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For discussion
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LegCo Panel on Health Services
Proposal on the Regulation of Medical Devices

Introduction

The Consultation Document on Health Care Reform released by the Health and Welfare Bureau in 2000 has proposed to carry out a comprehensive review of the present statutory regulations in relation to the use of medical equipment with a view to ensuring that patients would receive quality service.

2. This paper reports on the work done in this area so far and outlines a preliminary proposal on the regulation of medical devices.

Background

3. A medical device generally refers to: "any instrument, apparatus, appliance, material or other article, excluding drugs, used for diagnosis, treatment, monitoring, or rehabilitation purposes, or for the purpose of investigation, replacement, modification of body structure or a physiological process". Products which may be regarded as medical devices range from sophisticated equipment such as pacemakers used by health professionals to simple products such as bandages and thermometers bought over-the-counter by members of the public.

4. The Department of Health (DH) is working with the Electrical and Mechanical Services Department to review the current situation and propose an appropriate regulatory system for medical devices in Hong Kong.

Local situation

5. Currently, there is no specific legislation to regulate the importation, sale or use of medical devices in Hong Kong except for those containing

radioactive substances or pharmaceutical products which are regulated through the Radiation Ordinance (Cap. 303) and the Pharmacy and Poisons Ordinance (Cap. 138) respectively. Other controls include the Occupational Safety and Health Ordinance (Cap. 509) and the Undesirable Medical Advertisements Ordinance (Cap. 231) which safeguard the safety of workers and control advertisement related to medical matters respectively.

6. To obtain an overview of the sale and use of medical devices in Hong Kong, a local survey was conducted between January and May 2002. The objectives of the survey are to gather information on the types of products being marketed in Hong Kong and to collect opinion on the regulation of medical devices from traders including manufacturers, importers and selected operators in the trade

7. A total of 6 local manufacturers and 154 importers engaging in the medical device industry responded to the survey. Preliminary result showed that medical device products marketed in Hong Kong mainly come from USA, European Union, Japan and China. 80% of the traders who responded to the survey agreed that there should be some form of control on medical device to ensure public safety. Further analysis of the respondents and non-respondents estimated that there are around 600 importers of medical devices in Hong Kong importing some 20 000 types of devices. There are about 30 local manufacturers who mainly manufacture accessories or parts to a medical device.

Overseas experience and international trends

8. Research into overseas legislations revealed that most developed countries have legislations in place with regard to the regulation and control of medical devices. However, laws vary significantly in different countries. With a view to safeguarding public health and removing trade barriers, the Global Harmonisation Task Force (GHTF), which is a voluntary consortium with representatives from the trade and regulatory authorities from USA, Canada, Australia, Japan and the European Union, was formed in 1992 to harmonise the standards and principles of regulating medical devices. The GHTF has developed reference standards and recommended regulatory authorities to adopt such standards when devising control over medical devices.

9. Medical devices cover a wide range of products. Based on their level of risk to patients and users, medical devices are classified into four classes

by the GHTF:

Class	Level of Risk	Examples
I	Low	Surgical scissors, tongue depressor, bandages, dressings, walking aid, etc.
II	Medium	Injection needle, suction pump, gastroscope, transdermal stimulator, etc.
III	Medium	Lung ventilator, contact lens disinfectants, orthopaedic implants, X-ray machine, laser, etc.
IV	High	Heart valve, implantable pacemaker, etc.

10. Overseas experience shows that the majority of medical devices belong to Class I, II and III while only about 5% of the products in the market belong to Class IV.

11. The GHTF recommends that regulatory control be proportional to the level of risk associated with the device. More stringent control should be imposed on devices of higher risk. Such control may be in the form of pre-market approval through individual product registration. The effectiveness of a product is to be evaluated by clinical trials. Tracking of products is undertaken for particularly high risk products. For low risk devices, the level of control ranges from listing of products with licensing authority, self-declaration of safety by manufacturers to no control.

Proposal on Regulation of Medical Devices in Hong Kong

(I) Regulatory framework

12. To safeguard the health and safety of patients, users and the public, a system of control over the supply and use of medical devices in Hong Kong is proposed -

(II) Principles of regulation

13. The regulatory controls should be proportional to the level of risk associated with a medical device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on the regulators, the trade and industry nor delay the introduction of new products that will benefit patients.

