For Information on
8 **November 2010**

Legislative Council Panel on Health Services
Proposed Regulatory Framework for Medical Devices

Purpose

This paper briefs Members on the proposed regulatory framework for medical devices.

Background

2. A voluntary Medical Device Administrative Control System (MDACS) has been established by the Department of Health (DH) since 2004 to raise public awareness of the importance of medical device safety and pave the way for implementing the long-term statutory control.

3. In 2005, we briefed this panel the progress of the development of the MDACS and the publicity programmes to promote public awareness of the voluntary listing system under the MDACS. To prepare for the establishment of a statutory regulatory framework, a Regulatory Impact Assessment (RIA) was conducted from 2007 to 2008 to examine the implications of the possible options for the proposed statutory regulation of medical devices. A brief summary of the RIA findings are at **Annex**.

Proposed regulatory framework

4. The proposed regulatory framework is modeled largely on the recommendations of the Global Harmonization Task Force (GHTF) and World Health Organization (WHO)[1]. A risk-based approach is adopted whereby the level of control will be proportional to the degree of risk classified according to GHTF's recommended classification scheme.

5. The proposed regulatory measures can be categorized into three main areas: (i) pre-market control – to ensure medical devices conform with

[1] GHTF was formed in 1992 to harmonize the standards and principles for the regulation of medical devices. In 2003, the WHO issued a booklet entitled "Medical Device Regulations: Global Overview and Guiding Principles" providing guidance for different countries in setting up or modifying their regulatory systems for medical devices.

the requirements on safety, performance, and quality before allowing them to be placed on the market; (ii) post-market control – to enable swift control measures against defective or unsafe medical devices; and (iii) use control – to restrict the possession and use of certain high-risk medical devices.

Definition and classification of medical devices

6. The term "medical devices" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It covers devices that are used for the purpose of investigation, replacement, modification or support of the anatomy or physiological process of the human body. These range from simple devices like hot/cold pads to sophisticated devices like breast implants and high power laser machines. Devices used for examination of human specimens are also included under the term.

7. For the purpose of the proposed legislation, the definition of medical device will be largely based on GHTF's recommendation[2]. However, the experiences of other countries with regulatory control show that, despite the attempt to provide a clear definition for medical device, a number of products appears to be "borderline" cases. It is therefore proposed that the legislation should empower the Director of Health (DoH) to designate through a form of Schedule those products which are to be included into regulatory control under the proposed legislation taking into account the local situation and stakeholders' expectations.[3]

8. It is also proposed that the GHTF's classification methods be adopted to achieve consistency with international practices. Based on their

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[2] According to GHTF's recommendation, medical device means "(A) any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of –

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

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means; and (B) accessories for medical devices."

[3] One example is non-corrective contact lenses which do not fall squarely within the definition of medical device but it is intended for use on human body and that it carries the potential of causing adverse effect on human body in a similar way to corrective contact lenses.

risks to patients, users and other persons, medical devices other than in-vitro diagnostic medical devices (IVDMDs) are classified into four classes according to the classification rules recommended by GHTF (e.g. invasiveness, length of retention in body, location of implant, etc.). Examples of devices belonging to respective classes are shown as follows –

Class	Risk Level	Examples
I	Low	Surgical drill, tongue depressor, bandage, dressing, walking aid
II	Medium - Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator, acupuncture needle, corrective contact lens
III	Medium - High	Condom, Lung ventilator, contact lens disinfectant, orthopaedic implant, X-ray machine[4], laser
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter

9. As for IVDMDs, they are also classified into four classes according to classification rules recommended by GHTF with respect to their risks to individual user and the public as follows –

Class	Risk Level	Examples
A	Low individual risk, Low public health risk	Clinical chemistry analyzer, prepared selective culture media
B	Medium individual risk, Low public health risk	Pregnancy self-testing, anti-nuclear antibody, urine test strips
C	High individual risk, Medium public health risk	Blood glucose self testing, HLA typing, PSA screening, rubella
D	High individual risk, High public health risk	HIV blood donor screening, HIV blood diagnostic

[4] Devices which emit ionizing radiation (such as x-ray machine) or contain radioactive substances are also required to comply with the Radiation Ordinance, (Cap 303) which controls their import, export, possession and use.

Pre-market control

10. Pre-market control measures involve the registration of medical devices, local manufacturers, importers/exporters, distributors, authorized representatives (ARs), and conformity assessment bodies (CABs). To be registered, they must meet the registration requirements stipulated by DH.

Registration of medical devices

11. Registration or listing with DH is required before a medical device can be placed on the local market. The registration requirements for different classes of devices will commensurate with the risk associated with the medical device. It is proposed that registration or listing of medical device be implemented in phases, starting with the highest risk devices, to allow adequate time for the trade to adapt.

12. To facilitate access to unregistered devices under certain special circumstances, it is proposed that the legislation may provide exemptions from registration. DH will be empowered to grant special approvals for non-registered medical devices to be used in specific situations such as clinical research, on a named-patient due to special needs or for educational purpose.

