MDS – REQ 8

Requirements for Advertisement Approval and Launching Awareness and Charity 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 the requirements and procedures for:

- Obtaining approval for the advertisement of medical devices.
- Obtaining approval to launch awareness and charity campaigns that include the use, display, or distribution of medical devices.

Scope

The requirements of this document shall apply to medical devices intended to be advertised and addressed to the public in the Kingdom, or to these medical devices that will be used, displayed, or distributed as part of awareness or charity campaigns. This document also applies to the following parties:

- Medical devices manufactures inside the Kingdom.
- Authorized representatives of medical devices manufactures outside the Kingdom.
- Distributors and importers of medical devices.
- Healthcare providers.
- Organizers of awareness and charity campaigns in which medical devices are used, displayed or distributed.

These requirements shall not apply to medical devices that are imported for display or training purposes only. These medical devices shall be subject to the requirements for importing and exporting medical devices published on the SFDA's website.

Background

The SFDA issued this document according to the "Medical Devices Law" issued by Royal Decree No. (M/54) dated 06/07/1442 in reference to the following: Article (24) stipulates, "Medical devices and supplies may not be advertised nor promoted without the SFDA's approval. Advertisement and promotion shall be in accordance with the conditions determined by the Regulations."- Article (25) stipulates, " "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."

Requirements

A. General Requirements for obtaining approval for medical device advertisement

SFDA's approval shall be obtained prior to publishing promotional or advertising material for medical devices, whether directed to ordinary users or health practitioners, and the following shall be adhered:

1. The advertised medical device has obtained a marketing authorization certificate.
2. Advertisements shall not contain anything that contradicts the provisions of Islamic Sharia and public decency, and must follow societal customs and values and not offend public taste.
3. The advertising material shall not contain any misleading information for the user that contradicts the manufacturer's claims. Furthermore, it shall not include any phrases that could be misconstrued.
4. Avoid misleading the layperson in advertisement materials and publications directed to the public, including information on the Internet.
5. Advertising materials and publications directed to persons concerned with the use of medical devices shall contain information compatible with their needs.
6. Medical devices sales representatives shall have sufficient information about the medical devices to ensure providing accurate marketing information.
7. The advertisements shall not directly or indirectly offend any other medical device. And it shall not include any comparisons to the products of other competing companies.
8. The language used in the advertising material shall be Arabic if it is directed to lay person, and English if it is directed to healthcare practitioners, other languages may be used provided that they match the language used in the advertising material, and take into account the needs of people with disabilities.
9. The advertisements 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, directly or indirectly, in the content of the advertisement.
11. The advertisement material should not violate the “Law of Printed Materials and Publication” issued by Royal Decree No (M/32) dated 9/3/1421 AH, as well as all other applicable laws in the Kingdom.

12. In the event of holding introductory lectures or seminars about the medical device, whether in person or remotely, visual or audio, compliance with the requirements and instructions of other relevant stakeholders is required.
13. The establishment may appoint an advertisement agency licensed by the competent authority to submit the application for advertisement approval on its behalf, provided that the authorization is certified by the Chamber of Commerce.
14. The following shall be obtained by the applicant for advertisement approval:

    14.1 The establishment number in the system.

    14.2 Medical devices establishment license.

15. 15. When an advertisement agency submits an application, the documents listed in paragraph (1.14) shall be provided to the beneficiary establishment, in addition to obtaining authorization from the abovementioned establishment.
16. 16. When the application is submitted by a healthcare provider, the establishment number must be obtained in the system.
17. 17. Advertisement materials shall include the following:

    17.1 The medical device name.

    17.2 The manufacturer's name or trademark.

    17.3 The marketing authorization certificate number (when the application is on the first track) or the advertisement approval number for the medical device (when the application is on the second track).
18. The advertisement should not contain the establishment number in the system.
19. When changing the advertised media to another of the means specified in the approval request form, additional approval is not required, provided that, adhering to the same content and approval validity remains valid.
20. In the case of a request for approval to advertise the medical device and its accessories, or more than one medical device/supply that has been combined into a single marketing authorization application, the financial fee shall be paid only once. Meanwhile, advertisement of a device accessory without the main device, the financial fee shall be paid for the application advertisement approval.
21. Manufacturers and authorized representatives shall be responsible for the following:

    21.1 Ensuring that all advertisement materials for the medical devices have been approved by the SFDA Before using them..

21.2 Providing the distributors and importers, if any, a copy of all approved advertisement materials, with identifying the intended recipient as either "lay persons" or "health practitioners."

