COP-05:2024(E)

Medical Device Administrative Control System (MDACS)

Code of Practice for Listed Distributors of Medical Devices

Code of Practice: COP-05

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

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	01 March 2024	• First issue of COP-05 in March 2024	COP-05:2024(E)
1	2 April 2024	• “Make” is replaced with “Manufacturer”	COP-05:2024-1(E)

Table of Contents

1. Introduction

1.1 The purpose of this document is to stipulate the requirements which the Listed Distributor of medical devices has to comply with.

1.2 Distributors are listed on the List of Distributors by their names, telephone numbers, addresses and Listing Numbers.

1.3 The Listed Distributor needs to demonstrate its ability to provide medical devices under the Medical Device Administrative Control System (MDACS) requirements.

1.4 This document should be read in conjunction with Guidance Note GN-09 (Guidance Notes for Listing of Distributors of Medical Devices).

2. Requirements for Listed Distributors of medical devices

2.1 Premises and equipment

2.1.1 The Listed Distributor shall have properly manned premises in Hong Kong where distribution of medical device(s) is carried out. Where appropriate, premises should include, but not limited to, office, receiving area, storeroom, medical device maintenance area and dispatching area.

2.1.2 Actions shall be taken to prevent unauthorised persons from entering the premises.

2.1.3 Storeroom should be of sufficient capacity to allow the orderly storage of various categories of medical devices.

2.1.4 Storeroom should be clean and free from accumulated waste and vermin. Cleaning records should be kept. There should be pest control measures. Records of any pest control measures taken should be kept. There should be appropriate programme for the clean-up of any spillage to ensure complete removal of any risk of contamination.

2.1.5 Storage conditions for medical devices shall be in compliance with the instructions on the label.

2.1.6 Recorded temperature and appropriate humidity monitoring data should be available for review and inspection. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.

2.1.7 Equipment used for monitoring of storage conditions or measuring equipment used for determining product quality should be calibrated and maintained at defined intervals. Relevant records should be kept.

2.2 Implementation and maintenance of procedures

2.2.1 The Listed Distributor shall have documented procedures for distribution and post-market activities. The Listed Distributor shall implement and maintain the procedures in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP. Records shall be established and maintained by the Listed Distributor to provide evidence of conformity to the requirements and the effective implementation of the procedures.

2.2.2 The Listed Distributor shall document the procedures to define the controls needed for the identification, storage, security and integrity, retention time and disposition of records. The Listed Distributor shall also retain the records for a period of time not less than the projected service life of the medical device as defined by the manufacturer, or seven (7) years after the date of product distribution, whichever is longer.

2.2.3 The documented procedures shall be reviewed regularly. In the event of irregularities and deficiencies found in the documented procedures, the causes of irregularities and deficiencies shall be investigated, and corrective and preventive actions (CAPA) shall be taken. The results of such revision shall be recorded and retained for a period of time which is in accordance with Clause 2.2.2.

2.2.4 Keeping of supply records

2.2.4.1 The Listed Distributor shall have the documented procedure for keeping of supply records and an updated list of all the medical devices distributed. The supply records should include the manufacturer, model, batch number, serial number,

quantity of medical devices, as appropriate. Such records shall contain sufficient information to trace the distributed medical device(s) and to permit prompt and complete withdrawal of the device(s) from the market when needed.

2.2.5 Handling, storage and delivery of medical devices

2.2.5.1 The Listed Distributor shall have the documented procedure 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 IVD medical device that requiring cold chain management;

(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;

(g) Periodic stock reconciliation to compare the actual and recorded stocks. All significant stock discrepancies should be investigated to check that there have been no advertent mix-ups, incorrect issue and misappropriation of medical devices; and

(h) 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.

2.2.6 Management of product recalls and field safety notices

2.2.6.1 The Listed Distributor shall have the documented procedure in managing product recalls and field safety notices (that including field safety corrective actions, product modifications, etc.). The procedure should describe how the Listed Distributor manages or assists in managing product safety alerts issued by MDD or other overseas authorities, and safety notices or advisory notices issued by manufacturers, importers or LRPs.

2.2.7 Managing reportable adverse events in Hong Kong

2.2.7.1 The Listed Distributor shall have the documented procedure in managing reportable or potentially reportable adverse events as defined in Guidance Notes GN-00 (Definitions and Abbreviations for Medical Device Administrative Control System) involving any of the medical devices which have come to the attention of the Listed Distributor. The Listed Distributor shall seek the consent of the reporting party and refer the reportable adverse event to the LRP, or the manufacturer and MDD if there is no LRP. If the reporting party does not agree, the Listed Distributor shall ask the reporting party to report the adverse event direct to the LRP, or the manufacturer and MDD if there is no LRP.

