الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MEDICAL DEVICES SECTOR

Implementing Rule Document

MDS – IR4

Version 1.0

IMPLEMENTING RULE ON ESTABLISHMENT LICENSING

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Our mission is to ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

SFDA

Our mission is to ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products.

Medical Devices Sector

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implementing rules are administrative methods used as a part of medical device regulation as a force of law. It should be relied on, to ensure medical devices placed on the market of the KSA will achieve an appropriate level of safety and performance with regard to the manufacture, supply and use of medical devices, to address every aspect of relevant legislation. Please refer to the SFDA – MDS regulation 2009 for legislative requirement.

Further Information

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Table of Contents

Chapter One: General Rules 1

Chapter Two: Licensing of Establishments Importing Medical Devices 4

Chapter Three: Licensing of Establishments involved in the Distribution of Medical Devices within the KSA..... 7

Chapter Four: Refusal or Suspension of an Establishment License 10

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Chapter One: General Rules

Article One

This document is an Implementing Rule adopted by the Saudi Food and Drug Authority (SFDA) on the basis of the Medical Devices Interim Regulation and, in particular, Article 43 thereof, issued by Saudi Food and Drug Authority Board of Directors Decree number 1-8-1429 and Dated 27 December 2008.

Article Two

This Implementing Rule, in accordance with the Medical Devices Interim Regulation, specifies and refines the provisions of its Chapter Five in relation to the licensing of establishments involved in the importation and/or distribution of medical devices to the KSA market.

Article Three: Definitions

For the purpose of this Implementing Rule the following definitions apply:

KSA: means the Kingdom of Saudi Arabia.

SFDA: means the Saudi Food and Drug Authority.

Party: means any natural or legal person.

Medical Device: means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

A) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,

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– Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

B) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Applicant: means any party established within the KSA required to provide information for establishment licensing purposes.

Authorised Representative (AR): means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

Distributor: means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Importer: means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.

Manufacturer: means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.

Placing on the market: means the first making available in return for payment or free of charge of a medical device, with a view to distribution and/or use within the KSA, regardless of whether it is new or fully refurbished.

Local Manufacturer: means manufacturer established within the KSA.

National Registry Number: means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.

Person: means a term that includes legal entities such as a corporation, partnership or an association.

Supply Chain: means different elements of the distribution activities of a medical device occurring between it being available for importation into the KSA and it being put into service.

Establishment : means any place of business within the KSA that is involved in the manufacture and/or placing on the market and/or distribution of medical devices or acting on behalf of the manufacturer .

Labelling: means written printed or graphic matter,

A) Affixed to a medical device or any of its containers or wrappers,

B) Information accompanying a medical device related to its identification and/or technical description,

C) Information accompanying a medical device related to its use,

But excluding shipping documents.

Registration: means the process by which a party submits information to the SFDA regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the KSA market.

Licensing: means the process whereby the SFDA issues an establishment licence to a party which permits it to undertake the activity of either importing or distributing a medical device within the KSA.

Article Four: General Principles

A) Chapter Five of the Medical Devices Interim Regulation requires:

1. Organisations involved in the importation of medical devices into the KSA shall have an establishment license for this activity, issued by the SFDA. Such organisations shall submit the information specified in Article Seven of this Implementing Rule and have post-licensing responsibilities specified in Article Nine.

2. Organisations involved in the distribution of medical devices within the KSA shall have an establishment license for this activity, issued by the SFDA. Such organisations shall submit the information specified in Article Twelve of this Implementing Rule and have post-licensing responsibilities specified in Article Fourteen.

B) This Implementing Rule specifies and/or completes the relevant requirements of the Medical Devices Interim Regulation in order to ensure their uniform application by all the parties involved.

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Chapter Two: Licensing of Establishments Importing Medical Devices

Article Five: General

A) Establishment licensing is intended to ensure that any organisation importing medical devices into the KSA is able to undertake:

1. All necessary customs procedures; and
2. The procedures specified by the manufacturer for storage , transportation, handling and tracing the medical devices it imports.

B) Only organisations holding a valid establishment license, issued by the SFDA, are permitted to import medical devices into the KSA.

Article Six: Parties subject to establishment licensing for importation activities

A) Importers, and any authorised representative or distributor performing importation activities, hereafter referred to as applicants, are required to obtain an establishment licence for this activity from the SFDA. Each of these organisations must be in possession of an establishment National Registry Number, assigned to it by the SFDA, before it applies for an establishment licence.

B) Healthcare facilities and the professionals working within them, importing devices for their own use only, are not required to be licensed.

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 submit information to the SFDA, through its website. 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) Name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) and the establishment National Registry Number of the registered place of business of the applicant organisation, together with the name and/or position held of the person responsible for the licensing application.

B) The name of the manufacturer of the medical devices that the applicant imports or intends to import, together with the establishment National Registry Number of that manufacturer's authorised representative.

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

D) 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.

E) 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 selected from: active implantable devices, anaesthetic and respiratory devices, dental devices, diagnostic, electro mechanical medical devices, hospital hardware, in vitro diagnostic medical devices, non-active implantable devices, ophthalmic and optical devices, reusable instruments, single use devices, technical aids for disabled persons, diagnostic and therapeutic radiation devices, complementary therapy devices, biologically derived devices, IVD laboratory equipment.

F) 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.

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

H) A commitment to inform the SFDA of any change to the information previously submitted, within 10 calendar days of the change occurring.

I) The date when the information is submitted.

Article Eight: Responsibilities of the SFDA

The SFDA shall:

A) Acknowledge to the applicant that the information required for establishment licensing has been received and is sufficient;

B) Verify that the information submitted by the applicant is satisfactory and meets the requirements of the Medical Devices Interim Regulation and of this Implementing Rule;

C) Issue the applicant with an establishment license for its importation activities, valid for 1 year, when it is satisfied that the relevant requirements have been met; and

D) On an annual basis, request each licensed importer to confirm that the information previously provided continues to be accurate.

