MDS-G002

Guidance on Innovative Medical Devices

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Introduction

Innovative Medical Devices have an important role in improving and facilitating both patients' and physicians' 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.

The SFDA has introduced a pathway for Innovative Medical Devices to accelerate the regulatory process to allow patients access to novel technologies with significant benefits over available products while ensuring safety and effectiveness. This guidance contains information for manufacturers on the designation criteria, associated review processes, and outlining the features of the pathway.

Purpose

The purpose of this guidance is to define the designation criteria for Innovative Medical Devices, to outline the requirements for applying through the Innovative Medical Devices Pathway, and to explain the submission process.

Scope

This guidance applies to the innovators, developers, manufacturers, and authorized representatives of Innovative Medical Devices.

Background

SFDA has issued this guidance document in reference to Article nine of the "Medical Devices Law" issued by The Council Of Ministers Board of Directors decree No. (3777) dated 04/07/1442 H indicating that the SFDA may exempt the innovative medical device from some of the requirements and procedures to obtain a marketing authorization; in a manner that does not affect its safety and effectiveness when used, in accordance with "Medical Devices Executive Regulation".

Innovative Medical Devices Pathways

The SFDA has developed a pathway for Innovative Medical Devices to provide continuous regulatory assessment and feedback during all development phases of the Innovative Medical Devices. SFDA aims to accelerate the Innovative Medical Devices assessment allowing patients access to novel technologies with significant benefits over available products and providing better treatment and diagnosis. This program will continue to require providing evidence in which that the medical device meets the Essential Principles. The program is intended to facilitate access to both Innovative Medical Devices that have been on the market or are yet under development. The pathway is comprised of two stages: Pre-Submission Assessment and Priority Assessment for Marketing Authorization. The process of Innovative Medical Devices Pathways is outlined in a flowchart.

Pre-Submission Assessment Pathway

The first stage is intended to provide continuous regulatory assessment and guidance on the regulatory requirements during all medical devices' development phases prior to applying for marketing authorization.

Priority Assessment for Marketing Authorization Pathway

The second stage is intended for Innovative Medical Devices seeking priority assessment designation when applying for marketing authorization.

Innovative Medical Device Designation Criteria

This section outlines the criteria for eligibility for a medical device to be considered innovative. A medical device may be designated as an Innovative Medical Device if it meets the following conditions:

- The medical device is designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market.
- The medical device provides a considerable clinical/medical advantage over existing alternative treatments.
- Any other criteria to be determined by the authority and published through the website.

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, and applicants will be notified of the status of their application, whether it is accepted for priority review or not.

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. Therefore, they may present higher risks and must be subject to comprehensive and rigorous review.

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 facilitations which assist both parties to maintain a continuous dialogue and to prioritize the review of Innovative Medical Devices:

Facilitations for Pre-Submission Assessment Pathway

- **Preliminary Regulatory Feedbacks**

This service will be free of charge prior to submitting Medical Device Marketing Authorization (MDMA) request to SFDA. Pre-submission assessment is the first stage of the pathway. It will provide the applicants with ongoing feedback and guidance regarding their applications and will explain SFDA requirements. Moreover, the developers/manufacturers will be notified in advance of the regulatory expectations of the proposed device.

Facilitations for Priority Assessment for Marketing Authorization Pathway

- **Prioritizing Evaluation**

Innovative Medical Devices will be placed at the front of the review queue of marketing authorization requests and 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.

- **Granting Conditional Marketing Authorization**

Conditional marketing authorization could be granted for some Innovative Medical Devices to support existing clinical evidence. Conditional marketing authorization allows the applicant to market the Innovative Medical Device under SFDA post-market requirements, such as limitation of sales, limitation of procuring centers, conducting post-market surveillance studies, etc. Conditional approval could lead to obtaining final marketing authorization only if the applicant fulfilled all SFDA requirements.

- **Announcement Release**

Once the Innovative Medical Device obtains marketing authorization, SFDA may announce on its website and/or other channels that the Medical Device Marketing Authorization has been obtained for the Innovative Medical Device, which will be highlighted and visible to the community.