B. Special Requirements to obtain advertisement approval on websites or social media platforms

1. Approval shall be obtained for advertisement material directed to the public in the Kingdom via the Internet or social networking sites, whether it is a Website, or a social media platform registered inside or outside the Kingdom.
2. Approval shall be obtained Individuals' advertisement materials on social media platforms must be approved.
3. The advertisement shall be available on the website itself and not through external links.
4. It is not permitted to provide information directed to health practitioner on sites dedicated for laypersons.
5. If individuals publish advertisements on social media platforms, the SFDA shall be notified via e-mail (AD.L@sfda.gov.sa) at least (12 hours) prior publishing the advertisement. The SFDA shall be provided with the advertiser's name social media account, as well as the date of publication of the advertisement
6. Responses to inquiries in advertisement material published on social media shall not include any information that has not been previously approved.
7. The script's text shall be submitted as a copy of the advertisement material for the live video or audio advertisement. The whole content of the recorded video or audio material must be submitted.
8. In the case of individual advertisement, a contract shall be concluded between the establishment and the individual advertiser via social media platforms. Each party shall keep a copy of this contract, in addition to including a copy with the documents attached to the application. The contract shall include the following:

    8.1 advertisement material content.

    8.2 The time frame for displaying advertisement materials.

    8.3 Specify a social media platform for publishing advertisement materials.

    8.4 Specify the location of the advertisement's broadcast (state-city).

    8.5 Contract duration.

Responsibilities of the applicant after obtaining advertisement approval

After obtaining approval for advertisement, the applicant shall be responsible of the following:

1. Adherence to the medical devices law and its implementing regulation, the requirements in this document, and the SFDA's relevant circulars issued or published on its website.
2. Advertisement materials shall not be used after the validity period determined in the advertisement approval letter has expired.
3. Write down the advertisement approval number or marketing authorization certificate number, in accordance to paragraph No. (17) in the "General Requirements" section.
4. Stop advertisement when new information indicates the existence of risks resulting from the use of the medical device or its ineffectiveness, or when the SFDA requests it.
5. Notify the SFDA and the manufacturer or authorized representative of the medical device or accessory that is to be advertised.
6. Bearing responsibility for the consequences of any incorrect information or allegations in advertisements, even after obtaining SFDA approval.
7. Compliance with the provisions of all applicable laws and regulations in the Kingdom.

The application process, the required documents, and the finance fee required to obtain approval for the advertisement

The application process, the required documents	Advertisement approval shall be obtained via one of the two tracks listed below: First track: The manufacturer or authorized representative provides the advertising materials one of the technical files in the request for marketing authorization. or, Second track: submitting a request for advertising approval through the following steps: **1. The application shall include the following:** 1.1 An official letter in Arabic addressed to the SFDA that includes the company's logo and seal. 1.2 A copy of the SFDA's marketing authorization certificate

	1.3 Application form for advertisement approval if directed to lay person (see Appendix 1) and if directed to health practitioners (see Appendix 2). 1.4 A copy of the advertising material. 1.5 Documents and papers proving the allegations, if advertising material includes any allegations (such as: faster, better, ratio, no harm or side effects, diagnosis, treatment, or appearance of effects and results within few seconds, minutes, or days, etc.). These supporting documents shall be valid and issued by considerable authorities. 1.6 Attach an invoice for payment of the financial fees (see Appendix 3) 1.7 If there is a request to renew or extend advertisement approval: 1.7.1 A copy of the approved advertising material 1.7.2 A copy of the advertisement approval letter that is to be renewed or extended. 1.8 In the event of holding a medical device introductory lecture or seminar to health practitioners, the application shall be submitted at least (14) days prior to the date of the lecture or seminar, with the following additional documents attached: 1.8.1 A copy of the hall reservation confirmation/ link to registration and invitation. 1.8.2 Speakers' CVs, certificates, and qualifications. 1.8.3 A copy of the speakers' national ID/Iqama/passport. * If the content is approved, it can be used for a year from the date of approval, if no changes are made to the previously approved content **2. The application shall be submitted using one of the two methods listed below:** 2.1 Submitting the application to the advertisement License Section in the Operations Sector, provided that all of the above-mentioned documents are printed and attached to a CD. 2.2 Sending the application in (PDF) format to (Communications.Adm@sfda.gov.sa) with all attachments as a single (PDF) attachment. The official letter shall be included on the first page of the file. Following the completion of the

