MDS – G11

GUIDANCE ON
MEDICAL DEVICES
ADVERTISING REQUIREMENTS

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DEFINITIONS & ABBREVIATIONS

Definitions

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.
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.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Establishment	any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.
Advertising of Medical Devices	means any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.
Medical Devices National Registry (MDNR)	is the database of registered establishments and the medical devices they manufacture or import or distribute.
National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
Medical Device National Listing Number	means the code assigned by the SFDA to a single medical device, that has been included in a marketing authorization application, to indicate the device is authorized to be placed on the KSA market and facilitate traceability.

Abbreviations

SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDIR	Medical Devices Interim Regulation
MDNR	Medical Device National Registry
MDEL	Medical Devices Establishment License
MDMA	Medical Devices Marketing Authorization
MDAL	Medical Devices Advertising License
R&L	Registration & Licensing Executive Department
AR	Authorized Representative

INTRODUCTION

Purpose

The purpose of this document is to clarify **advertising requirements** of medical devices such that they comply with the requirements of the Medical Devices Interim Regulation.

Scope

This document is applicable to any medical devices**:**

- **Manufactures**.
- **ARs**.
- **Distributors**.
- **Healthcare facilities**.

Background

- **Advertising** of medical devices **means** any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.

- **Marketing material** includes, for example:
  - Product brochures.
  - Product catalogue.
  - Information on clinical performance.
  - Publications from technical magazines.

- **Advertising material** includes, for example:
  - **written material**. (e.g. newspaper, professional magazine)
  - information available on the following :
    - Internet.
    - Television.
    - Radio.
    - Exhibition materials.
    - Medical lectures and seminars.
  - **information** available **in electronic form**. (e.g. CD)

- Where advertising or marketing material is required, SFDA requires the parties in the supply chain to **submit the proposed advertising to the SFDA for approval** in order to ensure any performance or safety claims are consistent with the information provided with the original MDMA.

- Two situations apply to get **approval** of advertising and marketing material:
  - as part of MDMA procedure, the applicant is required to submit all the advertising and marketing material that will be used in the KSA.
  - separate approval (MDAL).

REQUIREMENTS

I. General Rules

General	1	Any advertising or marketing material shall be **approved** by the SFDA/MDS before its use and it shall be submitted on an **ongoing** basis not only for MDMA purposes.
	2	Any modification, **including translation**, will require a new approval.
Content of advertising and marketing material	3	The advertising and marketing material shall: ○ **not mislead** the user regarding the performance of the medical device as specified by the manufacturer. ○ **avoid misleading lay persons**, where the advertising to the general public, including on the internet. ○ include the **relevant information compatible with professional specific needs**, where the advertising to professionally qualified. ○ **include** the following: ○ name of device. ○ name and address of manufacturer. ○ **document control reference number** (it is required in case of as part of MDMA procedure). ○ **medical devices advertising license number** (it is required in case of separate approval). ○ **not include** the **SFDA logo nor** the **establishment National Registry Number,** that is issued through SFDA's **MDNR,** but may include the **Medical Device National Listing Number** issued through SFDA's **MDMA**. ○ **not** include phrases that might be misinterpreted. ○ **not** violate the Saudi law of "Printed Materials and Publication".
Language of advertising and marketing material	4	The advertising and marketing material shall be: A. in **English**, where it is intended for professionally **qualified**. B. in **Arabic**, where it is intended for **lay persons.**
Medical **sales representatives/ promoters**	5	Medical **sales representatives/promoters** shall have **sufficient knowledge** to be able to provide appropriate information about the medical devices they promote.
MDAL **Pre-requisite**	6	when the advertising and marketing material is **prepared and submitted by a distributor** or **healthcare facility** on its own behalf,

		they shall be, before it applies for an MDAL, in possession of the following: ○ establishment National Registry Number that is issued through **MDNR**. ○ **MDEL** (Healthcare facilities are **not required** to have MDEL)
	7	The **relevant medical device** shall have **Medical Device National Listing Number** that is issued through SFDA's **MDMA**.
Submitting advertising material to SFDA	8	There are **two situations for submitting** of advertising and marketing material: A. as **part of MDMA procedure**, the applicant is required to submit all the advertising and marketing material that will be used in the KSA. This situation is applicable when the advertising and marketing material: • **prepared** and **submitted** by a **local manufacturer**, or • **prepared** by an **overseas manufacturer** and **submitted** by its **AR**. B. **separate approval** , which is called MDAL. This situation is applicable when the advertising and marketing material is **prepared and submitted by a** licensed **distributor** or a registered **healthcare facility** on its own behalf. The applicant may provide the SFDA/MDS R&L at Ad.MD@sfda.gov.sa with following documents: • **application form** of medical devices advertising (see **annex 1**) • a copy of **advertising materials**. • in case of the advertising material includes any **claim** (e.g. faster, best ..etc.), applicant shall provide **valid documents** for supporting the claim. • in case of giving **a presentation** which will be used in medical lectures, seminars, or workshops, applicant shall provide a copy of the **presentation**, **hall reservation** and **speakers CVs**.
The **approval**	9	Once satisfied, A. when the advertising and marketing material is **submitted** as a part of **MDMA procedure**, the **SFDA will consider the submitted material approved once the MDMA is issued**. B. when the advertising and marketing material is **prepared and submitted by a** licensed **distributor** or a registered

