Discussion Forum

Proposed Framework for Statutory Regulation of Medical Devices

Medical Device Control Office
Department of Health

September 2010

Background

- **No specific legislation** in Hong Kong regulating the import, distribution, sale or use of medical devices except for those which contain pharmaceutical or radioactive substances, or emit ionising radiation
- **Increasing public concerns** over the safety of medical devices

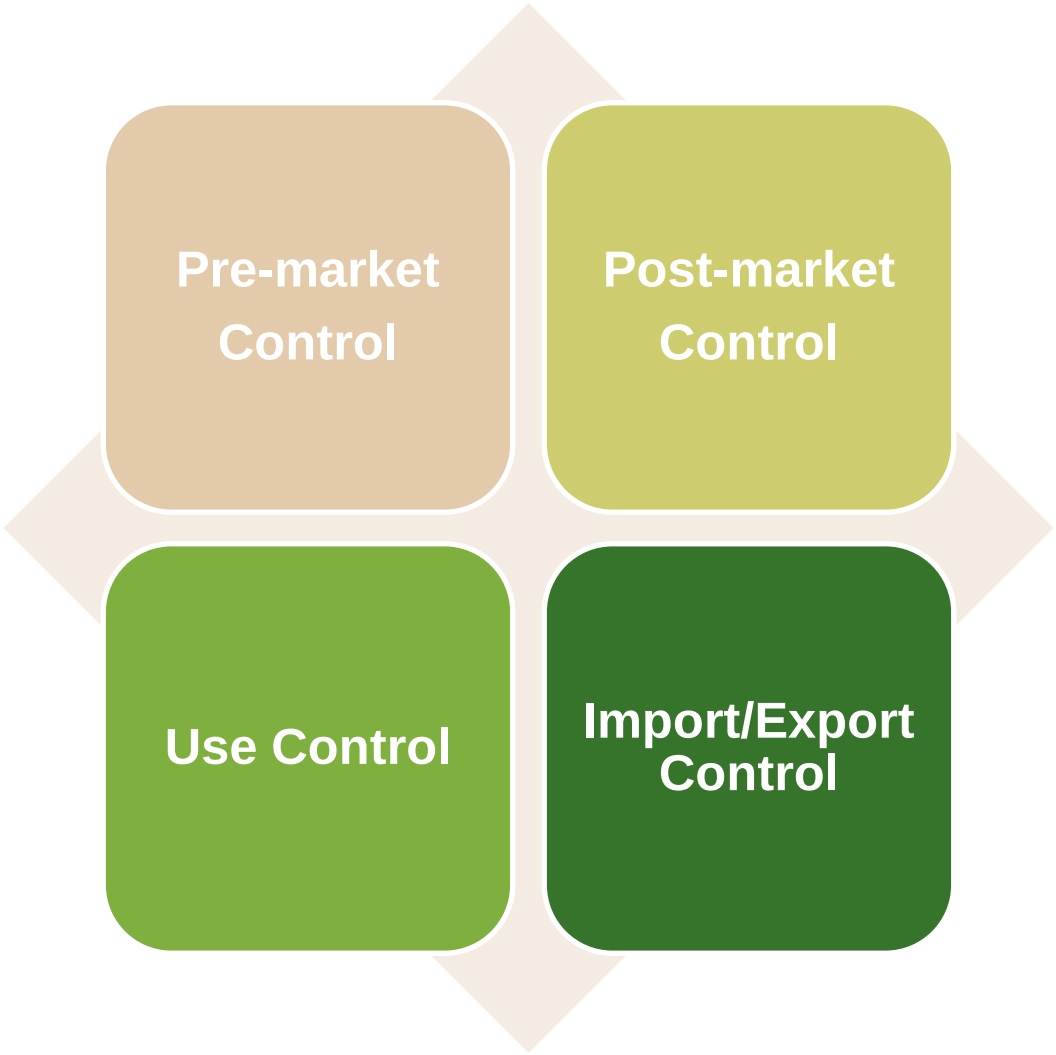
Background (cont'd)

