COP-01:2021(E)

Medical Device Administrative Control System (MDACS)

Code of Practice

for

Local Responsible Persons

Code of Practice: COP-01

中華人民共和國

香港特別行政區政府衞生署

Department of Health

The Government of the Hong Kong Special Administrative Region

The People's Republic of China

Revision History

Version Number	Date of Revision	Summary of Revisions	Reference Number
0	1 Sep 2005	• First issue of COP-01	COP-01:2010(E)
1	30 Sep 2021	• Update document format; and • Rename of Medical Device Control Office to Medical Device Division	COP-01:2021(E)

Table of Contents

1. Introduction

1.1 Medical Device Administrative Control System

1.1.1 The Medical Device Administrative Control System (MDACS) features both a listing system and an adverse event reporting system. Under the former, lists of medical devices, importers, distributors and local manufacturers conforming to the requirements of MDACS are maintained by the Medical Device Division. The adverse event reporting system requires reportable or potentially reportable adverse events involving listed devices to be reported to the Medical Device Division, who will ensure that event investigation will be carried out and any necessary corrective and preventive measures implemented.

1.2 Local Responsible Person

1.2.1 The Local Responsible Person (LRP) in respect of a listed device is the applicant who applies to list the device. The LRP must be a legal person incorporated in Hong Kong, or a natural or legal person with business registration in Hong Kong. Unless the LRP itself is the manufacturer of the device, it must have been, before applying to list the device, duly designated as the LRP for the device by the manufacturer.

1.3 This Code of Practice

1.3.1 The MDACS has a multitude of requirements that the LRPs have to comply with. Clause 3 below specifies the basic obligations of the LRP, whereas clause 4 sets out the rules regarding delisting and appeals.

2. Guidance Notes Issued by the MDD

2.1 In case of any conflicts between the requirements in this document and those in the Guidance Notes, the latter prevail. Requirements stated in the Guidance Notes, whether or not also stated in this document, are valid requirements of the MDACS.

So are any requirements that are stated in this document but not in the Guidance Notes. When used in this document a term that is defined in the Guidance Notes will have the meaning thus defined, unless the context otherwise requires.

3. Obligations of Local Responsible Persons

3.1 Efficient communication channels

3.1.1 The LRPs are responsible for communicating with the users, importers, distributors, public and the Government and to manage the pre-market and post-market matters of the corresponding devices. The LRPs shall maintain efficient communication channels with the manufacturers such that any updated device information can be disseminated to the related parties effectively, while feedbacks can be collected and delivered to the manufacturers for actions.

3.2 Application for listing medical devices

3.2.1 The LRPs are persons making the applications for listing their medical devices under the MDACS, and are responsible for communicating with the Government regarding their applications. The LRP must provide the MDD with further information or further labelling samples related to the application if this is requested by the MDD. Whether during or after the application process, the LRP cannot refuse any request by the MDD for inspection of the originals or certified true copies of the documents referred to in the application and any other relevant documents (including documents prepared and/or being kept by the manufacturer). Within two weeks of receiving such a request, the LRP must produce the required originals or certified true copies for inspection by the MDD.

3.3 Keeping of supply records

3.3.1 The LRP shall maintain an updated list of importers, distributors and the supply records of devices, including the make, model, batch number, serial number, and quantity of devices, as appropriate, such that the details of devices imported and supplied in Hong Kong can be traced when needed.

3.4 Complaint handling

3.4.1 The LRP shall have in place a procedure to handle complaints. A telephone number, a fax number and/or an email address shall be provided to the public for collecting comments and complaints from the users and the public.

3.5 Maintenance and services arrangements

3.5.1 The LRP shall offer or arrange other parties to provide preventive and corrective maintenance, including calibration, provision of spare parts and other services, if applicable, to the users when requested.

3.6 Tracking of specific medical devices

3.6.1 Clauses 3.6.2 and 3.6.3 apply to the high-risk medical devices specified in Appendix 1 of GN-01.

3.6.2 The LRP shall have in place a tracking system that tracks down to patient level the devices specified in clause 3.6.1 above. Where this tracking is not possible for any individual devices (e.g. the tracking does not have the patient's consent), the system is still required (1) to track the devices down to the user-facility level (so that, if a need to recall these devices arises, the recall can still be effected through the assistance of these user facilities) and (2), for each of these devices, to keep track of the following: (a) the date the device was put into service or (for an implantable device) implanted into a patient, and (b) (if tracking of these is also possible) the date the device permanently retired from use or (for an implanted device) the date it was explanted.

3.6.3 For the categories of devices specified in clause 3.6.1, the LRP shall submit surveillance reports (which may be based on local or overseas data or both) to the MDD at least once a year. The MDD reserves the right to revise the submission schedule as it sees appropriate or necessary, and in case of any such revision the LRP will be notified accordingly.

