Proposed Document:
GN-10 Guidance Notes for Listing of Local Responsible Persons

8 April 2019

Medical Device Control Office

Department of Health

Please refer to the proposed document for details

Issued Document – Guidance Notes

[GN-00] Guidance Notes for Definitions and Abbreviations for MDACS

[GN-01] Overview of the Medical Device Administrative Control System

[GN-02] Guidance Notes for Listing Class II, III & IV Medical Devices

[GN-03] Guidance Notes for Adverse Incident Reporting by LRPs

[GN-04] Conformity Assessment Framework and Conformity Assessment Bodies

[GN-06] Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices

[GN-07] Guidance Notes for Listing of Importers of Medical Devices

[GN-08] Guidance Notes for Listing of Local Manufacturers

[GN-09] Guidance Notes for Listing of Distributors

[GN-10] Guidance Notes for Listing of Local Responsible Persons

Issued Document – Code of Practice

[COP-01] Code of Practice for Local Responsible Persons (May 2019)
[COP-02] Code of Practice for Conformity Assessment Bodies
[COP-03] Code of Practice for Listed Local Manufacturers
[COP-04] Code of Practice for Listed Importers of Medical Devices

Listing Local Responsible Persons - Objectives

- Recognise the importance of LRPs in
  - Applying listing of medical devices
  - Provision of post-market activities
- LRPs serve as a communication hub between manufacturer and users, distributors, public and the Government
- To promote quality management practices of LRPs

Definitions & Roles

- **Local Responsible Person (LRP) of a medical device**
  - 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 requirements of LRP

Requirement of LRPs

- Documented Procedures and Quality Management
  - Keeping of Transaction Records
  - Complaint Handling
  - Tracking of Specific Medical Devices
  - Management of Safety Alerts, Field Safety Notice and Field Safety Corrective Actions
  - Managing Reportable Adverse Incidents in Hong Kong
  - Maintenance and Services Arrangements
  - Handling, Storage and Delivery of Medical Device

Requirements of LRPs (Cont'd)

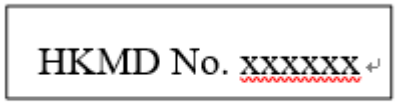
- Related to listing of medical devices
  - Making applications for Listing Medical Devices
  - Reporting Changes
  - Post-market Surveillance Reports
  - Special Listing Information

Requirements of LRPs (Cont'd)

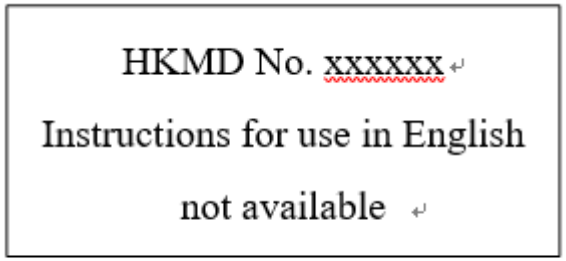
- Efficient Communication Channels
- Regular Checking and Review of Operation
- Making Local Facilities and Records Available for Inspection
- Responsibilities in respect of advertisements
  - Any representation that the LRP is listed Local Responsible Person
    - State that listing of LRP carries no implication that its medical devices are listed
    - State that if the medical devices presented is listed in MDACS or not
  - Advertised claims of listed MD shall align with those indications listed under MDACS.

Special Listing Information

- The device's Listing Number
- A statement if the device's instructions for use are available only in English or only in Chinese



(a)



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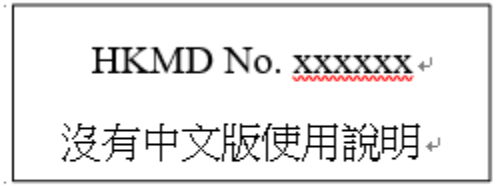

(c)

Special Listing Information (Con'd)

- The LRP information
  - name,
  - address,
  - contact telephone / fax numbers

in both English and Chinese wherever applicable.

- *On the outer packaging on every device or sale unit, or*
- *On a document delivered together the details are printed*

LRP Listing Requirements

- To be listed, an LRP shall
  - a legal person with business registration in HK
- 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 **3-year validity**
  - **LRP Listing Number** for Class II/III/IV medical device and Class B/C/D IVDMD listing applications

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 or special conditions in the cases of conditional approval
  - 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**
  - MDCO has the discretion to suspend all the listed medical devices
  - No new listing application could be submitted
  - The LRP shall continue post-market surveillance and vigilance activities for devices already marketed

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.

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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-10 are welcome.

Please let us have your comments on or before 18 April 2019.

Thank You!