Article Nine: Post-license responsibilities of organisations importing medical devices into the KSA

Licensed organisations involved in the importation of medical devices are required to comply with the relevant requirements of the Medical Devices Interim Regulation. These include:

A) To act in accordance with the procedures or practices referred to in Article Seven, paragraphs C, D, F, G and H of this Implementing Rule.

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 organisation responsible for importing the device;
3. Names and contact details of the manufacturer of the medical devices and, when applicable , of his authorised representative;
4. Identification of the medical devices;
5. Marketing authorisation 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, duly signed by the manufacturer.

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 authorisation.

D) Where the importing organisation 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, he shall take appropriate measures, inform the SFDA of his concerns and also, where appropriate, the manufacturer of that device.

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Chapter Three: Licensing of Establishments involved in the Distribution of Medical Devices within the KSA

Article Ten: General Principles

A) Establishment licensing is intended to ensure that any organisation distributing medical devices within the KSA is able to undertake the procedures specified by the manufacturer for storage , transportation, handling and tracing the medical devices it distributes.

B) Only organisations holding a valid establishment license, issued by the SFDA, are permitted to distribute medical devices within the KSA.

Article Eleven: Parties subject to establishment licensing for distribution activities

Distributors together with local manufacturers and authorised representatives performing distribution activities, hereafter referred to as applicants, are required to obtain an establishment licence for this activity from the SFDA. Where a retail pharmacy distributes medical devices, it shall be subject to licensing requirements for these activities alone. Each of these organisations must be in possession of an establishment National Registry Number, assigned to it by the SFDA, before it applies for an establishment licence.

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 submit information to the SFDA, through its website. 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) Name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) and establishment National Registry Number of the registered place of business of the applicant organisation, together with the name and/or position held of the person responsible for the licensing application.

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

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

D) The medical device/s the applicant intends to distribute within the KSA . Instead of identifying the specific medical device , the applicant may indicate the category of medical

devices to which the device/s belongs selected from : active implantable devices, anaesthetic and respiratory devices, dental devices, diagnostic, electro mechanical medical devices, hospital hardware, in vitro diagnostic medical devices, non-active implantable devices, ophthalmic and optical devices, reusable instruments, single use devices, technical aids for disabled persons, diagnostic and therapeutic radiation devices, complementary therapy devices, biologically derived devices, IVD laboratory equipment.

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.

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 each medical device it distributes; and an attestation that it will implement and maintain this procedure.

G) A commitment to be involved in the manufacturer's post-market surveillance activities.

H) A commitment to inform the SFDA of any change to the information previously submitted within 10 calendar days of the change occurring.

I) The date when the information is submitted.

Article Thirteen: Responsibilities of the SFDA

The SFDA shall:

A) Acknowledge to the applicant that the information required for establishment licensing has been received and is sufficient;

B) Verify the information submitted by the applicant is satisfactory and meets the requirements of the Medical Devices Interim Regulation and of this Implementing Rule ;

C) Issue the applicant with an establishment license for its distribution activities, valid for 1 year, when it is satisfied that the relevant requirements have been met; and

D) On an annual basis, request each licensed distributor to confirm that the information previously provided continues to be accurate.

Article Fourteen: Post-license responsibilities of distributors

Licensed organisations 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:

A) To act in accordance with the procedures or practices referred to in Article Twelve, paragraphs C, E, F, G and H of this Implementing Rule.

B) To obtain from each manufacturer for whom it distributes medical devices within the KSA, a written agreement to act on the manufacturer's behalf for specified tasks.

C) To ensure its staff and other resources are sufficient in number and skill to discharge the obligations placed upon it by each distribution agreement.

D) For every medical device it distributes, to ensure each medical device is accompanied by its labelling and the marketing authorisation, issued by the SFDA, that permits the medical device to be placed on the KSA market.

E) For every medical device it distributes, to make available upon request:

1. The manufacturer's signed Declaration of Conformity that the medical device complies with the requirements of the Medical Devices Interim Regulation; and
2. A copy of any advertising or marketing information that relates to the KSA market.

F) To use its best endeavours to ensure it distributes 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 authorisation.

G) Where the distribution organisation 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, he shall inform the SFDA of his concerns and also, where appropriate, the manufacturer of that device.

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Chapter Four: Refusal or Suspension of an Establishment License

Article Fifteen: Refusal to license

A) The SFDA shall refuse to issue a license for establishments involved in importation and/or distribution of medical devices, if it has reasonable grounds to believe that issuing such a license would not ensure an appropriate level of quality and/or performance of the devices when they are put into service by the end user.

B) If the SFDA intends to refuse the establishment license, it shall notify the applicant in writing of the reasons of the refusal and information of the procedure to appeal the action taken.

Article Sixteen: Refusal, Suspension or Withdrawal of an issued license

A) The SFDA shall suspend the license of establishments involved in importation and/or distribution of medical devices, if it has reasonable grounds to believe that the licensee has contravened any of the relevant provisions of the Medical Devices Interim Regulation, or of this Implementing Rule, or has made a false or misleading statement in its application.

B) Before suspending an establishment license, the SFDA shall send the licensee a notice that sets out the reason for the intended suspension and, if appropriate, corrective actions to be taken as well as the time during which they shall be implemented.

C) The suspended establishment license shall be reinstated if the situation that gave rise to its suspension has been properly corrected .

D) If the required corrective actions have not been adopted in due time , the establishment license shall be withdrawn .

E) The SFDA shall provide information to the licensee on the procedure to appeal the action taken .

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