Medical Device Regulatory Update

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

27 July 2018

Matters related to Legislative Proposal

- A refined legislative proposal on regulation of medical devices was discussed in meeting of the LegCo Panel on Health Services on 16 July 2018.
- Support letters for the proposal were received from various organisations while the disappointment on the removal of “Use Control” from some LegCo members was noted.
- Stakeholders will be engaged in finalising details of the legislative proposal while the Medical Devices Bill based on the refined proposal is being worked on, aiming to be introduced 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 30 September 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 applicant shall respond to any issues raised by using the application dossier submitted, without supplementary submissions
- All issues raised should be effectively addressed to satisfaction of MDCO within the date specified
- Listing would be revoked

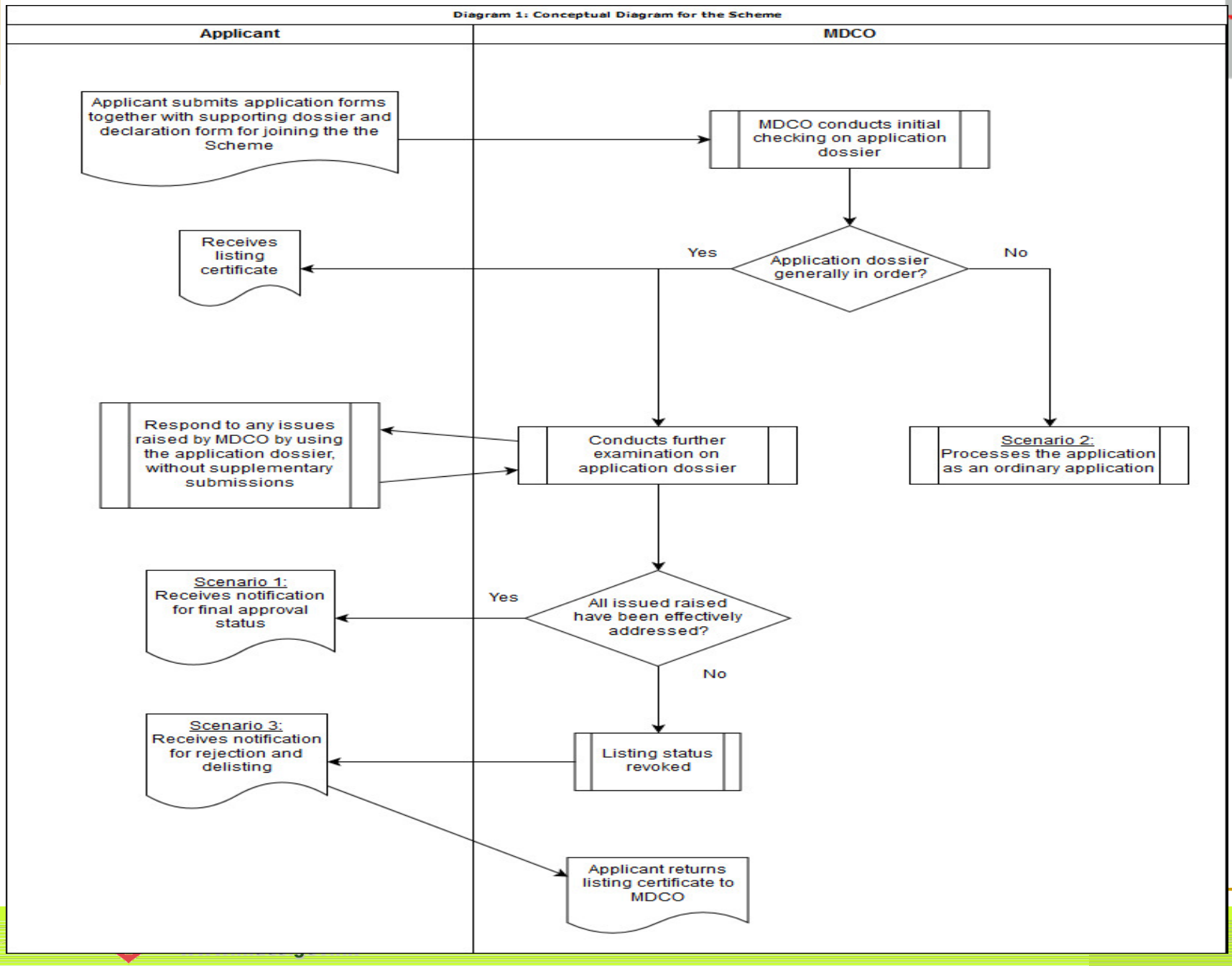
Diagram 1: Conceptual Diagram for the Scheme
Applicant
MDCO
Applicant submits application forms together with supporting dossier and declaration form for joining the the Scheme
MDCO conducts initial checking on application dossier
Application dossier generally in order?
Yes
No
Receives listing certificate
Respond to any issues raised by MDCO by using the application dossier, without supplementary submissions
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

