Central Administration for Pharmaceutical Care

General Administration for Regulation of Marketing and Advertising Materials

Guidelines Regulating Advertising and Promotion of Medical Devices

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I. Introduction

This Guidance Document on Advertisement for Medical Devices is intended to provide guidance in ensuring good marketing practices and advertising messages which promote the quality use of medical device in a socially responsible and ethical manner. This guide states that "No person shall make any misleading claims in respect of a medical device in any advertisement.

Advertising encompasses written or spoken words, and any pictorial representation or design, used to promote the sale of medical devices, generally by highlighting the approved device claims

Medical device advertisements aim to inform and attract consumers, directly impacting sales. Therefore, ads must be ethical, avoiding exploitation, and comply with regulations ensuring accurate and reliable information.

II. Definitions

i. Advertisement & Promotion

The two terms are used interchangeably and include any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals (HCPs) or public /to promote the prescription, recommendation, supply, administration or consumption of its products through all media.

ii. Applicant of Material

The Marketing authorization holder (MAH) or the scientific office or their authorized delegates, which are responsible for advertising, promotional, educational or awareness activities and submitting the material to Egyptian Drug Authority (EDA).

iii. Medical device

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such mean.

iv. Indication for use

A general description of the disease(s) or condition(s) the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. The indications include all the labelled uses of the device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population. The indications for use are generally labelled as such, but may also be inferred from the Directions for Use.

v. Physical characters

Tangible features that define the device such as: material, shape, size, Weight, color, and other physical attributes.

III. Scope

These guidelines cover the following material types for medical devices regulated by EDA:

a. **Advertising materials**:
Advertising materials are directed at HCPs to promote the prescription, recommendation, supply, administration, or consumption of products through any media.

b. **Educational materials:**
Educational materials intended to answer a specific question about a certain medical device in a non-promotional nature,
Patient information provided by a doctor as part of prescribing treatment with a medical device. Patient information must contain only factual information of significance to the patient (and relatives) in connection with the use of a medical device. The information must not be inconsistent with the intended purpose declared by the manufacturer. Patient information will be considered as advertising if containing claims, information, images, illustrations, or the like which, wholly or mainly, serve promotional purposes.

c. **Disease awareness:**
Informative material about health and disease, provided there is no direct or indirect mention of a specific medical device (a specific product).

d. **Press releases:**
that give factual and concise details about a medical device and are generally newsworthy. A "press release" which appears as an advertisement because of subjective content, misleading information, exaggerations or strongly intrusive form, etc. will not be considered a press release. It will be considered as an advertisement for a medical device.

e. **Portfolios of the products** that display the available products
- It can contain the medical device name, indication, price, and pack shot.
- It must be secured or gated in case of products used only by HCPs

Those materials can be in the following forms:

i. **Printed:**
To be distributed or displayed E.g. Newspapers, Magazines, Booklets, Flyers and Consumer leaflets, Banners, Posters, Stands and outdoor advertising including billboards.

ii. **Electronic:**
E.g. Audiovisual media, television or radio commercials, promotional scripts for use by telephone helplines, promotional text messages SMS, E-Mail.

iii. **Online:**
Such as websites, online platforms, and social media.

Exemptions

Not every piece of information about medical devices is covered by the rules on advertising of medical devices. The following list includes examples of information that is not advertising and thus not governed by the rules of Advertising of Medical Devices.

i. Label and User's manual

ii. Necessary and specific information or documentation that serves safety purposes, and not promotional purposes, e.g., information about new risks or manufacturing defects. this information needs to be reviewed with Pharmaceutical Vigilance General Administration.

IV. General Regulatory Considerations

- The file is submitted to the General Administration for the Regulation of Marketing and Advertising Materials through the PROMAT electronic platform.

- In case of materials published on websites / platforms:

  1. The applicant of material can also submit a master file for a campaign for the same product, containing a number of claims. (<30 or 30-60)

  2. After issuance of the master file approval, the applicant of material can use the claims in different posts after notification of the venue without the need to submit a notification for each advertisement.

