

醫療儀器的規管



Regulation of Medical Devices

諮詢文件

Consultation Document



中華人民共和國

香港特別行政區政府衛生署

Department of Health

Government of the Hong Kong Special Administrative Region

The People's Republic of China

Regulation of Medical Devices in Hong Kong

Consultation Document
July 2003

Department of Health
Government of the Hong Kong Special Administrative Region

CONTENTS

	Paragraph
I. INTRODUCTION	1.1 - 1.6
II. OVERSEAS EXPERIENCE	
Overview	2.1 - 2.3
Regulatory approach	2.4 - 2.5
Pre-market control	2.6 - 2.8
Post-market control	2.9
Control on use of medical devices	2.10
III. LOCAL SITUATION	
Existing control.....	3.1 - 3.5
Concern over the use of medical devices by non-medical professionals	3.6 - 3.8
Adverse reporting and surveillance system	3.9
The local market	3.10
Summary.....	3.11
IV. THE PROPOSED FRAMEWORK	
Overview	4.1
Objectives of the regulatory system	4.2
Principles of regulation	4.3 - 4.5
Definition of a medical device.....	4.6
Classification of medical devices	4.7 - 4.8
Scope of control	4.9
Pre-market control	4.10 - 4.26
Control on use and operation of selected high risk medical devices	4.27- 4.31
Post-market control	4.32 - 4.40

V. CONSIDERATION FOR NON-ORTHODOX DEVICES	5.1 - 5.2
--------------------------------------------------------	-----------

VI. WAY FORWARD

Overview	6.1
Administrative control system	6.2 - 6.5
Charges	6.6 - 6.7
Advice sought	6.8 - 6.9

Annexes

CHAPTER 1 : INTRODUCTION

1.1 Medical devices range from sophisticated equipment such as cardiac pacemakers used by health care professionals to simple products such as bandages and thermometers bought over the counter by the public. As a result of technological advances, medical devices play an increasingly important role in the delivery of quality health care services. The use of unsafe devices affects the health of patients, users and the public. Medical devices, therefore, should not be regarded merely as consumer goods.

1.2 As the designs of medical devices have become much more user friendly with advances in technology, persons with little training may also use devices originally intended for use by medical professionals. For instance, high-power laser and intense pulsed light equipment are now used by non-medical professionals in beauty parlours. In recent years, members of the public have expressed concern over the safety of medical devices and the health hazards arising from the use of devices by untrained personnel.

1.3 The Consultation Document on Health Care Reform released by the former Health and Welfare Bureau in December 2000 proposed to carry out a comprehensive review of the present statutory regulations in relation to, among other things, the use of medical devices with a view to ensuring that patients would receive quality service. In this connection, the Department of Health (DH) has worked with the Electrical and Mechanical Services Department (EMSD) to review the current situation and propose an appropriate regulatory system for medical devices in Hong Kong.

1.4 The proposed regulatory framework for the control of the manufacture, sale and use of medical devices is based on the concept of risk management. With a risk-based classification of medical devices, the level of regulatory control applicable to a medical device takes account of the risk associated with the device.

1.5 A medical device in general refers to any instrument, apparatus, appliance, material or other article, excluding drugs, used for human beings 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.

1.6 This consultation document invites views and suggestions from the public, medical device trade and industry, health care professionals and interested bodies on the regulatory framework proposed in this paper.

CHAPTER 2 : OVERSEAS EXPERIENCE

Overview

2.1 Many countries and regions like the European Union (EU), the United States of America (USA), Australia, Canada and Japan have already set up their own systems for the control of medical devices. While they have a common goal to ensure the **quality, safety and effectiveness** of medical devices, their approaches of control differ.

2.2 The Global Harmonization Task Force (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.

2.3 The GHTF encourages the adoption of best practices to ensure the quality, safety and effectiveness of medical devices through the publication and dissemination of harmonized guidance documents. The GHTF recommends that the level of regulatory control should take into account the risks and benefits associated with use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on the regulators or the trade.

