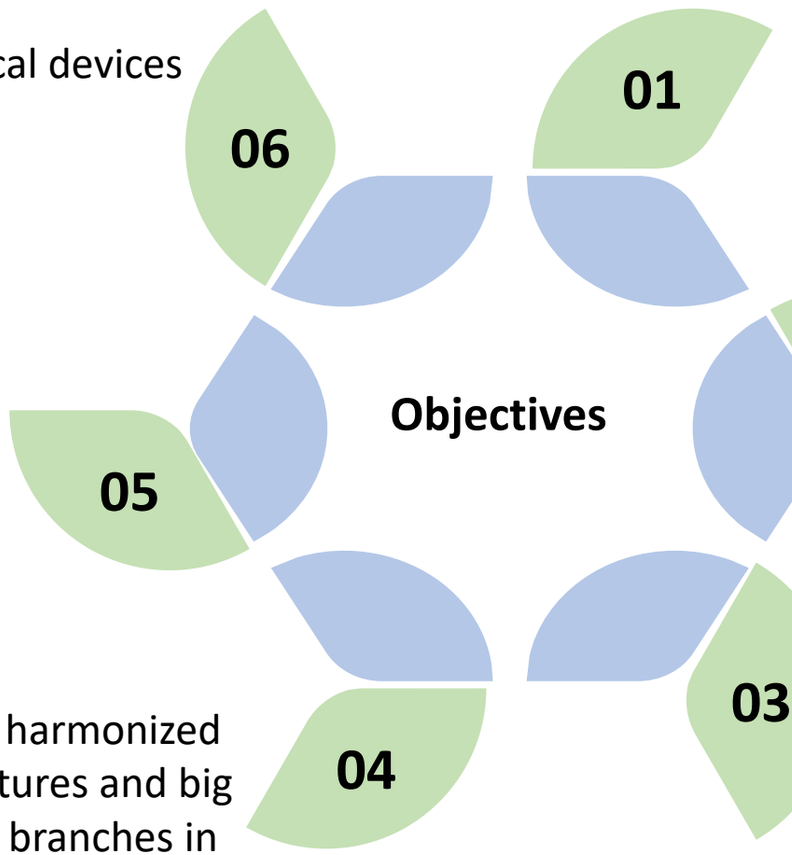
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

SFDA's Role in Supporting (local manufacturing) and (innovation) in the Field of Medical Devices

Article Nine of Medical Devices Law

"The authority may exempt the innovative medical device from some of the requirements and necessary procedures to obtain a marketing authorization; in a manner that does not affect its safety and effectiveness"



Protect the public health in Saudi by applying the procedures and requirements that assures the patient's safety as well as end user

Taking measures and assign responsibilities to ensure conformity of law requirements

Enhance the Kingdom's leading role internationally in the medical devices field

Support investments by having harmonized law which encourages manufactures and big corporates to invest and launch branches in the Kingdom

Effective economic impact for the Saudi market

Support innovation and medical devices technology development

Innovative Medical Devices Pathway

- “MDS-G002”

InnovativeMedicalDevicesMDS-G002.pdf (sfda.gov.sa)

