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1. UAE Rule book: sources to consider

Main sources in relation to traditional promotional practices

• Federal Law No 5 of 1980 on the prints and publications
• Cabinet Resolution No 7 of 2007 on health advertisement regulations
• Ministerial Resolution 430 of 2007 on health advertisement regulations
• Federal Law No 7 of 1975 concerning the practicing the profession of Human Medicine
• MOH Code of Ethical Practices for the Promotion and Distribution of Medical Products of November 2017
• Mecomed Code of Ethical Business Practices 2017

→ overlap in regulations
2. Health Advertisements and MOH approval process

Ministerial Resolution 430 of 2007 on **health advertisement regulations**:

**Advertisement for Medical Device:**
- only allowed if medical device is authorised for circulation in UAE

**Medical devices not subject to registration:**
- classification certificate/FDA approval-CE certificate
- subject to criteria
- requires prior approval from MOH – process
2. Health Advertisements - Definition

What is a health advertisement?

Definition advertisement in Ministerial Resolution 430 of 2007 on health advertisement regulations:

“Any information about the medical product in written, photographic and broadcasting form of a design, in the form of a product packaging in any of the media whether audio, visual and printed, in the form of posters in public places or in promotional form through the means of personal, technical or electronic messages communication.”

- very broad definition
- promotional aspect?
- Practice: what is a health advertisement? Examples
- Internal process: set of criteria, pos/neg list, case assessment, deviation records, functional involvement
2. Health Advertisements

Criteria to be met for Health Advertisements:

1. The Advertisement shall not constitute a violation of the laws and regulations applicable in the State in general and more particularly the laws on prints and publications, on practicing the profession of human medicine, on the practice of non-physicians and non-pharmacists to certain medical professions, the law on practicing the profession of pharmacy and pharmaceutical institutions and the law of private health care institutions herein referred to in this Regulations.
2. The Advertisement shall include only correct and balanced announcements.
3. The Advertisement shall not cause any prejudice to UAE customs or Islamic values.
4. The Advertisement shall not include whatsoever harm towards third parties' products or facilities.
5. The Advertisement shall not include exaggeration and alarming expressions such as: "unique - incomparable - unprecedented - best product - beware of imitations - etc."
6. The Advertisement's announcement shall not use mislead expressions such as "very limited quantity - seize the opportunity" and such other similar expressions.
7. The Advertisement shall not hurt the public moral.
8. The Advertisement shall not include matters misleading public opinion. The content thereof shall be genuine and sincere without implying any construction or interpretation.
9. The Advertisement shall not include incitement for non-guaranteed and non-genuine expectations concerning the product's effectiveness.
10. The Advertisement shall not lead to inappropriate auto-diagnosis or treatments of possible consumers' serious diseases.
11. The Advertisement shall not mislead directly, or by means of indication, confirmation, comparisons, contradictions, or omissions.
12. The Advertisement shall not misuse the consumers' confidence, use their knowledge, or contain a language that could cause fright or adversity.
13. The Advertisement shall not contain any matter that could make persons believing that they are suffering from serious diseases, or that harmful consequences could result from unused medical products. Sun protection preparations, if the Advertisement's claims comply with actual health messages, are excluded herefrom.
14. The Advertisement shall not warn of or harm to a substitute product for the product advertised health unauthorized state.
15. The Advertisement shall not encourage inappropriate or excessive consumption.
16. The Advertisement shall not contain whatsoever pretense, announcement, or indication stating that the products' success is definite, veracious, magic, miraculous, or are a certain, guaranteed, and confirmed treatment.
17. The Advertisement shall not contain any pretense, announcement, or indication stating that the products are safe, and using thereof shall not cause any harm, or do not bear side effects.
2. Health Advertisements

Criteria to be met for Health Advertisements:

18. The Advertisement shall not aim at minors.
19. Advertisements shall not present any personal motivation in favor of any pharmacist assistant, or such other retailer not specialized in health care, to recommend or import pharmaceutical products.
20. Any scientific information shall be presented in an accurate, well-balanced and non fallacious fashion.
21. The scientific terms used must be appropriate, correctly informative and easily understandable by the targeted public. The publication of a research result shall comprise the identity of the researcher and the financial sponsor of the research.
22. Comparative Advertisements must be well balanced and not misleading whether with regard to the pharmaceutical products advertised for, the medical products or categories of medical products with which they are compared. The points of comparison shall be real and reflect the scientific proof. The comparisons shall not prove that the other medical products or categories of medical products are harmful or ineffective.
23. The Advertisements may refer to the sponsorship of any party provided that such party is practicing a medical activity and provided the advertiser produces the explicit approval of such sponsoring party.
24. The Advertisements may comprise an authentication by experts in medical care in their professional capacity, or by approved medical entity in the country provided that the advertiser produces a written consent on the authentication.
25. The evidences and certificates must be authenticated and true, not misleading, explaining the typical cases only and not obtained through illegal means.
26. The Advertisement shall not comprise any sampling (except for the medical apparatus and sun preventing preparations).
2. Health Advertisements

