTC), and doctors and beauticians. The Working Group agreed that an examination should be developed by VTC to provide an avenue for IPL operators, including beauticians, to obtain accreditation. Operators will be regarded as trained practitioners if they pass the examination, and certificates will be granted to them. Veteran practitioners may opt for sitting for the examination directly. The ultimate objective is to ensure that IPL operators would have received some forms of training and to enhance better consumer protection. VTC is developing the syllabus for reference of prospective students and training institutions interested in organizing such training courses. The first examination is expected to be held within this year.

7. Regarding post-market control, two systems have been introduced as part of the MDACS. They are the Safety Alert and Recall System and the Adverse Incident Reporting System. The Safety Alert and Recall System, launched in January 2005, is a system through which DH maintains surveillance on safety alerts and recall notices issued by overseas authorities or manufacturers and alert the relevant parties in Hong Kong. So far there were

[3] Based on their risk to patients and users, medical devices are classified into four classes as recommended by GHTF, with Class I being the groups of devices with lowest risks and Class IV the highest. The level of control of the devices are based on their classification. Examples of Class IV devices include heart valve and implantable pacemaker. Examples of Class I devices include tongue depressor and walking aid.

two incidents for which DH issued public alerts. The first incident happened in April this year and was related to a random measurement unit error of a blood glucose testing machine used by patients with diabetes. The second incident was related to a worldwide recall of certain implantable cardiac defibrillators issued by a foreign company in mid June. In both cases, DH issued alerts to concerned parties, such as Hospital Authority, private hospitals, nursing homes, professional medical associations and relevant patients' groups, for them to take appropriate action. As regards the Adverse Incident Reporting System, DH has not received any local report of adverse incident since its launch.

Way forward

8. Publicity programmes are also in hand to promote public awareness of the listing system. These programmes include the launching of a thematic website providing educational materials about the MDACS, and the issue of fact sheets, leaflets and promotional articles. We will also organize seminars on various topics to the general public as well as healthcare staff working in private hospitals and elderly homes. When the certifying examinations are ready, we will also educate the public to identify properly trained beauty personnel who are certified to provide IPL service.

9. DH is in the preparatory stage of drawing up guidance notes and holding briefing sessions for the listing of Class II and III devices which shall take place from early 2006 onwards.

Department of Health
June 2005

Annex

For discussion on
9 February 2004

Paper No. CB(2)1180/03-04(06)

Legislative Council Panel on Health Services
Regulation of Medical Devices:
Outcome of Public Consultation and the Proposed Way Forward

Introduction

In response to the need to regulate the supply and use of medical devices, the Administration consulted this Panel on 12 May 2003 on the proposal to introduce a regulatory framework for medical devices. This paper reports on the outcome of public consultation and the Administration's thinking on the way forward.

Background

2. With advances in technology, medical devices play an increasingly important role in the delivery of quality health care services. Incidental to the increasing use of medical devices is the health risk to the users and patients brought about by unsafe devices and inappropriate operation by unqualified personnel. Currently, there is no specific legislation to regulate the manufacture, import, sale and use of medical devices in Hong Kong except for those containing pharmaceutical products or radioactive substances. There is no pre-market control to assess the safety, effectiveness and quality of medical devices. Product information is sometimes inadequate for users to make informed choices on its safe use. The lack of control over use of medical devices by untrained personnel has caused safety concerns because both users and clients/patients may be affected. The absence of formal adverse incident reporting and proactive surveillance system makes it difficult to investigate and recall defective medical devices in a prompt manner.

3. In 2003, the Government proposed to develop a risk-based regulatory framework to control the supply and use of medical devices to protect public health on the one hand while ensuring continued access to new technologies on the other. The proposed approach is largely in line with the globally harmonized model for regulating medical devices recommended by the Global Harmonization Task Force (GHTF) (i.e. a group formed by representatives from regulatory authorities and medical device industries). This will enable the consumers to benefit from internationally accepted best practice and timely access to new and safe devices.

Proposed Framework

4. The scope of control will include pre-market control through registration of products and traders, post-market control through establishing an adverse incident reporting system, and control on the use and operation of selected medical devices.

Public Consultation

5. A consultation document on the "Regulation of Medical Devices" setting out the Administration's initial thinking was issued in July 2003. During the consultation period from July to September 2003, five public forums were held and 25 meetings with key stakeholder groups were convened to gauge views from interested parties and the general public. A total of 323 written submissions were received from members of the public, consumer and patients' right groups, medical devices and beauty trade, healthcare professional associations, healthcare institutions, certification bodies, Legislative Council members and District Councils, statutory bodies and academic institutions.

Analysis of Feedback

6. After careful analysis of the extensive feedback received, the Administration noticed that there is general support from different sectors of the community on the principles of regulation, definition and classification of medical devices and the scope of control as set out in the consultation document. Specific concerns were raised by respondents on the definition of medical devices, financial burden on traders, and delay on the import of new devices with the introduction of regulation, etc. There were also suggestions from servicing personnel to set up a separate licensing and certification system for them, and comments from the medical device traders and healthcare personnel to include regulation of retailers.