Regulatory approach

2.4 Overseas authorities in countries or regions like the EU, the USA and Canada classify their medical devices into three or four classes according to the degree of risk. In general, low-risk devices are external to the body, and if applied correctly, involve minimum risk to the patients e.g. tongue depressors, bandages and walking aids. The higher risk devices penetrate the human body, involve a high-energy source, or are used to sustain life e.g. cardiac pacemakers and implantable electrodes.

2.5 There are usually two levels of regulatory control, namely, pre-market and post market control.

Pre-market control

2.6 Pre-market control means that the regulatory control is prescribed before the device enters the market. There are usually two components of control - on the product and on the trader.

2.7 On the aspect of product control, a regulatory authority may, in accordance with the risk of the device, require the manufacturer to seek permission before putting the device on the market. This is called pre-market approval. For high-risk devices, the GHTF recommends that pre-market approval should be given only to products which meet safety, quality and effectiveness requirements. Assessment is performed on the effectiveness of devices based on standards and criteria prescribed on the design, manufacturing process, auditing process and clinical performance. In the USA, the Food and Drug Administration carries out its own assessment on devices. In the EU, regulatory authorities designate conformity assessment bodies known as 'notified bodies' to carry out the assessment. For low-risk products, the GHTF recommends that control can be less stringent. Assessment of low-risk devices by regulatory authority may not be necessary. The manufacturer can make a declaration that his product is safe and effective.

2.8 On the aspect of control over the traders, regulatory authorities may require the registration of manufacturers or their representatives and importers. The objective is to allow regulatory authorities to keep track of the manufacturers and importers. The manufacturers should report and investigate adverse incidents and carry out necessary remedial actions.

Post-market control

2.9 The GHTF recommends that a post-market surveillance system be set up for medical devices. The system aims to collect data on the performance and safety of selected high-risk devices on the market so that precautionary measures can be taken to minimize any potential public health risk associated with their use. In addition, the manufacturers, or their representatives, should be required to report any adverse incidents that led to death or serious injury of the user, patient or any other person. Near miss cases are also reportable. Report of adverse incidents could facilitate the recall of problematic devices and prevent the recurrence of the problem. The USA, the EU, Australia, Japan and Canada have all put in place post-market control similar to that recommended by the GHTF.

Control on use of medical devices

2.10 Existing overseas regulatory systems on medical devices generally control the products, the manufacturers and the parties responsible for putting the devices on the market, but not the operators of medical devices. Nonetheless, there have also been concerns in overseas communities about the use of medical devices by non-health personnel, such as the use of lasers in beauty parlours. Different countries have adopted different legislations to address the problem of laser use. The UK and some states of the USA require registration of premises where medical lasers are used. In some other states of the USA, and Singapore, operators of medical lasers must obtain a certificate or a licence from the regulatory authority.

CHAPTER 3 : LOCAL SITUATION

Existing control

3.1 Currently, there is no specific legislation to regulate the importation or sale of medical devices in Hong Kong except for those containing pharmaceutical products or radioactive substances. Pharmaceutical products are regulated through the Pharmacy and Poisons Ordinance (Cap. 138) whereas the possession and use of all irradiating apparatus and radioactive substances are regulated through the Radiation Ordinance (Cap. 303).

3.2 The statutory regulation of certain health care professionals, whereby the practitioner is required to ensure the safe and appropriate treatment for patients, also provides incidental control on the use of medical devices. The Medical Registration Ordinance (Cap 161) and the Dentists Registration Ordinance (Cap 156) regulate the medical practitioners and dentists respectively.

3.3 Under the Occupational Safety and Health Ordinance (Cap. 509), employers are responsible for ensuring, so far as reasonably practicable, the safety and health at work of their employees. This Ordinance also applies to employers in industries making use of medical device and it is their duty to provide and maintain medical devices in a safe condition. They also have to ensure the safety and health of their employees through providing information, instruction, training and supervision as necessary.

