MDS - G1

GUIDANCE FOR MEDICAL DEVICE IMPORTERS AND DISTRIBUTORS

SFDA

PART I
Pre-License Activities of Importers & Distributors

A. Registration Requirements

*Exerts from CHAPTER FOUR of the **MEDICAL DEVICES INTERIM REGULATION***

Article Ten

Manufacturers established within the KSA, authorized representatives, **importers** and **distributors** of medical devices shall:

A. Register their establishments with the SFDA.

Article Twelve

A manufacturer located in the KSA or an authorized representative may, at the same time, act as the **importer** and/or **distributor** of medical devices.

Article Thirteen

A. The registrant shall before it is involved in the supply of any medical device to the market for the first time:

   1. Submit information for registration purposes.

   2. Provide the required medical device listing information to the Medical Devices National Registry (MDNR).

B. Attest to their accuracy.

C. Update the data previously provided to the MDNR for establishment registration purposes annually, or as required by the SFDA, or within 10 calendar days of the occurrence of any significant change to the relevant information.

Article Fourteen

A. The SFDA shall issue a National Registry Number for each establishment.

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Exerts from Implementing Rule MDS-IR 2 ***Establishment Registration***

Article Eight

For the purpose of registration, and irrespective of device classification, each registrant shall fill in the relevant application form and submit the following information to the SFDA:

A. An indication whether the registrant is a local manufacturer, an authorized representative, an **importer** or a **distributor** of medical devices intended to be supplied to the KSA market and a description of its activities related to manufacturing and/or importation and/or distribution.

B. Name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) of the place of business of the registrant together with the name and position held of the person responsible for the registration within that organization.

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E. An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the establishment National Registry Number allocated to the registrant shall be provided.

F. The date when the information is submitted.

Article Nine:

The SFDA is responsible for:

D. Assigning an establishment National Registry Number to each registrant.

Article Ten:

The registrant is required to :

B. Attest to its accuracy [i.e. of the registration information].

C. Update the information provided within 10 calendar days of the occurrence of any change or when requested to do so by the SFDA, in order to maintain the accuracy of the registration information.

COMMENTS

1. Each **importer** and **distributor**[1] requires an Establishment National Registry Number issued by the SFDA before it is permitted to apply for a license and import or distribute medical devices within the KSA. Implementing Rule MDS-IR2 ***Establishment Registration*** provides information on this procedure.

2. The application for registration will be made electronically through the Medical Device National Registry (MDNR) which is found on the SFDA website and, together with Implementing Rule MDS-IR2, prescribes the information that has to be provided before the SFDA assigns a National Registration Number to the **importer** or **distributor** (see exert above).

3. The **importer** and **distributor** shall attest that the information specified in the electronic application is accurate and will be regularly updated.

1 'Importers' are understood to be organisations involved in the activity of importing medical devices into the KSA. 'Distributors' are understood to be organisations involved in the activity of distributing medical devices within the KSA.

4. The same website is used to update previously submitted information. In this case the **importer** or **distributor** has 10 calendar days from the occurrence of the change to provide the SFDA with revised information.

5. Where an **authorized representative** has also a legal entity involved in importation or distribution activities of medical devices within the KSA, it is subject to all the additional requirements and responsibilities of such an **importer** or **distributor**.

6. **Local manufacturers** or **retail pharmacies** are deemed to be **distributors** if they place medical devices on the KSA market.

7. The SFDA/MDS may ask the registrant to confirm the registration information it holds remains true and complete.

B. Applying for a License – General Provisions

*Exert from CHAPTER FIVE of the **MEDICAL DEVICES INTERIM REGULATION***

Article Fifteen:

A. Local manufacturers involved in distribution activities, as well as **importers, distributors,** and authorized representatives involved in importation or distribution activities, shall apply for an establishment license.

B. The applicant shall provide:

1. The establishment national registry number assigned to it by the SFDA after registering with the MDNR.

2. The category of medical devices the applicant intends to supply to the KSA, and the contact details for the manufacturer of the device.

3. An attestation that the establishment has documentary evidence that it complies with the responsibilities specified in Article Sixteen.

4. An indication of any change to the information submitted within 10 calendar days of the change.

COMMENTS

1. Each organization involved in the **importation** and/or the **distribution** of medical devices within the Kingdom of Saudi Arabia (KSA) require an establishment license, issued by the SFDA, before it undertakes such activities.

