MDS – REQ 8

Requirements for Obtaining SFDA Approval for Advertisement and Launching Awareness and Charitable Campaigns for Medical devices

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"Translated Copy"

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Introduction

Purpose

The purpose of this document is to specify and clarify:

- Requirements and procedures for obtaining SFDA Approval on Medical Device Advertising Material.
- Requirements and procedures for obtaining SFDA approval to conduct awareness or charitable campaigns that include use or display of medical devices.

Scope

Requirements of this document shall apply to the following activities:

- Advertising of medical devices.
- Awareness or charitable campaigns that include use or display of medical devices.

This document also applies to all related parties, including:

- Manufacturers.
- Authorized representatives.
- Distributors.
- Importers.
- Healthcare providers.
- Media that broadcast or publish a content aimed at the public in the Kingdom.
- Advertising agencies.
- Individual advertisers.
- Organizers of awareness or charitable campaigns that include use or display of medical devices.

These requirements shall not apply to display of medical devices samples in exhibitions, festivals or workshops. Such medical devices shall be subject to the "Requirements on Importation and Shipments Clearance of Medical Devices" (MDS-REQ5).

Background

This document has been issued by the SFDA in reference to:

- Article (24) and (25) of the *"Law of Medical Devices and Supplies"* issued by Royal Decree No. (M/54) dated 06/07/1442H, which stipulate the following:

- "Medical devices and supplies may not be advertised nor promoted without the SFDA's approval. Advertising and promotion shall be in accordance with the conditions determined by the Regulations.".
- "Awareness and charitable campaigns, and the like, relating to medical devices and supplies may not be organized without the SFDA's approval. Such campaigns shall be in accordance with the conditions determined by the Regulations.".

- Articles (24/1), (25/1), and (25/2) of the *"Implementing Regulations of the Law of Medical Devices"*, issued under Board of Directors Resolution No. (3-29-1443) dated 19/02/1443H.

1. General Provisions and Requirements

SFDA's approval shall be obtained prior to publishing advertising material for medical devices, whether it is aimed to laypersons or healthcare practitioners, and the following shall be adhered:

1) The advertised medical device has obtained a valid “Medical Device Marketing Authorization” (MDMA) certificate.
2) The advertising material shall not contain any content that violates the provisions of Islamic Sharia and public morals, and shall comply with societal customs and values and not violates public decency.
3) The advertising material shall not contain any misleading information for the user that contradicts the claims specified by the manufacturer, nor shall it include any statements that may be misinterpreted.
4) Avoid using advertising content aimed at the public that may mislead the layperson, including information on the Internet or any other media.
5) Advertising materials and publications shall include information that is consistent with the needs of the intended users of the medical devices.
6) Personnel involved in the marketing of medical devices shall have sufficient information about them to ensure the provision of accurate information related to their marketing.
7) The advertising shall not, directly or indirectly, offend any other medical device and it shall not include any competing comparisons to the products of other firms.
8) The language used in the advertising material shall be Arabic if it is aimed to the laypersons, and English if it is aimed to healthcare practitioners, other languages may be used provided that they match the language used in the advertising. The needs of persons with disabilities shall be taken into consideration.
9) The advertising material shall not contain any claims that have not been approved by the SFDA.
10) The name or logo of the SFDA or any other regulatory body (whether internal or external) shall not be used in the content of the advertising directly or indirectly.

11) The advertising material shall not violate the "Law of Printed Materials and Publication" issued under Royal Decree No (M/32) dated 3/9/1421H, its implementing regulations, and any amendments issued thereto, in addition to all applicable laws in the kingdom.
12) Obtaining the required approvals from the competent authorities and complying with the requirements and instructions of other relevant authorities in the event of conducting lectures or introductory seminars about the medical device or medical supply, whether held in person or remotely, and whether in visual or audio format.
13) The establishment may appoint an advertising agency licensed by the competent authority to submit the application for SFDA approval on Medical Device Advertising material on its behalf, provided that the authorization is certified by the Chamber of Commerce.
14) In the event of conducting introductory lectures or seminars/presentations on a medical device aimed to healthcare practitioners, the application for approval shall be submitted at least (14 working days) prior of date of conducting the lecture or seminar.
15) The following shall be obtained by the applicant for SFDA approval on Medical Device Advertising material:
    a. Establishment registration number in the "SFDA E-Services" portal.
    b. Establishment license (Manufacturer, Authorized Representative, Importer, Distributor).
16) When the application is submitted by a healthcare establishment, the establishment registration number shall be obtained via the "SFDA E-services" portal.
17) Advertising materials shall include the following:
    a. Medical device name.
    b. Manufacturer's name or trademark.
    c. (MDMA) certificate number (for applications submitted through the 1st track) or the approval number and the Quick Response (QR) code (for applications submitted through the 2nd track).
18) The advertising shall not contain the establishment registration number in the "SFDA E-Services" portal.