Criteria to be met for Health Advertisements:

27. All Advertisements shall be characterized with the following:
   • Credibility: the Advertisements shall show the nature, quality and properties of the medical products.
   • Evidence: all claims contained in the Advertisement shall be proved and sustained with scientific studies.
   • Accuracy: the recommendations relating to the use of the medical products shall be mentioned with accuracy in moderate terms and must be pertinent.
   • Comparative advertising: the recommendations shall not include comparisons with medical products or related products unless scientifically substantiated.
   • Non-distinguishing use: Advertisements shall not encourage - directly or indirectly - the non-distinguishing, non-indispensable or excessive use of medical products.
   • Use of scientific data: the Advertisements shall not exploit the ignorance of the public by introducing scientific data that are difficult to be verified by the public.
   • Fear and superstitions: Advertisements shall not give rise to fear in the minds of the public.
   • Language: the medical Advertisements shall be made in an accessible and easily understood language and avoid the difficult medical jargon.
   • Research results shall not be misused through the use of excerpts not revealing other realities or the use of adaptations from the technical and scientific bulletin.
   • Advertisers shall refrain from using jargons and irrelevant scientific matters in claims seeming to have a scientific basis in contradiction with the reality.
   • Refunding the price: Advertisements shall not contain any offer to refund the price to non-satisfied customers.
   • Trial use: Advertisements shall not propose any trial use of the medical products.
   • Pregnant women or breast-feeding mother: Advertisements shall not propose any medical products.
   • Certificates issued by non specialists: such certificates are not authorized in general.
   • Logos, initials and trademarks: the Advertisement shall not contain the logo, initials or trademark of any party unless authorized in writing by such party.
   • Normal way of life: advertisers must not give the impression that the normal way of life needs the use or consumption of a medical product in particular.
   • Stress: Advertisers shall not claim that the use of a medical product in particular is necessary to relieve modern life stress.
   • Sportive and educational performances: Advertisements shall not claim that the use of a medical product in particular helps improving sportive and educational performances.
   • Recovery: Advertisements shall not comprise any words, expressions or explanations claiming the recovery from any illness except palliating the pain of the symptoms thereof.

Criteria also set forth in other sources including Federal Law No 5 of 1980 on the prints and publications (more general) and MOH Code of Ethical Practices for the Promotion and Distribution of Medical Products of November 2017 (some further clarifications included around concepts such as not misleading and taking into account evidence)
2. Health Advertisements – licensing process

Process for obtaining license for Health Advertisement:

- **Competent authority**: UAE MOH - Regulation, Licensing and Advertisement Department

- **Application** is online and needs prior registration of the applicant

- **Document requirements** depend on the type of Health Advertisement: typically for medical device: copy of advertisement material, MOH registration certificate for the product, classification certificate for products not subject to registration requirement and copy of CE certificate or approval in country of origin, customs clearance certificate
2. Health Advertisements – licensing process

Process for obtaining license for Health Advertisement:

- **Process steps:**
- **Timeline:** 1-3 working days
- **Application fee:**
  - ✓ Dependent on type of applicant, type of advertisement; and validity period
  - ✓ Each language version triggers separate fee
- **Right to suspend/deregister license**
  under specific circumstances

### Procedures and steps

1. Customer will register (for the first time) in the advertising licensing services program.
2. Customer will log into the service; fill out the electronic form and attach the required documents.
3. Customer will pay the application nonrefundable fees.
4. The concerned officer will examine the advertisement and related documents.
5. Concerned officer either to approve the advertisement, request making amendments or attach required documents.
6. Upon approving the advertisement:
7. Customer will pay the fees electronically or through Customers’ Happiness Centers.
8. Customer will print the advertising design indicating MOHAP approval and the license issuance and expiry dates.
2. Health Advertisements – Non-compliance

- Increased “later approval” fees and possibly additional “modification” fees
- Deregistration/suspension license (e.g. wrong documents submitted)
- Investigation by MOH and possible referral for criminal prosecution
- Fine: not less than 1,000 and not more than 5,000 AED unless more severe sanction based on another law
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