  3. The applicant of material will be required to submit follow-up fees according to the required duration (6-month,12 months, 24 months).

- No need to submit the scientific office license.

- The importer name must be stated in each published material.

- Publishing on E-commerce venues doesn't require submission with the commitment of the applicant of material to state only the physical characters of the medical device.

V. Timelines

1. Timeline of Printed Electronic (P/E) materials:

Requested Approval	EDA Initial response (Working days)	Company Reply (Working days)	EDA Second response (Working days)
Fast <50 pages	**6**	**30**	**4**
Fast >50 pages	**12**	**30**	**6**
Normal	**21**	**30**	**8**
Extension	**7**	**NA**	**NA**
Variation 1 & 2	**3**	**5**	**5**
Variation 3	**3**	**NA**	**NA**

2. Timeline of Online materials:

Requested Approval	EDA Initial response (Working days)	Company Reply (Working days)	EDA Second response (Working days)
New Single/Combined File (<5 slides) with UGCs responses (<20 responses)	**4**	**20**	**4**
New Single/Combined File (<5 slides) with UGCs responses (20:50 responses)	**4**	**20**	**4**
New Single/Combined File (<5 slides) with UGCs responses (>50 responses)	**6**	**20**	**4**
New Single/Combined File (5:15 slides) with UGCs responses (<20 responses)	**4**	**20**	**4**
New Single/Combined File (5:15 slides) with UGCs responses (20:50 responses)	**4**	**20**	**4**
New Single/Combined File (5:15 slides) with UGCs responses (>50 responses)	**6**	**20**	**4**
New Single/Combined File (16:50 slides) with UGCs responses (<20 responses)	**6**	**20**	**4**
New Single/Combined File (16:50 slides) with UGCs responses (20:50 responses)	**6**	**20**	**4**
New Single/Combined File (16:50 slides) with UGCs responses (>50 responses)	**6**	**20**	**4**
Master File (<30 claims)	**6**	**20**	**4**
Master File (30:60 claims)	**12**	**20**	**6**
Extension	**5**	**NA**	**NA**
Variation One	**3**	**5**	**5**
Variation Two	**3**	**5**	**5**
Variation Three	**3**	**NA**	**NA**

VI. General Requirements

i. Publication, release or any form of dissemination of advertisements on medical devices requires a "prior approval" from Egyptian drug authority.

ii. Prior approval is not required in case of brand reminders

- Brand reminders may include:
  - The medical device name
  - The medical device registration number
  - Active ingredient(s).
  - A non-promotional logo or image.
  - A company / manufacturer name or logo.
  - Dosage form
  - Quantity of package contents.
  - Price
  - Pack shots
- Brand name reminders must not include:
  - Indications or uses
  - Promotional claims including promotional tag lines and/or statements.

- In case of violating the guidelines regarding the regulations of reminders, the applicant of material will be obliged to submit reminders for previous approvals.

iii. **Advertising should:**

1. Include product name, the manufacturer, and approval number / QR code.
2. Include the following:
   a statement of the uses of the medical device, a safety statement including the appropriate precautions to be taken in the use of the device, any contra-indications to the use of the medical device.
3. Include the PV disclaimer
   "For any suspected adverse reactions report to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of the Applicant of Material". With a hyperlink or contacts of the reporting channel (15301)
   " في حالة حدوث أي اثار عكسية يرجي إبلاغ مركز اليقظة الصيدلية المصري وقسم اليقظة الخاص بالشركة "15301
4. Include the disclaimer
   "Please read the product information carefully and follow directions for use".
   يرجى قراءة المعلومات الخاصة بالمنتج واتباع التعليمات بدقة
5. Advertisements on registered "professional use only" medical devices are not allowed unless the advertisement is distributed only to HCPs.
   with some cases can be allowed for public exceptionally with specific criteria mentioned in Section ***Prohibitions / special prohibitions to PUBLIC***