19) In case the SFDA approval on Advertising material is requested for a medical device and its accessories, or for multiple devices grouped under a single (MDMA) application, the applicable fee for approval shall be paid once only.
20) A separate application shall be submitted for each individual advertising format if the applicant has more than one advertising format.
21) Additional approval is not required when changing the display medium to another medium specified in the application form, provided that the same approved content is used and the approval remains valid.
22) Upon receiving a notification from the SFDA that the application is "incomplete," the applicant shall provide the required missing documents within (90 days) from the date of the notification; otherwise, the application will be considered "VOID" and a new application shall be submitted.
23) The SFDA has the right to void previously approved advertising applications, with justification provided.
24) If the approval request is rejected, or if a decision is issued to suspend or void the approval, the applicant has the right to appeal the decision within (30 days) from the date of decision issuance.
25) If the SFDA issues a decision rejecting the appeal, the applicant has the right to submit the appeal within (30 days) from the date of the rejection decision.
26) If a decision is issued by the SFDA to reject the appeal, the decision shall be considered "FINAL".
27) The SFDA has the right to suspend the approval to request clarification or interpretation of the advertising content, or if new information emerges indicating potential risks associated with the use of the medical device, or concerns about its effectiveness.
28) The SFDA has the right to suspend or cancel the approval if any violation is detected.
29) The SFDA has the right to suspend the advertising license if any additional uses of the medical device are mentioned other than its primary intended use.
30) Manufacturers and authorized representatives shall provide distributors and importers, if any, with a copy of all approved advertising materials, specifying the target audience as either "laypersons" or "healthcare professionals."

2. Special Requirements for Obtaining SFDA Approval on Advertising Materials Displayed or Broadcasted on Websites or Social Media Platforms

1) Approval from the SFDA shall be obtained for advertising material published on global websites (the Internet) or social media platforms when targeting laypersons in the Kingdom, regardless of whether the website or social media platform is registered inside or outside the Kingdom.
2) In the event of advertising through content creators on social media platforms, the individual shall hold a "Mawthooq" license for advertising content creation. In addition, approval from the SFDA for the advertising material shall be obtained.
3) When advertising through a website, the website shall not rely on other advertising links that have not been approved by the SFDA.
4) It is not permitted to display information intended for healthcare professionals on websites designated for laypersons.
5) If the advertising material is posted or broadcast by a content creator on social media platforms, the SFDA shall be provided with the intended visual or audio material to be published, or with the text of the content to be broadcast, at least (12 hours) before publication. This shall be sent via email to (AD.L@sfda.gov.sa), along with the advertiser's name, social media account, and the planned publication/broadcast date and time.
6) Responses to inquiries on published advertising material on social media shall not include any information that has not been previously approved.
7) A script shall be submitted as a copy of the advertising material for any live-streamed visual or audio advertising, while the full recorded visual or audio content shall be submitted for pre-recorded advertising.
8) When advertising through a content creator on social media platforms, a contract shall be concluded between the establishment and the content creator, with each party retaining a copy. A copy of the contract shall also be submitted with the advertising approval request, and the contract shall include the following:

    a. The advertising content.
    b. The duration of display of the advertising material.
    c. The social media platform on which the advertising material will be published or broadcast.
    d. The contract duration.

