Proposed Document:
GN-09 Guidance Notes for Listing of Local Responsible Persons (LRPs)

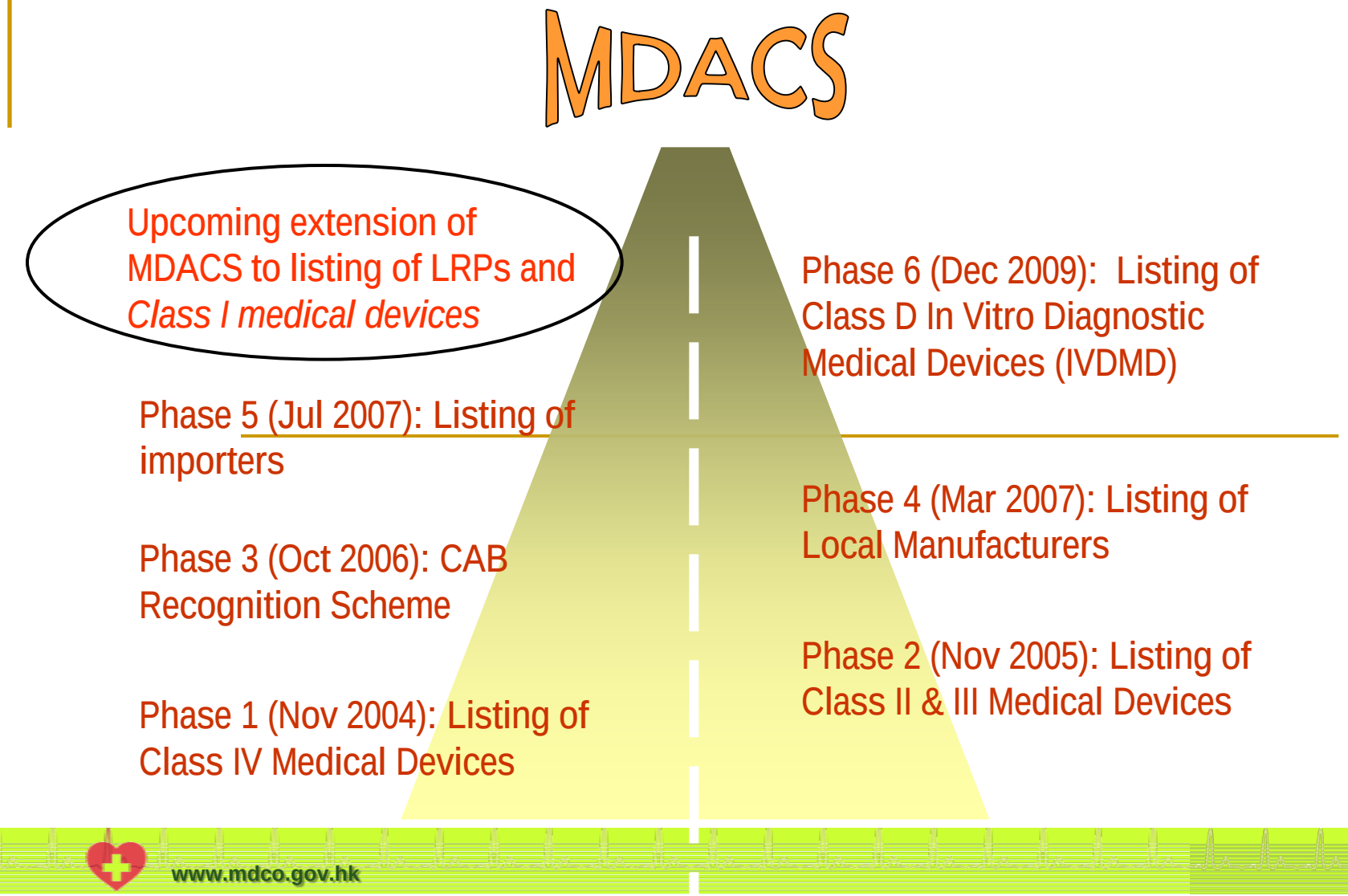
14 April 2010

Medical Device Control Office

Department of Health

Please refer to the proposed document for details

Towards a Complete Medical Device Administrative Control System (MDACS)



Listing Local Responsible Persons (LRPs) - Objectives

- To identify the person responsible for a particular medical device being placed on the market
- To provide better traceability of LRPs for public health or safety issues
- To promote quality management practices of LRPs

Definitions & Roles

- **Local Responsible Person (LRP) of a medical device**
  - an entity who places that particular medical device on the Hong Kong market
- **A listed LRP of a medical device under MDACS**
  - undertakes listing application for the medical device &
  - is supported by the manufacturer to perform the obligations of an LRP
- **Placing a medical device on market**
  - The first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Hong Kong market, regardless of whether it is new or fully refurbished

Obligations of LRPs

- Making applications for Listing Medical Devices
- Documented Procedures and Quality Management
- Efficient Communication Channels
- Distribution Records
- Complaint Handling
- Tracking of Specific Medical Devices (e.g. mechanical heart valves, implantable pacemakers, implantable defibrillators, implantable ventricular support systems and implantable drug infusion systems)
- Surveillance Reports
- Product Alerts, Modifications and Recalls

Obligations of LRPs (Cont'd)

- Managing Reportable Adverse Incidents in Hong Kong
- Maintenance and Services Arrangements
- Reporting Changes
- Making Records Available for Inspection
- Observe the responsibilities in respect of advertisements (e.g. any representation that the Government has endorsed the safety, quality, efficacy or effectiveness of a listed medical device is not allowed)
- Special Listing Information
- Storage and Shipment Requirements

LRP Listing Requirements

- To be listed, an LRP shall
  - EITHER be a legal person incorporated in HK, OR a natural or legal person with business registration in HK; and
  - have an office in Hong Kong
- Listed LRP of a medical device shall
  - EITHER be the manufacturer of the device, OR the third parties designated by the manufacturer of the device; and
  - Have placed or intend to place that medical device on market

Note

- LRPs who already have their medical devices listed under MDACS or have submitted device listing application to MDCO before is not required to apply again.