2. Such an organization is normally an '**importer**' or '**distributor**' but may be a local manufacturer distributing its own or another manufacturer's medical device, or an authorized representative of an overseas manufacturer involved in the importation or distribution of medical devices, or a **retail pharmacy** distributing medical devices.

3. Organizations involved in both importation and distribution will have both activities included on the establishment license.

4. Each organization intending to import and/or distribute medical devices in the KSA shall have obtained an Establishment National Registry Number from the SFDA, before it applies for an establishment license (see 'Section A' above).

5. Each **importer** shall, in cooperation with the authorized representative(s) of one or more manufacturers shall decide which category(ies) or group(s) of medical devices it intend to import into the KSA and establish the contact details of the manufacturer(s) concerned.

6. Each **distributor** shall, in cooperation with either the local manufacturer(s) or with the authorized representative(s) of one or more manufacturers, as relevant, shall decide which category(ies) or group(s) of medical devices it distribute within the KSA and establish the contact details of the manufacturer(s) and authorized representative(s) concerned.

7. The device category is selected from: active implantable devices; anaesthetic and respiratory devices; dental devices; electro mechanical medical devices; hospital hardware; In Vitro Diagnostic medical devices; non-active implantable devices; ophthalmic and optical devices; reusable devices; single use devices; assistive products for persons with disability; diagnostic and therapeutic radiating devices; complementary therapy devices; biologically derived devices; healthcare facility products and adaptations; laboratory equipment.

8. The application for establishment licensing will be made electronically through the Medical Device Establishment Licensing (MDEL) which is found on the SFDA website and must be completed by each **importer** and **distributor**. Guidance on the information to be provided is described in Section C below.

9. Once satisfied that the application meets the relevant requirements, the SFDA shall issue the applicant with an establishment license that is renewable annually.

10. Licensed organizations shall revise the information provided to the SFDA within 10 days of the change occurring when:

    - There is a change to its contact information;
    - There is a change to the category or group of medical device it imports or distributes.
    - It adds another manufacturer to those it already represents.

C. Applying for a License – Information to be Provided to the SFDA

*Exert from CHAPTER FIVE of the **MEDICAL DEVICES INTERIM REGULATION***

Article Sixteen:

The applicant shall:

A. Notify the manufacturer/s of the device/s listed in Article Fifteen (B), or his authorized representative/s, of his intention to place these devices on the market;

B. Ensure that medical devices are stored and/or transported under conditions specified by the manufacturer;

C. Ensure traceability of devices it supplies to the market and be involved in market surveillance of devices that have been put into service;

D. ensure the labeling accompanies each medical device together with a copy of the marketing authorization and undertake to inform the SFDA if they are unable to fulfil these obligations.

*Exerts from Implementing Rule MDS-IR4 **Establishment Licensing***

Article Seven:

Information to be submitted for the licensing of establishments involved in the importation of medical devices

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to import medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

A. The name of the overseas manufacturer of the medical devices that the applicant imports or intends to import, together with the name

of that manufacturer's licensed authorized representative and its establishment National Registry Number.

B. An attestation that the manufacturer has been informed, through its authorized representative, of the applicant's intention to import its medical devices into the KSA.

C. An attestation that the importer has used its best endeavours to establish that the imported device(s) is in compliance with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules.

D. The medical device/s the applicant intends to import from the manufacturer. Instead of identifying the specific medical device, the applicant may indicate the category of medical device to which the device belongs.

Article Twelve:

Information to be submitted for the licensing of establishments involved in medical device distribution.

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

A. The name of the manufacturer of the medical devices that the applicant intends to distribute, together with the Establishment National Registry Number of either the local manufacturer or, for medical devices manufactured outside the KSA, the authorized representative.

B. An attestation that either the local manufacturer or the authorized representative together with the importer, as applicable, has been informed of the applicant's intention to distribute its medical device(s) within the KSA.

C. The medical device category or generic device groups the applicant intends to distribute within the KSA.

COMMENTS

1. To ensure medical devices placed on the KSA market are suitable and properly supported:

   - any organization intending to import medical devices into the KSA; or
   - any organization intending to distribute medical devices within the KSA (including **retail pharmacies**);

shall do so only with the knowledge of the authorized representative(s) or local manufacturer(s) concerned, as relevant.

