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Medical Devices Advertising Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction

With reference to **Decision (48) 2020, Article (10) "**It is forbidden for any person to market or advertise the medical device and product unless obtaining a license from the Authority.
The marketing license for medical devices and products that comply with international quality and safety standards shall be valid for (12) months or until the expiry of the quality certificate of the device or product, whichever is earlier. The advertising license for medical devices and products is in accordance with international quality and safety standards, and the license is deemed to be cancelled in the event of a change of any pre-approved advertising content.**"**

Therefore, NHRA considered the importance of monitoring and controlling the advertising of medical devices to protect the general public from "false or misleading" advertisement.

This guideline is intended to clarify process and requirements of medical devices advertising for the manufacturers, importers, distributors, AR and HCF in order to comply with NHRA regulations and avoid legal issues.

2. Definitions

- **Medical Device**:

means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
3. Investigation, replacement, modification, or support of the anatomy or of a physiological process,
4. Supporting or sustaining life,
5. Control of conception,
6. Disinfection of medical devices,
7. Providing information by means of in vitro examination of specimens derived from the human body;
8. And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

- **Advertisement:**

means any words, whether written, printed, or spoken, and any illustrative representation or design, used or appearing to be used to promote the sale of medical device or the use of any method of treatment; it could be through newspaper, social media or brochures.

3. General Rules

1. All applicants should have a valid Commercial registration certificate
2. This guideline is applicable for the promotions, brochures, seminars, conferences, works shops except for educational materials (ex:training materials).
3. The Commercial registration certificate should contain one of the following activities Health care facility, marketing of medical devices.
4. Submission of advertisement request is free until now, fees may be applied later.
5. Any advertising or marketing material shall be approved by the advertising committee before its used and it shall be submitted prior to advertising or once there is a change in the previously approved advertisement.
6. Advertisement material/content should comply with advertisement committee guideline on NHRA website:
https://www.nhra.bh/Departments/HCF/MediaHandler/GenericHandler/documents/departments/HCF/Guidelines/GUIDELINES%20FOR%20ADVERTISING%20%20HEALTH%20SERVICES%20oct%2018.pdf

7. Validity of the advertisement will be as long as the details submitted to committee has not been changed.
8. Advertisement is only allowed for **registered medical devices.**
9. Any modification, including translation, will require a new approval.
10. The advertising and marketing material shall be:

- in English, where it is intended for professionally qualified persons.
- in Arabic and English, where it is intended for lay persons.

4. Misbranding and Off-Label

Misbranding occurs when advertising is false or misleading in any way. it is also applying if a label does not contain required information (refer to Labeling guideline).

NHRA enforces advertising and promotion of medical devices by reviewing labeling and intended use of medical devices.

Off-label marketing is the promotion of a medical device for a purpose other than what is stated on its label or artwork.

The consequences of promoting a product for off-label use could be significant and consider as a violation, if a company's improper off-label promotion causes a physician to prescribe a product for a non-approved use then the company has committed a violation. Violative off-label promotion could result in NHRA legal action.

5. Advertisement requirements

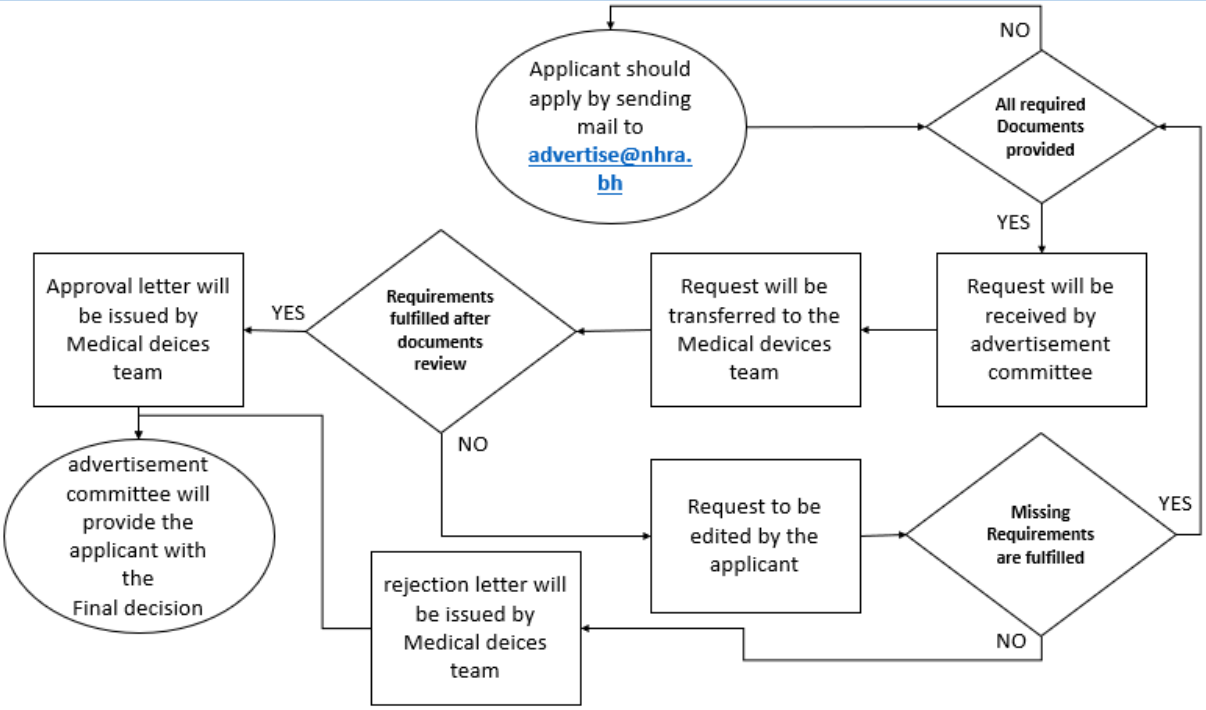
- Medical devices Advertising application form.
- Copy of advertising materials/content
- Supporting documents required for claims (artwork, label, catalogue leaflet).
- Health care facility NHRA license / Authorized Representative NHRA registration certificate.
- Advertiser valid CR.
- NHRA registration certificate.

5. How to apply

submission is done by sending the required documents by email to NHRA advertising committee at **advertise@nhra.bh** , then the request will be transferred to Medical Devices regulation team for review and approval.

If the documents are fulfilled, approval letter will be provided to the applicant by NHRA advertising committee.

6. flow chart


Applicant should apply by sending mail to advertise@nhra.bh
All required Documents provided
NO
YES
Request will be received by advertisement committee
Request will be transferred to the Medical devices team
Requirements fulfilled after documents review
YES
Approval letter will be issued by Medical deices team
NO
advertisement committee will provide the applicant with the Final decision
Request to be edited by the applicant
Missing Requirements are fulfilled
YES
NO
rejection letter will be issued by Medical deices team