Paper No. CB(2)2012/02-03(06)

For discussion
on 12 May 2003

LegCo Panel on Health Services

Regulation of Medical Devices in Hong Kong

INTRODUCTION

The paper sets out the proposed arrangements to regulate the supply and use of medical devices in Hong Kong.

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.

3. The Consultation Document on Health Care Reform released in 2000 proposed to carry out a comprehensive review of the present statutory regulations in relation to, among other things, the use of medical equipment with a view to ensuring that patients would receive quality service. Following a review by the Department of Health (DH) and the Electrical and Mechanical Services Department (EMSD), we have presented a preliminary proposal on the regulation of medical devices at the meeting of the Health Services Panel on 10 June 2002. We have since worked out more detailed arrangements which are set out below for Members' consideration.

THE PROPOSED CONTROL ARRANGEMENTS

4. The proposed regulatory controls over medical devices aim at safeguarding the health and safety of patients, users and the public. Medical devices should be safe, efficacious and of good quality. To safeguard public health, we propose to establish a mandatory system of control over the supply and use of medical devices in Hong Kong. The following aspects of the proposed regulatory framework are set out in this paper -

A. Principles of regulation
B. Definition of medical device
C. Classification of medical device
D. Scope of control
   (i) Pre-market control
   (ii) Control on the use and operation of selected medical devices
   (iii) Post-market control

A. Principles of regulation

5. To protect public health while ensuring our continued access to new technologies and friendly business environment, the level of regulatory controls should be commensurate with the risks associated with the device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators nor on the trade and industry.

6. The framework proposed in this paper is largely in line with the approach recommended by the Global Harmonisation Task Force (GHTF)[1], including definition and classification of medical device, essential principles of safety and performance, quality system requirements, vigilance system requirements, and the use of international standards. Modifications are made to suit local circumstances. If the global harmonized model for regulating medical devices is adopted, consumers will benefit from internationally accepted best practice and timely access to new and safe devices

[1] The GHTF was formed in 1992 by a group of representatives from regulatory authorities and medical device industries. The aim of the GHTF is to harmonize the standards and principles for the regulation of medical devices. The founding members of the GHTF are the USA, the EU, Canada, Australia and Japan.

B. Definition of a medical device

7. A medical device generally refers to: "any instrument, apparatus, appliance, material or other article, excluding drugs, used for diagnosis, treatment, or monitoring of diseases or injuries, or rehabilitation purposes, and when used, may change the structure or function of the human body".

C. Classification of medical devices

8. Classification rules will be drawn up closely in line with the recommendations made by GHTF. Based on their risk to patients, users and other persons, medical devices are classified into 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

9. As regards the types and models of medical devices marketed in Hong Kong, the survey conducted by EMSD in early 2002 revealed that about 31%, 60%, 9% belong to Class I, Classes II and III, and Class IV respectively.

D. Scope of control

10. The proposed regulatory framework covers pre-market control, control on the use of selected medical devices and post-market control.

(i) Pre-market Control

11. The pre-market control is levied on two dimensions: the product and the party that introduces the product into the local market. For the control on products, medical devices for sale must comply with the safety and performance requirements, which will be drawn up in line with internationally harmonized standards. For the control on the party that places the product on

the market, we recommend to require registration of manufacturers and importers in order to identify the persons responsible for carrying out any follow-up actions.

12. Medical devices are also required to meet labeling requirements. Such requirements aim at providing users with essential information to promote the safe use of the device and to identify the manufacturer or its local representative or the importer. Particulars to be shown in the label include the name and address of the manufacturer and its local representative or the importer, expiry date, warnings and/or precautions to take, special storage and handling conditions, where appropriate.

13. Exemption would be provided for medical devices imported for re-export only (without alternation or re-packaging of the product) and those manufactured in Hong Kong for export only. When there is an urgent or special need for a particular medical device that has not yet been registered, the regulatory authority may grant a one-time approval for importation of that device for use on that occasion for that particular patient only.

Product registration for medical devices of Class II or above

14. Under the proposed arrangements, all medical devices, except class I medical devices, must be registered before they can be sold in Hong Kong. There are three options for assessing whether the device complies with the standards and criteria required for registration -

(a) The first option is for the applicant to submit evidences of product safety, efficacy and quality to prove that the product is up to international standards. One example is that the products have already been approved for marketing in specified GHTF founding member countries. This option will shorten the time taken for assessment and in turn avoid the delay in introducing new and effective medical device into Hong Kong.

