Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Blog

Saudi Code of Conduct for Promotional Practices of Pharmaceutical and Herbal Product in the Kingdom of Saudi Arabia

Version Number 4

Contents

Vision:

To be a global leader based on scientific principles to enhance and protect public health.

Mission

The authority aims to protect the community through legislation and an effective regulatory system to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and animal feed.

Introduction

This document serves as a regulatory and ethical charter for the marketing practices of pharmaceutical and herbal products in the Kingdom of Saudi Arabia. All pharmaceutical and herbal product companies and factories operating in this field, as well as all healthcare professionals including physicians, pharmacists, and others, whether in the public or private sector, are required to adhere to it.

Objectives

1. Regulate marketing practices in accordance with the ethics of the medical and pharmaceutical professions.
2. Provide healthcare professionals with accurate and documented information about pharmaceutical and herbal products to make informed decisions regarding their use.
3. Create a conducive healthcare environment for fair competition among pharmaceutical establishments.
4. Develop and organize the relationship between pharmaceutical and herbal product companies and factories and healthcare professionals by providing accurate and reliable information about pharmaceutical and herbal products for the benefit of the patient.

General Principles

1. Pharmaceutical and herbal product companies and factories are responsible for providing healthcare professionals with accurate, up-to-date, and balanced information, unbiased about the pharmaceutical and herbal products they prescribe and dispense, drawing from their expertise and experience in the development of these pharmaceutical and herbal products.
2. Pharmaceutical and herbal product companies and factories share joint responsibility with healthcare professionals for providing patients with the same information.
3. Continuous education and information provision are essential for understanding and appropriate use of pharmaceutical and herbal products for prescription.

4. All marketing activities and practices must be conducted according to clear guidelines and measurable standards.
5. Information and advertising materials for products should assist healthcare professionals in delivering better healthcare services and comply with relevant regulations, laws, and instructions. Pharmaceutical and herbal product companies and factories should establish internal and external rules to ensure that such information and advertisements adhere to principles and regulations.

Article (1): Registration of the Product and Submission of the Approved Labeling

1-1: Marketing of any pharmaceutical or herbal product is not permitted before its registration with the Saudi Food and Drug Authority (SFDA).
1-2: Compliance with the regulations, laws, and instructions regarding advertising controls is mandatory. All advertisements and marketing materials for any pharmaceutical or herbal product must adhere to Article 10 and Article 31 of the of the Pharmaceutical and Herbal Products and Installations Law, its implementing regulations and the circulars and instructions of the Saudi Food and Drug Authority.

Article (2): Advertising and its Contents

2-1: All advertising materials for pharmaceutical or herbal products must align with the claims approved by the SFDA, under which the product is registered.
2-2: Advertisements and promotional materials directed towards healthcare practitioners for pharmaceutical and herbal products must contain the following information:

a) Brand name of the product.
b) The generic name.
c) Name and address of the entity marketing the product or the agent responsible for its marketing.
d) Scientific reference for the information published in the advertisement.
e) Approved uses by the SFDA, including dosage, method of use, precautions,

contraindications, and side effects. This information can be condensed provided a barcode in the advertisement leads to a Summary of Product Characteristics (SPC) approved by the SFDA, and healthcare practitioners are directed to refer to the approved SPC.

2-3: Non-promotional Souvenir items are non-monetary items provided by pharmaceutical and herbal product companies and healthcare practitioners for promotional purposes, such as pens, notebooks, and others. Non-promotional promotional materials do not require an application for SFDA approval.

2-4 Conditions for non-promotional promotional materials:

a) The drug must be registered with the SFDA.
b) Must be free of medical claims.
c) Distribution is limited to healthcare practitioners.
d) They must not be convertible to cash, such as purchase vouchers.

2-5: Guidelines for Non-Promotional Promotional Materials:

a) Limited to the trade or generic name.
b) The actual value must not exceed one hundred (100) Saudi Riyals.
c) They must have an office or professional use nature.
d) Company logos may be printed on these materials.
e) Distribution should be reasonable.

2-6: The purpose of the guidelines for non-promotional promotional materials is to coordinate the distribution of such materials by pharmaceutical and herbal product companies and similar entities to healthcare practitioners and healthcare institutions.

2-7: Pharmaceutical and herbal product companies commit to withdrawing non-promotional promotional materials upon request.

