COP-01:2019(E)

醫療儀器的規管

Regulation of Medical Devices

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
Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	01 September 2005	First issue of COP-01.	COP-01:2005(E)
1.0	XX May 2019	● Revised Section 1 Introduction. ● Deleted Section 2 Guidance Notes Issued by the MDCO. ● Renumber and Rewritten Section 3 Obligations of Local Responsible Persons to Section 2 Requirements for listed Local Responsible Persons. ● Added Section 3 Undertaking by listed Local Responsible Persons. ● Rewritten Section 4 Rules Regarding Delisting and Appeals to Section 4 Delisting, and Section 5 Appeal. ● Added Section 6 Enquiries and Section 7 References.	COP-01:2019 (E)

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1. Introduction

1.1 The purpose of this document is to stipulate the requirements with which the listed Local Responsible Persons (LRPs) of medical devices has to comply.

1.2 LRPs are listed on the List of Local Responsible Persons by their names, telephone numbers, addresses and LRP Listing Numbers.

1.3 LRPs serve as hubs of communication between the manufacturers and the users, importers, distributors, the public and the Government such that they can provide quality services to ensure the safe and efficacious use of the devices.

2. Requirements for listed Local Responsible Persons

2.1 Documented procedures and quality management

2.1.1 The LRPs are required to implement and maintain documented procedures to cope with pre-market and post-market activities. LRPs are encouraged to implement quality management system covering the full scope of their business related to the MDACS.

2.2 Efficient communication channels

2.2.1 The LRPs are responsible for communicating between the manufacturers and the users, importers, distributors, the 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.

2.3 Application for listing medical devices

2.3.1 The LRPs are entitled to make applications for listing their medical devices under the MDACS. They are responsible for communicating with the MDCO regarding their applications.

2.4 Keeping of transaction records

2.4.1 The LRP shall implement and maintain documented procedures for the keeping of transaction records and maintain an updated list of importers, distributors and transaction records of devices imported. The transaction records shall include the make, model, batch number, serial number, and quantity of devices, as appropriate. Such records shall contain sufficient information to trace the sold and distributed medical device(s) and to permit a prompt and complete withdrawal of the device(s) from the market when needed. The transaction records shall be retained for a period of time not less than the service life of the product as defined by the manufacturer, or at least seven (7) years from the date of distribution, whichever is longer.

2.5 Complaint handling

2.5.1 The LRP shall implement and maintain documented procedures to handle complaints. The LRP shall provide a telephone number, a fax number and/or an email address to the public for collecting comments and complaints. The LRP shall also provide a 24-hour telephone number for communication with the MDCO in case of emergency. The procedure shall include, but not limited to, the following key activities:

(a) Receiving and evaluating information to determine if the feedback, constitutes a complaint;
(b) Investigating complaints;
(c) Reporting to regulatory authorities as appropriate;
(d) Handling of complaint related devices;
(e) Determining and initiating corrective or preventive actions on the basis of risk; and
(f) Defining requirements for complaint records.

2.6 Tracking of specific medical devices

2.6.1 Clauses 2.6.2 applies to the following categories of high-risk medical devices:

(a) Mechanical heart valves;
(b) Implantable pacemakers, their electrodes and leads;
(c) Implantable defibrillators, their electrodes and leads;
(d) Implantable ventricular support systems; or

(e) Implantable drug infusion systems.

2.6.2 The LRP shall implement and maintain documented procedures for tracking of specific medical devices and have in place a tracking system that tracks those devices down to patient level the devices specified in clause 2.6.1 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 devices is also possible) The date the device permanently retired from use or (for an implanted device) the date it was explanted.

2.7 Post market surveillance reports

2.7.1 Upon the approval and renewal of listing, the MDCO may notify LRPs to submit post market surveillance reports of their medical devices at specified time intervals. The LRPs shall submit surveillance reports to the MDCO in accordance with the requirements specified. The report shall include, but not limited to, the reporting period, number of devices sold, number of complaints received, number of field safety corrective actions (e.g. device recalls and product modifications, etc.) initiated and number of adverse incidents reported in Hong Kong and overseas. Analyses of complaints (including adverse incidents) and any actions (including field safety corrective actions) taken shall be included in the reports. Information and statistical data could be based on data acquired from local and overseas.

2.7.2 The MDCO may request LRPs to submit surveillance reports of their medical devices from time to time or change the submission schedule on a need basis.

2.8 Management of safety alerts, field safety notices and field safety corrective actions

2.8.1 The LRP shall implement and maintain documented procedures to manage safety alerts, field safety notices and field safety corrective actions. Upon the issuance of field safety notices and field safety corrective actions by the manufacturer and safety alerts by overseas authorities, the LRP shall inform the MDCO of the related details and actions to be taken in Hong Kong as soon as possible, and not later than ten (10) calendar days after the LRP becomes aware of the issuance. The LRP shall follow up the actions, and shall submit progress reports to the MDCO as requested until the case is concluded. For matters related to safety alerts, field safety notices and field safety corrective actions, the LRP shall contact the MDCO through mdco_alert@dh.gov.hk.