iv. General principles of advertisements

General principles	Details
Truthfulness	Advertisements should: • Truthfully state the nature, quality and properties of the medical device • Not mislead in any way by ambiguity, exaggeration, omission or otherwise
Intended use	Claims made in an advertisement shall be consistent with the intended use of a medical device as approved by EDA and shall not promote a medical device outside its approved intended users or patient groups
Substantiation	All claims made in the advertisement must be substantiated with scientific evidence. The Applicant of Material must have evidence from studies, literature, journals, etc. to support any factual information and must make this evidence available to the EDA**.**
Accuracy	Recommendations relating to the use of the medical device should be accurately stated in moderate terms and should be relevant to their properties.
Indiscriminate use	Advertisements should not directly or indirectly encourage indiscriminate, unnecessary or excessive use of the medical device. Nor give the impression that the general health could deteriorate by not using the medical device
Use of scientific data	Advertisements should not exploit public ignorance by including unverifiable scientific data. Avoid the misuse of research results and unnecessary quotations from technical and scientific publications.
Fear and superstition	Advertisements should not arouse fear in the minds of the public nor should they exploit the public's superstition
Language	• Medical advertisements should be in simple to understand language and avoid confusing jargon. • Used terms should be relevant to the target audience.
Endorsements and testimonials from HCPS	Advertisements should not carry testimonials or recommendations by HCPs.

User testimonials	Testimonials featured in advertisements should reflect: • The typical experience of an average user of the medical device • The medical device's intended purpose • That testimonials based on fictitious characters are not framed to give the impression that real people are involved.
Logos, initials and trademarks	Advertisements should not make use of: • Initials, logos and/or trade service marks of any firm, company or institution without prior written permission • EDA's name and logo • The names and logos of any professional groups linked to EDA
Guaranteed	There should not be any claim or implication that the medical device is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure.
Claims of safety	There should not be any claim or implication that the medical device is safe, has no side effects and that their use will not cause harm.
Discourage from medical advice	Advertisements should not in any way discourage the public from seeking the advice of a medical professional or might lead to erroneous self-diagnosis.

VII. Prohibitions / special prohibitions to PUBLIC

a) Serious diseases

Advertising to the **general public** that claim, indicate or suggest that the medical device will prevent, alleviate or cure any of the following diseases or conditions is not allowed
Examples of serious diseases include

1. Diseases of the eye (e.g. blindness, cataract)
2. Cancer
3. Drug addiction
4. Deafness
5. Diabetes and other metabolic/endocrine diseases
6. Epilepsy or fits
7. Diseases or defects of the heart or cardiovascular disease (e.g. Hypertension)
8. Mental disorders, diseases and conditions (e.g. Insanity)
9. Kidney diseases
10. Leprosy
11. Paralysis
12. Tuberculosis
13. Menstrual disorders
14. Impotency, Frigidity or impairment of sexual function
15. Infertility
16. Conception and pregnancy
17. Miscarriage or abortion
18. Asthma
19. Chronic insomnia
20. Hernia or rupture
21. Serious infectious diseases including AIDS and HIV-related diseases

The above list is non-exhaustive and may be subject to change by the Authority

To assess whether a disease is serious, a number of factors are taken into account, specifically whether the disease would **typically require the assistance of a doctor**, cause severe pain, lead to permanent deterioration in health, confine the person to bed, lead to incapacity or could potentially shorten the person's life or reduce life quality.

b) Special medical devices intended for use by HCPs

Prohibitions the advertising of medical devices that are intended for the exclusive use of HCPs in their treatment of patients to any other than HCPs. It is a condition that the medical device according to the manufacturer is intended for the exclusive use by HCPs. This could be surgical instruments and implants intended to be used only by doctors or dentists in the course of treating their patients.