14. The proposed framework is largely formulated in line with the recommendations made by the GHTF, including the definition and classification of medical device, essential principles of quality and safety, vigilance system requirements, and the use of international standards.

(III) The scope of control

15. The scope of control is broadly classified into three main areas –

(A) Pre-market control;
(B) Control on use and operation; and
(C) Post-market control of medical devices.

(A) Pre-market Control

(a) The primary objective of pre-market control is to safeguard against the introduction of substandard or unsafe medical devices into the local market.

(b) The pre-market control covers two dimensions: the product and the party which introduces the product into the local market.

(c) A risk-based approach is proposed to be adopted for the regulation of products. Taking into account the level of risk, only medium and high-risk products are required to be registered. They must comply with the safety standards, criteria and labeling requirement before they are approved for registration and sale. For products that belong to the low risk group, a notification to the health authority upon introduction into the local market would be sufficient.

(d) The products will be assessed in accordance with criteria relating to safety, quality and efficacy. A panel comprising biomedical engineering and healthcare experts will carry out the assessment of the technical documents.

(e) With respect to the party which introduces the product into the local market, some form of registration is recommended to identify the person responsible for placing the devices on market and carrying

out any follow up actions. This person may be the manufacturer, importer or the local representative who will be responsible for registering medical devices marketed in Hong Kong. He/She will be required to report any adverse incidents associated with the use of the products, including mishaps that take place overseas, so that appropriate alerts will be issued to users in Hong Kong.

(B) Control on use and operation of medical devices

(a) To prevent the improper use of medical devices by unqualified persons, the proposed framework requires that operators other than registered healthcare professionals must obtain licence to operate selected equipment. An example is to control the user of laser and intense pulse light equipment in beauty parlours. Only those who have successfully completed the training and certification programmes recognised by the DH are qualified to obtain the licence.

(b) The licensing condition may require that the use of the selected medical device by non-medical personnel be limited for specific purpose or a procedure be prescribed by a registered healthcare professional. Operators are required to comply with the code of practice issued by the DH.

(C) Post-market control and adverse incident reporting

(a) After a medical device has been placed on the market, mechanisms should be put in place to monitor and report problems with medical devices.

(b) It is proposed that manufacturers or their representatives should be held responsible for instituting recall of defective products and notifying DH.

(c) Mandatory reporting of serious problems occurring locally is necessary to identify medical devices for further modification or product recall. It also allows timely dissemination of information to healthcare professionals and the public to prevent re-occurrence of the incident.

(d) In line with international practice, mandatory adverse reporting system requires manufacturers or their local representative to report adverse incidents which reasonably suggest that a medical device may have caused or contributed to the death of a patient, or serious injury or illness of a patient.

(e) Healthcare professionals and institutions are encouraged to report on a voluntary basis to the DH of any adverse incidents or serious complications arising from the use of medical device. It is also recommended that injuries incurred with the use of medical devices by non-healthcare professionals can be reported under this system. This serves to identify and collect information on the incorrect use of medical devices. Where necessary, control on users of such devices should be exerted.

Consultation with stakeholders

16. In summary, the proposed regulatory framework covers registration for manufacturers and importers, registration or notification for medical devices, licensing of users of selected medical devices and a reporting system to identify medical devices with serious problems in the market.

17. The consultation exercise on the proposed regulatory framework will be carried out in the coming months. Details of the regulatory system will be developed in consultation with the consumers representatives, the healthcare and engineering professionals, the industry, the operators and other stakeholders who will be or may be affected by the regulatory system.

Way Forward

18. As it will take some time to prepare a mandatory regulatory system, it is proposed to put in place an administrative control system before the enactment of the new ordinance. This system will follow the same principles as the proposed legislative system. The manufacturers, importers, products and operators of selected medical equipment are invited to list their medical devices with the DH on a voluntary basis. An adverse incident reporting system will also be set up.

19. The administrative control system serves a number of purposes, including: arousing public awareness on the safe use of medical devices; enabling the traders to familiarise themselves with the future mandatory requirements; facilitating the trading of the listed products which follow most of the recommended requirements of the GHTF as well as providing an opportunity to collect more comprehensive information and feedback from the industry as a tool to fine tune the long-term regulatory system.

20. Members are invited to note and comment on the proposal.

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Department of Health
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