MDS-G43

Guidance on Innovative Medical Devices

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Introduction

Innovative Medical Devices have an important role in improving and facilitating both patient's and physician's quality of life. The delays in access to Innovative Medical Devices could limit treatment access to technologies that provide superior effectiveness and could reduce physician and patient choices. To accelerate the access to Innovative Medical Devices while ensuring safety and effectiveness, the SFDA has introduced an Innovative Medical Device Designation process to improve the review processes for Innovative Medical Devices. This guidance contains information for manufacturers on the operation of the designation and associated review processes.

Purpose

The purpose of this guidance is to define the criteria for Innovative Medical Devices and to outline the requirements for Innovative Medical Devices to facilitate the SFDA registration process.

Scope

This guidance applies to the manufacturer, authorized representatives, importers, and distributors of Innovative Medical Devices.

Background

SFDA has issued this guidance document in reference to Article Four of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by decree No. (4-16-1439) dated 27/12/2017 stipulating that "medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization. The SFDA may exempt any medical device and shall announce the exempt medical devices on its website taking into consideration the public interest". The SFDA may accelerate the access to Innovative Medical Devices, while ensuring safety and effectiveness, where:

a) delays in access to such devices could harm the patients in various ways;
b) delays in access could limit access to technologies that provide superior effect and could reduce physician and patient choices; and
c) delays in access restrict available treatment options to approved technologies that may not provide the treatment features needed for a given patient group.

Innovative Medical Device Designation

A medical device may be designated as an Innovative Medical Device if it meets the following criteria:

a) the medical device is designed with innovative features in the technology, indications for use, or performance specifications that have no equivalence in the market; and
b) use of the device is in the best interest of patients; and at least one of the following criteria is met:
    1. the device provides considerable clinical advantage over an existing SFDA approved technology; or
    2. the device provides considerable clinical advantage over an existing approved alternative treatment; or
    3. there are no SFDA approved alternative device technologies nor treatments available to patients.

Applicants must justify how the medical device meets these criteria to SFDA.

SFDA may request additional information from applicants if needed to make a final determination about Innovative Medical Device Designation status.

SFDA Facilitation for Innovative Medical Devices

It is important to understand that Innovative technologies by their very nature are new and less well understood than established technologies. They therefore present higher risks and must be subject to comprehensive and rigorous review.

Most delays in medical device reviews arise from deficiencies in submissions which require the applicant to prepare additional information or in some cases withdraw applications pending performance of additional device testing or clinical evaluation.

In order to ensure that applicants are well prepared, provided optimum submissions and the reviews proceed as smoothly as possible, SFDA has introduced the following processes which assist both parties to maintain a continuous dialogue and to prioritise the review of Innovative Medical Devices:

- ***Prioritizing Evaluation***

Innovative Medical Devices will be placed at the front of the review queue and will be evaluated in priority ahead of other submissions. Because of the novelty of the technology, reviews will need to be thorough. Priority treatment does not mean that reviews will be shortened or reduced in any way, but it does mean that the review will commence sooner after receipt of submission files.

- ***Assigning Case Manager***

On successful designation, SFDA will notify the applicant of the designation and assign a single Case Manager to oversee the review of the application. The Case Manager will then communicate directly with the applicant to provide a roadmap and a timeline. The Case Manager is responsible for ensuring that the application proceeds smoothly and is afforded priority treatment. The Case Manager will continue to communicate frequently with the applicant throughout the review as required by in person meetings, teleconferences or by email.

- ***Granting Conditional Approval***

Conditional approval could be granted for an Innovative Medical Device. Conditional approval allows the applicant to distribute the approved Innovative Medical Device under SFDA post-market requirements, such as limitation of sales, limitation of procuring centers, conducting of a post-market surveillance study, etc. Conditional approval will lead to obtaining final approval only if the applicant fulfilled all SFDA requirements.

