DRAFT FOR COMMENTS:

Guideline on Advertising of Medicines

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Guideline on Advertising of Medicines

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Acronyms:

DSC	Drug Safety Center
GSL	General Sale List
ADM	Advertisement of Medicines
MD	Ministerial Decision
OTC	Over-the-Counter
PL	Patient Leaflet
PLD	Pharmaceutical Licensing Department
PV&DID	Pharmacovigilance and Drug Information Department
SmPC	Summary of Product Characteristics
SO	Scientific Office
PE	Pharmaceutical Establishment

Definitions

Authorization	The official approval issued by the Drug Safety Center for Advertising of Medicine.
General Sale List	Medicines approved for sale in retail outlets (e.g., supermarkets, convenience stores), listed in Annex 2 of the MD No. 198/2023
Medicine	A substance or combination of substances used for diagnosing, preventing or treating disease in humans or animals.
Advertising of Medicine	Any written, audible, visual, or other material intended to advertise or providing information about a medicine, whether directly or indirectly.
Minister	Minister of Health
Over-the-Counter	Medicines allowed to be dispensed by pharmacies without a medical prescription. These are listed in Annex 1 of the MD No. 198/2025.

CHAPTER ONE

Introduction

Advertising of Medicine significantly influences public health and consumer behaviour. Recognizing that medicines possess both therapeutic benefits and risks, advertising must consistently uphold the highest standards of ethics, accuracy, balance, and scientific justification.

Legal basis

- Article (23) of the "Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments", issued by the Royal Decree No. 35/2015, states "It is prohibited for any person to advertise or introduce a medicine except after obtaining an authorization for that purpose from the Drug Safety Center (DSC), in accordance with the terms and procedures specified by a Ministerial Decision."

- Ministerial Decision No. 135/2025: Defines the terms and procedures governing ADM.

Purpose

The aim of this guide is to clarify requirements for ADM, ensuring accuracy, safety, ethical integrity, and regulatory compliance.

Scope

This guideline applies to ADM of human medicines, herbal medicines, health products, OTC and GSL.

Structure

This is the first version of this guideline, and it consists of four chapters. CHAPTER ONE covers introduction to the guideline as well as its purpose, scope and structure. CHAPTER TWO covers the procedure. CHAPTER THREE covers the responsibilities. CHAPTER FOUR comprises of the document version control, followed by references and annexes.

CHAPTER TWO

2.1 Pharmaceutical Establishments (PEs) Licensed to Conduct Advertising of Medicines (ADM)

2.1.1 The following pharmaceutical establishments are required to obtain a license from the DSC prior to engaging in the ADM:

- Pharmaceutical companies (PCs)
- Local agents (LAs)
- Pharmaceutical Consultancy Offices (PCOs)

2.1.2 **Scientific Offices – Exemption from Licensing**

- Scientific Offices are permitted to conduct ADM activities without obtaining a license. This exemption is based on their legally defined role to:
  - Provide technical information on medicines currently registered and marketed in the Sultanate.
  - Ensure the accuracy and consistency of all promotional materials with the information approved by the Ministry of Health (MOH).
  - Support scientific activities related to registered medicines within the Sultanate.

- Scientific Office Requirements for ADM:
  - Submit prior notification to the DSC via the MOH e-Portal (Submission Type: *AD Notification by SO*) before initiating any ADM activity.
  - Adhere fully to the provisions of the **Omani Medicines Promotion Code.**

2.2 Licensing Requirement for ADM

2.2.1 **Medicine Registration**

- The medicine must be **registered** with the DSC.

2.2.2 **Consistency with approved SmPC & PL**

- ADM content **must be consistent** with the Summary of Product Characteristics (SmPC) and Patient Leaflet (PL).

2.2.3 **Target Audience Specification**

- The ADM must **clearly define the intended audience**, such as patients, healthcare professionals, or the general public.

2.2.4 **Compliance with Public Morality & Health Safety**

- The content **must not violate public order or decency (e.g.** obscene or indecent visuals**).**
- The content should not include any materials likely to **harm public health (e.g.** encouraging off-label use**,** downplaying risks or overstating benefits).

2.2.5 **No Misleading or Comparative Claims**

- The advertisement must **not contain misleading information,** unsubstantiated claims, or exaggerations (e.g. using terms like “best,” “most effective,” or “quicker”).