- To protect public health, the Hong Kong Government planned to develop a **risk-based statutory regulatory framework** to control the supply and use of medical devices
- A voluntary **Medical Device Administrative Control System (MDACS)** has been implemented in phases since **2004** so as to pave way for long-term statutory control

Principles

- The proposed regulatory framework is modeled largely on the recommendations of the **Global Harmonization Task Force (GHTF)** and the **World Health Organization (WHO)**
- **Definition:** In line with the GHTF's recommendation
- **Classification:** risk-based approach according to the GHTF's recommended classification rules

Proposed Framework



Proposed Framework (cont'd)

- **Pre-market Control**

To ensure that devices conform with requirements on **safety, performance and quality** before placing on the market

- Registration of medical devices
- Registration of authorized representatives (ARs) designated by manufacturers
- Registration of local manufacturers
- Registration of importers/exporters
- Registration of distributors
- Registration of Conformity Assessment Bodies (CABs)

Proposed Framework (cont'd)

- **Post-market Control**

  To implement control measures against defective medical devices

  - Adverse events reporting and investigation
  - Recall notices and mandatory recalls
  - Sample test of selected medical devices
  - Tracking of specified medical devices
  - Trend reports for complaints and adverse events

Proposed Framework (cont'd)

- **Use Control**

  To restrict the possession and use of specified devices which may cause significant harm if used improperly

  - **Business operator's licence** for certain specified medical devices (e.g. intense pulsed light equipment, high power medical laser)

Proposed Framework (cont'd)

- **Import/Export Control**

  To strengthen the traceability of high risk medical devices and products that may be subject to misuse

  - **Import/export licence** for specified medical devices (e.g. IPL, high power laser, breast implants etc.)

Definition and Classification of Medical Devices

Definition of Medical Device

- In line with GHTF's definition of medical device

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 –

1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
3. investigation, replacement, modification, or support of the anatomy or of a physiological process;
4. supporting or sustaining life;

Definition of Medical Device (cont'd)

5. control of conception;
6. disinfection of medical devices;
7. 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.

(b) accessories for medical devices

Classification of Medical Devices

- In line with GHTF's classification rules
- Medical devices are classified into classes I, II, III & IV with ascending risk level based on GHTF's 16 rules
- In-vitro diagnostic medical devices (IVDMDs) are classified into classes A, B,C & D with ascending risk level based on GHTF's 7 rules

Classification of Medical Devices (cont'd)

Table 1: Classification of Medical Devices

Class	Risk Level	Examples
I	Low risk	Surgical drills, saw, tongue depressor, bandage, dressing, walking aid, surgical mask, wheelchair
II	Medium – Low risk	Hypodermic syringe, suction pump, endoscope, digital thermometer, contact lens
III	Medium – High Risk	Ventilator, contact lens disinfectant, orthopaedic implant, X-ray machine, laser, condom
IV	High risk	Artificial heart valve, implantable cardiac pacemaker, heparin-coated catheter, breast implant

Classification of Medical Devices (cont'd)

Table 2: Classification of In-vitro Diagnostic Medical Devices

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

Classification of Medical Devices (cont'd)

- **Medical Devices under Schedule**

  The Director of Health may include specific devices, e.g. decorative contact lens, into a Schedule for regulatory control under the proposed legislation, after taking into account the local situation and stakeholders' expectations

Pre-market Control

- **Registration of**
  - Medical Devices
  - Authorized Representatives (ARs)
  - Local Manufacturers
  - Importers/Exporters
  - Distributors
  - Conformity Assessment Bodies (CABs)
- Registrants would be required to observe a set of conditions of registration to be stipulated by DH

Pre-market Control (Cont'd)

- **Registration of Medical Devices**
  - Registration with the regulatory authority is required before a medical device can be placed on the local market
  - Devices must conform to requirements on **safety, performance and quality**
  - Implementation **in phases**
  - Exemptions : e.g. DH's approval required for non-registered medical devices to be used in clinical research or on a named patient due to special needs