With the exception of the following:

1. Substance intended to be used for dermal filling
2. Equipment intended to be used to reduce, remove or destroy adipose tissue examples: laser/cryogenic/ultrasound
3. Lasers and Intense pulsed light (IPL) equipment, for skin resurfacing or hair removal or other skin treatment examples: Hair removal, aesthetic lasers /equipment

The previous examples can be targeted to the public with the commitment of adding:

- All important information related to the use of the product for example:
  - injection protocol, when the injection effect begins, how long the injection effect lasts,
  - side effects, and contraindications,
- The following disclaimer:

يتم استخدام المنتج فقط تحت اشراف الطبيب المعالج

VIII. Claims

- **Therapeutic claims**
  There shall not be therapeutic claims which imply the cure of any illness or disease other than from the relief of its symptoms and according to the intended use and/or indication of the device.

- **Efficacy claims**
  it would not be acceptable to imply that 90% felt better if the research is based on a higher dosage than that recommended for the medical device

- **Claims relating to ageing and premature ageing**
  Advertisements shall not suggest or imply a device will control, retard or reverse the physiological processes associated with ageing or premature ageing.

- **Claims concerning the brain, memory and concentration**
  Advertising shall not claim “improvement or enhancement of brain or memory functions”, “improving mental performance, IQ or intelligence” or “prolonging, improving or enhancing concentration”.

- **Claims relating to immunity against specific disease(s)**
  Advertisements shall not claim to provide immunity against specific diseases.

- **Claims relating to stress**
  Advertisements shall not promote the use of a particular device to prevent or reduce the stress of modern living.

- **Claims relating to performance in sports and studies**
  Advertisements shall not imply that the use of a particular device can improve performance in sports and studies

- **Claims concerning weight management**
  Advertisements for medical device indicated for weight loss, reduction or management shall have an appropriate balance between claims of device effectiveness and references to healthy diet and physical activity. There shall not be claims that a device offers quick weight loss results or physiological thermogenic (fat burning) activity. There shall be a statement in the advertisement encouraging “a well-balanced diet plan and exercise’

- **Claims related to device origin**
  There should not be over emphasis on the manufacturer or foreign country of origin in promoting the efficacy of a medical device.

- **Natural claims**

- Advertisements shall not suggest that the safety or effectiveness of a medical device is due to the fact that it is natural nor claim that a device is “natural” unless all of its components or materials are made with naturally-sourced forms
- Advertisement must not be misleading by claiming that a medical device act “naturally”

- **Device novelty claims**

  Advertisements relating to novelty of the advertised medical device shall not be misleading and the medical device must have been introduced in Egyptian market for not more than 12 months.

- **Safety claims / safety communication**

  Claims pertaining to medical device safety shall not imply that the device is not associated with or free from any side effects. Phrases such as “no side effects”, “no harmful effects”, and “no toxic or adverse effects” shall not be used

  Any statement related to safety shall be specific and based on data approved by EDA

- **Video Supers**

  - Duration: The statement related to safety should remain on screen for as long as required to ensure that it can be easily read in its entirety
  - Contrast: The type should either be a light colour over a predominantly dark background or a dark colour over a predominantly light background. Opacity should be set at 100%.

- **Audio**

  The statement related to safety should be communicated in a clear, understandable manner. The volume should be no lower than that of the main message.

- **Printed/Electronic or Online**

  Type size, font, contrast and copy placement should be sufficiently prominent for an average consumer to read and comprehend

- **Use of asterisks to qualify claims**

  Asterisks may be used to qualify or expand claims that are in essence correct. Asterisks must not be used to contradict claims that would otherwise be false or misleading. Qualifying statements should be positioned close to the original claim.

- **Guarantees**

  A ‘guarantee’ means that the product will work for 100% of the population, 100% of the time. For example, 'gets rid of pain' implies that the pain will cease as a result of the product being taken and hence it is a guarantee

  Examples listed below are not guarantees, and are therefore likely to be acceptable under this rule:

  claims which are preceded by ‘can’, ‘may’ or ‘helps’, for example:

  - 'can' (e.g. ‘can get rid of pain’)
  - 'may' (e.g. ‘may relieve your symptoms for 24 hours’)
  - 'helps' (e.g. ‘helps get rid of pain’)

  claims such as ‘relieves’ or ‘soothes’, (e.g. ‘relieves pain’). Although these claims indicate an improvement in symptoms, they do not imply that the symptoms will be completely resolved.

