

# MDS - G4

## GUIDANCE FOR OVERSEAS MANUFACTURERS

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## PART I

### Preparing for medical device marketing authorization

#### A. Designation of authorized representatives

*Exerts from chapter four of the **MEDICAL DEVICES Interim Regulation***

##### Article eleven

When the manufacturer is located outside the KSA he shall appoint an authorized representative to act on his behalf.

*Exerts from implementing rule MDS-IR5 **Licensing of Authorized representatives***

##### Article five: general

- A. Establishment licensing is intended to ensure that an authorized representative
- Has been properly appointed to represent a particular manufacturer in the KSA;
  - Possesses a written mandate describing the activities for which it acts on the **manufacturer's** behalf and these are sufficient to ensure the proper application of the relevant provisions of the Medical Devices Interim Regulation; and
  - Has set up appropriate procedures to comply with the mandated activities.
- B. Only an authorized representative holding a valid establishment license, issued by the SFDA, is permitted to legally act on behalf of the **manufacturer** in relation to the relevant provisions of

the Medical Device Interim Regulation and the corresponding implementing rules.

- C. The authorized representative shall have separate licenses for each **manufacturer** it represents within the KSA.
- D. Where a **manufacturer** intends to make available more than one category of medical device to the KSA market, it may designate a different authorized representative for each category.

#### **Article six:**

Activities to be performed by an authorized representative

- A. The mandate established between the **manufacturer** and the authorized representative shall be in writing, specify the mandated activities and be subject to the laws of the KSA.
- B. The mandate shall, at a minimum, allow the authorized representative to:
  - 1. Represent the **manufacturer** in its dealings with the SFDA.
  - 2. List each medical device category or generic device group intended to be supplied to the KSA market.
  - 3. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 **Marketing Authorization**.
  - 4. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in implementing Rule MDS - IR7 **On Post-Marketing Surveillance**.
  - 5. Make the following information available to the SFDA when so required in relation to its market surveillance activities.

- The marketing authorisation issued by the SFDA for the listed medical devices.
  - The documentation which was used to demonstrate compliance with the regulation of the relevant GHTF founding member jurisdictions.
  - The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of implementing Rule MDS – IR 6 on **Marketing Authorisation**.
6. Inform the SFDA of any incidents that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the **manufacturer** has taken or intends to take.
  7. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the **manufacturer** for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the **manufacturer** has taken or intends to take.
  8. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.
- C. The **manufacturer** may, under his sole responsibility, authorize his representative to perform tasks other than those specified in paragraph B of this article.

## COMMENTS

1. Every **manufacturer established outside the KSA** (i.e. an **overseas manufacturer**) is required to appoint an authorized representative resident within the KSA.
2. An authorized representative may represent more than one manufacturer provided it has the necessary mandates and licenses.
3. There is no requirement in the Interim Regulation **for an overseas manufacturer** to be registered with, or licensed by, the SFDA. However, the authorized representative must be both registered and licensed before it may act on the **overseas manufacturer's** behalf. A guideline Entitled *Guidance For Authorized Representatives* is available on the SFDA website and provides an overview of the registration and licensing process. One important requirement is to provide the SFDA with a copy of the written mandate between the overseas manufacturer and authorized representative. The minimum content of the mandate is described in article six of Implementing ruleMDS-IR5 *Licensing of Authorized Representatives* (see exert above).

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## PART II

### Applying for Medical Device Marketing Authorization

#### B. General Provisions and Application Procedure

*Exert from chapters 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 authorisation.

**Article five:**

Accessories of medical devices shall, for the purpose of this Interim Regulation, be treated as if they are medical devices in their own right and shall comply with all relevant provisions of the Interim Regulation.

**Article six:**

To obtain marketing authorisation, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use.

#### COMMENTS

1. From 14<sup>th</sup> 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. Marketing authorization is required for

- all medical devices whatever their risk class;
- contact lenses for cosmetic as well as for medical purposes; and
- laser surgical equipment intended for cosmetic as well as medical purposes.

It is not required for medical devices designed and constructed by health facility staff for internal use within that health facility, alone.

4. While an accessory to a medical device is not of itself a medical device, the Interim Regulation applies equally to it (see Article 5 above), and the **manufacturer** must obtain a marketing authorization to supply it to the KSA.
5. Before an **overseas manufacturer** may apply, through its authorized representative, for KSA marketing authorization for one of the medical devices it manufactures, it must.
  - comply with the regulatory requirements that would permit it to place the device on the market of one of the GHTF Founding Member jurisdictions (namely, Australia, Canada, Japan, the USA, or the EU). The manufacturer may choose which of these jurisdictions it uses as the basis of its authorized representative's subsequent SFDA marketing authorization application (MDMA).
  - comply also with provisions specific to the KSA concerning, for example, labeling, storage/installation and advertising.
6. The **overseas manufacturer** shall provide its authorized representative with the information it requires to complete the electronic application forms found on the Medical Device Marketing Authorization (MDMA) portion of the SFDA's website. For further information on this subject, including language requirements for the documentation to be provided, the **overseas manufacturer** should refer to:
  - Implementing Rule MDS-IR6 *Marketing Authorisation*;
  - the electronic application forms found on the Medical Device Marketing Authorization (MDMA) portion of the SFDA's website; and
  - MDS-G5 *Guidance on Marketing Authorization Procedures*.