3.4 Health claims are regulated through the Undesirable Medical Advertisements Ordinance (Cap. 231), which prohibits advertisements related to the curative or preventive effects of products on diseases listed in the Ordinance.

3.5 The Working Group on Laser Safety under the Committee on Science and Technology finalised "The Laser Safety Code of Practice" in 1991. The Code was distributed to the trade and users of laser equipment for their voluntary compliance. The Code of Practice contains guidelines for laser safety in industry, manufacturing, entertainment and display, as well as beauty therapy and bio-stimulation. The Code recommends that users and owners of lasers of Class 3 or above register their laser equipment with the Government Laser Safety Officer of EMSD within three months of purchase.

Concern over the use of medical devices by non-medical professionals

3.6 While the Occupational Safety and Health Ordinance (Cap. 509) protects the safety of the employees at work, there is no specific legislation to regulate the use of medical devices on clients by personnel without appropriate training.

3.7 According to the survey conducted by EMSD in early 2002, some of the beauty parlours possessed medical lasers. The majority of these parlours claimed to have followed the "Laser Safety Code of Practice".

3.8 According to the information provided by Consumer Council, it received a total of 36 complaints on the use of medical laser by non-medical personnel in beauty parlours from 2001 to 2002. These complaints were mainly about dissatisfaction with the services provided or excessive charges. Of the cases, 3 complainants alleged that they had suffered from allergic reaction after laser treatment and 6 alleged they had scarring or burn after the laser procedure.

Adverse reporting and surveillance system

3.9 Currently, there is no formal reporting system to identify medical devices with serious problems in the market for follow-up action. EMSD, as the main agency responsible for maintaining medical devices in DH and hospitals under the Hospital Authority, would follow up with manufacturers in case of device problems. DH, on receipt of medical devices alert notices from overseas sources, would disseminate the information to private hospitals, the Hospital Authority and healthcare professionals. Neither manufacturers nor importers are required to keep distribution records or report adverse incidents to the health authority. Should a problematic device be placed on the market, remedial actions may not be taken in a timely fashion to protect public health.

The local market

3.10 In order to have better understanding of the sale and use of medical devices in Hong Kong, a local survey was conducted from January to March 2002 by EMSD to gather information on the types of products being currently marketed. The survey shows that the majority of medical devices in Hong Kong are imported, mostly from the USA, the EU, Japan and the Mainland.

Summary

3.11 The problems related to medical devices in Hong Kong are summarized as follows -

- No pre-market control to assess the safety, effectiveness and quality of medical devices to safeguard public health;
- No specific control on the use of selected medical devices by non-medical professionals to ensure the safety of consumers;
- No formal adverse incident reporting and proactive surveillance system;
- Inadequate product information for the public and operators to make informed choices on the safe use of medical devices.

In view of the above, there is a need to develop an appropriate regulatory system to control the supply and use of medical devices in Hong Kong.

CHAPTER 4 : THE PROPOSED FRAMEWORK

Overview

4.1 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 proposed regulatory framework covers the following aspects -

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

A. Objectives of the regulatory system

4.2 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, effective and of good quality.

B. Principles of regulation

4.3 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.

4.4 The proposed framework is largely in line with the approach recommended by the GHTF, 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.

4.5 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.

C. Definition of a medical device

4.6 A medical device generally refers to: “any instrument, apparatus, appliance, material or other article, excluding drugs, used for human beings 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”. The detailed definition proposed by the GHTF is at Annex A.

D. Classification of medical devices

4.7 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, bandage, dressing, walking aid
II	Medium - Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator
III	Medium - High	Lung ventilator, contact lens disinfectant, orthopaedic implant, X-ray machine, laser
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter

4.8 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, Class II and III, and Class IV respectively.

E. Scope of control

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

(i) Pre-market Control

4.10 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.

4.11 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.

4.12 Exemption would be provided for medical devices not for sale or use in Hong Kong i.e. medical devices imported for re-export only 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

4.13 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.

