Medical Device Regulatory Update

Medical Device Control Office
Department of Health
The Government of Hong Kong SAR

9 Nov 2018

Matters related to Legislative Proposal

- Regarding the refined legislative proposal on regulation of medical devices put forward in the LegCo HS Panel meeting on 16 July 2018,
  - seven submissions from associations or colleges of medical professions and the MD industry associations received;
  - meeting with LegCo member and >50 beauty industry representatives expressing their views on 24 August 2018.
- Drafting of the Medical Devices Bill in progress; aiming to introduce the Bill to the LegCo in the coming legislative session.

Listing application of medical devices under the MDACS

A trial to study the feasibility for LRP to demonstrate their medical devices conform to the “Essential Principles of Safety and Performance of Medical Devices” (Technical Reference: TR-004) by presenting valid marketing approvals obtained from the China Food and Drug Administration, as satisfying the conformity assessment requirements of the MDACS.

From 1 June 2018 to 31 December 2018

Revised GN-07 (Guidance Notes for Listing of Importers of Medical Devices)

All applications received on or after 1 June 2018 must be completed with the revised application form

Existing Importers are required to submit supplement information to demonstrate their compliance to the new requirements before 1 June 2019

Notice to local manufacturers in applying for medical device registration in Mainland China

CFDA now recognizes the following two certificates as equivalent to the “marketing approval” obtained from the place of origin of the device, may use as one of the supporting documents in applying for medical device registration in Mainland China:

1.“Certificate of Listing” of medical devices under the Medical Device Administrative Control System (MDACS) with legal manufacturers in Hong Kong;
2.“Certificate to CFDA” (for devices outside the scope of the MDACS).

Trial Scheme for Provisional Approval of Class II/III/IV Medical Device Listing Applications

- No safety issues associated with the device globally
- Two or more independent regulatory agencies' approval have been obtained out of the 5 GHTF founding countries
- Dual track application system
- The application dossier should be submitted in accorded format and completed with quality corresponding information

Trial Scheme for Provisional Approval of Class II/III/IV Medical Device Listing Applications

- Aimed to complete the listing application without supplementary submissions
- All issues raised should be effectively addressed to satisfaction of MDCO within the date specified, usually in two weeks time
- Discretion of MDCO to accept supplementary information
- Listing would be revoked