Requirements

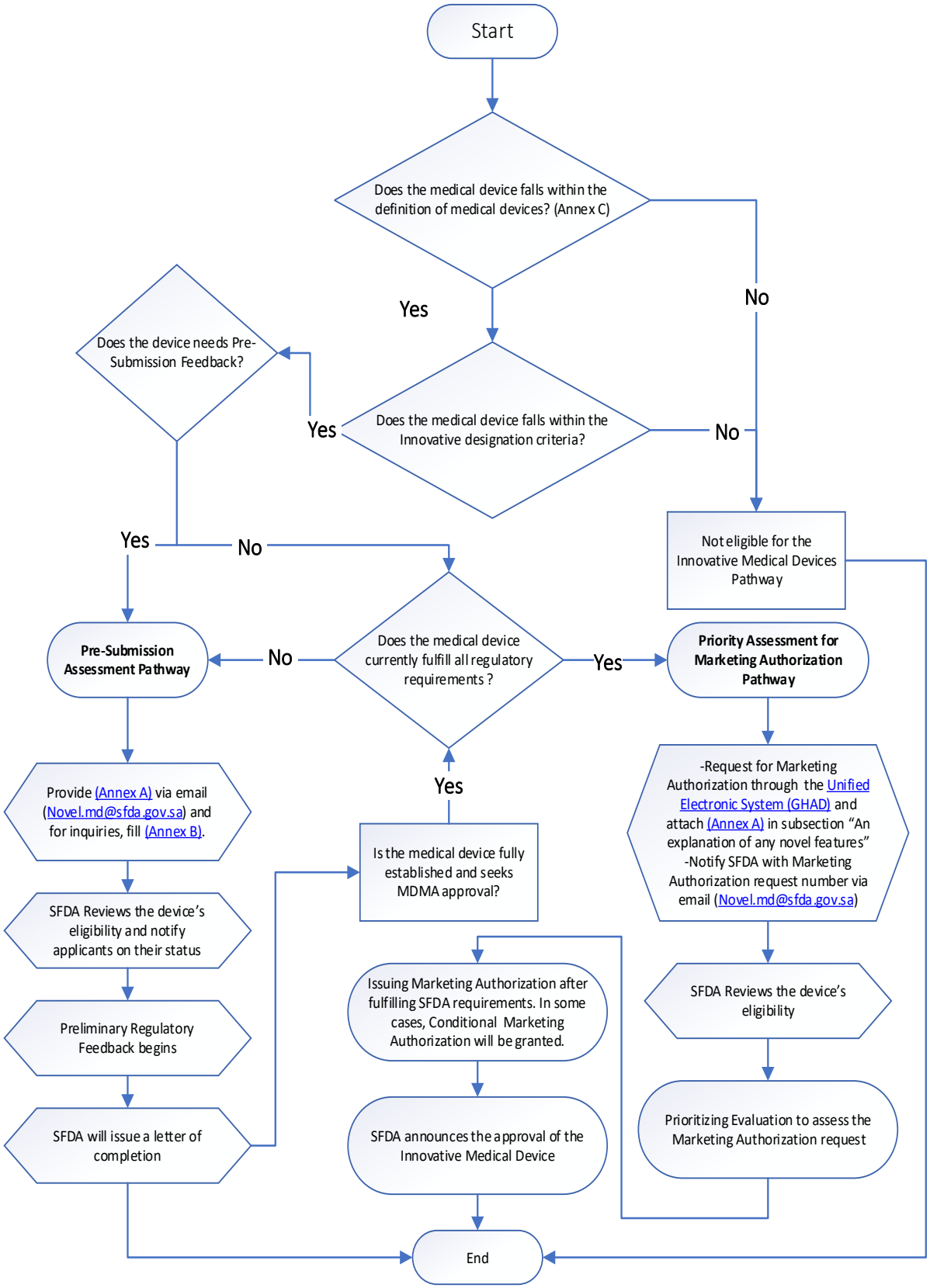
General	1	Applicants shall comply with the following: - Medical Devices Law. - Medical Devices Executive Regulation. - MDS-REQ1: Requirements for Medical Device Marketing Authorization. - Innovative Medical Device Designation Criteria. - Evidence of device safety and effectiveness by meeting the Essential Principles for Safety and Performance requirements.
SFDA Prerequisites	2	- Applicants must fill the required form listed in "Required Documents". - Applicants shall provide any existing evidence of compliance with "MDS-REQ1: Requirements for Medical Device Marketing Authorization". - 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 by meeting the Essential Principles for Safety and Performance requirements.
Specific Requirements for Pre-Submission Assessment Pathway	3	- Applicants shall provide the required form (Annex A) via email (Novel.md@sfda.gov.sa). - For inquiries, applicants can fill "Innovative Medical Device Inquiries Form" (Annex B). - SFDA will review applications to determine the devices' eligibility, and may require additional supporting documentation or clarification. - SFDA will notify the applicants of the status of their applications. - When the Pre-Submission Assessment is complete, SFDA will issue a letter of completion.
Specific Requirements for Priority Assessment for Marketing Authorization Pathway	4	- Applicants submit a request for Priority Assessment for Marketing Authorization through the Unified Electronic System (GHAD) and attach the required form (Annex A) in subsection "An explanation of any novel features". - Applicants notify SFDA via email (Novel.md@sfda.gov.sa) with the MDMA request number.