- **Government / EDA Approval**

➢ Any representation that states or implies endorsement, approval or recommendation by EDA is prohibited

➢ claim that “Product X is authorized for sale by EDA” is acceptable, as is the inclusion of the registration/approval numbers

- **Comparative claims**

  It is acceptable to make comparative statements, provided they are balanced and fair, **supportable** and do not refer to an identifiable product.

  Advertising shall not denigrate or discredit, either directly or by implication, a competitor product

- **‘Before’ and ‘after’ claims**

  if claims “after” and “before” are made, the advertiser should state the details clearly and fairly and do not mislead consumers. All claims shall not depict a more serious or exaggerated condition.

IX. Contraceptive Devices

- Contraceptive devices, other than intrauterine devices, may be advertised to the general public.
- Male and female condoms may be advertised to the general public for the purpose of preventing the transmission of sexually transmitted diseases if the label of the condom claim that it reduces the risk of transmitting sexually transmitted diseases.

This is an exemption from the prohibition.

X. Advertising of dental care products

- It is permitted in advertisements for dental care products to indicate that using the dental care products may prevent

  1) dental plaque, 2) caries (dental cavities), 3) gingivitis (inflammation of the gums) and 4) periodontitis (inflammation of the tissues surrounding the teeth).

This is an exemption from the prohibition.

The applicant of material shall provide evidence to support the information to EDA.

XI. Availability Ads

- It is submitted as promotional material
- It must be supported by evidence of availability
- In case of distributors: it must be supported by evidence of distribution.
- **It must include**
  - MD name
  - The applicant of material name
  - Availability claim
  - Importer name
  - EDA approval details & QR code (as mentioned in general requirements)
- **It can include**
  - Applicant of material logo
  - Quantity of the package
  - Price
  - Pack picture (if it doesn't contain claim)
    if the pack picture contains claims/ indications, it can be permitted in venues directed only to HCPs e.g., pharmacy invoices
  - In case of distributors: The distributor's name, Telephone no. & mobile app or website to order

- **It must NOT include**
  - Any promotional / claim or picture
  - The claim "available in ALL pharmacies/stores"

XII. Specific population

A. Pregnant or lactating women

Advertisements shall not suggest or recommend any medical device, for use by pregnant or lactating women unless the device is complying with the intended purpose(s) and/or indication(s) of a device as approved by EDA

All such advertisements shall encourage a cautious approach before use and include a statement that women should consult their healthcare professional before use.

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B. Children

Due to their lack of experience, Advertisements for medical devices must not be directed exclusively or principally at children e.g., on a website for children or in a children's magazine.

C. Elderly

Advertisements for medical devices used by the elderly shall have a statement that regular supervision by HCPs is encouraged.

"استشر طبيبك قبل الاستخدام"

D. People with disabilities

Images depicting people with disabilities handling the medical devices shall not be over emphasized, and such advertisements are encouraged to mention the need to seek health professional advice and supervision to ensure proper device use.

"استشر طبيبك قبل الاستخدام"

XIII. Dosage forms registered as medical devices

- examples: Lubricating, sprays, gels, creams …

- Refer to Nonprescription medicine guidelines

XIV. Online Advertisements

- Refer to Guidelines for Online Promotional, Educational and Awareness Materials Activities
- All rules applied to materials targeted to HCPs or public should be applied in case of medical device materials "when applicable"

XV. Printed /Electronic Advertisements

- All rules applied to Printed & Electronic materials should be applied in case of medical device materials.

XVI. References

(1) https://www.bakermckenzie.com/-/media/files/insight/publications/2016/01/promoting-medical-devices-globally/pmpg_china.pdf?la=en
(2) https://laegemiddelstyrelsen.dk/en/devices/registration-and-marketing/marketing-and-advertising/~/media/C3E28514CC994543A8EF6DBBCD6D3C79.ashx
(3) https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part7_Advertising_of_therapeutic_products.pdf
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(15) EDA Online guidelines
(16) EDA Non-prescription medicines guidelines
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