(b) The second option is to obtain certification issued by a conformity assessment body (CAB). A CAB is a certification organization designated to carry out product assessment to ascertain whether the requirements and standards are complied with. The main benefit of making use of CAB for certification is the flexibility of drawing

various expertise for assessment.

(c) In the third option, manufacturer can prove the safety of its products through submitting the whole set of technical documentation and clinical evaluation / trial data to the regulatory authority for assessment. However, this option demands more resources and is feasible only if the regulatory authority has qualified staff in the relevant areas to perform the assessment.

15. Manufacturers are responsible for obtaining product registration for their products if their products are to be sold in Hong Kong. If the manufacturer does not have a business establishment in Hong Kong, he must appoint a local representative to obtain the product registration on his behalf.

16. Different types of documentation are required in line with the risk level of the medical device. For Class IV devices, requirements are most stringent including submission of human clinical data. For Class III and II devices, requirements are less stringent and the submission of human clinical data is not required.

Class I medical devices

17. Class I medical devices belong to the low-risk category for which the least stringent control is necessary. While pre-market product assessment and registration is not recommended, we propose to require importers to keep a list of Class I products they have imported to facilitate recall of devices where necessary.

Registration for the local manufacturers, local representatives of overseas manufacturers and importers

18. Manufacturers and traders who introduce medical devices into the market are responsible for complying with the regulatory requirements specified for their medical devices. We recommend registering all local manufacturers of medical devices who sell medical devices in Hong Kong and local representatives of overseas manufacturers of medical devices belonging to Class II and above.

19. The local representative of an overseas manufacturer can be a local office of the manufacturer, an importer, a supplier, a retailer, a law firm, an

accountancy firm, or any type of private company appointed by the manufacturer to act on his behalf. The representative must maintain linkage with the overseas manufacturer and be able to obtain his support when necessary. If a product has already been registered by a manufacturer or his local representative, any importers can import that product without the need for another product registration.

20. The concept of manufacturer's local representative is adopted by many overseas regulatory systems of medical devices such as the US system and the EU system. The concept is also recommended by the GHTF. The benefits of this concept include: maintaining a single point of contact between the manufacturer and the regulatory authority on matters relating to registration and recall of products, avoiding multiple registration of same product by various importers, ensuring local support from manufacturer for products which have entered the local market through multiple importers.

21. All importers are required to be registered. These importers are responsible for complying with a code of practice issued by the regulatory authority. The code of practice sets out requirements on obtaining product confirmation from the manufacturer or its local representative, labelling for medical devices, reporting adverse incident to the manufacturer or its local representative and putting in place a recall system.

22. Importers are required to provide the regulatory authority, on an annual basis, a list of imported medical devices of Class II and above. They are also required to notify the regulatory authority of any new types of medical devices they import into Hong Kong. The annual provision of devices list by importers will enable the regulatory authority to keep track of all devices of Class II and above being sold in Hong Kong and to require traders to carry out recalls when necessary.

(ii) Control on use and operation of selected high risk medical devices

23. The objective of control over the use and operation of medical devices is to prevent unnecessary harms or complications arising from the improper use of medical device. Currently, there are incidental controls provided by the laws regulating healthcare professionals such as doctors and dentists to ensure the safe and appropriate treatment of patients.

24. However, in the absence of control arrangements, persons without proper training and qualification may also use devices originally intended for use by medical professionals. A medical device in the hands of an untrained operator may pose health risk to the users and patients. An example is the use of medical lasers or intense pulsed light equipment in beauty parlours. To address this problem, we propose to limit the use or operation of certain medical devices to specified personnel. For instance, the use of Class 3B and 4 lasers intended for medical or beauty therapy and intense pulsed light devices are proposed to be operated by trained personnel only. Owners of these devices are required to file an application with the regulatory authority to possess the machine and to undertake to comply with a set of conditions of use. A code of practice setting out the requirements on operators in terms of training, safety precautions and maintenance of devices will also be promulgated.

25. The types of selected devices of which the use need to be controlled would be determined and published by the regulatory authority from time to time.

Control on servicing and maintenance of medical devices

26. As the operators are responsible for the safe use of the medical devices, separate control on servicing and maintenance of medical devices will not be required. This practice is also in line with the regulatory systems in overseas countries.

