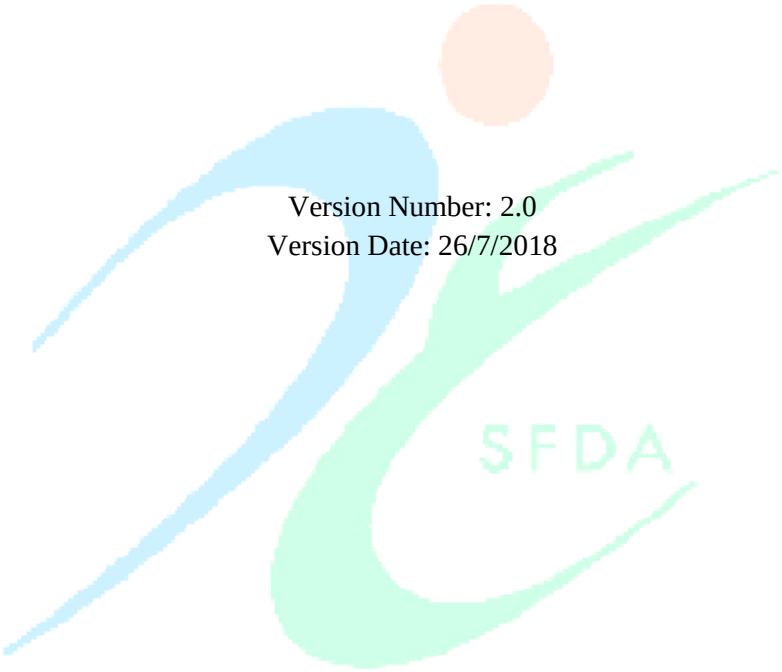
MDS-IR7

Implementing Rule on
Post-Marketing Surveillance



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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 Forty Five thereof, issued by Saudi Food and Drug Authority (SFDA) 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 Eight in relation to the post-market surveillance of medical devices which have been authorized by the SFDA to be placed on the KSA market. It is also intended to ensure the uniform application of the relevant requirements by all the parties involved.

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.

AHWP: Asian Harmonisation Working Party

Party: means any natural or legal person.

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

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.

In-vitro medical devices: means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

Labeling: 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.

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.

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.

Local manufacturer: means a manufacturer established within the KSA.

Authorized Representative: 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.

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.

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.

User: means the person or authority responsible for the use or maintenance of a medical device.

Global Harmonization Task Force (GHTF): countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA.

Note: GHTF was disbanded in 2012 and its mission has been taken over by the IMDRF.

Authorizing GHTF CA: means the Competent Authority of the GHTF Founding Member country or jurisdiction that forms the basis of a manufacturer's application for marketing authorization within the KSA.

Asian Harmonization Working Party (AHWP): means a group of countries, other than GHTF Founding Members, working to achieve harmonization in medical devices regulation among themselves.

NCA: means the National Competent Authority responsible for medical device regulations within that country.

National Competent Authority Report (NCAR): means a report received from GHTF National Competent Authority members concerning a medical device related adverse event and recalls.

Safety Alert Dissemination System (SADS): means a report from AHWP National Competent Authority members concerning a medical device related adverse event and recalls.

National Centre for Medical Device Reporting (NCMDR): means an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.

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.

Putting into service: means the stage at which a device has been made available to the final user as being ready for use for the first time in the KSA for its intended purpose.

Corrective action: means an action to eliminate the cause of potential nonconformity or other undesirable situation.

Field safety corrective action: means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

Field safety notice: means a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.

Harm: physical injury or damage to the health of people or damage to property or the environment.

Adverse event: means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labeling or the instructions for use which may lead to compromise the health or safety of patients, users or third parties.

Reportable adverse event: means any adverse event or any technical or medical reason leading to a Field Safety Corrective Action, which, directly or indirectly, might lead to or may have led (a) to the death of a patient, a user or another person or (b) to a serious deterioration in their state of health.

Serious public health threat*:* means any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

Medical device vigilance system: means all actions comprising an adverse event reporting procedure.

Post-marketing follow up: means measures by which a manufacturer gathers information to identify performance shortcomings or problems associated with the use of its medical device that are apparent only after its widespread, or long term use.

Article Four: General principles

A. Chapter Eight of the Medical Device Interim Regulation requires the SFDA to take all appropriate measures to ensure that medical devices authorized by the SFDA to be placed on the market in the KSA are subject to post-marketing surveillance and comply with the requirements of the Interim Regulation.

B. 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.

C. Medical device vigilance is a process whereby an adverse event involving a medical device that is authorized to be placed on the KSA market and put into service, of which the manufacturer has been informed, is investigated by the manufacturer and reported to the SFDA, where appropriate. The SFDA may monitor this investigation process. Where justified, the manufacturer and/or the SFDA shall take all appropriate measures to reduce or remove the likelihood of the incident occurring again.

