# Saudi Code of Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia

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# (Saudi Code of Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia)

Drug Sector

Saudi Food and Drug Authority

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## Vision:

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

## Mission:

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

## Questioned Documentation:

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## Introduction

The code herein is an ethical charter for pharmaceutical product marketing practice in KSA and shall be adhered by all pharmaceutical companies and manufactories in this field and all healthcare professional. Such as doctors, pharmacists, and others, whether in the public or private sector.

## Objectives

1. Regulating marketing practice in line with medical and pharmaceutical ethics.
2. Provide healthcare professional with accurate and documented information on pharmaceutical products to make sound decisions regarding their uses.
3. Creating a healthy environment suitable for decent competition between pharmaceutical establishments.
4. Develop and regulate the relations of pharmaceutical companies and manufactories with healthcare professional by providing accurate and reliable information of pharmaceutical products for the benefit of the patient.

**General Principles**

1. Pharmaceutical companies and manufactories have a responsibility to provide healthcare professional with accurate, up-to-date, balanced, and unbiased information of the pharmaceutical products they prescribe and dispense that derive from their experience and expertise in the process of developing these pharmaceuticals.
2. Pharmaceutical companies, manufactories and healthcare professional are responsible to provide patients with the same information.
3. Continuing education and the provision of information are essential for the process of understanding and absorbing the appropriate use of prescribed pharmaceutical products.
4. All marketing activities and practices shall be conducted in accordance with clear and measurable controls and standards.
5. Information and advertising for pharmaceutical products shall be designed to assist healthcare professional to provide a better health service and conform to relevant regulations and instructions. Pharmaceutical companies and manufactories shall also establish internal and external rules to ensure that such information and declarations conform to principles and provisions.

**Article (1) Marketing Authorization and Approved Labeling**

1-1 A pharmaceutical product must not be promoted for sale or supply before issuing the marketing authorization license.

1-2 according to the national laws and regulations, all advertising and promotional materials of pharmaceutical product must be in approved and certified by the Saudi Food and Drug Authority.

**Article (2) Promotion and its substantiation:**

2-1 All promotional and labelling materials of the pharmaceutical product should be in conformance with the uses that approved by Saudi Food and Drug Authority.

2-2 Advertisements for pharmaceuticals shall contain the following information:

A. Trade name of the product.
B. Generic name.
C. The name and address of the company or the Agent responsible for marketing the product.
D. The scientific reference for scientific information published by the advertisement.
E. The Advertisement should include the information which mentioned in the product›s internal leaflet such as; the uses of the approved product, the dosage, administration, precautions, contraindications, and side effects.

2-3 When announcing a reminder of a pharmaceutical products, it shall include simplified information about the product. Noting that if more information is desired, contact the establishment that has the right for marketing.

2-4 Advertising or marketing of the pharmaceutical product considers the provisions of Islamic Law, the applicable laws and regulations in addition to the social, ethical and cultural norms of society.

2-5 The study should not be published or presented in a way leaving Incorrect Impression or misleading to the nature, results, scope, application, summary, or significance of this study

2-6 When comparing similar products or substitutes, that comparison shall be presented statistically that is clearly useful in the medical application. Furthermore, all these comparisons shall be supported in a practical, balanced manner, and with consistent medical evidence.

2-7 Availabilityof (in-vitro) study or study on animals should not be presented in a way leading to incorrect impression or misleading on the possibility of linking these medical results and application on the human.

2-8 When presenting or quoting information from a medical source, no sense of what the researcher or reference intended shall be distorted.

2-9 The advertiser shall clarify the scientific references supporting the information upon request. Thereby allowing the recipient to assess the information.

2-10 Any comparison between different medicinal pharmaceuticals should be based on comparison point relevant to the product. The advertising and comparison should not be misleading or reducing the significance of other product.

2-11 This information should be submitted upon request from the advertiser not later than (30) days from the date of request.

2-12 Any activity or promotional program should not be in a way pertains indirect advertising go particular product representing conduct of marketing research for the purpose of prejudice to particular product or conduct continuing education program hiding behind advertising to particular product.

2-13 Promotion shall be by encouraging the moderate use of pharmaceutical products and presenting them objectively. Without exaggerating in highlighting their characteristics, and it is not permissible to imply that a drug product or an active ingredient has a specific distinction, quality or characteristic unless it is possible to prove that.

2-14 It is not permitted in any way to have the efficacy or quality of products registered in KSA or to provide information in this regard.

2-15 It is not permitted to declare that a product has no side effects, toxic risks, dangers of addiction, etc., unless the information is documented and based on scientific facts.