- It must also **avoid disparaging comparisons** with other medicines (e.g. claimed a branded medication was more effective than its generic equivalents

2.2.6 **Other Additional Conditions**

- The advertisement **should include** the **brand name** and the **active ingredient(s)** name.
- The name or logo of the MOH or DSC must not be used, directly or indirectly, in the advertisement or the introduction content, nor any name or logo of another internal or external regulatory body.
- The granted approval issued by the DSC does not exempt one from obtaining necessary approvals from other competent authorities in accordance with what is legally required.

- The following activities are not considered advertisements:

  - Reference material, factual informative statements or announcements, and price lists, provided that they do not make a medicinal claim.
  - Information relating to human health or diseases where there is no reference to medicines.
  - Correspondence, possibly accompanied by material of a non-advertisement nature, to answer a specific unsolicited question about a medicine.

2.3 Procedures for Obtaining an ADM License

2.3.1 The applicant must submit a request for an ADM license through the MOH e- portal.

2.3.2 Upon successful submission, an automated confirmation of receipt will be issued by the DSC via the e-portal.

2.3.3 The licensing process includes the following steps:

- The applicant is required to complete the designated online form and submit it electronically through the MOH e-portal.
- The following supporting documents must be uploaded through the portal:
  - A copy of the ADM intended for the medicine.
  - A valid copy of the medicine's registration certificate.
  - Proof of payment of the applicable fee.
  - Any additional documents or data may be requested by the DSC.

2.4 Review and Follow-Up

2.4.1 The Drug Safety Center (DSC) shall assess the ADM license application and issue a decision within **60 days** from the date of complete submission. A complete submission is defined as the receipt of all required documents and information as specified in Section 2.3.3. In the event no decision is issued within the prescribed period, the request shall be deemed rejected by default.

2.4.2 In cases where the submission is incomplete or deficient, the applicant shall be formally notified of the missing elements. A maximum period of **30 days** from the date

of notification shall be granted for the applicant to provide the outstanding information. Failure to comply within this timeframe shall result in the cancellation of the application without further notice.

2.4.3 Applicants whose requests have been rejected may reapply by submitting a new ADM license application after a minimum of **30 days** from the date of rejection.

2.5 ADM License Validity and Renewal

2.5.1 The initial ADM license shall be valid for a period of **three (3) months** from the date of issuance. The license may be renewed for successive periods of the same duration, subject to DSC approval.

2.5.2 To initiate a renewal, the applicant shall submit a renewal request to the DSC no later than **twenty (20) days** prior to the expiration of the current license.

2.5.3 Renewal applications shall be reviewed and approved under the same terms, conditions, and procedures applicable to the original ADM license.

2.6 Applicant's Responsibilities

When applying for or using an ADM license, the license holder shall:

1. **Include the License Number**
   - Ensure that the approved license number is clearly displayed on all ADM materials.
2. **Use the Approved Format**
   - All content must strictly adhere to the format and wording as approved by the DSC. Any deviation is prohibited.
3. **Avoid Unauthorized Modifications**
   - No part of the approved ADM content may be modified after licensing without prior written approval from the DSC.
4. **ADM shall be restricted to pharmacists**
   - **Only pharmacists** are permitted to appear in ADM related to the medicines.
   - Influencers (including social media personalities, celebrities, or patient advocates) shall not be featured in any ADM activity.

5. **Follow Approved Publication Channels**

- *Over-the-Counter (OTC) and General Sales List (GSL) medicines:*

- May be advertised to both the public and healthcare professionals.

- *Prescription-Only Medicines (POM):*

- May only be advertised in scientific journals, at medical conferences, or during direct interactions with pharmacists, their assistants, or licensed healthcare professionals.

2.7 Right to Appeal

2.7.1 An appeal may be submitted to the Minister of Health against any decision issued by the DSC within **sixty (60) days** from the date on which the applicant was officially notified of the license refusal.

2.7.2 The appeal must be decided upon within **thirty (30) days** from the date of its submission; If no decision is made within this period, the appeal shall be deemed rejected by default.

