Notice to Service Recipient

Guidance for Implementing the Updated Safety Requirements for Medical Devices in Registration, Re-registration, Variation process and Post-marketing process

Year 2022

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Introduction

This guidance concerns with the implementation of updated safety requirements for local and imported medical devices that will be registered in the Egyptian Drug Authority during registration, re-registration, variation and Post-marketing procedures.

Version No. 1.1

This guidance does not apply to medical equipment and in vitro diagnostic devices. They shall continue to apply their guidance regarding these issues.

Definitions

Legal Manufacturer:

It is the manufacture responsible for designing, manufacturing and packaging the medical device before launching it in the market in its name, regardless these procedures were carried out by the manufacture itself, its representative or by a third party where the legal manufacturer shall remain the responsible party for the medical device quality.

Marketing authorization Holder (MAH):

It is the applicant company to register the medical device in Egypt and it is legally responsible for that device in Egypt.

Summary of Marketing History (SMH):

It is a document prepared by the legal manufacturer and submitted by the marketing authorization holder. Such document contains information about the product safety such as - but not limited to - the number of adverse reaction reactions / incidents resulting from the medical device use, sales, number of countries where the Medical Device is registered and marketed globally and if there is regulatory action taken for the medical device in previous period before time of application for (registration/re-registration/variation) or in process of post-marketing follow up.

List of Abbreviations

Name	Abbreviation
Summary of Marketing History	SMH
Active Implantable Medical Device	AIMD
Field safety Notice	FSN
Field safety Corrective Action	FSCA
Medical Device Vigilance	MDV
Medical Devices safety Unit	MDSU
Manufacturer Incident Reports	MIRS
Periodic Summary Reports	PSRs

First: The guidance of implementing the updated safety requirements of medical devices within the framework of registration, re-registration and variation

- **For registration/re-registration procedures of medical devices that were previously registered before activating this guidance:**

- For class (I) and class (IIa) devices that have no recalls/ regulatory actions issued for them during the previous three-year period from the date of applying for registration/ re-registration:

Hard copy of declaration 1 (attachment No. 2) signed, stamped and dated from the legal manufacturer shall be submitted stating that there was no recalls/ regulatory actions have been taken during the previous three-year period from the date of applying for registration in Egypt. This declaration shall be sent by the legal manufacturer to the Central Administration of Medical Devices via registered mail and not via the marketing authorization holder in Egypt.

- **For the following Classes:**
  - **I & IIa devices with regulatory action**
  - **IIb devices**
  - **III & AIMD devices**

1. The Marketing authorization holder shall submit a summary of the marketing history(SMH) for these devices (attachment No. 1) for a **period of three years** before date of applying for registration / re-registration of devices previously registered before activating this guidance . This SMH shall be prepared by the legal manufacturer and shall be submitted to the Medical Devices Safety Unit, based on a transfer letter issued by the Central Administration of Medical Devices.
2. **An electronic copy** of the declaration 2, signed, stamped and dated by the legal manufacturer (attachment No. 3) shall be submitted by the marketing authorization holder to the Medical Devices Safety Unit MDSU).

❖ **Regarding re-registration procedures of any medical device to be registered after activating this Guidance**

(Class I, IIa with/without Regulatory action, IIb, III & AIMD)

1. The marketing authorization holder shall submit a summary of the marketing history of the devices (attachment No. 1) for a **period of ten years** before date of applying for **re-registration**. This SMH shall be prepared by the legal manufacturer and shall be submitted to the Medical Devices Safety Unit, based on a transfer letter issued by the Central Administration of Medical Devices.
2. The marketing authorization holder shall submit an **electronic copy** of the declaration 1 or 2, according to medical device classification. That electronic copy should be signed, stamped and dated by the legal manufacturer (attachment No. 2, 3) and shall be submitted to the medical Devices Safety Unit.

❖ **For the variation of (Class I, IIa with/without regulatory action, IIb, III & AIMD)**

1. The marketing authorization holder shall submit a summary of the marketing history of the devices (attachment No. 1) for the variants for a period **three years before applying for variation .**That summary shall be prepared by the legal manufacturer and shall be submitted to the Medical Devices Safety Unit, based on a transfer letter issued by the Central Administration of Medical Devices in case of the device require to be transferred to the Safety Unit according to the framework of the Central Administration of Medical Devices.
2. The safety of the medical devices that subjected to variation will be followed up according to the guidance of following up the medical devices in the Post-marketing phase according to the medical devices class.
3. The marketing authorization holder shall submit an **electronic copy** of the declaration 1 or 2, according to medical device classification. That electronic copy should be signed, stamped and dated by the legal manufacturer (attachment No. 2, 3) and shall be submitted to the medical Devices Safety Unit.

Note:

A grace period of 6 months has been set to submit a summary of the marketing history and any other required files to Medical Devices Safety Unit. That grace period shall start from posting date of the transfer letter issued by Central Administration of Medical Devices, and it shall not be accepted to receive any file after the expiry of this grace period.

Second: Guidance for Implementing the Updated Safety Requirements of Medical Devices within the post-marketing framework

1. The marketing authorization holder shall periodically submit a summary of the marketing history of the devices (attachment No. 1) which is signed, stamped and prepared annually, or each two years or on demand. This summary shall be submitted to the Medical Devices Safety Unit, as from the

date of obtaining the final registration license as shown in the following table:

Class	Submission rate	Report type
Class I	When request	Summary of the marketing history of the devices
Class IIa	Each two years	Summary of the marketing history of the devices
Class IIb and Class III	Every year	Summary of the marketing history of the devices

2. The first summary of the marketing history of the device after registration, which shall be submitted periodically (annually/each two years/on demand) based on the device classification and its reporting period will be determined by medical devices safety unit. The marketing authorization holder must be committed to periodically submit the summary of the marketing history of the medical device at the date specified in letter by Medical Device Safety unit.
3. In case of the information provided in the report is insufficient to evaluate the device safety, other procedures shall be taken to evaluate the product safety, such as conducting a study, proactive surveillance or other measures to ensure the product safety in Egypt.
4. The marketing authorization holder in Egypt shall be obligated to report any recall procedures (RECALL), (FSN) or (FSCA) that take place globally. Also it shall follow up on the devices in the Egyptian market, monitor all the incidents caused by the devices and report them to the Medical Devices Safety Unit via the e-mail "pv.md@edaegypt.gov.eg" provided that the Medical Devices Guidelines “MDV Guidelines” shall be consulted to get more details on the procedures of evaluating causality, conduct an “Investigation” and the required corrective plan.

All the serious incidents that occur within Egypt shall be reported according to the following Time frame:

Serious public health threat	Death or an unanticipated serious deterioration in a person's state of health	Any other serious incident
Immediately, not later than 2 days after the manufacturer becomes aware of that threat.	Immediately, not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.	Immediately, not later than 15 days after they become aware of the incident.

The marketing authorization holder shall appoint a responsible person of the vigilance of medical devices and to authorize someone to act on his behalf, provided that the following conditions shall be met:

- Holding a certificate in a medical field, provided that he shall hold certificates from reliable training programs in the field of vigilance of medical devices.
- The contact information for the delegated person and his representative shall be accessed (telephone name, e-mail, national ID, educational qualification). In the event of changing the delegated person or his representative, the Devices Safety Unit shall be notified of the new information immediately via the e-mail, and the delegated person or his representative must be easily contacted.

Note:

The currently applied forms shall be updated starting from the next calendar year.