الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MEDICAL DEVICES SECTOR

Implementing Rule Document

MDS – IR2

Version 1.0

IMPLEMENTING RULE ON ESTABLISHMENT REGISTRATION

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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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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 Chapters Three and Four in relation to the registration of establishments located within the KSA involved in the manufacture and/or supply of medical devices to the KSA market, with the Medical Device National Registry.

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

and

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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.

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.

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.

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.

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.

Registrant: means any party established within the KSA required to provide information for establishment registration or medical device listing purposes.

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.

Article Four: General Principles

A) Chapter Four of the Medical Devices Interim Regulation require local manufacturers, authorised representatives, importers, and distributors of medical devices, hereafter referred to as registrants, to register their establishments with the SFDA's Medical Device National Registry (MDNR). Such organisations shall submit the information specified in Article 8 of this Implementing Rule.

B) The information in the MDNR enables the SFDA to carry out tasks relating to the implementation of the Medical Devices Interim Regulation and the associated Implementing Rules. Furthermore, while safeguarding commercially sensitive material, the database may be consulted by the authorized parties.

C) 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: Establishment Registration Requirements

Article Five: General

A) Establishment registration is intended to provide information on the parties involved in manufacturing and/or supplying medical devices to the KSA market.

B) Providing establishment registration information to the SFDA does not remove from the registrant its obligation to comply fully with all the other provisions of the Medical Devices Interim Regulation that apply to it.

Article Six: Parties subject to registration

A) Local manufacturers, authorised representatives, importers and distributors of medical devices are subject to registration requirements. Where a retail pharmacy distributes medical devices, it shall be subject to registration requirements for these activities alone.

B) Any person who changes the intended use of, or modifies a finished medical device in a way that affects its safety or performance , without acting on behalf of the original manufacturer, and who makes it available for use under his own name is deemed to be the manufacturer of the modified device and is subject to establishment registration requirements.

Article Seven: Timing of registration

The registrant shall submit information for establishment registration purposes before it is involved in the supply of any medical device to the KSA market for the first time.

Article Eight: Information to be submitted for registration purposes

For the purposes of registration, and irrespective of device classification, each registrant shall submit the following information to the SFDA through its website.

A) An indication whether the registrant is a local manufacturer, an authorised 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 organisation.

C) Where the registrant is an authorised representative, it shall also provide the 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 manufacturer(s) on

whose behalf it is acting, together with the name and position held of the person responsible within the manufacturer's organisation.

D) Where the registrant is a local manufacturer who intends to supply more than one finished medical device to the KSA market and the different types of finished medical devices are manufactured at different sites, it shall provide the name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) of each site, together with the name and position held of the person(s) responsible for the registration within the local manufacturer's organisation.

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: Role of the SFDA

The SFDA is responsible for:

A) Providing a mechanism that allows incorporation of either a new entry or updated information, into the MDNR database within 30 days of the information being received;

B) The maintenance and security of the MDNR database;

C) Acknowledging to the registrant that the required information has been received and is acceptable;

D) Assigning an establishment National Registry Number to each registrant;

E) Retaining an archive of information on organisations previously assigned an establishment National Registry Number but are no longer involved in supplying medical devices to the KSA market; and

F) On an annual basis, requesting each registrant to confirm that the information provided for medical devices listing purposes continues to be accurate.

Article Ten: Role of the Registrant

The registrant is required to:

A) Provide the SFDA with the establishment registration information specified in Article 8;

B) attest to its accuracy;

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; and

D) Respond to the SFDA's request to confirm that the information provided for establishment registration purposes continues to be accurate.

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