2-8: Pharmaceutical and herbal product companies bear full responsibility for any violation of the guidelines and conditions of non-promotional promotional materials.

2-9: When presenting non-promotional promotional materials for a pharmaceutical or herbal product, they must include the trade name or scientific name of the product, and it is permissible to print the company logo on these materials.

2-10: When advertising pharmaceutical or herbal products, compliance with Islamic Sharia principles, laws, regulations, social, ethical, and cultural norms of society must be observed.

2-11: Studies should be published or presented in a manner that does not leave a false or misleading impression about the nature, results, scope, application, summary, or importance of the study, while adhering to the regulations of the Saudi Food and Drug Authority (SFDA).

2-12: When comparing products or similar alternatives, statistical comparison should be provided that clearly supports their medical application. All such comparisons must be scientifically balanced and supported by consistent evidence.

2-13: Comparison between products should not be made without approved clinical studies.

2-14: Comparison between biological products and their licensed equivalents should not be misleading, promoting minor differences in inactive ingredients that have no therapeutic effect.

2-15: Laboratory or animal studies should not be presented in a way that could create a false or misleading impression about the possibility of linking these research results to human application.

2-16: When presenting or quoting information from a source, no distortion or misinterpretation of the researcher's or reference's intended meaning should occur.

2-17: Advertisers must clarify the scientific references supporting the information upon request, allowing the recipient to assess the information.

2-18: Any comparison between different pharmaceutical or herbal products must be based on relevant comparison criteria, and advertising and comparison must not be misleading or diminish the significance of the other product.

2-19: When a healthcare practitioner requests information about a pharmaceutical or herbal product, such information must be provided within a period not exceeding 30 days from the date of the request.

2-20: Promotional and marketing programs must not diminish the importance of other products, nor should they indirectly promote another product.

2-21: Promotion should encourage moderate use of products and present them objectively without exaggerating their features. Implying that a product has specific distinguishing qualities or quality is not permissible unless it can be proven.

2-22: It is not permissible to cast doubt on the effectiveness or quality of products registered in the Kingdom of Saudi Arabia or provide information to this effect.

2-23: It is not permissible to state that a product has no side effects, toxic risks, addiction risks, or other hazards unless the information is documented and based on scientific facts.

2-24: The advertising and promotional material in electronic media directed at consumers shall be subject to the same rules as non-electronic media advertising and promotional material, including websites, electronic applications, and electronic games, whether registered within or outside the Kingdom.

2-25: Advertising and promotional material in electronic media directed at healthcare practitioners shall be subject to the same rules as non-electronic media advertising and promotional material, including websites, electronic applications, and electronic games, whether registered within or outside the Kingdom.

2-26: Financial or material incentives shall not be provided to healthcare practitioners in any form to encourage them to prescribe or dispense drugs.

2-27: Non-promotional promotional materials may be provided to healthcare providers symbolically, with a maximum value of 100 Saudi Riyals per item and not exceeding 500 Saudi Riyals per year, provided they are related to the medical field or have medical significance that can be beneficial in their work.

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2-28: These non-promotional promotional materials must bear the trade name or scientific name of the product being promoted.
2-29: Grants may be provided to government or private hospitals, not individuals, in the form of assistance for furnishing a department or purchasing equipment as stipulated in the regulations and decisions governing this matter.
2-30: Books, scientific references, information, anatomical models, or other similar educational materials may be provided to healthcare providers if they have an educational purpose, provided they are of moderate value.
2-31: All advertising and promotional materials must be medically approved by the responsible person within the institution, who must be qualified scientifically and medically for this purpose.
2-32: The Saudi Food and Drug Authority must be notified of confirmed information regarding complications, serious and unexpected side effects associated with pharmaceutical or herbal products.

Article (3) Direct Communication with Consumers

1- Pharmaceutical and herbal product companies, as well as healthcare practitioners, have a shared responsibility to provide accurate, balanced, non-misleading information in line with the marketing standards outlined in Article (2) and regulations issued by the General Authority for Food and Drug Administration and the Ministry of Health.
2- Pharmaceutical and herbal product companies, in addition to healthcare practitioners, contribute to consumer awareness and provide them with information related to medicines, diseases, and related matters, ensuring the highest standards of accuracy, balance, and fairness, while adhering to the rules mentioned in this regulation and regulations issued by the General Authority for Food and Drug Administration and the Ministry of Health.
3- Information provided to consumers should be separate from information provided to healthcare practitioners.