2. Article Seven A) to D) and Article Twelve A) to C) of Implementing Rule MDS-IR4 Establishment Licensing (see exerts above) specify much of the information to be provided on the electronic licensing application form, for importation and distribution activities respectively.

D. Storage, Handling and Transportation Requirements

Exerts from Implementing Rule MDS-IR4 ***Establishment Licensing***

Article Seven:

Information to be submitted for the licensing of establishments involved in the importation of medical devices

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA Where the applicant intends to import medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

F. A general description of the procedure the applicant will follow to comply with the manufacturer's requirements for the storage, handling, and transport of medical devices it imports, and an attestation that it will implement and maintain this procedure.

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Article Twelve:

Information to be submitted for the licensing of establishments involved in medical device distribution

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

E. A general description of the procedure the applicant will follow to comply with the manufacturer's requirements for the storage, handling, and transport of medical devices it distributes; and an attestation that it will implement and maintain this procedure.

COMMENTS

1. The procedure should:
    - ideally be part of a quality management system and include the records and controls such a system requires;
    - identify a member of staff responsible for ensuring the manufacturer's requirements for the storage, handling and transport of its medical devices are identified and properly implemented; and that all personnel involved in such activities have the appropriate experience and training to undertake the duties assigned to them;
    - where the organization imports or distributes medical devices from one or more manufacturers, identify the range

of different requirements and accommodate them all within the procedure;

- provide evidence that medical devices are stored apart from other goods and under conditions complying with the instructions of the manufacturer, in particular, concerning ambient humidity, temperature and light requirements;
- ensure that storage conditions including those in the receiving bay, will prevent damage, deterioration or other adverse effects of the medical devices pending their distribution; and are properly monitored and, where appropriate, recorded[2];
- specify the action to be taken in the event of deviations from the required storage conditions;
- describe the storage area, and the method used to include a secure area/s within it for the purpose of storing separately:
  - any quarantined medical devices or, where necessary.
  - devices incorporating dangerous and/or hazardous substances.
- incorporate a system to ensure the medical device inventory is properly rotated (i.e. either 'first in…… first out' or 'expiration date' driven) and that any device exceeding its expiry date, or shelf life, is quarantined prior to disposal;
- incorporate a procedure to quarantine devices subject to a recall and/or field safety corrective action or to identify non-defective devices that have been returned from a user or other organization from other inventory until a decision on further action has been reached in cooperation with the manufacturer; and
- ensure that medical devices are properly packed, handled and stored for transportation as well as transported in a suitably vehicle, taking into account the manufacturer's instructions with respect to temperature, humidity, vibrations

2 It is the responsibility of those organisations with a storage area to ensure they comply with other relevant KSA regulations (e.g. building requirements and fire regulations) that apply to such facilities.

and the risk of physical damage. Ensure that these factors are properly monitored and, where appropriate, recorded during transportation.

2. In particular, **importers** should use their best endeavours to ensure:

   - receiving bays in the ports of entry protect the delivered medical devices from weather conditions during unloading; and
   - medical devices subject to special storage measures are identified and properly stored at the point of entry in accordance with the manufacturer's instructions.

E. Traceability Requirements

Exert from Implementing Rule MDS-IR4 ***Establishment Licensing***

Article Seven:

Information to be submitted for the licensing of establishments involved in the importation of medical devices

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

E. A general description of the procedure the applicant will follow to trace individual medical devices through that part of the supply chain with which it is directly involved, and an attestation that it will implement and maintain this procedure.

Article Twelve:

Information to be submitted for the licensing of establishments involved in medical device distribution

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

D. A general description of the procedure the applicant will follow to trace individual medical devices through that part of the supply chain with which it is directly involved, and an attestation that it will implement and maintain this procedure.

COMMENTS

1. The procedure should:

   - ideally be part of a quality management system and include the records and controls such a system requires;
   - apply to every medical device and provide a system to identify the device's manufacturer, device category, device Listing Number, device type or description, manufacturer's device identifier number (e.g. catalogue number) and the device code allocated by the GHTF Founding Member (if any);
   - identify the manufacturer or **importer** who has supplied the organization with the medical device and the date it was received;
   - identify the **distributor** or user to whom the organization supplies the medical device and the date of shipment; and
   - ensure records are accurate and up to date, and that they are retained for 5 years after the life expectancy of the medical device or, where relevant, for 5 years after the expiration date of any IVD medical devices.

