COP-04:2024(E)

Medical Device Administrative Control System (MDACS)

Code of Practice for

Listed Importers of Medical Devices

Code of Practice: COP-04

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

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3	2 April 2024	• “Make” is replaced with “Manufacturer” • Update document format	COP-04:2024(E)

Table of Contents

1. Introduction 1

2. Requirements for listed importers of medical devices 1

3. Undertaking by listed importers of medical devices 6

4. Delisting 6

5. Appeal 6

6. Enquiries 7

7. References 7

1. Introduction

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

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

1.3 A listed importer needs to demonstrate its ability to provide medical devices under the Medical Device Administrative Control System (MDACS) requirements.

2. Requirements for listed importers of medical devices

2.1. Implementation and maintenance of procedures

2.1.1 For the purpose of fulfilling the requirements of a listed importer, the listed importer must have a properly manned office in Hong Kong where business operations for the import of medical device(s) are carried out. It shall implement and maintain the following procedures in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP. The content of these procedures shall cover the key elements specified in Appendix I of Guidance Notes GN-07 (Guidance Notes for Listing of Importers of Medical Devices). Records (including, but not limited to, those listed in Appendix I) shall be established and maintained to provide evidence of conformity to the requirements and the effective implementation of the procedures. The listed importer shall implement the procedures to define the controls needed for the identification, storage, security and integrity, retention time and disposition of records. The listed importer 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 on which the MD is supplied to another person, whichever is longer.

2.1.1.1 Ensuring the standard of medical devices imported

(a) The listed importer shall maintain the documented procedure in ensuring the medical devices that are imported and supplied are in quality and originated from a qualified manufacturer. The procedure shall include, but not limited to the following key activities:

(i) Ensure the medical device manufacturer maintains a quality management system, which includes but not limited to the handling of adverse incidents and implementing corrective and preventive actions for safety alerts/recalls; and

(ii) Ensure the safety, efficacy/ performance and quality of the medical devices to be imported.

2.1.1.2 Keeping of supply records

(a) The listed importer shall maintain the documented procedure in maintaining the supply records of the medical devices he/she imports and supplies. 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 imported medical device(s) and to permit prompt and complete withdrawal of the device(s) from the market when needed. For specific medical devices requiring tracking indicated in Guidance Notes GN-01 (Overview of the Medical Device Administrative Control System), the additional information stipulated in Clause 2.1.1.7 shall also be kept.

2.1.1.3 Handling, storage and delivery of medical devices

(a) The listed importer shall maintain the documented procedure in handling, storage and delivery of medical devices to fulfill the following requirements:

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

(ii) Identification and appropriate storage, handling and delivery of medical devices that require special storage or transport conditions;

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

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

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

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

(vii) 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.

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

2.1.1.4 Management of safety alerts, field safety notices and recalls

(a) The listed importer shall maintain the documented procedure in managing field safety notices (product recalls, alerts and modifications, etc.) affecting any of the imported medical devices, which may be issued by the manufacturers, LRPs or other regulatory authorities from time to time.

2.1.1.5 Managing reportable adverse events in Hong Kong

(a) The listed importer shall maintain 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 importer. The listed importer is required to seek the consent of the reporting party for referring the reportable adverse event to the LRP (the manufacturer and the MDD if there is no LRP). If the reporting party does not consent, the listed importer should ask the reporting party to report the adverse event directly to the LRP, the manufacturer or the MDD.

(b) 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 importer shall work closely with the LRP (the manufacturer and the MDD if there is no LRP) and render all necessary assistance to the LRP and/or manufacturer in reporting any reportable adverse event related to a medical device particularly if the device is found on the supply records.

2.1.1.6 Complaints handling

(a) The listed importer shall maintain the documented procedure in handling complaints related to any of the imported medical devices. The procedure shall include, but not limited to, the following key activities:

(i) Receiving and evaluating information to determine if the feedback constitutes a complaint;

(ii) Investigating complaints;

(iii) Reporting to regulatory authorities as appropriate;

(iv) Handling of complaint related devices;

(v) Determining and initiating corrective or preventive actions on the basis of risk; and

(vi) Defining requirements for complaint records.

2.1.1.7 Tracking of specific medical devices

(a) The listed importer shall maintain 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.

2.1.1.8 Maintenance and services arrangements

(a) The listed importer shall maintain the documented procedure in providing preventive and corrective maintenance services to the medical devices, including calibration, provision of spare parts and other maintenance services.

2.2. Requirements for inspections

2.2.1 Upon request by the MDD, the listed importer shall:

(a) Make available to the MDD for inspections, as soon as possible, the supply records, documented procedures and other requested documents maintained by them; and

(b) Allow the MDD to perform inspections of the listed importer's premises where business operations are carried out as well as any

related storage and/or transportation facilities. The listed importer must make provision for such inspections and provide all the necessary assistance to the MDD to facilitate the conduction of the inspections.

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

2.3.1 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 importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, it shall at the same time include a statement to the effect that:

(a) The listing of an importer 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.

2.3.2 Where the representation that the importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, is in writing, then the statements required by 2.3.1(a) and 2.3.1(b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

2.4 Notification of changes

2.4.1 The listed importer shall notify the MDD as soon as possible but no later than four (4) weeks after changes made to the information submitted such as contact details and importer particulars. The MDD has the discretion to request the listed importer to produce documentary evidence of the change within two (2) weeks.

3. Undertaking by listed importers of medical devices

3.1 A listed importer 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 importer;

(b) Any defective design of the medical devices of the listed importer;

(c) Any defect in such medical devices; and

(d) Any information supplied by the listed importer to the Government.

4. Delisting

4.1 An importer on the List of Importers may be delisted from the List if any of the following circumstances arise:

(a) The listed importer has been wound up, dissolved or otherwise has ceased to exist;

(b) The delisting is requested by the listed importer;

(c) The listed importer fails to comply with the MDACS requirements including, but not limited to, those stipulated in clause 2; or

(d) The listed importer does not 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.

5. Appeal

5.1 The importer may appeal against a decision of the Importer Listing Approval Board to reject an application for listing an importer or to remove a listed importer from the List of Importers within fourteen (14) working days of being notified of the decision.

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

5.3 An appeal lodged after the time limit will not be considered.

6. Enquiries

6.1 Enquiries concerning this document and the listing of importer should be directed to:

Medical Device Division,

Department of Health

Telephone number: 3107 8484

Facsimile number: 3157 1286

E-mail 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 Importers of Medical Devices. Guidance Notes GN-07.