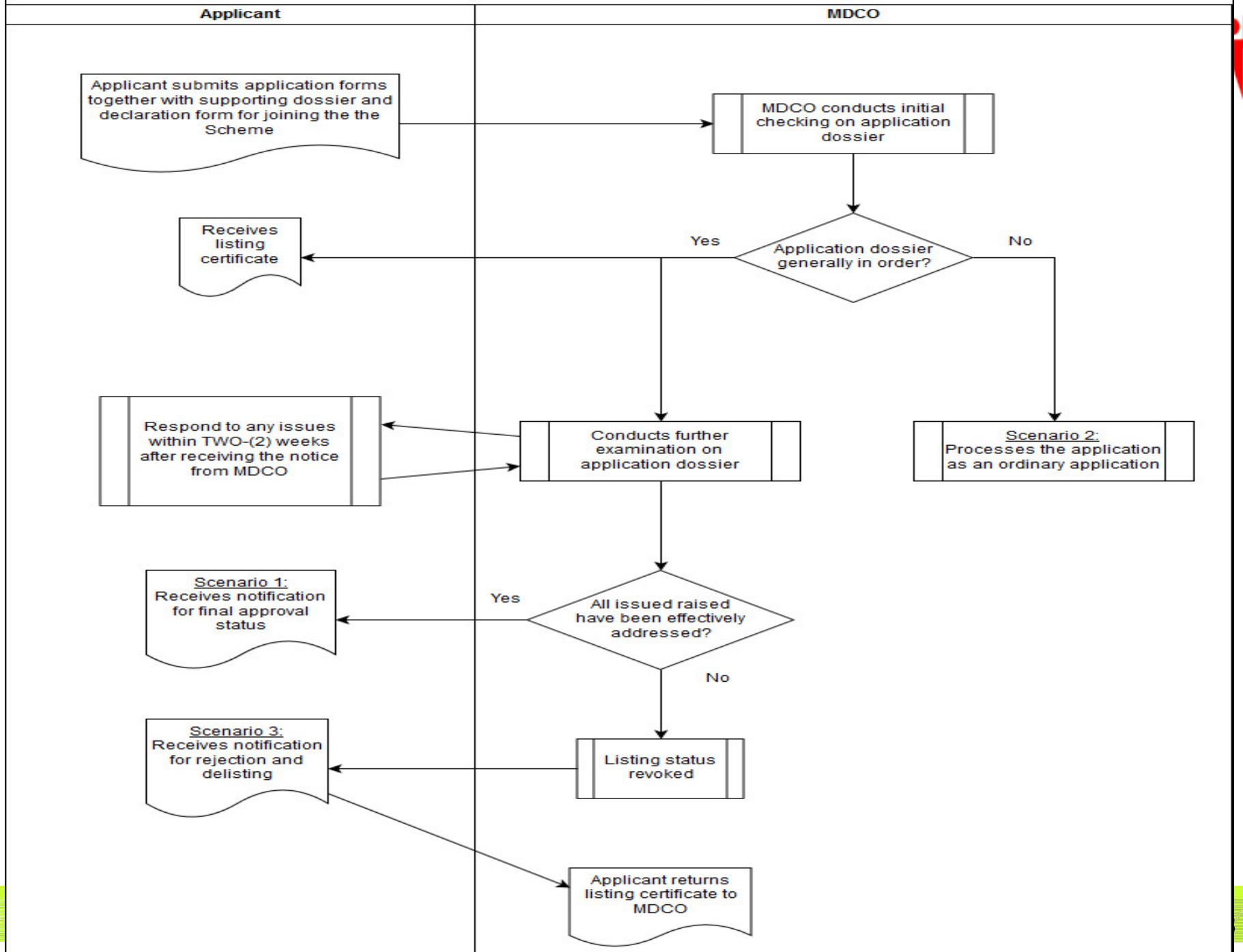
Diagram 1: Conceptual Diagram for the Scheme
Applicant
MDCO
Applicant submits application forms together with supporting dossier and declaration form for joining the the Scheme
MDCO conducts initial checking on application dossier
Application dossier generally in order?
Yes
No
Receives listing certificate
Respond to any issues within TWO-(2) weeks after receiving the notice from MDCO
Conducts further examination on application dossier
Scenario 2: Processes the application as an ordinary application
All issued raised have been effectively addressed?
Yes
No
Scenario 1: Receives notification for final approval status
Scenario 3: Receives notification for rejection and delisting
Listing status revoked
Applicant returns listing certificate to MDCO

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

- To recognize the importance of LRPs in applying listing of medical devices and provision of post-market activities.
- To promote quality management practices of LRPs
- To ensure quality compliance of LRPs on MDACS requirements

LRP Listing Eligibility

- To be listed, an LRP shall
  - EITHER be a 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

- Entities submitting applications for listing their first medical device shall have applied to become a listed LRP.

- 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.

Obligations of LRPs

- Documented Procedures and Quality Management
- Efficient Communication Channels
- Making applications for Listing Medical Devices
- Keeping of Transaction 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)
- Post Market Surveillance Reports
- Field Safety Notices and Field Safety Corrective Actions

Obligations of LRPs (Cont'd)

- Managing Reportable Adverse Incidents in Hong Kong
- Maintenance and Services Arrangements
- Handling, storage and delivery of medical device
- Regular checking and review of operation
- Reporting Changes
- Making Records Available for Inspection
- 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

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
  - Listing Certificate with **3-year validity**
  - **LRP Listing Number**

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**

Possible change in MDACS

- **Updating GN-06 to accept listing of class B and C IVDMD**
- **Inviting comments by end Dec 2018**
- **Conducting a short briefing on 4 Dec 2018**

Possible change in MDACS

Addition of intended use on MDCO website

- Limitation on the wording
  - length
  - style of writing (e.g. repetitive wording)
  - advertisement (e.g. smallest in the world)
  - avoid comparison (e.g. replacing other technology)

Thank you !