2.8 Suspension of the ADM License

2.8.1 The DSC may suspend an ADM license if new evidence emerges indicating:

- A risk to public health or safety associated with the licensed medicine.
- Lack of therapeutic efficacy of the medicine being advertised or introduced.

2.9 Handling of Violations

2.9.1 **Role of the Pharmaceutical Licensing Department (PLD)**

- The Pharmaceutical Licensing Department within the DSC shall oversee compliance with ADM license conditions and implement enforcement measures as follows:

a) Monitoring and Media Surveillance

- The PLD shall monitor all forms of media to detect unauthorized ADM content or violations of license terms.

- Any advertisement activity conducted without a valid ADM license or in breach of approved conditions shall be documented and addressed.

b) Inspection Visits

- The PLD shall conduct inspection visits to licensed pharmaceutical establishments.
- If a violation of ADM license conditions is identified, the case shall be formally documented and referred to the Pharmaceutical Violations Committee for further action.

2.9.2 Pharmaceutical Violations Committee

- Violations of the provisions outlined in Ministerial Decision No. 135/2025 shall be subject to the penalties stipulated in Chapter 6 of Royal Decree No. 35/2015 concerning the regulation of pharmacy practice and pharmaceutical establishments.

CHAPTER THREE

Responsibilities:

Pharmaceutical Licensing Department (PLD): Responsible for overseeing the submission, evaluation, and issuance of ADM licenses in accordance with the requirements of Ministerial Decision No. 135/2025.

- **Drug Control Department (DCD):**
  Responsible for managing the registration and clearance of medicines that are subject to ADM licensing.
- **Pharmacovigilance and Drug Information Department (PV&DID):**
  Responsible for ensuring that the information provided to the public and the HCPs is accurate by verifying that the information matches the PLI and the SmPC.
- **Stakeholders** (Pharmaceutical Companies, local Agents, pharmaceutical consultant offices and Scientific Offices):
  Responsible for ensuring that all ADM activities are conducted in full compliance with the provisions of Ministerial Decision No. 135/2025 and this guideline, including obtaining the required licenses and adhering to approved formats and conditions.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2025

References:

The Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments issued by Royal Decree No. 35/2015.

The Executive Regulations of the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments issued by Ministerial Decision No. 113/2020.

Ministerial Decision No. 135/2025 regarding the conditions and procedures for advertising or introducing of medicines

Department of Health – Abu Dhabi (2019) *Abu Dhabi Decision No. 37/2019 on the Regulation of Health Information and Advertising*, issued 18 August 2019.

Egyptian Drug Authority (2015) *Guidelines Regulating Advertising and Promotion of Non-prescription Medicines in Egypt*. Cairo: EDA.

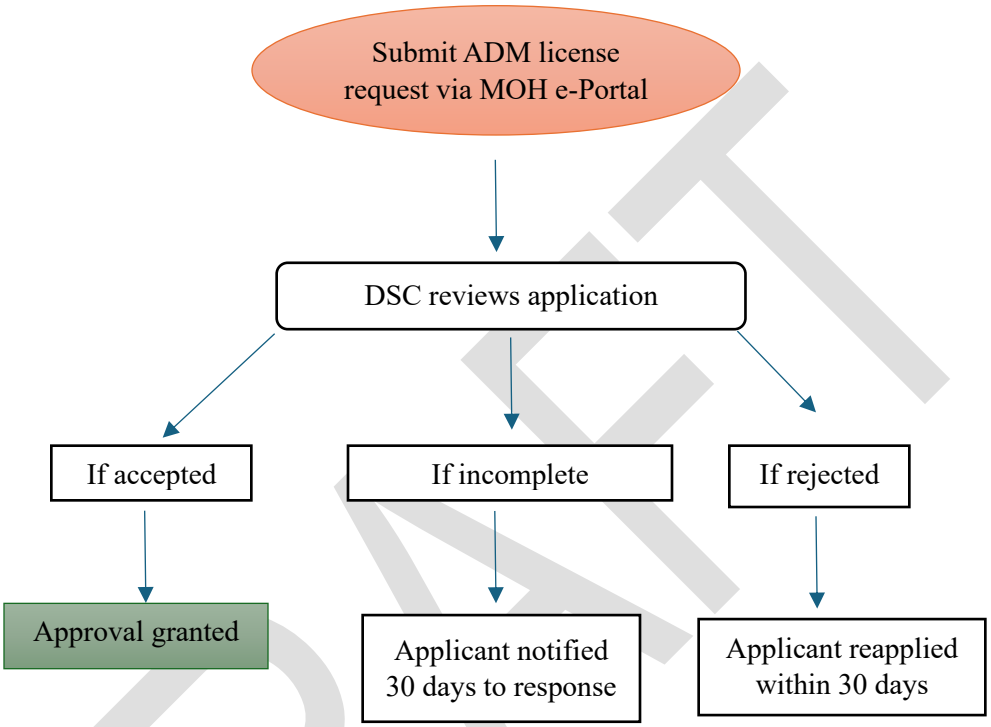
Medicines and Healthcare products Regulatory Agency (MHRA) (2020) *The Blue Guide: Advertising and Promotion of Medicines in the UK*. 3rd ed., 3rd revision, November 2020. London: MHRA.