Requirements

For Innovative Medical Devices, SFDA will require evidence of device safety and effectiveness. This evidence may be in the form of clinical study data and other relevant data that provides evidence that the medical device is safe and effective. In additional, SFDA will require all documentation typically needed for approval based on the risk class of the device (MDS-G5: Guidance on requirements for Medical Device Listing and Marketing Authorization). Furthermore, documents required for review of Innovative Medical Devices are listed in the Required Documents section below.

The applicant should apply for Designation as an Innovative Medical Device at the same time as submission of the MDMA application. This is done by completing the Innovative Device Application Form and Innovative Device Application Summary as detailed below and including these forms with the submission application.

Required Documents

In addition to all the required documents placed in "MDS-G5: Guidance on requirements for Medical Device Listing and Marketing Authorization", the required documentation for the Innovative Medical Devices are listed in the table below.

	Required Documents	Notes
1	Innovative Medical Device Declaration Form	– The applicant must fill out and sign the form placed in appendix A and attach it to the Unified Electronic System (GHAD) (subsection "An explanation of any novel features" of section 6 "Device and Accessories Information" on the technical file assessment (TFA) marketing authorization submission).
2	Innovative Medical Device Summary	– The applicant must fill out the Innovative Medical Device Summary placed in appendix B and attach it to the Unified Electronic System (GHAD) (subsection "An explanation of any novel features" of section 6 "Device and Accessories Information" on the technical file assessment (TFA) marketing authorization submission).

Annexes

Annex A: Innovative Medical Device Declaration Form

General Information	
Applicant	
Device Name	
Intended Use	
Indications	
Risk Class (A, B, C or D)	
Is the medical device designed with innovative features in the technology, indications for use, or performance specifications that have no equivalence in the market and is in the best interest of the patient?	**If the answer is yes, please check the appropriate box** The device provides considerable clinical advantage over an existing SFDA approved technology. ☐ The device provides considerable clinical advantage over an existing approved alternative treatment. ☐ There are no SFDA approved alternative device technologies nor treatments available to patients. ☐
Rationale for considering the device as an Innovative Medical Device.	
Attestations: I confirm that the information given in this form is true, complete and accurate.	
Name:	
Signature:	

Annex B: Innovative Medical Device Summary

The applicant shall submit innovative technology summary regarding the following:

Device Description	-	Device operation (how to use the device).
	-	Environment of use (health care facility, home, other) [specify].
	-	Mechanism of action (scientific description).

Device Identification	-	List of all key device components.

Device Characteristics **(address all that apply)**	-	Software
	-	Biologic
	-	Drug
	-	Any materials contacting patient
	-	Single-use
	-	Sterile
	-	Sterilization methods
	-	Other characteristics

Material used	-	General type of material used. • Animal origin • Human/Tissue • Medicinal substance used in device.
	-	Duration and type of contact.

Level of Evidence	-	Pre-clinical data. • Animal Studies • Usability Study.

(identify and discuss)		• Software Validation. • Sterilization Validation. • Risk- Benefit Analysis • Any other lab testing.
	-	Clinical Investigation documentation and Investigator's Brochure: • Pilot Study (if applicable). • Pivotal Study (if applicable). • Primary safety endpoint identified: (if yes, describe). • Primary effectiveness endpoint identified: (if yes, describe).
	-	Clinical Evaluation/Literature Review

Annex C: Definitions & Abbreviations

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.
Innovative Medical Device	A medical device may be designated as an Innovative Medical Device if it meets the following criteria: a) the medical device is designed with innovative features in the technology, indications for use, or performance specifications that have no equivalence in the market; and b) use of the device is in the best interest of patients; and at least one of the following criteria is met: 1. the device provides considerable clinical advantage over an existing SFDA approved technology; or 2. the device provides considerable clinical advantage over an existing approved alternative treatment; or 3. there are no SFDA approved alternative device technologies nor treatments available to patients.
KSA	Kingdom of Saudi Arabia
Label	means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;
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.
Medical devices	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.
Risk	means the combination of the probability of occurrence of harm and the severity of that harm;
SFDA	Saudi Food and Drug Authority