2.9 Managing reportable adverse incidents in Hong Kong

2.9.1 The LRP shall establish documented procedures to manage adverse incidents in Hong Kong. The LRP is required to observe the reporting requirements in the Guidance Notes GN-03 (Guidance Notes for Adverse Incident Reporting by Local Responsible Persons) and handle reportable adverse incidents in Hong Kong.

2.9.2 The submission of an adverse incident 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 incident that has occurred in Hong Kong is reported to the LRP directly or from other sources, the LRP shall conduct an investigation into the incident and report to the MDCO in accordance with the requirements specified under the Guidance Notes GN-03. The investigation may be done in conjunction with the manufacturer or other parties. If the incident has caused any death or serious injuries or is of a serious public health concern, the report shall reach the MDCO as soon as possible but not later than ten (10) calendar days after the LRP becomes aware of the incident. For other reportable or potentially reportable events, the LRP shall, within thirty (30) calendar days of becoming aware of it, report the event to the MDCO. Upon request, the LRP shall also provide assistance to the MDCO to conduct a separate investigation.

2.10 Maintenance and services arrangements

2.10.1 The LRP shall implement and maintain documented procedures to handle maintenance and service arrangements, and offer or arrange other parties to provide preventive and corrective maintenance, including calibration, provision of spare parts and other services to the users when requested.

2.11 Handling, storage and delivery of medical device

2.11.1 The listed LRP shall implement and maintain documented procedures in handling, storage and delivery of medical devices to fulfill the following requirements:

(a) Protection from environmental conditions that may affect the safety or performance of medical devices;

(b) Identification and appropriate storage, handling and delivery of medical devices that require special storage or transport conditions, for instance the low temperature requirement for IVD medical device;

(c) Stock rotation (first-expiry first-out) for medical devices that have a limited shelf-life or expiry date;

(d) Proper handling of medical devices to prevent damage, deterioration or contamination;

(e) Identification, segregation and control of nonconforming, returned or recalled medical devices to prevent them from being inadvertently sold/issued;

(f) Adequate and sufficient incoming and outgoing inspection to ascertain the safety, performance and quality of the medical devices received and to be issued; and

(g) Delivery procedures, including verification of orders and physical inspection of label description, type and quantity of medical devices to avoid incorrect medical devices from being delivered/received.

2.11.2 The LRP shall also make reference to the “Requirements on storage of pharmaceutical products” from the website of Drug Office, Department of Health (website: http://www.drugoffice.gov.hk/) where applicable for storage of medical devices containing pharmaceutical products and for those having specific storage requirements, such as temperature and humidity. In general, there must be adequate storage facilities with appropriate measures in

monitoring the storage conditions (e.g. temperature and humidity).

2.12 Regular checking and review of operation

2.12.1 All operation procedures and records related to the handling and control of medical devices shall be reviewed regularly and documented. In the event of irregularities and/or deficiencies found in the operation procedures and record keeping, the causes of irregularities and/or deficiencies shall be investigated and corrective and preventive measures shall be taken and documented.

2.13 Reporting changes

2.13.1 When there is any major change to the information that has been submitted in relation to the listed LRP (e.g. change of LRP's address, change of documented procedures related to the MDACS, etc.) or the listed devices (e.g. change of model number, change of device design, etc.), the LRP shall notify the MDCO as soon as possible and in no case later than ten (10) calendar days. It is the discretion of the MDCO to require the LRP to submit a new application for the device based on the information submitted.

2.14 Making local facilities and records available for inspection

2.14.1 The MDCO has the discretion to inspect the local facilities of the LRP, original records and supporting documents claimed to be in the possession of the LRP or copied to the MDCO by the LRP when considered necessary. The LRP shall accommodate the request of on-site inspection raised by the MDCO and produce the required originals or certified copies for inspection within two (2) weeks after receiving the notice from the MDCO. The MDCO may conduct announced or unannounced on-site inspection to the LRP.

2.15 Responsibilities in respect of advertisements

2.15.1 The LRP shall not publish or cause to be published any advertisements or other commercial promotional materials that contravene applicable ordinances such as the Undesirable Medical Advertisement Ordinance (Cap. 231).

2.15.2 The MDCO disapproves of references of all kind, in advertisements or other

commercial promotional materials of medical devices, to the MDACS, except 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 MDCO;

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

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

2.15.3 The MDCO 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 that may lead to delisting of the LRP.

2.15.4 Where any document, statement, information, claim, advertisement, promotional material (or any other communication by any means) published to the public, customers or potential customers includes any representation that the LRP is a listed Local Responsible Person, or that the LRP is in compliance with the MDACS requirements on listed Local Responsible Person, it shall at the same time include a statement to the effect that:

(a) The listing of a Local Responsible Person carries no implication that its medical devices are listed; and

(b) Clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.

2.15.5 Where the representation that the LRP is a listed Local Responsible Person, or that the LRP is in compliance with the MDACS requirements on listed Local Responsible Person, is in writing, then the statements required by 2.15.4(a) and 2.15.4(b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

2.15.6 All advertised claims of a listed medical device shall align to the indications and instruction for use as listed with the MDCO. Information that has not been listed or which may potentially or indirectly extend the usage of a listed medical device must not be included in advertisements. This is to ensure information provided in the advertisement falls within the scope of the listed use of the medical device.