## PART III

### Activities After the Device Receives Marketing Authorization

#### C. Post-Marketing Responsibility for 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. When submitting information for a medical device MDMA, the **overseas manufacturer's** authorized representative is required to provide any existing advertising or marketing material that is intended to be used in the KSA after the medical device has been authorized to be placed on the market. In addition, the **overseas manufacturer's** authorized representative is responsible for ensuring any subsequent advertising and marketing materials (either newly prepared material or revised versions of the material submitted through the MDMA) are approved by the SFDA before they are used by the **overseas manufacturer**, its authorized representative or its distributor/s.
2. Once the medical device has been approved by the SFDA for marketing in the KSA, the **overseas manufacturer's** authorized representative shall write to the SFDA asking for the previously provided advertising and marketing material, if any, to be approved. The letter shall include 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 **overseas**

**manufacturer** shall provide its authorized representative with the required information.

3. Any newly prepared or revised advertising or marketing material is submitted manually by the **overseas manufacturer's** authorized representative 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 **overseas manufacturer** shall provide its authorized representative with the required information.
4. The SFDA shall review the submitted advertisements and marketing materials to confirm any performance or safety claims are consistent with the information provided with the original MDMA.
5. The SFDA may ask the applicant to provide additional information and documentation before it reaches a decision.
6. Once satisfied, the SFDA will approve the submitted material in writing and it is only then the **overseas manufacturer**, its authorized representative or its distributor/s may use it.
7. The **overseas manufacturer** shall, through its authorized representative, supply its distributor(s) with a copy of all approved advertising and marketing materials (including any submitted through the MDMA) and indicate the proposed recipient (e.g. nurse, paediatrician, oncologist, radiographer, biomedical engineer, lay person) and placement (e.g. newspaper, professional magazine, television, radio, internet) of any advertisement.

#### **D. Storage, Handling and Transport of Medical Devices**

1. The overseas manufacturer shall ensure the medical devices it manufactures are properly packed, handled, stored and transported as they are transferred from the manufacturing site to the

customer via the supply chain. To do so, the **manufacturer** shall take account of the likely modes of transport, the environmental conditions to be encountered both within and outside the KSA (e.g. temperature, humidity, vibrations), and provide adequate protection from physical damage. It shall also:

- a. provide written instructions on the required transportation, handling and storage conditions, in both the Arabic and English language, to:
  - organizations responsible for transporting its devices;
  - importers;
  - distributors; and
  - users.
- b. ensure the packaging of a consignment of medical devices is clearly identified and that an individual medical device within the consignment is accompanied by all relevant documentation, such as, the instructions for installation, maintenance and use, in the language required by the Interim Regulation.

## E. Post-Marketing Surveillance of Medical Devices

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

### Article Thirty

Where the SFDA has reason to believe a **manufacturer**, an authorized representative or another party in the supply chain of a medical device has made a misleading or fraudulent claim of the medical device, it shall investigate and take action as appropriate to the circumstances.

### Article Thirty One

If during its market surveillance activities, the SFDA comes across a non-

compliance that has implications for public health, it shall alert patients, users or other persons, as appropriate.

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### Article Thirty Three

The SFDA shall review adverse events reported to its NCMDR and take appropriate action to safeguard public health.

### Article Thirty Four

The SFDA shall establish a mechanism to issue Field Safety Notices to medical device users and, where relevant, patients. Before issuing such a Notice, its text shall be discussed with the organizations responsible for **manufacturing** the device and supplying it to the KSA

## COMMENTS

1. CHAPTER EIGHT of the Medical Device Interim Regulation requires the SFDA to take all appropriate measures to ensure that medical devices authorized to be placed on the KSA market are subject to post-marketing surveillance (see exert from the Interim Regulation, above). It 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. Implementing Rule MDS-IR7 *Post-Marketing Surveillance* and the associated guidance published on the SFDA website describe the **manufacturer's** responsibilities in respect of this procedure. These include requirements to:
  - report to the SFDA's National Centre for Medical Devices Reporting (NCMDR), any Field Safety Corrective Action that may affect medical devices supplied to the KSA; and

- investigate any adverse event of which it becomes aware. If the **manufacturer** confirms a malfunction or deterioration in the characteristics and/or performance of the medical device, as well as any inadequacy in the labeling or the instructions for use, has led, or might have led, to the death of a patient, user or third person, or to a serious deterioration in the state of health of a patient, user or third person, it shall submit an adverse event report to the SFDA and agree a corrective action plan.
3. An important aspect of effective post-market surveillance is the need of the SFDA, health authority and/or **overseas manufacturer** to identify an individual medical device so that it may be traced, examined, or recalled after it has been put into service. Therefore, the **manufacturer** is required to label the medical devices it manufactures with an unambiguous identification, such as batch code / lot number, or serial number, preceded by the word LOT or SERIAL NUMBER (or an equivalent symbol) as appropriate. In general, consumable and single-use devices have a batch code while powered medical devices have individual serial numbers.

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