Pre-market Control (Cont'd)

- **Registration of Authorized Representatives (ARs)**
  - Effective and efficient communications and mechanism for recalls
  - Designated by a local or overseas manufacturer
  - Apply for device registration and hold the certification of registration
  - Serve as the hub of communication among the users, manufacturers, importers/exporters, distributors and the regulatory authority
  - Take up the roles of the manufacturer locally for all matters related to the medical devices concerned

Pre-market Control (Cont'd)

- **Registration of Local Manufacturers**
  - Implement and maintain a quality management system in compliance with **ISO13485** or equivalent
  - Provide information and support to their ARs and the regulatory authority to facilitate investigation of adverse events, recall of devices and assessment of public health impact when needed
  - Regulatory authority may conduct inspections to ascertain whether the conditions for registration are met

Pre-market Control (Cont'd)

- **Registration of Importers/Exporters**
  - Improves the **traceability** of medical devices
  - Prevent those devices originally intended for re-export from being sold in Hong Kong
  - Importers/exporters are required to maintain detailed records of import and export of medical devices, both registered and unregistered
  - For certain specified medical devices that are of high risk or may be subject to misuse – need to apply for import/export licences and go through customs clearance

Pre-market Control (Cont'd)

- **Registration of Distributors**
  - **Distributors** are traders who sell medical devices for the purpose of resale or use, other than for personal use
  - Include traders who sell medical devices to healthcare facilities or healthcare service providers who may resell to consumers or sell services involving the use of such medical devices
  - Enhance the **traceability** of medical devices
  - Empower the regulatory authority to obtain distribution records along the supply chain

Pre-market Control (Cont'd)

- **Registration of Conformity Assessment Bodies (CABs)**
  - Designated by the regulatory authority to perform conformity assessment audits for manufacturers of medical devices

Post-market Control

- **Covers 3 key areas:**
  - Proactive surveillance
  - Adverse events reporting and investigation
  - Warning, recall, forfeiture and disposal

Post-market Control (Cont'd)

- **Proactive Surveillance**
  - ARs in conjunction with the manufacturers are required to keep track of the performance of their products
  - ARs may be required to submit surveillance reports (which may be based on local or overseas data or both) to the regulatory authority upon request
  - ARs are required to put in place a tracking system that enables the tracking of certain high-risk devices, e.g. artificial heart valves and implantable pacemakers, down to the user-facility level or patient level if appropriate

Post-market Control (Cont'd)

- **Adverse Event Reporting and Investigation**
  - Mandatory reporting of adverse events relating to medical devices is necessary to ensure public safety
  - ARs are required to report and investigate, with the support of the manufacturers, all reportable adverse events and instigate remedial actions to the satisfaction of the regulatory authority

Post-market Control (Cont'd)

- **Warning, Recall, Forfeiture and Disposal**
  - The regulatory authority will have the power to advise the public on unsafe medical device, to stop the continual supply of, to recall and to destroy the medical device concerned as the situation warranted with a view to protecting public health

Use Control

- **Control over Use of Specified Medical Devices by Non-medical Professionals**
  - To prevent harm or complications arising from the improper use of medical devices
  - Business operators of specified medical device (e.g. IPL, high power lasers) shall apply for a licence to operate the devices

Comments Sought

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1. The term **“Authorized Representatives (ARs)”** is used to replace the existing term “Local Responsible Persons (LRP)” under MDACS to be in line with the GHTF recommendations;
2. **Distributors** are required to register so that the distribution of medical devices from importers to retailers could be traceable;
3. **Import/export licenses** are required for specified devices that are of high risk or may be subject to misuse so that the import and export control of these products are enhanced; and
4. **Any other comments**

Contact

Comments can be submitted by post, email, or facsimile to the following addresses **on or before 30 September 2010**:

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Thank You!