Saudi Food and Drug Authority (SFDA) (2021) *Regulations and Procedures for Approving Advertisements for Non-Prescription and Herbal Products*. Riyadh: SFDA.

World Health Organization (1988) *Ethical Criteria for Medicinal Drug Promotion*. Geneva: WHO.

Annex

Appendix 1: Application for ADM Process Flow Chart



Appendix 2: Consumer-Directed Advertising of Medicine

Applicant Responsibilities	1. Comply with the provisions of **Royal Decree No. 35/2015** regulating the practice of the pharmacy profession and pharmaceutical establishments, its executive regulations, and all relevant ministerial decisions. 2. Adhere fully to the **terms, conditions, and procedures** outlined in **Ministerial Decision No. 135/2025** and this guideline.
Scope of Application	1. Over-the-Counter (OTC) Medicines 2. General Sales List (GSL) Medicines
ADM content and presentation requirements	1. **Mandatory Warning Statements:** All ADM materials (visual or audible) must include the following clearly legible warning statements: ▪ "These medicines may have side effects; please consult a doctor or pharmacist and read the patient leaflet." ▪ A **Call for Reporting** message encouraging the public to report any suspected adverse reactions, along with instructions or contact details for reporting to the Pharmacovigilance and Drug Information Department (PV&DID). ▪ For audible ads, the warning statements must be clearly spoken during the advertisement. 2. **Awareness Messages:** Where applicable, awareness statements must be included: ▪ "This medicine does not replace natural sources of vitamins." *(for vitamin products)* ▪ "Dietary supplements are not a substitute for a balanced diet and healthy lifestyle." *(for dietary supplements)* ▪ "If symptoms persist for more than 48 hours, please consult a doctor or pharmacist." *(for pain relievers).*

	3. **Font and Visibility Requirements:** Warning and awareness messages must be displayed in a font not less than one-third the size of the largest font used in the advertisement. 4. **Language Requirements:** The ADM text must be in standard formal Arabic. Any colloquial terms or healthcare-related terminology must be accurate and culturally appropriate. 5. **Multilingual Content:** ADMs may be presented in English or other languages, provided the content is consistent with the approved Arabic version. No additional fees are required for multilingual submissions. 6. **Multiple medicines in One Advertisement:** If an ADM includes more than one medicine, a separate licensing fee must be paid for each medicine that holds a unique registration number with the DSC. 7. **Form Completion:** Applicants must complete all sections of the ADM license application form without omissions.

Internet and Social Media Advertising Controls	1. All online ADM content must comply with the provisions of **MD No. 135/2025** and this guideline. 2. **Pre-approval is required** for any ADM published on websites or social media platforms targeting the public in the Sultanate, even if the content is hosted outside the country. 3. ADM must only appear on the **approved website or platform**. Any external links or redirects to other websites or ADM must be explicitly pre-approved by the DSC. 4. Information intended for healthcare professionals **must not** be included in content targeting the general public. 5. **Audience interaction features** (such as comments, hashtags, shares) on social media advertisements must be **disabled**.
Advertising through Licensed Pharmacists	Where ADM is conducted through a licensed pharmacist, the following conditions apply: 1. A **formal contract** must be signed between the pharmacist and the licensed pharmaceutical establishment (Pharmaceutical companies, Local agents, Pharmaceutical consultancy offices and the SO) 2. The following documents must be submitted alongside the license application: - Copy of the ADM content to be published - Start and end date of the advertising contract - Planned publication date - Platform(s) to be used - Copy of the pharmacist's professional license - Copy of a valid license issued by the **Competent Authority** confirming that the pharmacist is legally licensed to produce media or advertising content.