4.14 The first option is for the applicant to submit evidences of product safety, effectiveness 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 or regions. 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.

4.15 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.

4.16 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.

4.17 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.

4.18 Annex B provides examples of documentations required for assessing the eligibility for product registration. Different types of documentations are required in line with the risk level of the medical device. For Class IV devices, requirements are most stringent and the submission of human clinical data is required. For Class III and II devices, requirements are less stringent and the submission of human clinical data is not required.

Class I medical devices

4.19 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

4.20 Manufacturers and traders who introduce medical devices into the market have to comply with the regulatory requirements specified for their medical devices.

4.21 We recommend registering all local manufacturers who manufacture, alter or re-package medical devices which would be sold in Hong Kong, and local representatives of overseas manufacturers of medical devices belonging to Class II and above.

4.22 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.

4.23 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.

4.24 All importers are required to be registered. These importers have to comply 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.

4.25 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 models 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.

4.26 The following table summarizes the registration requirements on products and traders 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 overseas manufacturer or its local representative	Not required	Required	Required	Required
Registration of importer	Required	Required	Required	Required
Registration of retailer	Not required	Not required	Not required	Not required

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

4.27 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.

4.28 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.

4.29 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 and intense pulsed light devices intended for medical therapy and beauty procedure 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.

4.30 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

4.31 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

4.32 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

4.33 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 minimize any potential health hazards associated with their use.

4.34 The manufacturer or his / her local representative can submit data collected overseas to fulfill such surveillance requirement.

Adverse incident reporting by manufacturers

4.35 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.

4.36 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.

4.37 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. Explanatory notes on the criteria for reportable cases are provided in Annex C.

4.38 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

4.39 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, investigate 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.

4.40 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.

CHAPTER 5 : NON-ORTHODOX DEVICES

5.1 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 within 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

5.2 Most of these devices fall into the low risk category and would not be required to be registered 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.

CHAPTER 6 : WAY FORWARD

Overview

6.1 To be in line with international practice and filling the gaps in the existing control system, we propose to set up a risk-based statutory regulatory system on the supply and use of medical devices.

Administrative control system

6.2 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.

6.3 The manufacturers and importers of medical devices will be invited to list their product with the regulatory authority. The listing will be made public for consumers' reference. An adverse incident reporting system will also be set up.

6.4 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.

6.5 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.

Charges

6.6 To encourage participation in the administrative control system, no charges will be levied for the listing of products, manufacturers, authorized representatives and importers.

6.7 As for the mandatory system, the charges will be set at levels to achieve full cost recovery. The cost will be worked out taking into account the experience of the administrative control system.

Advice sought

6.8 We look forward to your views and comments on the regulatory system for medical devices proposed above. Please sent your comments on this Consultation Document before 30 September 2003 -

(a) Post : Medical Device Task Force
Department of Health
21/F, Wu Chung House
213 Queen's Road East
Wan Chai, Hong Kong

(b) Fax : 2573 7745 or 2157 9493

(c) E-mail : mdtf@dh.gov.hk

6.9 This consultation paper is also available at the following websites -

<http://www.dh.gov.hk/>

Definition of Medical Device

The definition of medical device adopted by the GHTF is used with minor modifications to suit local need. In general, a medical device refers to -

Any instrument, apparatus/implement/machine, appliance, implant, reagent/calibrator, software, material or other similar or related article, whether used alone or in combination to be used for human beings for the specific purpose of -

- diagnosis, prevention, monitoring, treatment or alleviation/mitigation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy/body structure or of a physiological process,
- supporting and sustaining life,
- control of conception,
- disinfection of medical device,
- providing information, by in vitro examination of specimens derived from the human body,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

An accessory to a medical device is subject to the same regulations as apply to the medical device itself. However, devices designed for the treatment or diagnosis of diseases and injuries in animals are outside the scope of the proposed regulatory framework.

Examples of documentation required for medical devices registration

Regulatory Approval

- Copies of all certificates, documentation of regulatory approval or clearance to manufacture, sell, import and export the medical device in countries or regions that are the founding members of the GHTF.