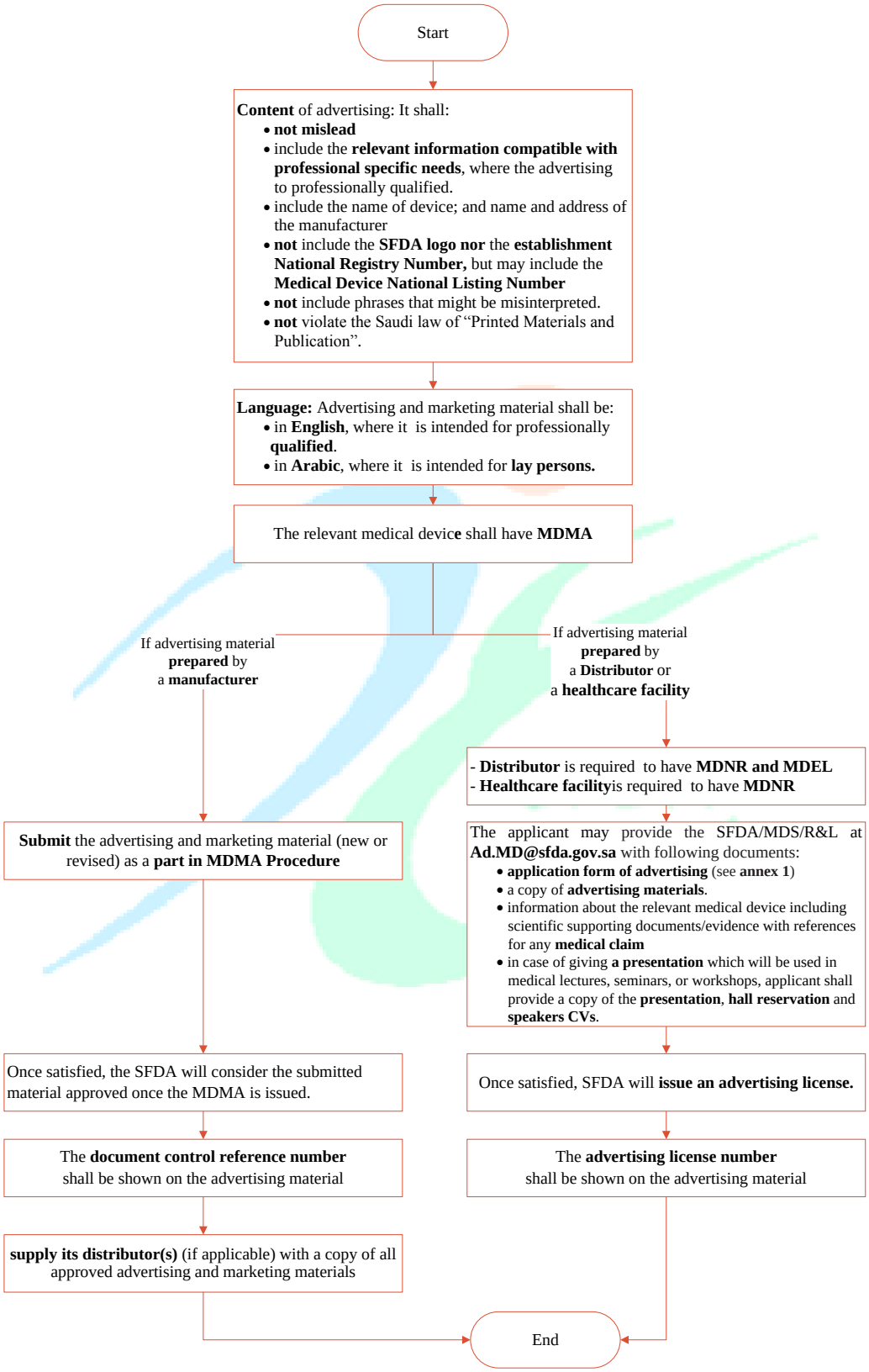
		healthcare facility on its own behalf, **SFDA will issue a medical devices advertising license** (MDAL)
Post-Marketing Responsibility	10	The manufacturers, ARs and distributers are **responsible for ensuring their medical sales representatives/promoters have sufficient knowledge** and they are able to provide appropriate information about the medical devices they promote.
	11	The manufacturer and AR: A. are **responsible for ensuring all advertising and marketing materials** (either that submitted with the MDMA, newly prepared material or revised versions of the material submitted through the MDMA) are **approved by the SFDA before they are used** by the manufacturer, its AR or its distributor(s). B. shall **supply its distributor(s)** (if applicable) **with a copy of all approved advertising and marketing materials** and indicate the following: ○ proposed recipient (e.g. nurse, pediatrician, oncologist, radiographer, biomedical engineer, lay person) ○ placement (e.g. newspaper, professional magazine, television, radio, internet) of any advertising.