MARKETING AUTHORIZATION AND APPROVED LABELING:

• A medical product must not be promoted in UAE prior to the grant of the marketing authorization allowing its sale or supply in the country
• A medical product must not be promoted outside of its approved indications
• All advertising and promotional materials must be in accordance with the approved labeling.
• This provision is not intended to restrict a proper non promotional scientific exchange of appropriate technical information concerning a medical product non authorized in the UAE, including information on investigational findings, in a scientific setting or at medical conferences.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTIONAL MATERIALS - INFORMATION TO BE MADE AVAILABLE:

• Promotional materials and advertisements, whether printed or electronic materials including audiovisual materials, must include the essential product information, in consistency with the approved insert leaflet, including:
  1) Brand name and name of active ingredient
  2) Name of the marketing authorization holder in UAE
  3) A scientific reference to be cited in case of medical claim
  4) Summary or short prescribing information: approved indications, dosage, administration, special precautions, contraindications and side effects.

• In the case of a reminder advertisement, which is a short advertisement containing the name of the product; the abbreviated prescribing information (referred to in article 2.1) can be omitted.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTION AND ITS SUBSTANTIATION:

Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medical product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTION AND ITS SUBSTANTIATION:

For example:

1) The results of a study, which are contradicted or questioned by another scientifically valid and clinically relevant study, may not be cited without qualifications;
2) A study should not be cited or presented in such a way that it could convey an incorrect or misleading impression of the nature, scope, results, implementation or importance of the study;
3) A study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical relevance of the investigation and its application in humans;
4) The report of such a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents and relevance of the report and the conclusions stated therein;
5) Statements of comparisons between different drugs or alternative treatments should be expressed in such a way as to make the statistical validity and clinical relevance clear; all comparisons must be scientifically appropriate and balanced;
6) Particular care should be taken that essential information regarding medical products’ safety, for example, contra-indications, precautions, and side effects, is appropriately and consistently communicated.
7) The words “safe” or “effective” should not be used without qualification.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTION AND ITS SUBSTANTIATION:

• Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from healthcare professionals.

• Promotion must encourage the rational use of medical products by presenting them objectively and without exaggerating their properties.

• When promotion refers to published studies, clear references should be given. Clinical data referenced to unpublished company sources should specify: “Data on file and available upon request.” Sufficient information to permit evaluation of referenced data must be made available to recipients of promotional communications either as an integral part of the promotional communication, as a reference to a published report, or upon request.

• Any comparison made between different medical products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTION AND ITS SUBSTANTIATION:

• All artwork, including graphs, illustrations, photographs and tables taken from published studies and included in promotional material should:

  1) Clearly indicate the precise source(s) of the artwork; and
  2) Be authentically reproduced; except where adaptation or modification is required, it must be clearly stated that the artwork has been adapted and/or modified.

• Particular care must be taken to ensure that artwork included in promotion does not mislead about the nature of the product or mislead about a claim or comparison.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

PROMOTION AND ITS SUBSTANTIATION:

Use of quotations in promotion:

1) Quotation from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

2) Quotations from medical literature or from personal communications associated with medical literature shall not change or distort in any way the intended meaning of the author, clinical investigator or the significance of the underlying work or study.
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

Requirements for distribution of promotion:

• should be in line with healthcare facilities approved policies, whenever in place
• only directed to those whose need for and interest in the particular information can be reasonably assumed
• Data privacy of HCPs should be observed and their data not shared
• Use of fax, emails, automated calling systems, text messages and other electronic communication tools for promotion require prior consent or request of HCP
• Full contact lists to be kept up to date but deletion request HCP to be respected
3. UAE Code of Ethical Practices for promotion and distribution of Medical Products

**Transparency of promotion:**

- Programs shall not disguise or misrepresent their true promotional intent. Examples include market research studies and programs intended to promote a specific product.
- Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter or be disguised as news or a third party report.
- Material relating to medicines and their uses which is sponsored by a company must clearly indicate that it has been sponsored by that company.
- Promotional material must not include any reference to registration authorities, unless the licensing authority specifically approves this.
- Market research results should not be used in promotion. For the purposes of this Code, “market research” is any collection and analysis of information that is generated by non-scientific means and thereby not presentable in a medical or scientific forum or acceptable for use for medical or scientific purposes.
- Medical products companies must ensure the transparency and adequacy of product information used in promotional materials.