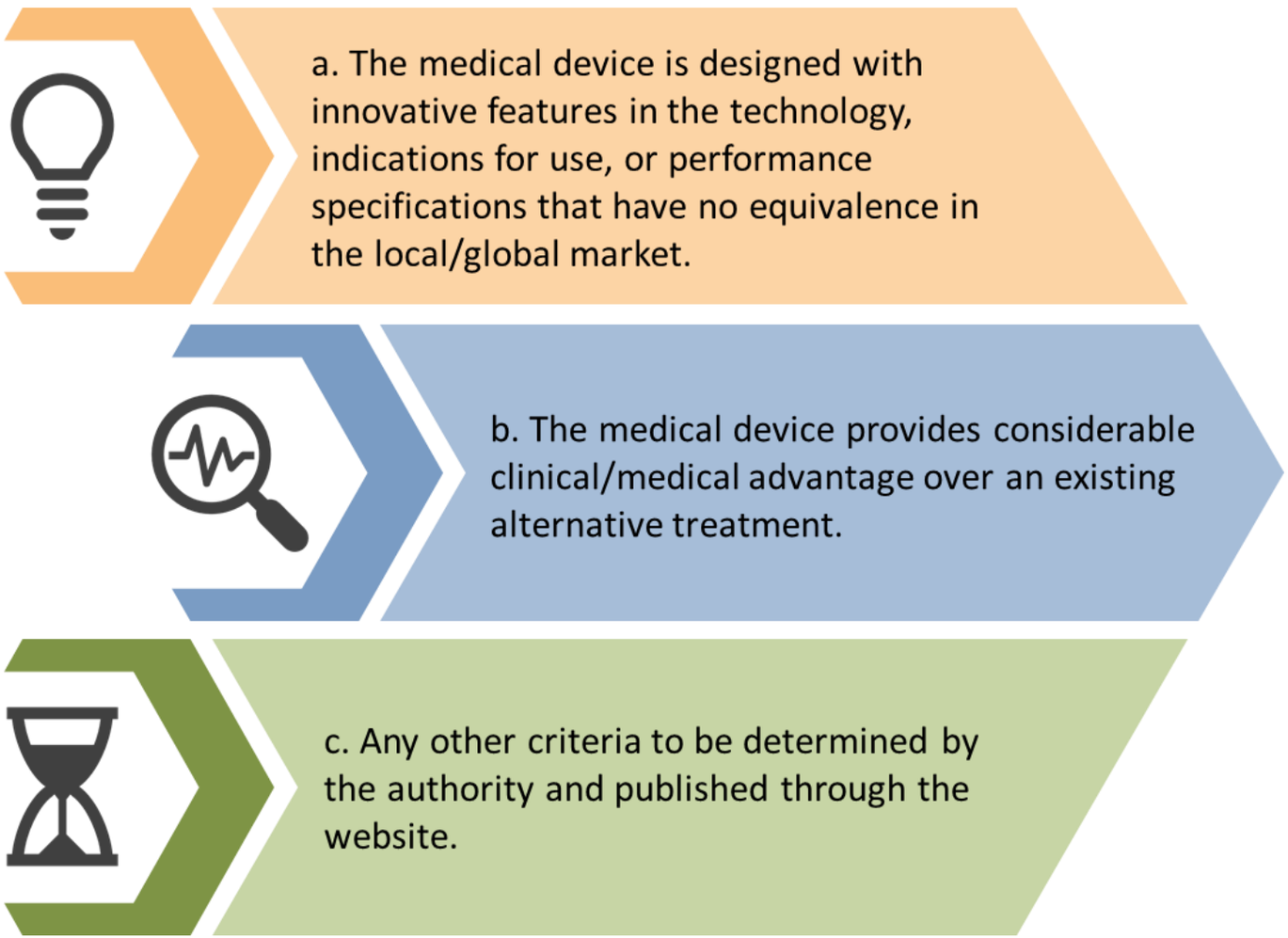
Innovative Medical Device Definition

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.

Innovative Medical Device Designation Criteria

Medical Devices Law-Article 9

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



Innovative Medical Devices Pathway's Objectives

01

Facilitate the registration procedures for innovative medical devices for international and local companies and encourage them to enter the Saudi market to increase the number of innovative medical devices and supplies registered in the Kingdom of Saudi Arabia.

02

Increasing the number of clinical studies and research on innovative medical devices.

03

Activating the role of the SFDA in developing the health system.

04

Accelerate the regulatory process to allow patients access to new technologies with significant benefits over available products.

05

Supporting local companies and manufacturers.