II. Required Documents

	Required Documents	Sample	Note
1	Medical devices Advertising **application form**	See **Annex 1**	• Submit the application form by email to SFDA/MDS R&L at **Ad.MD@sfda.gov.sa** • Before applying for medical devices advertising license (MDAL), establishment must be in possession of the following: 1. establishment National Registry Number that is issued through **MDNR**. 2. **MDEL**(Healthcare facilities are **not required** to have MDEL) 3. **MDMA**.
2	Copy of **advertising materials**.	N/A	See (point 3 and 4/ I.General Rules/ Requirements), in this document.
3	**Supporting documents required for claims**.	N/A	• It is required **in case of** the advertising material includes any **claim** (e.g. faster, best ..etc.) • It shall be **valid**. • It shall be in **English**.
4	Copy of **hall reservation**.	N/A	• It is required **in case of** giving a **presentation**, which will be used in medical lectures, seminars, or workshops. • It shall be in **English or Arabic**.
5	**Speakers CVs**.	N/A	

Note:
In case of giving a **presentation**, which will be used in medical lectures, seminars, or workshops, **relative principality regulation shall be considered**.

III. Flowchart



ANNEXES

Annex 1

Application Form of Medical Devices Advertising

نموذج طلب ترخيص دعاية وإعلان لجهاز/منتج طبي

المنشأة	اسم المنشأة	
	نوع المنشأة	☐ موزع ☐ مقدم رعاية صحية
	رقم المنشأة بالسجل الوطني للأجهزة والمنتجات الطبية	
	رقم ترخيص المنشأة	
الجهاز/المنتج الطبي	اسم الجهاز/ المنتج الطبي	
	رقم قيد الجهاز/المنتج الطبي بالسجل الوطني للأجهزة والمنتجات الطبية (المشار إليه في الإذن بالتسويق للجهاز/المنتج الطبي ذي العلاقة)	
المتلقي المستهدف		☐ ممرضون ☐ أطباء ☐ مهندسو الأجهزة الطبية ☐ فنيون صحيون ☐ اشخاص عاديون ☐ أخرى .....
وسيلة العرض		☐ إذاعة ☐ تلفزيون ☐ إنترنت ☐ صحف ☐ مجلات مهنية ☐ مواد للمعارض ☐ أخرى .....
المحاضرة / ورشة العمل/ التدريب	العنوان	
	الغرض	
	المكان	
	التاريخ	
	المحاضرون	
	ملاحظة: في حالة اقامة محاضرات طبية أو ندوات أو ورش عمل، يراعى التقيد باشتراطات وتعليمات الإمارة ذات العلاقة.	
التعهد	نتعهد بالتالي: ١. عدم تعديل صيغة المادة الدعائية أو الإعلانية بعد الموافقة عليها. ٢. لا تحتوي الدعاية والإعلان على أي معلومات مضللة للمستخدم عن إمكانيات الأجهزة والمنتجات الطبية المحددة من قبل المصنع. ٣. تجنب التغرير بالمستخدم العادي في المواد الدعائية والإعلانية والمنشورات الموجهة للمجتمع بما في ذلك المعلومات على الشبكة العنكبوتية. ٤. أن تحتوي المواد الدعائية والإعلانية والمنشورات الموجهة للأشخاص المعنيين باستخدام الأجهزة والمنتجات الطبية على المعلومات المتوافقة مع احتياجاتهم. ٥. أن يكون لدى الأشخاص المعنيين بتسويق الأجهزة والمنتجات الطبية المعلومات الكافية عنها بما يكفل تقديم المعلومات الصحيحة الخاصة بتسويقها. ٦. إبلاغ الممثل القانوني للجهاز/المنتج الطبي المراد الاعلان عنه بهذا الطلب.	

المرفقات:

☐ نسخة من المادة الدعائية أو الإعلانية

☐ نسخة من اثبات الادعاء الطبي (في حال وجود ادعاء طبي)

☐ نسخة من المحاضرة (في حال اقامة محاضرات/ورش العمل/تدريب)

☐ السيرة الذاتية للمتحدث/المتحدثين (في حال اقامة محاضرات/ورش العمل/تدريب)

☐ حجز الفندق (في حال اقامة محاضرات/ورش العمل/تدريب)

الختم

مدير عام المنشأة/ المفوض: .....

التاريخ: .....

التوقيع: .....