7. There was a general concern that control of selected high risk devices should be tightened through restricting its operation to trained personnel only. The medical and dental professionals suggested that only doctors and dentists should be allowed to use high risk devices like laser and intense pulsed light (IPL) equipment. Registered healthcare professionals like physiotherapists indicated that they needed to use those devices in the course of their professional practice. While the beauty

trade supported the control of these devices to safeguard consumers, they would like to be allowed to continue using IPL equipment, subject to meeting some prescribed training requirements. They emphasized that they would only use such device for beautification and not for medical treatment.

8. A summary of the comments received is at Annex.

Proposed Framework of Regulation

9. Taking into account the comments received during the consultation exercise, the Administration proposes the following regulatory framework.

(I) Objectives and Principles of Regulation

10. The proposed regulatory controls over medical devices aim at safeguarding the health and safety of patients, users and the public. Medical device should be safe, efficacious and of good quality.

11. The regulatory controls should be proportional to the level of risk associated with the medical device. At the same time, regulatory control should not place an unnecessary burden on regulators or on the trade and industry, nor deter the introduction of new products that will benefit the public.

12. In order to benefit consumers from internationally accepted best practice and timely access to new and safe devices, the proposed framework should be formulated in line with the recommendations made by the GHTF, which are also adopted for use by a number of developed countries.

(II) Definition of Medical Device

13. A medical device generally refers to any instrument, apparatus, appliance, material or other article, excluding drugs, used for human being for diagnosis, prevention, treatment, monitoring of diseases or injuries; or for rehabilitation purposes; or for the purposes of investigation, replacement or modification of body structure or function. In addition, it includes devices used for examination of human specimens. The definition is in line with the recommendation of the GHTF.

(III) Classification of Medical Devices

14. Based on their risk to patients and users, medical devices will be classified into four classes as recommended by the GHTF. The level of control of the devices will be based on their classification. The following table illustrates examples in the four classes.

Class	Risk Level	Examples
I	Low	Surgical drill, saw, tongue depressor, bandages, dressings, walking aid
II	Medium-low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator
III	Medium-high	Lung ventilator, contact lens disinfectants, orthopaedic implants, X-ray machine, laser
IV	High	Heart valve, implantable pacemaker, heparin-coated catheter

(IV) The Scope of the Control

15. The scope of control is broadly classified into three main areas, namely, pre-market control, control on use and operation and post-market control of medical devices.

Pre-market Control

16. The control will be levied on two dimensions. On the product side, devices of all classes will be required to meet labeling requirements before sale. All high risk and medium risk devices will require registration. On the trade side, all importers and local manufacturers will require registration, and so will local representatives of overseas manufacturers of high risk and medium risk devices. The following table summarizes the registration requirements with respect to different classes of medical devices:

	Class I	**Class II**	**Class III**	**Class IV**
Product registration	Not required	Required	Required	Required
Registration of local manufacturers	Required	Required	Required	Required

Registration of local representatives of overseas manufacturer	Not required	Required	Required	Required
Registration of importer	Required	Required	Required	Required
Registration of retailer	Not required	Not required	Not required	Not required

Post-market Control and Adverse Incident Reporting

17. The manufacturers will 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 or their representatives will be required to report any adverse incidents that have led to death or serious injury of the user, patient or other persons and will be held responsible for instituting recall for defective products and to notify the Department of Health.

Control on Use and Operation of Selected Medical Devices

18. The proper use of class 3B and 4 lasers (high powered lasers of power 5 mW or above) as well as IPL have been examined during the study. The concerned laser devices present an eye hazard and a potential fire or burn hazard. Delivering excessive energy to the target site can result in thermal damage to the skin, resulting in redness, severe blisters, pigmentation, ulceration, or even scarring of skin. The Administration therefore proposes to set up a licensing system to restrict the possession of class 3B and 4 lasers and to limit their use to only doctors and dentists. Registered healthcare professionals are also allowed to use these devices in the course of their practice. As for IPL, we propose to allow non-medical personnel, who have undergone recognized training, to use IPL to perform specified procedures such as hair removal and skin rejuvenation. The list of procedures could be expanded to take into account development in technology for risk reduction. Intermediate and low powered lasers (class 3A and below) are less hazardous in nature and control of use is not recommended.

Control on Servicing and Maintenance of Medical Devices

19. With regard to control on servicing and maintenance, many respondents on this issue raised concerns over the lack of regulatory

control on maintenance services provided for medical devices. Some of them suggested the Government to register servicing personnel of medical devices.

20. It is recognized that lack of calibration and maintenance of medical devices can jeopardize their safety and performance. In this respect, it is proposed to include the provision of maintenance services and technical support as one of the registration criteria of the device. Separate licensing control on servicing and maintenance is not required and this is in line with the regulatory practices in most of the overseas countries.

Way Forward

21. As the first step, we plan to implement an administrative control system in order to facilitate the transition to long-term statutory control. The administrative control system will pave the way and lay the foundation for the legislative system. Manufacturers, importers and local representatives are invited to list their medical devices on a voluntary basis. The listing will be made public for consumers' reference. An adverse incident reporting system for medical devices will also be set up.