Registration of local manufacturers

13. Local manufacturers are required to register with DH to ensure that they are capable of achieving the standards required for manufacturing medical devices. The registered manufacturers are required to provide information and support to their AR and/or DH to facilitate investigations of adverse events and recall of devices when necessary.

Registration of importers/exporters

14. Registration of importers/exporters is required to facilitate DH to keep track of the medical device in the market. Registered importers/exporters are required to maintain detailed records of import and export of medical devices, both registered and unregistered, and to obtain valid import/export licences for specified high risk medical devices.

Registration of distributors

15. The main purposes of registration of distributors are to enhance the traceability of medical devices and empower DH to obtain medical device distribution records along the supply chain when necessary. Distributors of medical device are traders who sell medical device for the purpose of resale or use, other than for personal use.

Registration of authorized representatives (ARs)

16. An AR is a natural or legal person designated by the local or overseas manufacturer to register the medical devices and hold the certification of registration. Owing to the large number of retailers and distributors of medical devices, ARs would be the focal point to facilitate tracing of medical device when recall is required.

17. Registration of ARs is considered necessary to ensure that suitable entities will be held responsible for following up matters related to problematic medical devices. ARs will have the right to place their registered medical devices on the local market. At the same time they have to take up the responsibilities such as reporting and investigating adverse events and managing product recalls of their registered medical devices.

Registration of conformity assessment bodies (CAB)

18. The proposed legislation empowers DH to designate CABs to perform conformity assessment audits on medical devices. CABs provide third party conformity assessment services to manufacturers. This proposal is in line with the global trend. It is proposed that CABs are required to register with DH so that their performance can be monitored.

Post-market control

19. Post-market monitoring of the performance of medical devices and reporting of problems associated with the use of the devices are important components of the regulatory framework. Post-market control covers (i) surveillance; and (2) warning, recall and prohibition of sale.

Surveillance

20. DH will establish a post-market surveillance system to monitor the safety, performance, and quality of medical devices in the market,

maintain vigilance on medical device safety alerts issued by overseas authorities and follow up as appropriate.

21. ARs in conjunction with the manufacturers are required to keep track of the performance of their products, for example, products compliants and failure rates, and submit surveillance reports to DH upon request. They are also required to report and investigate adverse events, and to instigate remedial actions to the satisfaction of DH.

Warning, recall, and prohibition of sale

22. The proposed legislation will provide the statutory basis for DH to advise the public on unsafe medical device, to stop the sale, to recall, and to destroy the medical device concerned as the situation warrants with a view to protecting public health. In order that warning message of an unsafe medical device could reach the public effectively, it is proposed that DoH be empowered to prescribe the form and manner that AR should publish such warning message.

Control over use of certain medical devices by those who are not statutorily registered healthcare professionals

23. The objective of imposing control over the use and operation of medical devices is to prevent unnecessary harm or complications arising from the improper use of medical devices.

24. It is proposed that operation of Class 3B and Class 4 high-power medical lasers be limited to statutorily registered healthcare professionals. As for intense pulsed light (IPL) equipment, those who are not statutorily registered healthcare professionals will be allowed to operate the equipment provided that they have undergone training and passed the IPL trade test run by reputable institutes, such as the Vocational Training Council (VTC). The proposed legislation will require business operators of this group of medical devices to apply for a licence to possess and operate the devices and undertake to comply with a set of licensing conditions, including safety precautions. The licensing conditions require that the business operator must ensure that the device is operated by trained and competent personnel. DH will issue guidance notes or code of practice to the business operator to assist them in understanding the conditions of use of this group of medical devices.

Appeal mechanism

25. It is proposed that an appeal board with members from external parties such as trade associations, medical associations, engineering institutions and academic institutes be appointed by the Secretary for Food and Health to handle appeal cases relating to licensing and registration.

Enforcement

26. The proposed legislation should empower DoH to deploy appointed persons to enforce provisions under the proposed legislation. The inspectors should have the power to inspect and search premises or conveyances, to examine, take and test samples, and to seize/seal, remove and retain any device or anything which appears to be evidence of an offence or in contravention of the proposed legislation.

Transitional measures in place

27. The MDACS, which operates on the basis of the guidelines developed in consultation with the relevant stakeholders, has been launched since November 2004 in phases to facilitate the transition to long-term legislative control. At present, the MDACS comprises listing of local manufacturers, importers, CABs and Classes II, III and IV medical devices as well as Class D IVDMDs. As at end September 2010, over 2000 applications for listing have been processed by DH.

28. As regards post-market control, DH has screened safety alerts and recall notices issued by overseas authorities or manufacturers since 2005. As of end September 2010, DH screened over 6,000 alerts and notices, among them over 1,000 are known to have affected Hong Kong. DH issued relevant safety alerts to the concerned parties such as the Hospital Authority, private hospitals, professional bodies as well as the general public.

29. 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 IPL. Following up the recommendations of the Working Group, VTC has implemented a trade test for IPL operators, including beauticians, to obtain certification.