		– SFDA will review the applications to determine the devices' eligibility, and may require additional supporting documentation or clarification. – SFDA will notify the applicants of the status of their applications. – Once accepted, applicants will have all distinctive pathway facilitations.

Required Documents

	Required Documents	Notes
1	Application Form for Innovative Medical Device	– See (Annex A)
2	Innovative Medical Device Inquiries Form (optional)	– See (Annex B)

Flowchart


Start
Does the medical device falls within the definition of medical devices? (Annex C)
Yes
No
Does the medical device falls within the Innovative designation criteria?
Yes
No
Does the device needs Pre-Submission Feedback?
Yes
No
Not eligible for the Innovative Medical Devices Pathway
Does the medical device currently fulfill all regulatory requirements ?
No
Yes
Pre-Submission Assessment Pathway
Priority Assessment for Marketing Authorization Pathway
Provide (Annex A) via email (Novel.md@sfda.gov.sa) and for inquiries, fill (Annex B).
SFDA Reviews the device's eligibility and notify applicants on their status
Preliminary Regulatory Feedback begins
SFDA will issue a letter of completion
Yes
Is the medical device fully established and seeks MDMA approval?
Issuing Marketing Authorization after fulfilling SFDA requirements. In some cases, Conditional Marketing Authorization will be granted.
SFDA announces the approval of the Innovative Medical Device
-Request for Marketing Authorization through the Unified Electronic System (GHAD) and attach (Annex A) in subsection "An explanation of any novel features"
-Notify SFDA with Marketing Authorization request number via email (Novel.md@sfda.gov.sa)
SFDA Reviews the device's eligibility
Prioritizing Evaluation to assess the Marketing Authorization request
End

Annexes

Annex (A): Application Form for Innovative Medical Device

1	Applicant Name	
2	Organization Information (name, address and contact information for company/university/manufacturer)	
3	Device Name	
4	Type of Medical Device (Medical Device (MD) or In-Vitro Medical Device (IVD))	
5	Device History (If the device has been previously authorized, address previous history interaction with regulatory; such as, FDA, EU, TGA etc.)	
6	Risk Class (A, B, C or D) and Rationale (Refer to MDS-REQ1 Annex 5 and MDS-G42)	
7	Choose the applicable Innovative Medical Device Designation Criteria	□ The medical device is designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market. □ The medical device provides a considerable clinical/medical advantage over existing alternative treatments. □ Other (explain in the below section)
8	Provide detailed rationale for considering the device as an Innovative Medical Device.	
9	Intended Use *Which may include:* – Indication of the device (treat/prevent/diagnose/monitor) – Patient population (age/gender/disease) – Body parts affected – Intended user	
10	Device Description *Which may include:* – Brief description (written/ diagram/picture) – Mechanism of action (how the device achieves its intended purpose)	

11	Device Characteristics (address all that apply) – Software – Biologic – Single use – Sterile (sterilization method) – Material used (Animal origin/human/tissue/medicinal substance) – Duration of body contact – Other characteristics (reagents/components/accessories)	
12	Level of Evidence (identify and discuss) Pre-clinical data: – Animal studies – Usability study – Software validation – Sterilization validation – Risk-benefit analysis – Any other lab test 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	
13	Attestations:	□ I confirm that the information given in this form is true, complete and accurate.

Annex (B): Innovative Medical Device Inquiries Form

1	Applicant Name:	
2	Device Name:	
3	Select the Primary Topics of Inquiries -General regulatory requirement -Risk classification -Design validation (pre-clinical data) -Product claims -Validity of clinical trials -Others:	
4	Brief Summary of Overall Inquiries	

Annex (C): Definitions and Abbreviations

SFDA	Saudi Food and Drug Authority
Authorized Representative (AR)	Individual or judicial or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Manufacturer	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.
MDMA	Medical Devices Marketing Authorization
Medical Device	Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Innovative Medical Device	The medical device is designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market.

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

Number & Date of the Previous Version	Changes Description
1.0 01/01/2020	• Update the following documents: ○ Guidance on Innovative Medical Devices (MDS-G43) to (MDS-G002).