Appendix 3: Healthcare Professionals (HCPs)-Directed Advertising of Medicine

Applicant Responsibilities	1. Comply with the provisions of **Royal Decree No. 35/2015** regulating the practice of the pharmacy profession and pharmaceutical establishments, its executive regulation, and all relevant ministerial decisions. 2. Adhere fully to the **terms, conditions, and procedures** outlined in **Ministerial Decision No. 135/2025** and this guideline.
Scope of Application	1. Prescription-Only-Medicines (POM) 2. Over-the-Counter (OTC) Medicines 3. General Sales List (GSL) Medicines
Conditions and Requirements	1. Product Registration Requirement: ▪ No ADM activity shall be permitted for any medicine unless it is registered or listed with the DSC. ▪ The DSC may grant exceptions for innovative, unregistered products for the sole purpose of scientific presentation in conferences and symposia targeting HCPs. 2. Approved Platforms for HCP-Directed ADM: Advertising of registered medicines to HCPs shall be limited to: ▪ Scientific journals, newsletters and bulletins ▪ Conferences and symposia ▪ Direct interactions with pharmacists, their assistants, or licensed healthcare professionals. 3. Content Requirements: All ADM content must be fairly balanced, presenting both benefits and risks, and must include: ▪ Safety information ▪ Efficacy data ▪ Contraindications and side effects ➤ This information may be summarized, provided a barcode is included in the material that directly links to the approved SmPC. The material must instruct the HCP to review the full SmPC as authorized by the DSC.

	4. Language Requirements: ADM materials may be presented in English only if the target audience is exclusively healthcare professionals. 5. Platform and Audience Restrictions ADM content must be published only on pre-approved platforms and to designated professional groups, without violating national regulations. 6. Ethical Code Compliance All ADM activities must comply with the provisions of the Omani Medicines Promotion Code once published. 7. Mandatory Statement All ADM materials must include the following disclaimer in a font size not less than one-third of the largest font used in the content: 8. "For any comments regarding the submitted materials, please contact the Drug Safety Center."
Advertising through Licensed Pharmacists	As in Consumer-Directed Advertising of Medicine

Appendix 4: Advertising of Medicines Application Form

Advertising of Medicines Application Form

Date of application: / /

1. Medicine information	
Trade Name	
Active Ingredient	
Pharmaceutical Dosage Form	
Medicine classification	☐POM ☐OTC ☐GSL
Applicant	☐Pharmaceutical Company ☐Local Agent ☐ Pharmaceutical Consultancy Office
Name of the Pharmaceutical Company/ Marketing Authorization Holder	
Name of the Local Agent	
Registration status/ Number	☐Registered / RN: ☐Not registered
2. Advertisement (AD)	
AD Type	☐Advertisement for a medicine ☐Introduction of a medicine
AD directed to	☐Consumers ☐Healthcare Professionals
Means of AD	☐Readable ☐Audible ☐Visible
AD media	☐Website: (Link) ☐Social media (Specify): ☐TV ☐Radio ☐Print ☐Other (Specify):
AD Language (s)	☐Arabic ☐English ☐Other (Specify):
3. Application	
Targeted audience	☐Male ☐Female ☐Children
Planned distribution dates	Start: End:
Application type	☐New ☐Renewal ☐Amendments
Advertising through a Pharmacist	Name: MOH Registration Number: Copy of the contract included: ☐Yes ☐No
4. Attachments	
A copy of the medicine advertisement: ☐Yes ☐ No	
A valid copy of the medicine's registration certificate: ☐Yes ☐ No	
Proof of payment for the prescribed fee: ☐Yes ☐ No	
Copy of the SmPC and PL: ☐Yes ☐ No	
5. Self-Declaration	
"I declare that all information provided herein is accurate, balanced, and compliant with the MD No: 135/2025. **Applicant:** Name: Position: Date: Signature: Stamp:	