(iii) Post-market Control

27. The responsibility of the manufacturer for the safety of a medical device does not end when it is put on the market. Monitoring the performance of devices and reporting of problems associated with the use of medical devices are important components of the regulatory cycle. The post-market control covers two specific areas: proactive surveillance and adverse incident reporting.

Proactive surveillance

28. We propose to require manufacturers to put in place a system to collect data on the performance and safety of selected high-risk medical devices. Permanent implants for supporting or sustaining human life are examples of such devices. As failure of such devices would cause serious adverse health

consequences or even death, precautionary measures should be taken to safeguard any potential health hazards associated with their use. The manufacturer or his / her local representative can submit data collected overseas to fulfill such surveillance requirement.

Adverse incident reporting by manufacturers

29. Currently neither the manufacturer nor the owner of the medical device is obligated to report any adverse incident. Local health facilities rely heavily on overseas official information sources. It is difficult to carry out timely intervention, as there is usually a considerable time lag between the occurrence of an adverse incident and the time it is made known to the local parties concerned.

30. Mandatory reporting of serious device problems is necessary to ensure the safety of medical devices. It provides an opportunity to identify the device with serious problem for remedial action including product modification or recall. It also allows timely dissemination of information to healthcare professionals and the public to prevent the recurrence of a similar adverse incident.

31. Mandatory adverse reporting system requires manufacturers or their local representatives to report adverse incidents that reasonably suggest there is a probability that a medical device has caused or contributed to the death of a patient, or serious injury or illness of a patient. Making this reporting system mandatory is common in overseas regulatory systems.

32. The responsibility of investigation on the incidents and conducting necessary follow-up action rests with the manufacturers or their local representatives. The manufacturers or their local representatives will also be required to report on the investigation result and the required follow up action, such as product recall. The regulatory authority will monitor the progress and overall management conducted by the manufacturers, and carry out the investigation as appropriate.

Adverse incident reporting by users

33. In line with overseas practices, healthcare professionals are encouraged to notify the manufacturers or local representatives of adverse incidents. The manufacturers will then identify any clustering of incidents, the

problem of the device, carry out any remedial action and report to the regulatory authority. In most systems, health care professionals and facilities are not obligated but are encouraged to report on a voluntary basis to the regulatory authority of an adverse incident or serious complications arising from the use of medical device.

34. We also recommend that injuries arising from the use of medical devices by non-health personnel be reported under this system. This serves to identify and collect information on the improper use of medical devices and enable the regulatory authority to exert control on users of such devices where necessary.

NON-ORTHODOX DEVICES

35. The scope of medical devices covers a very wide range of equipment, apparatus and articles. Some items, which may change the human anatomy based on non-orthodox medicine theory, may also fall into the description of medical devices. Some items are not intended for medical use. Others carry health or medical claims which cannot be substantiated according to orthodox medicine theory. Examples are as follows -

- Fitness device, e.g. gymnasium equipment
- Coloured/tinted contact lens
- Massage chair
- Magnetic mattress/pillow
- Magnetic bracelet/necklace/ear ring

36. Most of these devices fall into the low risk category and would not be subject to control under the proposed regulatory system. However, devices that emit energy or are invasive to human body would fall into Class II or above. In such cases, registration of medical devices would be required.

WAY FORWARD

37. We will soon consult relevant parties and members of the public on the proposed control arrangements. In order to facilitate the transition to long-

term statutory control, we propose to implement an administrative control system initially, which is based on the same principles as the proposed statutory control. The administrative control system serves to raise public awareness of the use of safe medical devices and enable the traders to familiarise themselves with the future mandatory requirements. It also provides an opportunity to collect more information and feedback from the industry as a reference to fine tune the long-term regulatory system. The administrative control system will be an important step in the successful implementation of the mandatory regulatory system.

38. The administrative control system will 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 and Class II devices and their importers, manufacturers and authorized representatives will follow in stages. The listing of manufacturers and importers of medical devices will be made public for consumers' reference. An adverse incident reporting system will also be set up. The final stage of implementing the control system will be completed with the introduction of the relevant legislation to enforce mandatory requirements.

MEMBERS' ADVICE

39. Members are invited to comment on the proposed arrangements set out in this paper.

Health, Welfare and Food Bureau
May 2003