2.16 Special Listing Information

2.16.1 The Special Listing Information of a medical device comprises (a) and (b) below:

(a) 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.

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

2.16.2 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 (6) months after the device is listed to meet this requirement.

2.16.2.1 Option (I)

(a) The information 2.16.1(a) shall be displayed on the outer packaging of every device or sales unit; and

(b) The LRP information 2.16.1(b) shall be displayed on the outer packaging of every device or sales unit, or on a document delivered together with the device.

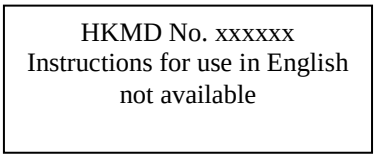
2.16.2.2 Option (II)

(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 2.16.2.2(a). This option shall not be adopted if it cannot be effectively implemented.

HKMD No. xxxxxx

(a)



(b)

(c)

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

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).

2.17 Taking over of medical device listing

2.17.1 The LRP who takes over the medical device listing shall assume all the responsibilities and requirements for the existing LRP of the listed medical devices including field safety corrective actions (e.g. product recalls and device modifications, etc.), adverse incidents reporting, etc. for products already and/or to be placed on market and to comply with all the applicable requirements of the MDACS.

2.17.2 The existing LRP shall continue with all the requirements, stipulated in Section 2, for the related products until the approval for the taking over is granted. The LRP who takes over the medical device listing shall then assume all the requirements for the LRP and becomes the new LRP of the related products.

3. Undertaking by listed LRPs

3.1 A listed LRP shall, on the terms set out in the "Undertaking by Applicant" in the Application Form, undertake inter alia to indemnify the Government of the Hong Kong Special Administrative Region against any loss or claim that flows from any of the

following:

(a) any act or default of the listed LRP;

(b) any defective design of the medical devices of the listed LRP;

(c) any defect in such medical devices; and

(d) any information supplied by the listed LRP to the Government.

4. Delisting

4.1 A device on the List of Medical Devices or a LRP on the List of Local Responsible Persons may be permanently or temporarily delisted or removed from the lists at the discretion of the MDCO, where any of the following circumstances arises :

(a) the manufacturer or the LRP has been wound up, dissolved or has ceased to exist;

(b) where the inclusion into the List of Local Responsible Persons or inclusion of devices into the List of Medical Devices has been approved on certain special conditions, failure of the LRP to comply with any of those conditions;

(c) the delisting is requested by the listed LRP.

(d) the listed LRP fails to comply with any of the MDACS requirements including but not limited to the LRP requirements as stipulated in Section 2;

(e) the manufacturer or the LRP fails to address or to adequately address a hazard of the device or to a public health or public safety concern;

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

(g) 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.

4.2 If an LRP is permanently removed from the List of Local Responsible Persons, all the listed medical devices represented by the LRP, if any, are automatically de-listed. However, the LRP shall continue the post-market surveillance, field safety corrective actions and vigilance activities for the devices already marketed. In the case that the de-listing is temporary, the MDCO has the discretion to suspend the medical devices

listed by the LRP and the LRP cannot submit any new applications for device listing until the de-listing is over. All post-market surveillance, field safety corrective actions and vigilance activities for the devices already marketed shall be continued by the LRP.

5. Appeal

5.1 Appeal against a decision to reject or conditionally approve an application for listing a device or an application for listing an LRP

5.1.1 Any appeal against a decision to reject an application for inclusion of a device into the List of Medical Devices, or an application for inclusion into the List of LRPs may be appealed against by the LRP within fourteen (14) calendar days of receiving the notification of rejection.

5.1.2 Where an application for inclusion of a device into the List of Medical Devices, or inclusion into the List of LRPs have only been conditionally approved, an appeal as to the conditions imposed may be submitted by the LRP within fourteen (14) calendar days of receiving the notification of conditional approval.

5.1.3 To lodge the appeal, the LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds for appeal.

5.1.4 Where a decision of the MDCO is appealed against under section 5.1.1 or 5.1.2, the lodging of the appeal does not suspend the decision unless the MDCO decides otherwise.

5.1.5 An appeal lodged after the corresponding time limit specified in section 5.1.1 and 5.1.2 will not be considered.

5.2 Appeal against a decision to delist a device or delist an LRP

5.2.1 A decision of the MDCO to delist a device or an LRP permanently or temporarily may be appealed against by the LRP within fourteen (14) calendar days of being notified of the decision.

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

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

5.2.4 An appeal lodged after the time limit specified in section 5.2.1 will not be considered.

6. Enquiries

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

Medical Device Control Office,
Department of Health.
Telephone number: 3107 8484
Facsimile number: 3157 1286
E-mail address: mdco@dh.gov.hk
Website: www.mdco.gov.hk

7. References

7.1 Department of Health. Adverse Incident Reporting by Local Responsible Persons. Guidance Notes GN-03.

7.2 Department of Health. Guidance Notes for Listing of Local Responsible Persons. Guidance Notes GN-10