30. DH has been organising workshops to brief traders on the listing system and to assist them in preparing listing applications under the MDACS. The listed medical devices are uploaded onto website for public reference.

DH has also launched publicity programmes to promote the public awareness of the listing system. These programmes include the launching of the thematic website providing educational materials about the MDACS, and the issue of fact sheets, leaflets and promotional articles. Seminars on medical devices (including overview of the medical device safety alert system and adverse event reporting system, and safe use of medical equipment) have also been organized for healthcare professionals from time to time.

Consultation

31. We have briefed the Business Facilitation Advisory Committee (BFAC) on the proposed legislative framework in March 2010. BFAC was in general supportive of the proposed regulatory framework and recommended the Administration to conduct a business impact assessment (BIA) at the detailed design stage.

32. A series of discussion forums were held between August and September 2010 to gauge the views of the industry. According to the feedback collected from the stakeholders after the discussion forums, the majority (91%) considered the latest proposed regulatory framework acceptable.

Proposed way forward

33. The current legislative proposal has taken into account the RIA findings, the views collected from the stakeholders and the public during consultations, as well as the experience gained from the operation of the MDACS since 2004. Refinements of this proposal over the existing MDACS are highlighted below -

(a) Registration of Class I medical devices, which belong to the low-risk category, is not covered under the MDACS. To enhance the efficiency of recalls, it is proposed that ARs be required to notify DH the Class I devices that they intend to supply in Hong Kong. This approach is similar to those adopted by Australia which is a GHTF member, and is also in line with the recommendations of the RIA report ;

(b) Only Class D IVDMDs are currently covered under the MDACS. It is proposed that all IVDMDs should be included in the regulatory scheme in future. The detailed proposal and the

enactment date of the regulation of IVDMDs will be determined at a later stage;

(c) Importers/exporters are required to maintain detailed records of import and export of medical devices and obtain import/export licences for specified high risk devices;

(d) Distributors (i.e. wholesalers) are required to register so that the distribution of medical devices from importers to retailers could be traceable; and

(e) The entity "Authorized Representatives" will be used to replace the existing term "Local Responsible Persons" under the MDACS to tally with the GHTF document. It is a change in the terminology.

34. To enable a smooth transition to statutory control, it is proposed that a streamlined registration arrangement be adopted for devices already listed on the MDACS.

35. As we are now preparing the details of the proposed legislation and in response to the BFAC's recommendation, we plan to carry out a business impact assessment (BIA) on the regulatory proposal. We will report to this Panel on the outcomes of the BIA study together with the details of the legislative proposal in 2011.

Advice sought

36. Members are invited to note the content of the paper.

Food and Health Bureau
November 2010

Annex

Brief Summary of the Findings of the Regulatory Impact Assessment

In 2007-2008, a Regulatory Impact Assessment (RIA) was conducted to examine implications of the possible options for the proposed statutory regulation of medical devices. The following stakeholders were consulted –

- manufacturers, importers, distributors and retailers of medical devices;
- owners, operators and users of medical devices;
- consumer / patients' rights groups;
- conformity assessment bodies; and
- randomly selected households

Consultations

Focus Group Discussions

- Over 1 100 invitations were sent to stakeholders and 9 discussion sessions with 105 participants were held; key concerns raised by the stakeholders included the fee rates and timing of the registration process, coverage of medical devices under the regulatory scheme, inclusion of in vitro diagnostic medical devices and control on the use and operation of laser machines.

Questionnaire Survey

- 198 questionnaires were received from stakeholders and 94% respondents support the regulation of medical devices by the government to ensure public safety. About 88% respondents agreed that the regulation of medical devices should include control on the use or possession of selected medical devices (e.g. medical lasers, intense pulsed light equipment).

Household Survey

- 1 100 completed questionnaires were received from the general public and the majority (78%) of interviewed household supported the proposed regulation.

- While the results of the RIA revealed that the majority of the respondents supported the implementation of statutory regulation of medical devices, a number of concerns were raised during the consultation, including –

  (a) the industry was concerned about the time taken for registration;

  (b) there were general concerns about the impact on small and medium enterprises (SMEs) and product availability if the registration process was too complicated, fees were too high or the registration times were too long;

  (c) there were concerns over the length of grace period;

  (d) the industry generally opined that the renewal fees on medical devices should be lower than the initial registration fee;

  (e) it would be important to ensure that the Hong Kong Government had adequate resources available to implement and enforce the proposed regulation; and

  (f) the industry was generally supportive of the need to control the use and operation of certain medical devices by non-medical professionals.

Recommendations

- The RIA recommended that the Administration should proceed with the regulatory scheme with the below elements -

  (a) including in-vitro diagnostic medical devices, with the actual enactment date of regulation to be determined at a later stage

  (b) excluding registration of Class I medical devices which should be monitored by registration of importers only;

  (c) control over the use of products by registering business operators rather than users;

(d) provision of an extended grace period;

(e) imposing a lower fee for product registration renewal; and

(f) minimising the compliance and enforcement costs where possible.