D. Market control is a procedure to ensure that in the absence of a medical device adverse event report, any medical device that has been authorized to be placed on the KSA market and is found, before it is put into service, to compromise the health or safety of patients, users or third parties, or does not comply with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules, is either withdrawn from the market, or subject to appropriate corrective action to eradicate the noncompliance.

E. The SFDA is responsible for ensuring both market control and medical device adverse event management are operated effectively.

Chapter Two
Medical Device Vigilance Activities and Post Marketing Follow Up

Article Five: General

A. The SFDA shall ensure the appropriate and efficient operation of the necessary medical device vigilance procedures. It shall, in particular, advise users and persons involved in the provision of healthcare in the KSA to inform without delay the manufacturer concerned of any adverse event and the SFDA of any reportable adverse event they become aware of, involving a specific medical device.

B. All parties concerned shall be made aware of the existence and responsibilities of the SFDA being the medical device vigilance authority. Furthermore, the SFDA shall indicate how it may be contacted to notify medical device reportable adverse events.

C. SFDA shall adopt and publish a guideline(s) to ensure a coherent and uniform application of Articles Six, Seven and Eight.

Article Six: Medical device reportable adverse events occurring within the KSA

A. The SFDA will encourage users and persons involved in the provision of healthcare within the KSA to inform the manufacturer, where appropriate, through its authorized representative and the SFDA, through its National Centre for Medical Device Reporting (NCMDR), of any adverse event that meets the following criteria:
    - Any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labeling or the instructions for use, which 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, use or third person.

B. When the SFDA receives the information it shall ensure that the manufacturer of the device, or his authorized representative, is immediately and fully informed of the adverse event.

C. The manufacturer shall investigate the adverse event, working in collaboration with the health practitioner or user concerned and with the SFDA. If the manufacturer confirms the event falls into the reportable category referred to in paragraph 1 above, it shall submit an adverse event report to the SFDA and agree a corrective action plan. Where justified, the SFDA shall issue a field safety notice to medical device users and/or hospital authorities, informing them of the manufacturer's corrective action plan and of the risks involved in continuing to use the device. The SFDA shall use its best endeavors to agree with the manufacturer the text of the field safety notice.

D. Once a corrective action plan has been agreed with the SFDA, the manufacturer shall submit a report to the authorizing GHTF CA, where applicable. This report is a written statement of the outcome of the relevant investigations performed and of the corrective action plan agreed with the SFDA.

E. If the manufacturer considers the event not to be a reportable adverse event, it shall provide the SFDA with a justification of its conclusion and with details of what use will be made of the information received.

F. As a member of the NCAR and SADS Reporting Programmes, the SFDA shall fulfil its membership responsibilities according to the programme's operating procedures.

Article Seven: Medical device reportable adverse events occurring outside the KSA

A. When an adverse event falling within the category described in Article Six paragraph 1 occurs outside the KSA and has potential consequences for a medical device that is placed on the KSA market, the manufacturer, through its authorized representative, shall immediately inform the SFDA of the circumstances and provide all available details on the medical device concerned and the measures taken in cooperation with the authorizing GHTF CA, where applicable.
B. Where the SFDA considers the adverse event is reportable and could have consequences for a medical device that is placed on the KSA market, it shall ensure the event is recorded at its National Centre for Medical Devices Reporting and properly managed.
C. When the manufacturer, having investigated the adverse event, decides to instigate a field safety corrective action within the KSA, the manufacturer through its authorized representative shall inform the SFDA of this decision. Where justified, the SFDA shall issue a field safety notice to medical device users and/or hospital authorities, informing them of the manufacturer's corrective action plan and of the risks involved in continuing to use the device. The SFDA shall use its best endeavors to agree with the manufacturer the text of the field safety notice.

Article Eight: Medical device reportable adverse events occurring during post-marketing follow-up

When an adverse event, which was identified during the manufacturer's post-marketing follow-up activities, leads to a field safety corrective action for a medical device that is authorized to be placed on the KSA market, the manufacturer shall inform the SFDA of the adverse event, through its authorized representative where appropriate, of the measures it intends to take and provide the SFDA with a copy of any relevant Field Safety Notice issued by the authorizing GHTF CA concerned.

Chapter Three
Market Control

Article Nine: General

A. The SFDA shall be the market controlling authority. It shall implement the appropriate market control policy and associated procedures, intended to monitor medical devices placed on the KSA market and to ensure, in cases of non-compliance, that appropriate actions to enforce conformity are taken. The procedures specify also the responsibilities of the organizations involved in importation and/or distribution activities regarding their market control activities and responsibilities.

B. The SFDA shall review the functioning of its market control activities periodically and take appropriate measures to increase their effectiveness, where necessary.

