MDS-G13

Guidance for Manufacturers of Home Use Medical Devices

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Introduction

Purpose

This guidance is intended to provide recommendations for manufacturers to reduce the risks associated with home use medical devices during pre-market and post-market.

Scope

This guidance is applicable for the following parties and products:

- manufacturers of home use medical devices, and authorized representatives.
- all home use medical devices and their accessories that will be supplied to the KSA market.

Background

Currently, SFDA does not have a specific regulatory structure for home use medical devices that defines the basic requirements, except the existing national provisions concerning labelling and conditions of supply and/or use. Therefore, SFDA issues this document to ensure safety and effectiveness of home use medical devices and to minimize the risks associated by using these devices for users, either patients or caregivers.

Manufacturers of home use medical devices shall comply with the Medical Devices Interim Regulation and should consider the recommendations specified in this document.

Recommendations for Manufacturers of Home Use Medical Devices

The SFDA recommendations are divided into the following categories:

A. Environmental Considerations

In the clinical setting, safety and effectiveness of medical devices can be assured in controlled environment. However, medical devices used at an environment outside of healthcare facility do not have this assurance. Therefore, manufacturers should consider the following environmental factors that could compromise safety or effectiveness of medical devices used at the environment outside of healthcare facility:

1. designing the device in a way that will permit the device to operate in its intended use location(s) (e.g., home, school, office, retail environment, train, plane, and car). Therefore the following should be considered:
    a) where the device will be used and stored, and how these locations would affect the user and the device's ability to function and operate safely and effectively (e.g., the electromagnetic interference of the medical devices with other electronic devices).
    b) the ability of the device to be moved in and out of the environment, and from place to place within the environment easily and safely without affecting the safety and effectiveness.
    c) the ability of the device to be operated in a non-sterile environment.
    d) the ability of the device to work in an expected temperature range in the intended use environment.
    e) the ability of the device to work in variable humidity levels that are expected to be present in the intended use environment.
2. specifying the type of water that is required to properly operate the device.
3. providing information for patient and caregiver about how can they operate and use the device in safe environment.
4. explaining any conditions under which the device should not be used. The user must be aware of these situations. (e.g., an electrical device should not be used in a wet environment).
5. explaining the conditions of proper storage of the device and its accessories.

B. User Considerations

A user of home use medical devices is a lay person, therefore manufacturers should consider the following:

1. designing the device to be friendly of using and understanding to reduce the likelihood of misuse.
2. designing the device to be able to prevent reasonably foreseeable misuse.
3. designing the device for user with a range of vision and hearing abilities and tactile sensitivities.
4. designing devices that take into account that users may not understand multiple steps, may receive minimal training or teaching on how to operate these devices, and may not be able to understand multiple warnings and precautions.
5. the children or adults might interact with the device in inappropriate ways.
6. the potential that users might have some type of cognitive impairment that could affect how they interact with the device.
7. providing clear information and specifications about proper protective grounding and about installing the device by a qualified professional if it will be installed permanently.
8. developing viewable instructions that request the user to read the entire instruction manual before trying to operate the device.
9. emphasizing to use a single-use device only once then explain to them about the proper disposal.
10. describing special actions that user must take to transport a device that is not usually moved from the user's home.
11. developing warnings and cautions at the beginning of the manual where the user will see them right away.
12. informing the user if the device need to be calibrated in another location and when.
13. informing the user if the device should not share an outlet with another electrical device or be connected to an outlet controlled by a wall switch.
14. informing the user about any information that are needed for safe operation of the device.
15. informing the user about the proper disposal of the device and its accessories in the home environment and help the user to understand the difference between biological waste and regular waste.
16. informing the user about the type of electrical adapter that is compatible with SASO standards, if any, that can be used and how to use it safely with the device.

17. developing an IFU that:
    a) describes the typical operation time or number of procedures and the typical service life of the power source.
    b) explains the ability of the device to be used while it is charging.
    c) explains the replacement process procedure.
    d) is simple, concise, and easily understood.

C. Design Considerations

Manufacturer should consider the following:

1. designing the device without the need for calibration, but if that is not possible, the device should be designed to require minimal calibration by the user.
2. designing the device to provide the following, if applicable:
    a) accurate and timely monitoring of patients' physiological condition(s)
    b) correct prediction of the patients' needs for therapy; and
    c) correct delivery of the predicted therapy.
3. designing the device in a way that has system to notify the patient/caregiver about the alarms if the noise levels may be high and are making it difficult to hear the alarm.
4. designing in accordance with the Saudi standard entitled "Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (SFDA.MD IEC 60601-1-11:2015)".
5. designing the device in a way of mechanisms that can prevent the patient from changing settings entered by the health care professional or caregiver.
6. designing the device that takes into account unreliable sources of electricity and poor electrical grounding.
7. designing the device with low requirements for maintenance to the extent possible. When maintenance procedures is required, it should be easy to follow, clearly explained, and have a logical flow.
8. designing the device to be able to inform the user how long he/she can expect the device to work on a fully charged battery, it will need to be recharged and replaced soon.
9. designing the device to be easy to be cleaned, disinfected, and sterilized with readily available supplies and use simple techniques.
10. developing a type of checkout procedure for safety and effectiveness if the device requires that.

D. Post-market Considerations

Manufacturer should consider the following:

1. developing a service or system in place that can provide technical assistance for users regarding questions about use and maintenance of the device especially if the device is life supporting or life sustaining.
2. informing the user about how to report any adverse event, that involves the device, to the establishment and SFDA.

Annexes

Annex (1): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
SASO	Saudi Standards, Metrology and Quality Organization
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.
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.
Lay person	individual that does not have formal training in a relevant field or discipline.
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 identification, technical description. c) information accompanying a medical device, related to its use, but excluding shipping documents.
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.
Accessory	means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.
Home Use Medical Device	is a medical device labeled for use in any environment outside of healthcare facility. This includes but not limited to home, office environments, schools, and vehicles. If the medical device is intended to be used in healthcare facilities and outside those facilities, it meets this definition.