3.7 Managing product recalls and field safety notices

3.7.1 Upon the issuance of product recalls and field safety notices by the manufacturer or overseas authorities, the LRP shall inform the MDD of the related details and actions to be taken in Hong Kong as soon as possible, and not later than 10 calendar days after their issuance. The LRP shall follow up the actions, and shall submit progress reports to the MDD as requested until the case is concluded. It is preferred that prior arrangements be made such that within four hours of the issuance of product recalls and field safety notices by the manufacturer, the same be also e-mailed direct to the MDD.

3.8 Managing reportable adverse events in Hong Kong

3.8.1 The LRP is required to observe the reporting requirements in the Guidance Notes GN-03. As a general rule an event involving a listed medical device and which has led to one or more of the following outcomes is reportable and must be reported by the LRP:

(a) death of a patient, user or other person;

(b) serious injury of a patient, user or other person;

(c) no death or serious injury occurred but the incident might lead to death or serious injury of a patient, user or other person if the event recurs.

3.8.2 The submission of an adverse event report does not, in itself, represent a conclusion that (1) the content of the report is complete or confirmed, (2) the device failed in any manner, or (3) the device caused or contributed to the incident. When a reportable or a potentially reportable adverse event that has occurred in Hong Kong is reported to the LRP directly or from other sources, the LRP shall conduct an investigation into the adverse event and report to the MDD as soon as possible. The investigation may be done in conjunction with the manufacturer or other parties. If the adverse event has caused any death or serious injuries or is of a serious public health concern, the report shall

reach the MDD as soon as possible but not later than 10 calendar days after the LRP becomes aware of the adverse event. For other reportable or potentially reportable adverse events, the LRP shall, within 30 calendar days of becoming aware of it, report the adverse event to the MDD. Upon request, the LRP shall also provide assistance to the MDD to conduct a separate investigation.

3.9 Making records available for inspection

3.9.1 The MDD has the discretion to inspect the originals or certified copies of records and documents claimed to be in the possession of the LRP or copied to the MDD by the LRP when considered necessary. The LRP shall produce the required originals or certified copies for inspection within two weeks after receiving the notice from the MDD.

3.10 Responsibilities in respect of advertisements

3.10.1 The advertisements or other commercial promotional materials shall not contravene the Undesirable Medical Advertisement Ordinance (Cap. 231).

3.10.2 References to MDACS in advertisements

3.10.2.1 The MDD disapproves of references of all kind, in advertisements of medical devices or other commercial promotional materials, to the MDACS, except if the references fall within the permissible exceptions in 3.10.2.2 below. In particular, the MDD disapproves of any representation that the Government has endorsed the safety, quality, efficacy, or effectiveness of a listed medical device. Such representation may be considered as an unjustified claim for the purpose of clause 4.1(d). The LRP must not publish or cause to be published any advertisement or promotional materials that make references to the MDACS except if the references fall within 3.10.2.2 below.

3.10.2.2 Notwithstanding 3.10.2.1, references to the MDACS in lawful advertisements or promotional materials will not be disapproved by the MDD if they are limited to the following forms and if the presentation of these together with other information in the advertisements or promotional materials is in a legitimately balanced manner:

(a) a statement to the effect that a certain medical device is listed with the

MDD;

(b) mention of the listing number of a listed medical device;

(c) pictures or photographs showing a listed device and/or its packaging, and incidentally, its listing number.

3.11 Obligation to indemnify the Government

3.11.1 The LRP shall sign the declaration as depicted in the application form to indemnify the Government against all losses and claims in relation to any of the following: any act and default of the LRP, any defective device design, any defects in the devices, and any information supplied by the LRP to the Government. The LRP shall consider adopting appropriate measures such as taking out insurance to cover its possible liabilities.

3.12 Special Listing Information

3.12.1 The Special Listing Information of a medical device comprises (i) and (ii) below:

(i) The device's Listing Number, and in case the device's instructions for use are available only in English or only in Chinese, a supplementary statement to inform the user of this fact. The information shall be displayed in the applicable format shown in Fig. 1 below.

(ii) The LRP information including the name, address, and contact telephone / fax numbers in both English and Chinese wherever applicable.

3.12.2 The LRP shall provide the Special Listing Information by complying with either Option (I) or Option (II) below. The LRP will have a grace period of six months after the device is listed to meet this requirement.

Option (I)

(a) The information (i) shall be displayed on the outer packaging of every

device or sales unit; and

(b) The LRP information (ii) shall be displayed on the outer packaging of every device or sales unit, or on a document delivered together with the device.