PART II
Post-Licence Activities of Both Importers and Distributors

F. Post-Market Surveillance Requirements

Exerts from Implementing Rule MDS-IR4 **Establishment Licensing**

Article Twelve:

Information to be submitted for the licensing of establishments involved in medical device distribution

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

F. A commitment to be involved in the manufacturer's post-market surveillance activities described in Implementing Rule MDS-IR 7.

COMMENTS

1. Post-marketing surveillance comprises two activities, namely medical device adverse event management, of which a medical device vigilance system is an integral part, and market control. Together these help to ensure and maintain a high level of patient health and safety with respect to medical devices.
2. **Distributors** are likely to have a role in assisting the device manufacturer to perform its market control activities and in implementing field safety corrective actions; it may have a role in reporting medical device adverse events to the manufacturer and to the SFDA.
3. While the primary obligations for the medical device vigilance system fall upon manufacturers and users of medical devices, for the purpose of establishment licensing organizations involved in distribution activities must make a written commitment to co-operate with the manufacturer as it executes its own responsibilities.

G. Medical Device Listing – General Provisions

*Exerts from CHAPTER FOUR of the **MEDICAL DEVICES INTERIM REGULATION***

Article Ten

Manufacturers established within the KSA, authorized representatives, **importers** and **distributors** of medical devices shall:

B. List medical devices with the SFDA.

Article Thirteen

A. The registrant shall before it is involved in the supply of any medical device to the market for the first time:

2. Provide the required medical device listing information to the MDNR.

B. Attest to their accuracy.

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D. Update the information data previously provided to the MDNR for medical device listing purposes annually, or as required by the SFDA, or within 10 calendar days of the occurrence of any significant change to the relevant information.

Article Fourteen

B. The SFDA shall issue a listing number for medical devices.

COMMENTS

1. To obtain an establishment license, the **importer** and **distributor** have to indicate the **categories** of medical device they intend to supply to the KSA market (See Section B Above) but do

not have to provide full details of the devices. Before particular medical devices within each category or group are placed on the KSA market for the first time these devices / must have been authorized by the SFDA and when these devices are imported or distributed within the KSA market, the **importers** and the **distributors** must provide **listing information** to the Medical Device National Registry (MDNR) for the devices concerned.

H. Medical Device Listing – Information to be Submitted to the MDNR

Exert from Implementing Rule MDS-IR3 ***Medical Devices Listing***

Article Six: Parties subject to listing requirements

A. Establishments involved in **importation or distribution activities** are subject to listing requirements. Where a **retail pharmacy** distributes medical devices, it shall be subject to listing requirements for this activity alone

Article Seven: Timing of listing

The registrant [i.e. the **importer** or **distributor**] shall submit listing information for marketing authorized medical devices when these devices are supplied to the KSA market.

Article Eight: Information to be submitted for listing purposes

For the purposes of medical device listing, the registrant shall access the electronic application form available in Section C of the MDNR by providing the Medical Device National Listing Number of the medical device it is supplying to the KSA market. It shall complete the electronic form submiting the following information:

A. Indicate the quantity, serial numbers or lot numbers, shipment date, and destination of the medical devices that are being supplied to the KSA market.

B. An indication that the information provided is either a new entry or an update of previously submitted information.

C. The date when the listing information is submitted.

COMMENTS

1. After the SFDA has authorized a medical device to be placed on the KSA market both importers and distributors are required to provide additional listing information to the Medical Device National Registry (MDNR) within 10 days of placing each authorized medical device onto the KSA market Implementing Rule MDS-IR3 Medical Device Listing (see exert above) describes the procedure.
2. Furthermore, additional device listing information is provided through the electronic form located in Section C of the MDNR before an authorized medical device is shipped to a customer or intermediary. It is opened by first entering the MDMA Certificate Number and then selecting from the list of the device types to which the certificate applies, the one for which additional information is being provided as follows:
   - the shipment date;
   - the quantity with serial numbers (or lot numbers) of the shipment, and
   - the destination of the medical devices that are to be supplied.
3. The same website is used to update previously submitted information, e.g. a change in the contact information. In this case the importer or distributor has 10 calendar days from the occurrence of the change to provide the SFDA with revised information.
4. The SFDA may ask the importer or distributor to confirm the listing information it holds remains true and complete.