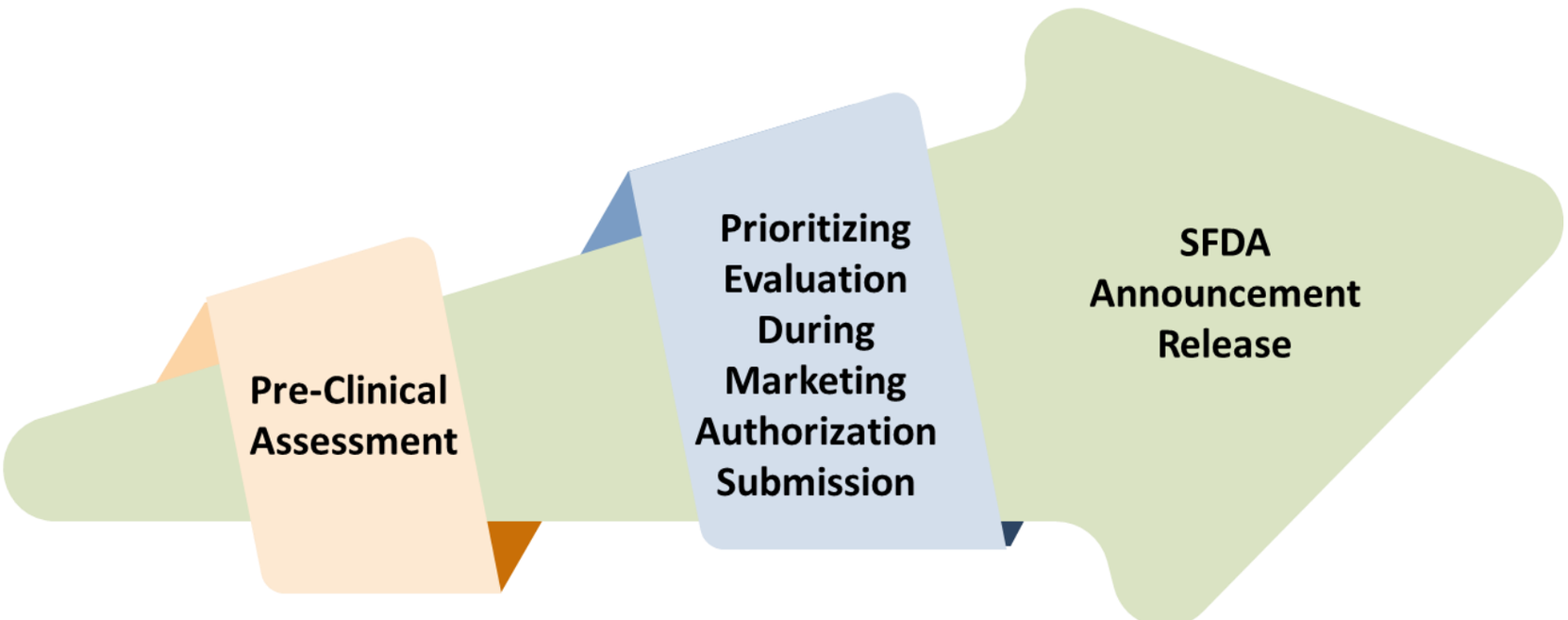
06

Cooperation and integration with partners from government agencies

Who is the Target Audience?

- Authorized Representatives of Manufacturers of Innovative Medical Devices
- Developers at Local Universities and Research Centers
- Manufacturers of Innovative Medical Devices

Pathway's Facilitations



Incentive Approach (1)

Pre-Clinical Assessment

- SFDA will provide a free of charge consultation and preliminary assessment prior submitting an application through GHAD System.

Benefits:

- Accelerate the time spent during the MDMA assessment.
- Provide a brief explanation of SFDA requirements and guidelines, including the Technical Files.
- Have knowledge on which guidance to follow.
- Providing channels of communication between the innovators and the authority, even in the absence of an authorized representative of the manufacturer in the Kingdom.

Incentive Approach (2)

Prioritizing MDMA Assessment

- SFDA will provide any needed assistance to successfully submit applications through GHAD system by continues facilitation and support during MDMA submission

Benefits:

- Faster submission of MDMA application.
- Continuous and direct communication with Legal Manufacturers and ARs regarding SFDA comments and feedbacks.

Incentive Approach (3)

SFDA Announcement Release

- Once the device is cleared, SFDA may announce on the web-page that the novel device “X” has been cleared.

Benefits:

- Support manufacturers of innovative medical devices by announcing innovative medical devices that the device has been authorized to be marketed on the authority’s website and on social media.
- This step will contribute to familiarizing the community and health practitioners with the latest medical technologies available in the local market

Applying to the Pathway

- Send a request to SFDA via email address (novel.md@sfda.gov.sa)
- Submit the required documentation (MDS – REQ 1, Annex 11).
- SFDA reviews the documentation including the device's eligibility, SFDA may accept or reject the request.
- SFDA notifies the applicants if their request has been accepted or rejected.
- Once accepted, SFDA requests all technical and provide a preliminary assessment at no charge.
- Once preliminary assessment is complete, SFDA will issue a letter of completion.
- Apply to Ghad System to obtain marketing authorization (MDMA) for the innovative medical device.
- Prioritize MDMA assessment for the innovative medical device.
- Obtain MDMA & SFDA announcement

Thank You

بالأهـم نهتـم