3. Application Procedures, Required Documents, and Fees for Obtaining SFDA Approval on Advertising Material

Application Procedures and Required Documents	Advertising approval shall be obtained via one of the two tracks listed below: 1st Track: submission of the advertising material by the manufacturer or the authorized representative as part of the technical documentation within (MDMA) application; or 2nd Track: submission of an application to obtain advertising approval through the electronic portal, subject to the following: • An account on the "SFDA E-Services" portal. • If advertising approval is requested for more than one medical device with different (MDMA) certificates within a single advertising format, all devices or medical supplies mentioned in the advertising shall be selected and submitted in a single approval application. • In the case of lectures, seminars, or introductory presentations on a medical device or medical supply directed to healthcare providers, resumes, certificates, and qualifications of the speakers shall be attached.
Application Review	The SFDA shall review the application to verify compliance with the requirements and shall respond to the applicant as follows: ▪ 1st Track: Within (35 days), in accordance with the "Requirements for Medical Devices Marketing Authorization" (MDS-REQ 1) published on the SFDA's website ▪ 2nd Track: Within (10 days). If there are any shortages, the applicant will be notified of the required corrective actions.
Updates to Advertising	When changes are intended to be made to previously approved advertising materials, one of the following procedures shall be followed: 1- Update (incorporate the changes) in the designated section of the technical file for the (MDMA) application; or. 2- If changes to the approved advertising material are required prior to publication, a request shall be submitted to the SFDA to update the advertising material via the following email address: (AD.L@sfda.gov.sa), provided that the request includes full details of the proposed changes. 3- Payment of the applicable fees for (MDMA) update requests in accordance to the circular " Fees and Review Times for Marketing Authorization Application".
Fees	1. If the advertising materials are submitted as part of the technical files within the marketing authorization application:

	Payment of the applicable fees for the marketing authorization application shall be in accordance to the circular "Fees and Review Times for Marketing Authorization Application" 2. If an application is submitted to obtain SFDA approval: a) (SAR 3,000) Three thousand Saudi riyals if the advertising is directed to lay persons. b) (SAR 6,000) Six thousand Saudi riyals if the advertising is directed to health practitioners.
Approval Validity	1. If the advertising material is submitted through the 1st Track, the validity period of the approval shall be aligned with the validity of the marketing authorization certificate. 2. If the approval is obtained through the 2nd Track, the approval shall be valid for (1) year. If the establishment wishes to extend the approval (for the valid approval) for more than (1) year and up to a maximum of **(**5**)** years, while maintaining the same approval number, an extension request may be submitted along with full payment of the applicable fees for the requested years and evidence of the previous approval. 3. The establishment may renew the approval (for an expired approval) for (1) year or more, up to a maximum of (5) years, while maintaining the same approval number, by submitting a renewal request along with full payment of the applicable fees for the requested years and evidence of the previous approval.

4. Applicant Obligations after Obtaining SFDA Approval on Advertising Material

1) After obtaining advertising approval, the applicant shall be responsible for complying with the following:
2) Adhering to the Medical Devices Law and its Implementing Regulation, the requirements stipulated in this document, and any related circulars issued by or published on the SFDA's website.
3) Refraining from using advertising materials after the expiration of the advertising approval validity period.
4) Including the advertising approval number and the Quick Response (QR) code (Barcode), or the marketing authorization certificate number, in the advertising material, provided that the number is clearly displayed without any additional text or indication, as specified in Clause (17) item (c) under the "General Provisions and Requirements" section.
5) Suspending advertising upon the emergence of new information indicating risks associated with the use of the medical device, or indicating lack of effectiveness, or when the SFDA issues a decision to suspend or revoke the advertising approval.
6) The establishment shall bear full responsibility for any incorrect or misleading information or claims contained in the advertising material, or for any consequences resulting from non-compliance with the relevant requirements, even after obtaining SFDA approval.
7) The applicable fees are non-refundable once the application is submitted.
8) Complying with all laws and regulations in the Kingdom.

5. Requirements for Obtaining Approval to Conduct Awareness or Charitable Campaigns Involving the Use or Display of Medical Devices

Individuals wishing to organize awareness or charitable campaigns involving the use or display of medical devices shall obtain prior approval from the SFDA and comply with the following conditions:

1) The medical device intended to be used or displayed shall hold a valid Medical Device Marketing Authorization (MDMA) certificate issued by the SFDA.
2) Awareness and educational activities shall be conducted by competent and qualified personnel.
3) The campaign shall not include any marketing references or promotional materials intended for commercial purposes.
4) Medical devices shall not be used on participants, attendees, or the general public during awareness or charitable campaigns unless written consent is obtained from the participant or their legal guardian, using the designated consent form.
5) Free samples shall not be distributed to participants, attendees, or the general public.
6) The campaign shall not be exploited for the sale of medical devices.
7) Materials used in the campaigns shall be written in English when targeting specialized professionals; Arabic shall be included when targeting the general public, while taking into account the needs of persons with disabilities.
8) All required approvals from the relevant authorities shall be obtained.
9) No used medical devices shall be donated unless the requirements stated in the section “Resale, Loaning, or Donating Used Medical Devices” under the “Requirements for Post-Market Surveillance of Medical Devices” (MDS-REQ 11) are fully complied with.
10) Compliance with any other conditions requested by the SFDA and published on its website.