I. Placing Medical Devices on the KSA Market

*Exert from CHAPTER TWO of the **MEDICAL DEVICES INTERIM REGULATION***

Article Four

Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of this Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization.

COMMENTS

1. From 14th February 2011 medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.

2. After 14th August 2011 only medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.

3. Local manufacturers and authorized representatives of overseas manufacturers are responsible for obtaining marketing authorization. The relevant procedure is described in MDS – G5 **Guidance on Marketing Authorization Procedures.**

PART III
Post-Licence Activities of Importers

J. Customs Authority Procedures

Exert from Implementing Rule MDS-IR4 ***Establishment Licensing***

Article Nine:

Post-license responsibilities of organizations importing medical devices into the KSA.

Licensed organizations involved in the **importation** of medical devices are required to comply with the relevant requirements of the Medical Devices Interim Regulation and its Implementing Rules. These include:

B. To ensure that each medical device presented to the KSA customs authorities is accompanied by all the necessary documentation and, in particular, by the:

1. Documentation required by the KSA customs authority;
2. Name and contact details of the organization responsible for importing the device;
3. Names and contact details of the manufacturer of the medical devices and, when applicable, of his authorized representative;
4. Identification of the medical devices;
5. Marketing authorization issued by the SFDA that permits the medical devices to be placed on the KSA market; and
6. Declaration of Conformity that the devices comply with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules, duly signed by the manufacturer.

COMMENTS

1. The **importer** should be familiar with the SFDA clearance requirements (refer to SFDA website) including the need to provide a copy of its Establishment License with each shipment, and the KSA customs requirements as they apply to medical devices and, in particular, the documents that must be presented to the Customs Authorities when the device(s) arrive at the port of entry.
2. The **importer** should establish a procedure to obtain the necessary documentation from the device manufacturer or its authorized representative. The procedure should ideally be part of a quality management system and include the records and controls such a system requires. Necessary documents for a consignment of product from a single manufacturer will include:
   - The name and contact details of the manufacturer and of its authorized representative;
   - A copy of the marketing authorization, issued by the SFDA, for each different type of medical device within the consignment;

     and
   - A declaration, signed by the manufacturer, that every medical device within the consignment is in conformity with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules.
3. The SFDA has the authority to reject any shipment of medical devices within 15 days of indicating to the importer that the accompanying documentation is incomplete or inadequate.
4. The **importer** should ensure that receiving bays in the ports of entry protect the delivered medical devices from weather conditions during unloading and that medical devices subject to special storage measures, specified by the manufacturer , are identified and properly stored at the port of entry.
5. Deliveries should be identified and examined on receipt in order to check that:

- the transportation container and outer packaging are not damaged,
- any temperature indicator incorporated into a shipment to monitor that temperature excursions experienced during transportation has not exceeded the limits specified by the manufacturer; and
- that the consignment corresponds to the order.

K. Other Post-License Responsibilities

Exert from Implementing Rule MDS-IR4 ***Establishment Licensing***

Article Nine:

Post-license responsibilities of organizations importing medical devices into the KSA

Licensed organizations **involved in the importation** of medical devices are required to comply with the relevant requirements of the Medical Devices Interim Regulation and its Implementing Rules. These include:

C. To import only those medical devices that comply with the requirements of the Medical Devices Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization.

D. Where the importing organization subsequently receives information that leads it to believe that a medical device with which it has been involved was not in conformity with the relevant requirements of the Medical Devices Interim Regulation and/or its Implementing Rules, it shall take the appropriate measures as specified in the Implementing Rule MDS-IR 7 on post-marketing surveillance.

COMMENTS

1. Each organization responsible for **importing** medical devices into the KSA has provided the SFDA with a written procedure to ensure medical devices are stored, handled, and transported as the manufacturer specifies (See Part I Section D). These procedures

must be implemented, followed, and maintained.

2. Each organization responsible for **importing** medical devices into the KSA has provided the SFDA with a written procedure to describe how it will trace an individual medical device as it progresses from through the port of entry to the distributor (See Part I Section E). This procedure must be implemented, followed, and maintained. See MDS – G6 Guidance for Post-Marketing Surveillance, available on the SFDA website for more information on this subject.