C. SFDA shall adopt and publish guidelines to ensure a coherent and uniform application of Articles Ten and Eleven.

Article Ten: Market control activities by the SFDA

A. Where the SFDA has reason to suspect a medical device, authorized to be placed on the KSA market, does not, under normal conditions of use, meet the manufacturer's specification for safety and performance, it shall undertake appropriate checks by means of documentary verifications and, where justified, by physical inspection and/or testing of medical devices, placed on the market but not yet to be put into service, to assess the non-compliance and analyse the factor(s) causing it. When noncompliance is proven, an examination is performed, where necessary, on an adequate sample of the medical devices to verify the systematic character of the non-conformity. Where relevant test reports or certificates, attesting conformity, issued by a NCA or, on a voluntary basis, a recognised Conformity Assessment Body, are made available to the SFDA, it shall take due account of such reports or certificates.

B. The SFDA shall first require the manufacturers, through its authorized representative where appropriate, the importers or the distributers to take the appropriate corrective action and ensure proper implementation. Where those actions are not applied or are not sufficient the SFDA shall take safeguard measures, as specified in Implementing Rule MDS- IR 8, to ensure that non-conforming devices are withdrawn from the market or their availability is prohibited or restricted. Furthermore, the SFDA shall take appropriate measures to ensure that potential users of the devices are informed accordingly.

C. Importers and distributors shall cooperate with the SFDA and assist it in performing an efficient market control. Importers shall submit, when required by the SFDA, the documentation it needs concerning the contact details of the local manufacturer or of the authorized representatives of the overseas manufacturers from whom they import devices. Distributers shall inform the SFDA of the address of the establishment that has supplied them with the devices and the address of the establishment or final user to whom they have supplied the devices.

Article Eleven: Market control by importers and distributors

A. Where an organization involved in the importation of medical devices into the KSA or one involved in furthering the availability of medical devices to end users has reason to believe that a medical device, it intends to place on the KSA market, does not comply with the relevant provisions of the Medical

Device Interim Regulation and its Implementing Rules, it shall take all appropriate actions within its competence to safeguard the health and/or safety of patients or to end the infringement. Furthermore, it shall inform immediately the SFDA and, when appropriate, the manufacturer concerned, where appropriate through its authorized representative, of its concerns and of the actions taken.

B. The SFDA shall review any reports submitted to it by importers or distributors, on issues relating to established health or safety non-conformities of medical devices and the corresponding actions taken. The SFDA shall, in close cooperation with the reporting person, decide on any further safeguard measure, as specified in MDS - IR 8, that it may consider necessary to supplement the actions mentioned above to end the infringement or to withdraw devices from the market to prevent the risks caused or expected to be caused by the medical devices concerned. They shall, where appropriate, inform all parties concerned within the KSA of the non-conformities they have identified and the measures taken.

Chapter Four
Confidentiality of Information

Article Twelve

A. Chapter Ten of the Medical Devices Interim Regulation places obligations upon the SFDA and other parties to observe confidentiality with regard to the information received while carrying out their duties, with the exception of the information described in paragraph (B) of this Article. The SFDA shall ensure that all parties involved in the application of the market control and device vigilance activities are aware of these responsibilities.

B. The following information shall not be treated as confidential:
   1. Information on the registration of persons responsible for supplying medical devices on the KSA market.
   2. Information to users sent out by the manufacturer or his authorized representative in relation to any field safety corrective action for the devices.
   3. Information contained in certificates issued, modified, supplemented suspended or withdrawn.
   4. Information to be given to overseas market surveillance authorities in order to ensure the effectiveness of market surveillance activities.

Article Thirteen

A. The SFDA will develop and organise training, exchange of experience and of best practice in carrying out the appropriate investigation of systematic device non-compliance or of incidents.

B. Without prejudice to the provisions of the Interim Regulation, cooperation with other NCAs may be part of initiatives developed at an international level, promoting exchange of information on medical devices at a global level.

C. Adverse event reports shall be made available on request and in confidence to the other NCAs subject to bilateral agreement.

Chapter Five
General Provisions

Article Fourteen: Application date

A. This Implementing Rule shall be published and made available on the SFDA website.

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

Annex (1): List of Changes on the Previous Version

Article No.	Change Type	From	To
Article One	Edit	43	Forty Five
Article Two	Edit	The present Implementing Rule, in accordance	This Implementing Rule, in accordance
Article Three/ Definition of Global Harmonization Task Force (GHTF):	Edit	Global Harmonization Task Force (GHTF): means the countries working to achieve harmonization in medical device regulation among themselves.	Global Harmonization Task Force (GHTF): countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA. Note: GHTF was disbanded in 2012 and its mission has been taken over by the IMDRF.
Article Three	Delete	GHTF Founding Members: means Australia, Canada, Japan the USA and the EU/EFTA.	-
Article Six/D	Edit	the manufacturer shall submit a report to the authorizing GHTF CA.	the manufacturer shall submit a report to the authorizing GHTF CA, where applicable.
Article Seven/A	Edit	in cooperation with the authorizing GHTF CA.	in cooperation with the authorizing GHTF CA, where applicable.
Article Eight	Edit	during the manufacturer's post-marketing follow-up activities performed in the framework of its GHTF authorization,	during the manufacturer's post-marketing follow-up activities,