Article (4) Use of Quotations in Promotion

1- Scientific integrity must be maintained when quoting from medical and scientific publications, or from personal communications related to medical publications. If information is adapted or modified, it must be indicated that the quotation has been adapted or modified, and accurate citation of the sources of the quotation is required.
2- It must be ensured that quotations from medical publications or from personal communications related to medical publications are not altered or distorted in any way from the intended meaning by the author, writer, clinical researcher, or the primary objective of the work or study, in a manner that does not conflict with the regulations of other governmental authorities.

Article (5) Postal Communication

1- The volume and frequency of materials sent by mail to healthcare facilities must be reasonable.
2- Healthcare practitioners should be informed when there is a need to certain precautions, new contraindications, or side effects that need to be communicated to them.

Article (6) Samples

1- Healthcare practitioners, including doctors and pharmacists, may be provided with free samples of pharmaceutical and herbal products for familiarization purposes, in accordance with the regulations stipulated in Article (13) and its regulatory provisions of the Pharmaceutical and Herbal Products and Installations Law and its implementing regulations.
2- Free samples must bear the label "Free Sample" and include the package insert of the product.

3- Pharmaceutical and herbal product companies are required to implement a system for monitoring and accounting for the distribution of free samples to individuals working in the field of promoting and familiarizing with their pharmaceutical and herbal products.

4- The following pharmaceutical and herbal products may not be provided as samples:

- Distribution or trading of free samples of Narcotics or Controlled medications is prohibited.
- Any other pharmaceutical products prohibited from distribution by the General Authority for Food and Drug Administration.

Article (7) Conferences, Seminars, and Continuing Health Education

1- All scientific or professional conferences and seminars organized or sponsored by a company and designated for healthcare practitioners must aim to achieve the main purpose of the event and adhere to the relevant instructions and rules. These events must also consider the following:

- The duration of the event should be proportional to the topics to be covered.
- They should be presented in a manner that effectively communicates information and adds scientific or educational value.
- They should primarily focus on promoting activities, objective discussions, and education.
- They should contribute to enhancing the attendees' knowledge of the topics to be presented.

2- Hospitality (whether international or local) is limited to travel expenses including tickets, meals, accommodation, original registration fees, and transportation costs, with reimbursement made upon submission of receipts.

3- Hospitality is restricted to participants in scientific or professional conferences and seminars without their companions.

4- All forms of hospitality provided to participating healthcare practitioners must be reasonable in level and exclusively designated for the main purpose, and must not exceed what the practitioners are willing to pay for themselves.

5- The scientific program should not include sponsorship of recreational; sports, or entertainment activities, and companies must avoid using venues known for their recreational facilities.
6- Companies must comply with the guidance regarding the meaning of the word "reasonable" as used in Article (7) and as stipulated or related to any applicable regulations.
7- Companies are required to adhere to the regulations specified by the healthcare facility regarding communication with any healthcare practitioner or their nomination regarding attendance at conferences, seminars, and continuing health education.

Article (8) Consultants

1- Healthcare practitioners who provide consultancy services to pharmaceutical companies shall be compensated reasonably for such services to cover travel, accommodation, and other applicable expenses incurred as part of rendering those services. Simple consultation or arrangements consultations, which cannot be used to justify compensating healthcare practitioners for their time, travel, accommodation, and expenses, are exempt from this provision. Consultancy arrangements are acceptable provided that the following conditions are met:
A. The need for consultant services shall be determined before requesting such services and entering into arrangements with potential consultants, with the selection of consultants being linked to the intended purpose, and the individuals responsible for selecting consultants having the necessary expertise to evaluate them.
B. There shall be a written agreement specifying the nature of the services to be provided by the consultant and stating the basis for compensation for these services.
C. The number of consultants to be contracted with shall be reasonable to achieve the intended purpose.
D. The contracting company shall retain records related to the services.

E. The company shall appropriately utilize the services provided by the consultants and use information from consultants appropriately, with disclosure made in an appropriate manner.

F. Emphasis shall be placed solely on consultancy services, and any social or other entertainment events shall be separate.

G. The company shall disclose information regarding the financial support provided to the consultants and provide documented receipts on the designated website determined by the General Authority for Food and Drug Administration.