Option (II)

(a) Measures shall be implemented by the LRP such that whenever the listed devices are supplied and delivered to the end-users or user facilities, with or without cost to them, the delivery shall include a document on which the Special Listing Information is printed or otherwise permanently documented (This requirement does not apply to any subsequent sales from the end-users or user facilities); and

(b) The LRP shall ensure support from all concerned importers, distributors and retailers to implement the measures in (a). This option shall not be adopted if it cannot be effectively implemented.

HKMD No. xxxxxx

(a)

HKMD No. xxxxxx
Instructions for use in
English not available

(b)

HKMD No. xxxxxx
沒有中文版使用說明

(c)

Note:
"xxxxxx" stands for the device's Listing

Fig. 1. If the instructions for use are available in both English and Chinese languages, the format in figure (a) shall be applied. The format in figure (b) or (c) shall be applied if the instructions for use are available only in Chinese or only in English.

Whenever figure (a), (b) or (c) is applied, it shall be with a printed rectangular border as shown. All the characters shall be of a uniform font size of not less than 2mm high. In (c) the Chinese characters shall be in kaishu (楷書).

3.13 Change of Particulars

3.13.2 Both during the application process and after an application is approved or conditionally approved, when there is any major change to the information that has been submitted in relation to the application (e.g. change of LRP's address, change of model number, change of device design etc.), the LRP shall notify the MDD as soon as possible and in any case within 10 calendar days of the change. It is the discretion of the MDD to require the LRP to submit a new application for the device based on the information submitted.

3.14 Validity of Listing Approval

3.14.2 An approval or conditional approval for listing a device will be valid for five years. The LRP must submit an application for continuation of the listing to the MDD at least 3 months before the expiry of this five-year validity period. Unless the application for continuation of the listing reaches the MDD within this time frame, the device may be delisted after the five-year validity period.

4. Rules Regarding Delisting and Appeals

4.1 Causes for delisting a device

4.1.1 A device on The List of Medical Devices may be permanently or temporarily delisted or removed from The List of Medical Devices at the discretion of the MDD, where any of the following circumstances arises -

(a) failure of the manufacturer or the LRP to comply with the requirements of the MDACS; or

(b) where the inclusion of the device into The List of Medical Devices has been approved on certain special conditions (Clause 5.10 of the Guidance Notes GN-01), failure of the manufacturer or the LRP to comply with any of those conditions; or

(c) the manufacturer or the LRP fails to address or to adequately address a hazard of the device; or

(d) where the manufacturer or the LRP has made an unjustified claim in an advertisement for the device, the LRP fails to comply fully with an instruction from the Department of Health requiring the LRP to publicize a statement to withdraw the claim. The instruction from the Department of Health may specify the way in which the statement must be publicized (e.g. by placing advertisements in at least four Chinese language newspapers and one English language newspaper in Hong Kong); or

(e) the manufacturer or the LRP has been wound up or has ceased to exist; or

(f) the MDD considers the delisting necessary for public health or safety considerations; or

(g) the delisting is requested by the manufacturer or LRP.

When a device is delisted, all entries on The List of Medical Devices related to the device (including the names and contact details of the manufacturer and the LRP) will be removed from The List of Medical Devices.

4.2 Appeal against a decision to reject or conditionally approve an application

4.2.1 A decision of the MDD to reject an application for inclusion of a device into

The List of Medical Devices may be appealed against by the LRP within 4 weeks of receiving the notification of rejection.

4.2.2 Where an application for inclusion of a device into The List of Medical Devices has only been conditionally approved, an appeal as to the conditions imposed may be submitted by the LRP within 4 weeks of receiving the notification of conditional approval.

4.2.3 To appeal, the LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds for appeal.

4.2.4 Where a decision of the MDD is appealed against under clause 4.2.1 or 4.2.2, the lodging of the appeal does not suspend the decision unless the MDD decides otherwise.

4.2.5 An appeal lodged after the corresponding time limit specified above will not be considered.

4.3 Appeal against a decision to delist a device

4.3.1 A decision of the MDD to permanently or temporarily remove a device from The List of Medical Devices may be appealed against by the LRP within 4 weeks of being notified of the decision.

4.3.2 To appeal, the LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds for appeal.

4.3.3 The lodging of an appeal against a decision of the MDD to delist a device does not suspend the decision unless the MDD decides otherwise.

4.3.4 An appeal lodged after the time limit specified in clause 4.3.1 will not be considered.

5. Enquiries

5.1 Enquiries concerning this document and the MDACS should be directed to:

Medical Device Division
Department of Health
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk/

5.2 All latest versions of published documents and application forms for MDACS are available at MDD website.