3. The SFDA will monitor organizations involved in the **importation** of medical devices to ensure they fulfil their post-license responsibilities. It will inspect records to confirm procedures are being followed properly and may undertake an audit visit.

4. Importers shall use their best endeavours to establish that medical devices to be imported into the KSA are in conformity with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules, therefore they should:

   - only act for manufacturers supplying medical devices that have been authorized by the SFDA to be placed on the KSA market;
   - scrutinise the documents provided to them to confirm they are complete and authentic; and
   - verify through observation that a consignment of medical devices is properly marked and appears to incorporate any necessary accompanying documents, as declared by the manufacturer.

5. Where an importer has proof, or a reasonable suspicion that one or more medical devices delivered is not in conformity with the Interim Regulation, it should prevent distribution of these devices until a decision has been reached with the manufacturer regarding their disposal or the means to bring it into conformity.

6. Importers should supply imported devices, together with all relevant documentation, only to distributors licensed by the SFDA.

PART IV
Post-Licence Activities of Distributors Only

L. Post-License Procedures and Activities

Exert from Implementing Rule MDS-IR4 ***Establishment Licensing***

Article Fourteen: Post-license responsibilities of distributors

Licensed organizations **involved in the distribution** of medical devices within the KSA are required to comply with the relevant requirements of the Medical Devices Interim Regulation. These include:

C. For the medical devices it distributes, to ensure each medical device is accompanied by its labeling and other relevant documentation.

D. To use its best endeavours to ensure it distributes only those medical devices that comply with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules, as signified by the SFDA issuing the manufacturer with a written marketing authorisation.

E. Where the distribution organization subsequently receives information that leads it to believe that a medical device with which it has been involved was not in conformity with the requirements of the Medical Devices Interim Regulation and/or an Implementing Rule he shall take the measures as specified in the Implementing Rule MDS-IR 7 on post-marketing Surveillance.

COMMENTS

1. Each **distributor** has provided the SFDA with a written procedure to describe how it will comply with the manufacturer's requirements for the storage, handling, and transport of medical devices it distributes (see Part I Section D). This procedure must be implemented, followed, and maintained.

2. Each **distributor** has provided the SFDA with a written procedure to describe how it will trace an individual medical device as it progresses through that part of the supply chain for which it is responsible (see Part I Section E). This procedure must be implemented, followed, and maintained.

3. Each **distributor** has made a commitment to assist manufacturers when they undertake post-market surveillance activities. To do so, it should establish, in cooperation with the manufacturer, procedures to ensure it has a properly managed involvement in any investigation of a reportable adverse event and in any subsequent corrective action plan. Detailed guidance is in Implementing Rule MDS-IR7 Post-Marketing Surveillance and associated guidelines. For the purpose of this guideline, particular attention should be paid to the following:

   - any field safety corrective action or withdrawal of a medical device from the market should be undertaken only with the agreement of the manufacturer. Comprehensive records of the process should be made available to the manufacturer and to the SFDA as required;
   - communication with customers should occur in a timely manner as agreed with the manufacturer; and
   - any returned medical devices or those subject to corrective action should be held in quarantine until they are disposed of or modified as required by the manufacturer or SFDA.

4. The SFDA will monitor organizations involved in the distribution of medical devices within the KSA to ensure they fulfil their post-license responsibilities. It will inspect records to confirm procedures are being followed properly and may undertake an audit visit.

5. Labeling falls into two broad categories, namely labels physically attached to a medical device and written material that is unattached. One responsibility of **distributors** is to ensure the written material, such as instructions for use, accompanies the device as it progresses through the supply chain and eventually reaches the user.

6. For each medical device it distributes, the **distributor** must hold a signed copy of the manufacturer's Declarations of Conformity.

7. For each medical device it distributes, the **distributor** must hold a copy of any advertising and marketing material submitted to the SFDA by the local manufacturer or authorized representative, as relevant, when marketing authorization for the device was applied for. In addition, the **distributor** must hold a copy of any advertising and marketing material, approved by the SFDA after the medical device has been authorized to be placed on the KSA market, whether prepared by a local manufacturer, authorized representative of an overseas manufacturer, or by the **distributor** on its own behalf (see Section M below).