22. The administrative control system will start with the listing of high risk (class IV) medical devices, their importers, manufacturers and local representatives in 2004. After review and evaluation, listing of class III medical devices and class II medical devices will follow in stages starting in 2005. The final stage of implementing the control system will be completed with the introduction of the relevant legislation to enforce mandatory requirements at a later stage. We will further consult the trade on the detailed administrative arrangements. In parallel, a working group will be formed with the medical professionals, beauty trade representatives and concerned parties to implement the recommendations as contained in paragraph 18.

23. Members are invited to comment on this paper.

Department of Health
February 2004

Annex

Summary of Comments Received on Proposals in the Consultation Document

Proposal	Gist of Comments Received
Objectives and principles of the proposed regulation	• Supported the proposed regulation in principle. • Opined that regulation is not necessary or need to be postponed. Reasons for opposing the regulation included no tangible benefit to the public, burden to the trade and drive small traders out of the market. • Regulation should be limited to medical devices intended for medical treatment or high risk products only. • Regulation should be cost-effective and not hinder introduction of newly developed medical devices into the local market. • Suggested minimum and essential quality, instead of good quality, should be adopted. • Supported to follow the proposed regulatory approach. Opined to follow the system of a particular country. • Suggested applying the same requirements on all classes of medical devices.
Classification of medical devices	• Agreed to set out classification rules in line with the GHTF. • Expressed different opinions on classification of certain medical devices. • Suggested having a list of classified products for easy reference. • Suggested an appeal system for re-classification of medical devices. • Devices used for beauty purpose should not be regulated as medical devices.

Scope of control	
Pre-market control	On Labelling: • Supported that medical devices need to have proper labelling. • Opined that compliance to labelling requirement is needed for high risk products only. • Commented on the technical details of labelling requirements.
	On product registration for medical devices of Class II or above: • Supported the proposed regulation. • Opined that registration is not necessary, some of the reasons mentioned include difficulty to obtain support from manufacturers, registration increase cost and delay introduction of medical devices. • Asked for a grace period before law enforcement. • Raised concern on some technical details, such as registration for product family and in-vitro diagnostic devices, quality assurance and appeal system.
	On options for assessment of conformity: • Supported the first option that approval in other GHTF founding member countries should be sufficient and can shorten the time for registration. • Agreed with the second option to set up accreditation system for conformity assessment bodies (CAB). • Opined that Government does not have the expertise to carry out the third option (i.e. full assessment by regulatory authority). • Asked for alternative mechanisms for approval of newly developed medical devices imported

	for clinical trial, demonstration and those have short product life-cycle. • Suggested that devices with a long history of use, custom-made, or imported without intention of resale, should be exempted from fulfilling all the registration requirements. • Commented on clinical evidence and documentation that are needed for product registration.
	On registration of traders: • Agreed to have a registration system. Suggested exemption of existing suppliers. • Disagreed to have a registration system. • Provided suggestions on the requirements for the registration of manufacturers, e.g. obtain ISO certification. • Suggested registering retailers, limiting distribution of certain medical devices to authorized channels or under supervision of qualified professionals only. • Separate licensing and certification system for preventive maintenance and servicing personnel should be available to maintain the quality of medical devices after sale. • Suggested having regular testing for the licence renewal of the device similar to the requirement for old cars.
Control on use and operation of selected medical devices	• Supported to control the use of selected devices. • Opined to have no control at all. • Expressed that the proposed regulation, particularly on operation of selected devices, would affect the business of the beauty trade. Suggested that properly trained non-healthcare personnel, such as beauticians, can use selected devices including laser and IPL machines. • Suggested that these devices can only be

	operated by medical or dental practitioners, or personnel under their direct supervision. • Suggested that certain medical devices can only be used or bought by specified healthcare personnel. • Opined that a clearer definition of "trained personnel" is required. • Suggested having a licensing system for owners and / or operators of selected devices. • Opined that training given by supplier is sufficient.
Post-market control	• Supported proposed regulatory framework. • Suggested proactive surveillance including tracking system of long term implants, software, monitoring of users and testing of products on sale in the market by the Government. • Suggested having a single Government department for co-ordination on investigation, inviting independent bodies to carry out investigation, setting out guidelines for recall actions and appeal mechanism. • Supported adverse incident reporting system. • Opined that healthcare workers or non-medical personnel in user facilities should be mandated to report adverse incidents. • Suggested the Government to set out mechanism to facilitate reporting by users.

Others Views and Suggestions	Gist of Comments Received
Trade perspective	➢ Requested for Government assistance to issue free sale certificates or provide advisory service to manufacturers. ➢ Opined that the Government should solicit views and advice from stakeholders with relevant expertise in the course of preparing the regulation.
Implement regulation by phases	➢ Agreed to prioritise and pilot the regulation in phases.
Enhance public education on safety and effectiveness of medical devices	➢ Urged the Government to enhance public education. Suggested topics include details of different phases of regulation, safety and effectiveness of non-orthodox medical devices, awareness on safety and use of medical devices.
Enforcement	➢ Suggested that regulatory authority should apply the same principle across all sectors that are using medical devices.