2-16 Monetary or material amounts shall not be provided in any way to healthcare professional to induce them to prescribe or dispense medication.

2-17 In-kind gifts can be given to health care providers in a symbolic manner, a maximum of 50 Riyal but no more than 500 Riyal per year, can be found. Provided that they are related to the medical field or have a medical connotation that can be used in their work.

2-18 In-kind gifts shall bear the trade name or the generic name of the product to be promoted.

2-19 Grants can be provided to governmental or private hospitals, not to individuals, in the form of assistance to furnish a department or purchase a device.

2-20 Books, scientific references, information, anatomical structures or other educational materials may be presented to health care providers if they have a purely educational purpose, so that they are of moderate value.

2-21 All medical advertising materials shall be approved by a responsible person inside the establishment, who shall be scientifically and medically qualified for this matter.

2-22 Priority should be given to notifying SFDA of the proven information about the serious and unexpected complications and side effects associated with the pharmaceutical products.

**Article (3) Direct to Consumer Communications**

3-1 Pharmaceutical companies, manufactories, and healthcare professional are responsible to provide information that is correct, balanced, not misleading, and in line with the marketing standards as foresaid in Article 2.

3-2 Pharmaceutical companies, manufactories and healthcare professional are responsible to educate the consumer and provide information related to medicines, diseases and related matters. Provided that they adhere to the highest standards of accuracy, balance and fairness, while observing the aforementioned rules.

**Article (4) Using quotations in promotion.**

4-1 Quotations 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 codes(s) in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

4-2 Note that quotations from medical publications or from personal communications related to medical publications will not be altered or distorted in any way from the meaning intended by the author, writer, clinical researcher, or the primary purpose of the work or study.

**Article (5) Postal communication.**

5-1 The volume and frequency of publications mailed to medical agencies shall be reasonable.

5-2 Respect the desire and request of the health professional to remove his name from the mailing list regarding the promotional material sent.

5-3 The list of health professional' names remains complete and up-to-date when needed to send the information to them regarding specific precautions, new contraindications, or side effects that they shall be informed of.

**Article (6) Samples.**

6-1 Healthcare professional, including physicians and pharmacists, may be given free samples of pharmaceutical products intended for identification of the product in small quantities within the limits of the percentage stipulated in Paragraph 15 of the Implementing Regulations for the Pharmaceutical Establishment and Preparations Law.

6-2 The free sample shall bear the phrase (free medical sample) and shall contain the product's package leaflet.

6-3 Pharmaceutical companies and manufactories shall implement a system to monitor and account for the distribution of free samples to their representatives.

6-4 It is not permitted to submit samples of the following pharmaceutical products:

- Pharmaceutical products that are used for psychological treatment or contain narcotic substances according to what they are defined under the Implementing Regulations of the Narcotics and Psychotropic Substances Control Law issued by Royal Decree No. M / 39 dated 8/7/1426 A.H.
- Any other medicinal products that SFDA prohibits distribution.

**Article (7) Symposium, Meetings and Continues Health Education:**

7-1 All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each an "**event**" organized or sponsored by a company must be held in appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and complies with the provisions of any applicable code(s). Such events should also:

- The duration of the event shall be proportional to the topics to be discussed.
- Shall be presented in way that delivers information and adds scientific or educational value.
- Dedicated mainly in terms of time and effort to promote substantive and educational activities and discussions.
- Contribute to enhancing the attendees' information about the topics to be presented.

7-2 Hospitality (whether international or local) is limited to the initial expenses of tickets, meals, accommodation, and registration fees, provided that compensation for these expenses is made by submitting receipts proven to.

7-3 Hospitality is restricted to people participating in the event only, not their companions.

7-4 All forms of hospitality provided to healthcare professional participating in the event shall be reasonable and determined exclusively by the main purpose of the event, and the hospitality provided to the health professional may not exceed what they are willing to pay for themselves.

7-5 The scientific event program shall not include sponsoring recreational events (sports or entertainment), and companies shall avoid using places known for their entertainment.

7-6 Companies shall comply with the directive regarding the meaning of the word "reasonable" as used in Article 7 and as stipulated or linked to any applicable charters.