8. **Distributors** shall use their best endeavours to establish that medical devices to be distributed within the KSA are in conformity with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules, therefore they should:

   - only act for manufacturers supplying medical devices that have been authorized by the SFDA to be placed on the KSA market;
   - only accept medical devices from importers duly licensed by the SFDA;
   - ensure the medical devices provided by the importer are accompanied by all necessary documents and that the importer's contact details are indicated on the outer packaging of the device or in a document accompanying the device;
   - request from the importer a declaration that it has performed all customs procedures and evaluations of the relevant documents showing compliance with the relevant regulatory provisions for the medical devices supplied;
   - scrutinise the documents provided to them to confirm they are complete and authentic;

- take, in cooperation with the manufacturers, all appropriate measures to prevent counterfeit medical devices entering their premises; and
- verify through observation that a consignment of medical devices is properly marked and appears to incorporate any necessary accompanying documents, as declared by the manufacturer.

9. Where a **distributor** has proof, or a reasonable suspicion that one or more medical devices delivered is not in conformity with the Interim Regulation, it shall prevent distribution of these devices until a decision has been reached with the manufacturer regarding their disposal or the means to bring it into conformity.

10. When supplying medical devices to customers, **distributors** should ensure they are accompanied by all relevant documentation, in particular, the instructions for installation, maintenance, and use, in the language required by the Interim Regulation and specified in Article Nine of Implementing Rule MDS-IR6 ***Marketing Authorization***.

M. Advertising and Marketing Material

Exerts from CHAPTER FOUR of the ***MEDICAL DEVICES INTERIM REGULATION***

Article Thirty Nine: Advertising

A. The advertising of a medical device for which the SFDA has not issued a marketing authorisation is prohibited.

B. All advertisement material must be approved by SFDA.

C. The advertising material shall not mislead the user regarding the performance of the medical device as specified by the manufacturer.

D. The advertising to the general public, including on the internet, shall avoid misleading lay persons.

E. Any advertising to persons qualified to use medical devices shall include the relevant information compatible with their specific needs.

F. Medical sales representatives shall have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.

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Exerts from Implementing Rule MDS-IR 6 ***Marketing Authorization***

Article Eight: Documentary evidence that the medical device complies with the National Provisions of the KSA

The applicant shall provide the SFDA with information and documentary evidence, as follows:

D. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA if any.

Article Nine: Language requirements for the documentation to be provided to, or kept available for inspection by, the SFDA

F. Advertising and marketing information shall be in English and, where justified, in Arabic.

COMMENTS

1. Applications for marketing authorization are made by either a local manufacturer or, where the manufacturer is established outside the KSA, by its authorized representative. As part of this procedure, the applicant is required to submit all the advertising and marketing material that the manufacturer has prepared already for use in the KSA. Marketing material includes, for example, product brochures, information on clinical performance, and publications from technical magazines. Advertising material includes, for example, written material; information available on the internet television or radio; and information available in electronic form. Advertising and marketing material may be prepared for professional persons, lay persons or both.

2. Where advertising or marketing material additional to that submitted and approved through the MDMA procedure (see exert from MDS-IR6 Marketing Authorization above, and the associated guidance document) is required, electronic copies of the proposed documentation must first be submitted to the SFDA for approval. Three situations apply:

    a. The revised material is prepared and submitted by a local manufacturer (see MDS – G2 **Guidance for Local Manufacturers**); or

    b. The revised material is prepared by an overseas manufacturer and submitted to the SFDA by its authorized representative (see MDS – G3 **Guidance for Medical Device Authorized Representatives**); or

c. The revised material is prepared and submitted by a licensed distributor on its own behalf.

3. The revised advertising or marketing material is submitted manually to the SFDA with a covering letter that includes the Medical Device National Listing Number of the relevant medical device, the proposed target recipient (e.g. nurse, paediatrician, oncologist, radiographer, biomedical engineer, lay person) and intended placement of any advertisement (e.g. newspaper, professional magazine, television, radio, internet, exhibition material, and the like).The SFDA shall review the submitted advertisements and marketing materials to ensure any performance or safety claims are consistent with the information provided with the original MDMA.

4. The SFDA may ask the applicant to provide additional information and documentation before it reaches a decision.

5. Once satisfied, the SFDA will approve the submitted material in writing and it is only then the **distributor** may use it.