2.2.7.2 The Guidance Notes GN-03 (Guidance Notes for Adverse Event Reporting by Local Responsible Persons) provides details about reporting adverse events. Where applicable, the Listed Distributor shall work closely with the LRP, or the manufacturer and MDD if there is no LRP, and render all necessary assistance to the LRP or the manufacturer in reporting any reportable adverse event related to a medical device particularly if the device is found on the supply records.

2.2.8 Complaints handling

2.2.8.1 The Listed Distributor shall have the documented procedure in handling complaints related to the medical devices. 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 and preventive actions on the basis of risk; and

(f) Defining requirements for complaint records.

2.2.9 Tracking of specific medical devices

2.2.9.1 The Listed Distributor shall have the documented procedure to track the high-risk devices specified in ”List of Medical Devices Requiring Tracking” in Guidance Notes GN-01 down to patient or user-facility level and pass all necessary information to the LRP.

2.2.10 Maintenance and services arrangements

2.2.10.1 The Listed Distributor shall have the documented procedure in providing preventive and corrective maintenance services to the medical devices, including calibration, provision of spare parts and other maintenance services.

2.3 Requirements for inspections

2.3.1 Upon request by MDD, the Listed Distributor shall:

(a) Make available to MDD for inspections of the supply records, documented procedures and other requested documents maintained by them within the specified timeframe; and

(b) Allow MDD to perform inspections of the Listed Distributor’s premises where business operations are carried out as well as any related storage and transportation facilities. The Listed Distributor shall make provision for such inspections and provide all the necessary assistance to MDD to facilitate the conduction of the inspections.

2.4 Requirements in respect of advertisement, promotional materials, etc.

2.4.1 The Listed Distributor 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).

2.4.2 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 distributor is a Listed Distributor, or that the distributor is in compliance with the MDACS requirements on Listed Distributors, it shall at the same time include a statement to the effect that:

(a) The listing of a distributor 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.

2.4.3 Where the representation that the distributor is a Listed Distributor, or that the distributor is in compliance with the MDACS requirements on Listed Distributors, is in writing, then the statements required by 2.4.2(a) and 2.4.2(b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

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

2.5 Notification of changes

2.5.1 The Listed Distributor shall submit Renewal and Change Application Form for Listed Importers/Distributors (Form MD203) to notify MDD no later than four (4) weeks after changes made to the submitted information of contact details and

distributor particulars. MDD has the discretion to request the Listed Distributor to produce documentary evidence of the change within two (2) weeks.

2.6 Notification of renewal of inclusion on the Listed of Distributor

2.6.1 The Listed Distributor should apply for renewal of its current inclusion on the List of Distributors (current listing) not less than three (3) months and not more than six (6) months before its expiry through the submission of Renewal and Change Application Form for Listed Importers/Distributors (Form MD203) and requisite documents as specified by MDD. If the current listing expires prior to a decision of its application for renewal is made by MDD, its current listing will be invalid and the distributor shall not be purported as a Listed Distributor, or that the distributor is in compliance with the MDACS requirements on Listed Distributors until MDD approves its renewal application. This clause supersedes Clause 6.1.1 in GN-09:2021.

2.6.2 If the current listing has expired but the distributor still intends to be a Listed Distributor, the distributor shall submit the application for inclusion on the List of Distributors again.

3. Undertaking by Listed Distributors of medical devices

3.1 A Listed Distributor 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 Distributor;

(b) Any defective design of the medical devices of the Listed Distributor;

(c) Any defect in such medical devices; and

(d) Any information supplied by the Listed Distributor to the Government.

4. Delisting

4.1 A distributor on the List of Distributors may be delisted from the List if any of the

following circumstances arise:

(a) The Listed Distributor fails to comply with the MDACS requirements including, but not limited to, those stipulated in Clause 2; or

(b) The Listed Distributor fails to address or adequately address a situation that gives rise or that might give rise to a hazard of its medical device or to public health or public safety concern; or

(c) The Listed Distributor has been wound up, dissolved or otherwise has ceased to exist;

(d) MDD considers the delisting necessary for public health or safety considerations.

(e) The delisting is requested by the Listed Distributor.

5. Appeal

5.1 The distributor may appeal against a decision of the Distributor Listing Approval Board to reject an application or to remove a Listed Distributor from the List of Distributors within fourteen (14) working days of being notified of the decision.

5.2 To appeal, the distributor shall write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds of appeal.

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

5.4 An appeal lodged after the time limit specified in Clause 5.1 will not be considered.

5.5 The distributor will be notified of the outcome of the appeal application within four (4) weeks following the submission of the appeal application and all the required supporting information (if applicable). The decision of the Medical Device Administration Appeal Committee shall be final.

6. Enquiries

6.1 Enquiries concerning this document and the listing of distributor 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: https://www.mdd.gov.hk

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

7. References

7.1 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

7.2 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

7.3 Department of Health. Adverse Event Reporting by Local Responsible Persons. Guidance Notes GN-03.

7.4 Department of Health. Guidance Notes for Listing of Distributors of Medical Devices. Guidance Notes GN-09.