Post-market Surveillance

- Provide evidence of established procedures and systems for distribution records, complaint handling, adverse incident reporting and recall

Product Information

- Device description, intended use, instructions of use, device labeling with a copy of the device label,
- Specifications of materials used in device manufacturing and packaging.

Conformity Document

- Copies of certification and document certifying conformity to product standards, quality, safety, and effectiveness requirements and quality systems in design and manufacturing.
- Quality plan
- Manufacturing process

Status of Device Distribution

- Date of first introduction & use, list of countries where it is marketed, a summary of the reported problems with the device and details of any recalls since the introduction of the device in the market.

Safety and Effectiveness Data (Class III or IV only)

- Risk assessment comprising of risk analysis, evaluation and reduction measures.
- Detailed information on safety and effectiveness studies, which includes pre-clinical and clinical studies, process validation studies, software validation studies where appropriate, and literature studies, with summary of studies and bibliography of published reports dealing with the device.
- Objective evidence on the biological safety of the device, if it contains animal or human tissue or its derivative.

Human clinical data (Class IV only)

- Peer-reviewed scientific literature dealing with the device, and the written report
- Results and conclusions of human clinical studies

Explanatory Notes on Adverse Incident Reporting

Introduction

The objective of the adverse event reporting and subsequent evaluations is to protect the health of patients, users and others by timely dissemination of information to prevent the recurrence or alleviate consequences of adverse events.

For the purpose of this document, the term "manufacturer" must be understood as including the manufacturer, its authorized representative or any other person who is responsible for placing the device on the market.

In general, the manufacturer should report an adverse event to the regulatory authority if in doubt.

Reporting Criteria

An adverse event is any event that meets all three reporting criteria listed below and should be reported to the regulatory authority without delay -

- (1) An event has occurred
- (2) The manufacturer's device is associated with the event
- (3) The event led to one of the following outcomes -
 - ✍ Death of a patient, user or other person;
 - ✍ Serious injury of a patient, user or other person; or
 - ✍ No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs

Examples of Adverse Events

- ✍ The light on the battery replacement indicator of a pacemaker fails to show up in time to warn the patient that the battery is coming to the end of its life.
- ✍ On an X-ray examination, the robotic arm of the X-ray machine is out of control and hits a patient.
- ✍ A piece of patient monitoring equipment suspended from the ceiling of the operating theatre falls to the ground without causing any human casualties. (Reporting is still necessary as it is a near incident).
- ✍ A manufacturer releases a batch of sub-standard blood glucose test strips, which lead to improper insulin dosages for diabetic patients and putting their lives at risk.
- ✍ A patient has to undergo an extra operation to put right a problem associated with the loosening of an implant.
- ✍ A mechanical pump fails to deliver an accurate dose of fluids to the patient.
- ✍ A patient suffers unintended burns to her adjacent organs when a surgeon uses a thermal device on the inner surface of her uterus. There is no warning of the unintended side effect on the label of the device.
- ✍ A surgeon intends to replace a heart valve for his patient. During the operation, he discovers that the heart valve is defective and uses an alternate heart valve for his patient.
- ✍ An external defibrillator fails to save the life of a patient because it does not deliver the intended amount of electrical shock on the patient.
- ✍ A commercially available heart valve fails to reach its expected technical standards under laboratory conditions e.g. in fatigue testing.

Exemption

Whenever any one of the following exemption rules applies, the adverse event does not need to be reported to the regulatory authority -

-  Defect in a new device normally detected by the user prior to its use, e.g. missing parts;
-  Adverse event caused by the condition of the patient;
-  Defect in a medical device at the end of its service life;
-  A fail-safe mechanism is functioning properly;
-  A slim chance of death or serious injury as a result of the incident;
-  Expected and foreseeable side effects;
-  Adverse events described in an advisory notice already issued by the manufacturer; or
-  Any other reporting exemptions granted by the regulatory authority