	procedure, the applicant will be provided with the application's registration number.
Review the request	The SFDA shall review the application and verify that the requirements are fulfilled. The SFDA shall reply as follows: First track: according to the requirements and procedures for medical device marketing authorization published on the SFDA's website Second track: within (10) days. - If there are any shortfalls, the applicant will be notified of them.
Amendment to advertisement	In the event of wanting to make changes to the previously approved advertisement, one of the following two actions shall be taken: 1- Update (include changes) in the related section of the technical file for the marketing authorization request. 2- Submit an application for new advertisement approval.
Financial fees	1. If the advertising materials are submitted as one of the technical files included with the marketing authorization request: 1.1 The marketing authorization request financial fee shall be paid in accordance with the requirements of marketing authorization for medical devices (1REQ-MDS). 1.2 Fees for updating marketing authorization requests (updating promotional material) (SAR1100) shall be paid. 2. Submitted a request to obtain advertisement approval: 2.1 (SAR 3,000) Three thousand Saudi riyals shall be paid if the advertisement targets lay persons. 2.2 (SAR6, 000) Six thousand Saudi riyals will be paid if the advertisement targets health practitioners.
Approval validity	1. If the advertising material is submitted as one of the technical files in the marketing authorization request, the approval validity shall be the validity of the marketing authorization certificate. 2. When obtaining advertisement approval, the approval will be valid for (one year) from the date of the approval notice. If the establishment wishes to extend the approval for more than one year, up to a maximum of five years,

	an extension request shall be submitted along with payment of the financial fees for the entire years and attach the proof of previous approval.

Requirements for obtaining approval to hold awareness and charity campaigns to use, display, or distribution of medical devices.

Individuals who wish to organize awareness and charity campaigns involving the use, display, or distribution of medical devices shall obtain SFDA permission and meet the following conditions:

1. The medical device intended to be used, displayed, or distributed shall obtain a marketing authorization certificate issued by SFDA.
2. Awareness and educational programs shall be introduced by competent and qualified person.
3. Shall not include any marketing references or commercial advertising materials.
4. Medical devices may not be used on participants, attendees, or the general public during awareness or charitable campaigns, unless the participant or his guardian consents and signs the declaration form.
5. It is not permissible to distribute free samples to participants, attendees, or the general public for marketing purposes.
6. When the material used in the campaign targets specialist, it shall be written in English; when it targets lay persons, it shall be written in Arabic, taking into account the needs of people with disabilities.
7. Obtaining all required approvals from the competent authorities.
8. It is not permissible to donate any medical devices unless fulfilling the requirements specified in the medical devices and supplies law and its implementing regulation, as well as the requirements for Post-Market Surveillance of Medical Devices.
9. Any other conditions required by the SFAD and published on its website.

The application process and the required documents to obtain approval to launch awareness or charity campaigns that include the use, display, or distribution of medical devices

The application process and required documents	The application shall include the following: 1. An official letter addressed to the SFDA from the Organizing Authority. 2. Information about the campaign, such as the campaign's objectives, location, date of launching, and organizers. The application shall be submitted after it has been prepared using one of the two methods listed below: 1. Submitting the application to the advertisement License Section in the Operations Sector, provided that all of the above-mentioned documents are printed and attached to a CD. 2. Sending the application in (PDF) format to (Communications.Adm@sfda.gov.sa) with all documents related to the campaign attached.
Review the request	The SFDA shall review the application and verify that the requirements are fulfilled. The SFDA shall reply to the applicant within (10) days. If there are any shortfalls, the applicant will be notified of them.
Financial Fees	N/A

Annexes

Annex (1): Application form for approval of medical device advertisement directed to lay persons

Request Type		☐ New request (for an advertisement that has yet to be approved) ☐ Approval renewal (for an advertisement with expired approval) ☐ Approval extension (for advertisement with valid approval)
Establishment	Establishment Name	
	Establishment Type	☐ Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer ☐ Healthcare Provider ☐ Advertising Agency
	The Establishment number in the system	
	The Establishment license number	
Medical Device	Medical Device Name	
	Medical Device number in the National Registry included in the marketing authorization certificate	
Advertisement Type * (Only one option to be selected)		☐ Readable (still Text and/or Image) ☐ Audible (audio) ☐ Visual (video or GIF)
Advertising Media		☐ Radio ☐ TV ☐ Newspapers ☐ Magazines ☐ exhibitions Materials ☐ Search engines ☐ Social media platforms (should be specified) ○ YouTube ○ Facebook ○ Twitter ○ Snapchat ○ Instagram ☐ Other …….
Individuals' social media account names of advertisers		

	……
Pledge	1. I hereby certify that obtaining approval for advertisements does not relieve the establishment of the responsibility of ensuring that the promotional and advertising material, the medical devices, and supplies to be advertised, are compatible with the Medical Devices and Supplies Law, its Executive Regulation, and any requirements and terms issued by SFDA. 2. I have reviewed the document "Advertisement approval Requirements and launching awareness and charity campaigns for medical devices" issued by SFDA, and the requirements contained therein were met. 3. Inform the manufacturer/authorized representative of the medical device to be advertised about this request. 4. Provide distributors and importers (if any) with a copy of all promotional and advertising materials that have been approved by SFDA.