Article (9) Lecturers

1- Lecturers shall be selected based on their academic qualifications and practical experience, and the company shall objectively evaluate the value and suitability of the information provided to the lecture's target audience.

2- Lectures presented should focus on educational programs and should be balanced, encompassing scientific, medical, and pharmaceutical information.

3- Pharmaceutical companies are obligated to disclose their relationship with the lecturer, as well as their direct or indirect sponsorship of scientific or educational activities.

4- Compensation for certain expenses, such as lecturer travel expenses, may be permitted, provided that the expenses are reasonable and not excessive.

5- Pharmaceutical companies should collaborate with multiple healthcare practitioners in delivering lectures and should not focus solely on one healthcare practitioner.

Article (10) Promotional Representatives for Pharmaceutical and Herbal Products

10-1 Each pharmaceutical company must ensure that its promotional representatives, including contracted individuals, who visit healthcare practitioners, pharmacies, hospitals, or other healthcare facilities related to the promotion of pharmaceutical products:

A. Are Saudi pharmacists who are licensed to practice.

B. Are well-informed about relevant regulations, systems, and all applicable laws and regulations.

C. Are appropriately trained.

D. Have sufficient scientific knowledge to provide comprehensive and accurate information about the products they promote.

10-2- Promotional representatives must provide a summary of the pharmaceutical or herbal product's characteristics to the individuals they visit, or present this summary to them in an appropriate manner.

10-3- Promotional representatives must immediately notify their company's pharmacovigilance center of any information received regarding the use of the company's pharmaceutical products, particularly reports of side effects.

10-4- Promotional representatives should choose the appropriate time and duration for visiting healthcare practitioners, pharmacies, hospitals, or other healthcare facilities.

10-5- Promotional representatives are not allowed to use unacceptable methods to gain access to healthcare practitioners, pharmacies, hospitals, or other healthcare facilities. They must identify themselves and the company they represent and provide proof of their identity.

10-6- The medical department is responsible for providing information related to the company's products, ensuring that this information is provided by a pharmacist. The medical department is responsible for approving any promotional materials before publication or distribution, approving the final form of the marketing material, and ensuring its compliance with the requirements of relevant regulations, laws, and instructions. It is also responsible for ensuring that the marketing material aligns with the product summary of characteristics and provides a fair and truthful representation of the facts related to the drug.

10-7- Each company must appoint at least one key employee responsible for overseeing the company and its subsidiaries to ensure compliance with applicable regulations.

Article (11) Disclosure

11-1 Companies and healthcare practitioners share responsibility in disclosing to the Saudi Food and Drug Authority (SFDA) all details of financial support provided, as specified by the SFDA. This includes, for example:

1. Consultation fees.
2. Lecture fees.
3. Fees for training courses, conferences, and scientific seminars.
4. Providing care for healthcare practitioners to attend educational events.
5. Grants for research and unrestricted educational grants.
6. Sponsorship of seminars and conferences.
7. Hospitality.
8. Providing scientific materials such as books or tools.

11-2 Companies are required to notify healthcare practitioners of the obligation to disclose any financial support they receive from the company to the SFDA. Companies must provide evidence of this when requested.

Article (12) Implementation Provisions

12-1 Companies and institutions operating in the field of marketing pharmaceutical and herbal products must adhere to a specific and clear mechanism forx monitoring compliance with these ethics.

Number and date of the previous version	Modification description
Version No. 2 - 01/08/2018	Modification in "Title". Modification in "Introduction". Modification in "Objectives". Addition and modification in "Article (1) Registration of the product and submission of the approved information card". Addition and modification in "Article (2) Advertising and its contents". Addition in "Article (3) Direct consumer contact". Addition in "Article (4) Use of quotations in promotion". Modification in "Article (5) Postal communication". Addition and modification in "Article (6) Samples". Modification of the title "Article (7) Meetings, seminars, and continuing education". Modification in "Article (7)". Modification in "Article (8) Consultants". Addition in "Article (9) Attendance". Modification of the title of Article (10) Sales and Marketing Representatives ". Addition in "Article (11) Disclosure". Modification in Article (12) Provisions for implementing the code."
Version No. 3 – 07/09/2022	Addition of the paragraph "Companies are required to adhere to the specific guidelines set by the healthcare institution regarding communication with any healthcare practitioner or their nomination regarding attendance of conferences, seminars, and continuing medical education" in "Article (7) Conferences, Seminars, and Continuing Medical Education."

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