6. Procedures and Required Documents for Obtaining Approval to Conduct Awareness or Charitable Campaigns Involving the Use or Display of Medical Devices

Application Procedure and Required Documents	**1. The application shall be prepared to include the following:** a) An official letter addressed to the SFDA from the entity organizing the awareness or charitable campaign. b) Information about the campaign, such as its objectives, location, launching date, and organizers. c) Copy of the marketing authorization certificate issued by the SFDA. d) Copy of the awareness materials to be used in the campaign. **2. The application shall be submitted after it has been prepared via one of the two methods listed below:** a) Submitting the application by printing the required documents and delivering them in hard copy to the" Advertising Licensing Section" in the "Operations Sector". b) Sending the application to the following email address (Communications.Adm@sfda.gov.sa) with all attachments combined into a single file in (PDF) format, where the official letter shall be placed on the first page of the file. The applicant will then be provided with a registration number for the application. **3. Application Review:** The SFDA shall review the application and verify compliance with the requirements. The applicant shall be notified of the outcome within (10 days). If there are any shortages, the applicant shall be informed of the required corrective actions.

Annexes

Annex (1): Abbreviations and Definitions

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Medical Devices Law
Regulation	Executive Regulations of the Law
Establishment	A legal entity involved in an activity related to medical devices.
Medical Device	Any instrument, apparatus, implement, implant device, 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 and supplies; providing information for medical or personal 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.
Medical supply	A medical substances or products used in diagnosis, treatment, prosthetics, orthotics, or in disability cases or other medical uses for humans, including medical gases.
Accessories of Medical Devices and Supplies	Any substance or product intended specifically to be used with a medical device or supply to enable it to achieve its purpose.
Advertising	Any statement, whether written, audible, visual, or otherwise, intended to promote and sell, directly or indirectly, the medical device, supply, or technology on it.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulation.
Healthcare provider	Any government or private establishment that provides health care services.
Layperson	A person who does not have formal education or training in a relevant field of healthcare or medical discipline.
License	A document issued by the SFDA to engage in any of the activities subject to this Law.
National Registry	The National Registry of Medical Establishments, Devices

	established by the SFDA.
Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Importer	An establishment in the supply chain that supplies a medical device to the Kingdom.
Distributor	An establishment in the supply chain that supplies a medical device to another distributor or its end user.
Applicant	A natural or legal person who meets the requirements and has been authorized by the establishment.

Annex (2): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
MDS - REQ 8 **Version No. 3.0** **Date: 15/06/2022**	General Provisions and Requirements • Amendment, addition, and removal of several clauses. • Clarification of application tracks and explanation of each track. Special Requirements for Obtaining SFDA Approval on Advertising Materials Displayed or Broadcasted on Websites or Social Media Platforms: • Addition of item (2): In the event of advertising through content creators on social media platforms, the individual shall hold a "Mawthooq" license for advertising content creation. Application Procedures, Required Documents, and Fees for Obtaining SFDA Approval on Advertising Material • Application Procedures and Required Documents Modify **2nd Track** to be: Submission of an application to obtain advertising approval through the "electronic portal". • Fees Addition of the requirement to pay the applicable fees for (MDMA) update requests. • Approval Validity: Addition of procedures related to extension and renewal of the approval. Applicant Obligations after Obtaining SFDA Approval on Advertising Material • Amendment to item (4). Requirements for Obtaining Approval to Conduct Awareness or Charitable Campaigns Involving the Use or Display of Medical Devices • Modifying item (5) to be: Free samples shall not be distributed to participants, attendees, or the general public. Procedures and Required Documents for Obtaining Approval to Conduct Awareness or Charitable Campaigns Involving the Use or Display of Medical Devices • Addition of the requirement to attach a copy of (MDMA) certificate issued by the SFDA. • Addition of the requirement to attach a copy of the awareness materials to be used in the campaign.