الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MEDICAL DEVICES SECTOR

MDS - IR3

IMPLEMENTING RULE ON MEDICAL DEVICES LISTING

Application Date: April 1st 2010

Version 4

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, effectiveness 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

Implementing Rules specify requirements which refine and/or specify the provisions of the Medical Devices Interim Regulation and they have force of law. Their application takes part in ensuring that medical devices placed on the KSA market achieve an appropriate level of safety and performance with regard to their manufacture, supply and use. Please refer to the SFDA Medical Devices Interim Regulation, published in the Umm Al-Qura Journal year 86 Issue No. 4249 dated 17 April 2009, for the general provisions and in SFDA

website: http://www.sfda.gov.sa/En/MedicalEquipments/Topics/interim+E.htm.

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 listing of Medical Devices when they are placed on the KSA market.

Article Three: Definitions

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

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.

Authorized 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.

Marketing Authorization Number: means the code assigned by the SFDA to one or more medical devices, that have been included in a single marketing authorization application, to indicate these devices are authorized to be placed on the KSA market.

Medical Device National Listing Number: means the code assigned by the SFDA to a single medical device, that has been included in a marketing authorization application, to indicate the device is authorized to be placed on the KSA market and facilitate traceability.

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 themanufacturer.

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.

Listing: means the process whereby a party submits information to the SFDA, regarding the identification of a medical device(s) that is supplied to the KSA.

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.

Licensing: 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 or acting on behalf of the manufacturer.

Article Four: General Principles

A. Chapter Four of the Medical Devices Interim Regulation require local manufacturers, authorized representatives, importers, and distributors involved in the supply of medical devices, hereafter referred to as registrants, to list the medical devices they placed on the KSA market, with the SFDA's Medical Device National Registry (MDNR). Such organizations shall submit the information specified in Article Eight of this Implementing Rule.

B. The information in the MDNR enables the SFDA to carry out their 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.

Chapter Two: Medical Device Listing Requirements

Article Five: General

A. Medical device listing is intended to provide information on medical devices placed on the KSA market.

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

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.

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 is deemed to be the manufacturer of the modified device and is subject to medical device listing requirements.

Article Seven: Timing of listing

The registrant shall submit listing information for SFDA 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 submitting 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.

Article Nine: Role of the SFDA

The SFDA is responsible for:

A. Providing a mechanism that allows incorporation of the medical device listing information.

B. The maintenance and security of the database.

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

D. Retaining an archive of information on medical devices that were previously assigned a Listing National Registry Number but are no longer being supplied to the KSA market, updated on at least an annual basis.

Article Ten: Role of the Registrant

The registrant is required to:

A. Provide the SFDA with the medical device listing information specified in Article Eight;

B. Attest to its accuracy;

C. Update the information provided within 10 calendar days of becoming aware of the occurrence of any change, or when

requested to do so by the SFDA, in order to maintain the accuracy of the listing database; and

D. Respond to any SFDA's request to confirm that the information provided for device listing purposes continues to be accurate.

Chapter Three: General Provisions

Article Eleven: Application Date

A. This Implementing Rule and the corresponding application form referred to in Article Eight shall be published and made available on the SFDA Website.

B. The application date of this Implementing Rule and of the provisions of the Medical Devices Interim Regulation to which it relates is April 1tst 2010.

C. Applications for medical device listing may be submitted to the SFDA from the application date referred to in paragraph B of this Article.