## Article (8) Consultants

8-1 Healthcare professional who provide consulting services to pharmaceutical companies are reasonably compensated for those services to cover travel expenses, accommodation and expenses owed as part of providing those services. Excluding simple advice or advice about arrangements where it may not be used to justify compensation for healthcare professional in exchange for their time, travel, residence and their expenses. The consultative arrangements are acceptable if the following is observed:

A. Determine the scope of the need for consultants' services before requesting those services and entering into arrangements with potential consultants. The choice of consultants is linked to the intended purpose and whoever responsible for selecting consultants, shall have the necessary expertise to evaluate them.
B. A written agreement specifying the type of the services required to be provided by the consultant and stating the basis for compensation for these services.
C. The number of consultants to contracted with shall be within a reasonable limit to achieve the desired goal.
D. The contracting company maintains records related to the services.
E. The company makes appropriate use of the services provided by the consultants. The information provided by the consultants shall be used appropriately and adequately advertised.
F. The focus shall be only on consulting services and any other social or entertainment events shall be banned.
G. The company uploads the consultants 'information and the details of their contracts to the private site specified by SFDA, provided that the consultant is obligated to disclose any previous consultations with any related company whether the advice is paid or free.

**Article (9) Lecturer**

9-1 The process of selecting the lecturer shall be based on the academic qualifications and scientific experience. Besides, the company shall objectively assess the value and the appropriateness of the information provided to the target audience of the lecture.

9-2 The lectures presented shall focus on educational programs and be balanced, so that they include scientific, medical, as well as pharmaceutical information.

9-3 Pharmaceutical companies are obligated to disclose their relations with the lecturer, and their direct/indirect sponsorship of scientific or educational activities.

9-4 It is permissible to compensate for some expenses such as travel expenses for the lecturer if the expenses are within reasonable limits and not exaggerated.

**Article (10) Sales and Marketing Representatives**

10-1 Each pharmaceutical company guarantees that its sales representatives, including those with contractual contracts, who visit healthcare professional, pharmacies, hospitals, or other healthcare facilities related to pharmaceutical product promotion:

A. Familiar with the requirements of the relevant charters and all applicable laws and regulations.
B. Properly trained.
C. They have sufficient scientific knowledge that enables them to provide complete and accurate information about the pharmaceutical products they are promoting.

10-2 The medical sales representatives are obligated to provide a summary of the properties of the pharmaceutical products to the people who visit or present the summery in an appropriate manner.

10-3 Medical sales representatives shall notify the Pharmacovigilance Center in their companies promptly of any information they receive regarding the use of the company's pharmaceutical products, especially reports about the side effects.

10-4 Medical sales representatives shall choose the appropriate time and duration to visit healthcare professional, pharmacies, hospitals, or other health care facilities.

10-5 Medical sales representatives shall not use unacceptable methods to have an interview with healthcare professional, pharmacies, hospitals, or other health care facilities but they shall introduce themselves and the company they represent and provide a proof of that.

10-6 The Scientific Office is responsible for providing information on the company preparations, which should be provided by a doctor or pharmacist. The Scientific Office shall be responsible for approving any promotional material before its publication or distribution, approving the final form of the marketing material and verifying its observance of the requirements of relevant laws, regulations and instructions. It is also responsible for verifying that the marketing material is consistent with the summary of product characteristics and that it is an honest representation of the facts related to the drug.

10 -7 Every company shall designate at least one principal employee who will be responsible for supervising the company and its subsidiaries to ensure that the standards are met.

**Article (11) Disclosure**

11-1 Companies and healthcare professional are responsible to inform SFDA all the details of the financial support that provided if the amount exceeds 50 or 500 riyal per year. That includes but is not limited to the following:

1. Consultations fees
2. Lectures fees
3. Training courses fees
4. Providing care for a healthcare professional to attend an educational event.
5. Research, scholarships and educational grants (restricted and unrestricted).
6. Sponsoring seminars and conferences.
7. Hospitality.
8. Providing scientific materials (such as books or tools).

11-2 The companies shall notify the healthcare professional that s/he shall disclose to SFDA any financial support s/he receives from the company, and the companies shall provide a proof of this upon request.

**Article (12) Provisions for the implementation of the Code**

12-1 Companies and institutions operating in the field of marketing of pharmaceuticals shall bound by a specific and clear mechanism to monitor breaches of these ethics.

12-2 The Chamber of Commerce and Industry Council, in coordination with SFDA, shall be formed from representatives of companies to ensure that companies and institutions operating in this field adhere to the Saudi Code of Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia.

12-3 Submit complaints regarding cases of breach of what is included in this code to the committee referred to in clause (12-2), which shall study the case and take the necessary action in its regard.

12-4 If the company does not abide by the binding decision of the committee referred to in clause (11-2) the committee addresses SFDA to take legal action against the company.