Obligations of LRP

COP – 01

Code of Practice for Local Responsible Persons

- Hub of communication
- Operating procedures
- Responsibilities in respect of advertisements

Obligations of LRP

COP – 01

Code of Practice for Local Responsible Persons

- Updating of contacts
- Submission of applications
- Hub of information
- Alerting / updating MDCO on equipment information and regulating situations around the world

Change in MD Listing

1. New renewal process (wef 1.1.2017)

- Provide essential document (mainly business registration cert)
  - Active safety cases
  - Change since last approval
- **Submit the change application within 10 days**
- Change application will be handled separately

Change in MD Listing

1. **New renewal process (wef 1.1.2017)**
   - **Involve a declaration on application form**
   - Same as last approved version
   - Does not imply the approval of change application in progress
   - Revision number on certificate of listing

香港特別行政區政府
衞生署
醫療儀器管制辦公室
網站：www.mdco.gov.hk

Medical Device Control Office,
Department of Health,
Government of the Hong Kong
Special Administrative Region
Website: www.mdco.gov.hk

表列證書
CERTIFICATE OF LISTING

表列號碼 Listing No. : XXXXXX

修訂本號碼 Revision No. : a

廠名、品牌及型號 Make, Brand Name and Model : XXXX

儀器名稱 Device Description : XXXXXXXXXXXX

製造商 Manufacturer : XXXXXXXXXXX

製造地點 Manufacturing Site : XXXXXXXXXXXXXXXXXXXXXXXXXXX

本地負責人 Local Responsible Person : XXXXXXXXX 有限公司
XXXXXXXXXXX Limited

茲證明上述產品已在衞生署的「醫療儀器行政管理制度」中表列，上述本地負責人已由製造商委任，並承諾遵守「醫療儀器行政管理制度」的規定。

This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.

發出日期 Date of issue : XXXX

有效至 Valid until : XXXX

衞生署署長
(溫遠光醫生代行)
(Dr WAN Yuen Kong)
for Director of Health

Medical Device Control Office
Renewal Form for Listed Medical Devices

To: Medical Device Control Office

For official use only
Date Received (dd/mm/yyyy): _____
Application No.: _____

Particulars of Application		
1	HKMD No.	
	Make	
	Model	
	Company Name	
	Contact Person	
	Telephone	
	E-mail	
2	A copy of valid Business Registration Certificate (number: _____) is enclosed.	
3	There are active recalls, field safety corrective actions or adverse incidents (local and worldwide) ☐ No ☐ Yes. Details are provided in separate sheets.	
4	There is change to the listing details since last approval ☐ No ☐ Yes (Please go to 4(i))	
	(i) Change application of the devices is submitted to MDCO ☐ Yes ☐ No. We will submit change application within 10 calendar days.	

Declaration

We acknowledge that the listing details of this renewal application would be the same as the last approved version. Approval of this renewal application does not imply the approval of any change application in progress.

We confirm that:

a. The applicant remains designated as Local Responsible Person by the manufacturer;

b. The applicant remains aware and complies with all device listing conditions (e.g. Post market surveillance);

c. All certifications / licences (e.g. ISO 13485 certificate for manufacturing site and recognized marketing approval) relating to the listed device remain valid and will be submitted to MDCO upon request; and

d. The information contained in this renewal form is true and correct.

Signature of Applicant:

Name: _____

Position: _____

Date (dd/mm/yyyy): _____

Company Chop

Change in MD Listing

2. Revised change application form (wef 2017 Mar)

- Change of legal manufacturer ➔ considered as a new device ➔ submit new application
- provide old / existing listing number ➔ facilitate the vetting process
- Change in address, phone no. and contact point of manufacturer ➔ change

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)

Possible change in MDACS

- **GN for LRP?**
- **Updating of issued documents**

Thank you !