Application for LRP Listing

- **Processing Time**
  - About 12 weeks after all required documents are submitted

- **Approved Applications**
  - Entry added to **the List of Local Responsible Persons** at the MDCO web page
  - Certificate with **5-year validity**
  - **LRP Certificate Number** for Class II, III and IV medical device listing applications and the future **on-line submission of Class I medical device listing** (to be launched later)

Delisting of LRP(s)

- **Possible causes:**
  - Has been wound up, dissolved or has ceased to exist
  - Requested by the listed LRP
  - Failure to comply with the MDACS requirements
  - Failure to address or adequately address a situation that gives rise or that might give rise to a hazard of its products or to a public health or public safety concern
  - Has made untrue, unjustified or misleading claims when advertising its products
  - MDCO considers the delisting necessary for public health or safety considerations

Delisting of LRP(s) (Cont'd)

- **Permanently de-listed**
  - All listed medical devices under the LRP will be removed from the List
  - The LRP shall continue post-market surveillance and vigilance activities for devices already marketed

- **Temporarily de-listed (Listing suspension)**
  - Status of listed of medical devices may not be affected
  - No new listing application could be submitted

Change of LRP for Listed Medical Devices

- An LRP can apply to **take over** the listing of medical devices from another LRP only if
  - The **applicant undertakes to assume the obligations and responsibilities** of the existing LRP of the listed devices **already and/or to be placed on market;**
  - The **existing LRP** of the listed devices **undertakes to provide** the applicant all necessary **support and information for** taking up the LRP obligations for **devices already marketed;** and
  - The **manufacturer** of the listed medical devices **undertakes to provide the applicant** with all the information and support to enable the applicant **to become the new LRP and fulfil its obligations**

Sample Agreement for the Taking Over the Device Listing

Proposed Document **Appendix 3**

Sample Agreement for the Taking Over of the Listing of Medical Devices under the Medical Device Administrative Control System

We, the following parties (Party 1, Party 2 and Party 3),

Party 1
Name of applicant: *Cardio Pro Company Limited*
Address: *23/F, 234 Hung To Road, Kwun Tong, Kowloon, Hong Kong*

Party 2
Name of existing Local Responsible Person (LRP): *Cardio Supplies Limited*
Address: *32/F, Metropolitan Centre, 123 Merry Street, Causeway Bay, Hong Kong*

Party 3
Name of manufacturer: *ABC Medical Incorporation*
Address: *1234N, Derby Road, Arlington, VA54321 USA*

hereby agree that:

1. The Local Responsible Person (LRP) of the following listed medical devices under the MDACS is to be changed from Party 2 to Party 1 with effect from the taking over date approved by the Director of Health, Hong Kong. The proposed taking over date is (dd/mm/yyyy) *02/06/2010*.

Make	Model	Medical Device Listing No. (HKMD No.)
ABC Medical	*HeartAid PL3000*	*040025*
ABC Medical	*HeartAssist PX900*	*040098*

2. The applicant (Party 1) undertakes to (i) assume all the responsibilities and obligations of the existing LRP (Party 2) including pre-market and post-market requirements and activities related to the medical devices depicted in Section 1 above; and (ii) comply with all the requirements of being a Local Responsible Person of the related products under the Medical Device Administrative Control System.

Proposed Document

3. The existing LRP (Party 2) undertakes to provide the applicant (Party 1) with all necessary support and information including distribution and maintenance records etc. required for taking up the LRP obligations of the devices depicted in Section 1. The existing LRP also undertakes that it will continue with all the LRP obligations of the related products until the taking over date approved by the Director of Health, Hong Kong.
4. The manufacturer (Party 3) undertakes to provide the applicant with all the necessary information and support so as to enable the applicant (Party 1) to fulfil its LRP obligations under the Medical Device Administrative Control System.

For and on behalf of the applicant (Party 1)

Signature: *<Signature of Cheung Mei-fong>* Date: *3 February 2010*
Name: *Cheung Mei-fong* Company Chop: *< Chop of Cardio Pro Company Limited>*
Position: *Manager*
Company Name: *Cardio Pro Company Limited*

For and on behalf of the existing LRP (Party 2)

Signature: *<Signature of Chan Tai-man>* Date: *10 February 2010*
Name: *Chan Tai-man* Company Chop: *< Chop of Cardio Supplies Limited>*
Position: *General Manager*
Company Name: *Cardio Supplies Limited*

For and on behalf of the manufacturer (Party 3)

Signature: *<Signature of John Smith>* Date: *20 February 2010*
Name: *John Smith*
Position: *International Regulatory Affairs Manager*
Company name: *ABC Medical Incorporation*

If You Have Comments, …

Your comments on the Proposed Document Guidance Notes GN-09 are most welcome.

Please let us have your comments on or before 30 April 2010.

Thank You!