Stamp

Establishment General Manager / Deputy

Date:

Signature:

Annex (2): Application form for approval of medical device advertisement directed to healthcare practitioners

Request Type		☐ New request (for an advertisement that has yet to be approved) ☐ Approval renewal (for an advertisement with expired approval) ☐ Approval extension (for advertisement with valid approval)
Establishment	Establishment Name	
	Establishment Type	☐ Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer ☐ Healthcare Provider ☐ Advertising Agency
	The Establishment number in the system	
	The Establishment license number	
Medical Device	Medical Device Name	
	Medical Device number in the National Registry included in the marketing authorization certificate	
Advertisement Type * (Only one option to be selected)		☐ Readable (still Text and/or Image) ☐ Audible (audio) ☐ Visual (video or GIF)
Advertising Media		☐ Scientific publications ☐ Websites dedicated to healthcare practitioners ☐ Newspapers and magazines ☐ CDs or USB flash drives ☐ Email ☐ Other ……
	Address	
	Purpose	

Lecture or orientation seminar on the medical device	Location/program name or attendance link	
	Date	
	Lecturer Name	
	Note: If a lecture or orientation seminar on the medical device is held, the regulations and directions of other relevant authorities must be followed.	
Pledge	1. I hereby declare that obtaining approval for advertisements does not relieve the establishment of the responsibility of ensuring that the promotional and advertising material, as well as the medical devices and supplies to be advertised, are compatible with the Medical Devices and Supplies Law, its Executive Regulation, and any requirements and terms issued by SFDA. 2. I have reviewed the document "Advertisement approval Requirements and launching awareness and charity campaigns for medical devices" issued by SFDA, and the requirements contained therein were met. 3. Inform the manufacturer/authorized representative of the medical device to be advertised with this request. 4. Provide distributors and importers (if any) with a copy of all promotional and advertising materials that have been approved by SFDA.	

Stamp

Establishment General Manager / Deputy

Date:

Signature:

Annex (3): How to issue an invoice for the advertisement of medical devices

1. Log into the Billing System for SFDA services.
2. Go to the “issue an invoice” option.
3. Go to the "Department Name" option.
4. Select "Advertising Licensing Section".
5. Go to the "Service Type" option and select the service.
6. Fill in the "Establishment Name" field.
7. Fill in the name of the medical device.
8. Click on the "Issue an Invoice" option.

Annex (4): Definitions and abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
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.
Advertisement	Any statement, whether written, audible, visual, or otherwise, intended to promote and sell, directly or indirectly, the medical device, supply, or technology on it.
Establishment	A legal entity engaged in an activity related to medical devices and supplies
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.
Healthcare provider	Any government or private establishment that provides health care services.

Lay Person	A person who does not have formal education or training in a relevant field of healthcare or medical discipline.
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.
License	A document issued by the SFDA to engage in any of the activities subject to this Law.
National Registry	The Authority's National Registry of Medical establishment, Devices, and Supplies
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.
Establishment number in the system	The SFDA number granted to the establishment allows it to engage in activities such as importing, distributing the medical device/supply, or representing the manufacturer.
Advertisement approval number	A number issued by the SFDA in response to the approval of an advertisement for a device or medical supply obtained (via the second track procedures) from the SFDA's Advertisement License Department in the Operations Sector.

Annex (5): Version History

Number & Date of the Previous Version	Modification Description
2.1 21/06/2021	• Replace the following document: ○ Guidelines for Advertisement Approval Requirements for Medical Devices and Products (MDS-G11). • Amend the clause of "approval request to advertise more than one medical device/supply" to be as follows, “In the case of a request for approval to advertise the medical device and its accessories, or more than one medical device/supply that has been combined into a single marketing authorization application, the financial fee shall be paid only once; in the case of advertisement of a device accessory without the main device, the financial fee shall be paid for the application advertisement approval”. • Add “Organizers of awareness and charity campaigns in which medical devices and supplies are used, displayed, or distributed” to the clause of "Scope". • Add “Requirements and procedures for obtaining approval to launch awareness and charity campaigns to use, display, or distribution of medical devices and supplies”. • Incorporate General Provisions and Requirements into one clause entitled "General Requirements". • Clarify the procedures for extending advertisement approval. • Clarify the advertisement approval validity. • Update “advertisement approval request form”. • Update and amend Definitions and Abbreviations in accordance with Medical Devices and Supplies Law and its Executive Regulation.