

Saudi Code

of Pharmaceutical Promotional Practices
in the Kingdom of Saudi Arabia



Drug Sector
Executive Directorate of communication and education

contains

Titel	Page
The CEO of Saudi Food & Drug Authority	5
The Executive Vice President For Drug Sector	7
General view (Introduction - Objectives - General Principles)	8
Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia Code of Saudi of Terms	
Article 1 Marketing Authorization and Approved Labeling	10
Article 2 Promotion and its substantiation	10
Article 3 Direct contact with consumer	12
Article 4 The use of Quotations in Promotion	13
Article 5 Post Communications	13
Article 6 Samples	13
Article 7 Symposium , Meetings and Continues Health Education	14
Article 8 Consultants	15
Article 9 Lecturer	16
Article 10 Sales and Marketing Representative	16
Article 11 Enforcement roles	18



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

بالأهم نهتم



Prof. Mohammed AlMeshal
The CEO of Saudi Food & Drug Authority

Since its establishment of the by the royal act No. (1) on 17/1/1424H, the Saudi Food and Drug Authority Works seriously and progressively in rebuild the Legislative structure for The drug market in the Kingdom, Recent scientific studies indicate that the Saudi pharmaceutical market is the largest market in the Middle East according to the terms of both number of units sold and/or pharmaceutical market size financially, which exceeded eleven Billion Saudi riyals in the year 2012.

With the beginning of drug registration and follow-up throw the Saudi Food and Drug Authority, the authority have introduced qualitative step by obligating the Scientific offices of pharmaceutical companies to follow the terms of Saudi Arabian code of ethics for marketing practicing of Saudi pharmaceutical products In Kingdom of Saudi Arabia which have been introduced in the second point of the sixth rule in special and pharmaceutical products and establishments guidance .

The aim of this Code is to ensure the access of health care providers to the correct and Reliable information, as well as creating a healthy environment for competition between the different pharmaceutical companies, and, more importantly, develop and regulate the relationship between pharmaceutical companies and the health care providers and to eliminate negative factors at this relationship.

We hope that all pharmaceutical companies, agents, and health care providers follow (committed to) the terms of this Code to get benefits for the kingdom and it citizens through corporation between SFDA and private sector according to this code.



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

بالأهم نهتم



Prof. Saleh Abdullah Bawazir
The Executive Vice President of Drug Sector

Due to the rapid development in the legislations and regulations at the field of drug and the emerges of some negative practices, Drug sector at the Saudi Food & Drug Authority (SFDA) along with its corporation with national committee of pharmaceutical manufacture in the chamber of industry board eliminated some of the negative pharmaceutical marketing practices.

The Saudi Code for the ethics of pharmaceutical products marketing in the Kingdom has been issued after conducting many meetings with the representatives of private sector and review the successful pharmaceutical experiences. This code was a result from the productive meetings with the private sector representatives. Although that this code is a moral convention (agreement) to practice the pharmaceutical marketing, all pharmaceutical institutions are required to be obligated to all of the code's articles, especially the ones which coordinate the relationship between the companies with their representatives and the physicians with the pharmacists.

The responsibility of providing the balanced and tendentious information to healthcare providers is on the pharmaceutical companies and manufactures. All activates and marketing operations must follow the standards and regulations that mentioned in the Code.

Our mutual aim (goal) is creating a fair competitive and suitable atmosphere between the pharmaceutical companies to increase the professional practice level of the health sector in the Kingdom.

In addition, we look forward that the obligation of this code will lead to make the Saudi pharmaceutical market and its practices as an icon which deserved to be followed. Also, we look forward for more professionalism in the pharmaceutical marketing practices which will affect positively on the healthcare level in the Kingdom.

Best wishes



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
بالأهم نهتم

General Principles :

1. The pharmaceutical companies/plants is responsible to furnish the health care providers with accurate, fresh, balanced, and not prejudiced information about the medications that prescribed by them, which is derived from their experience in developing of these medication.
2. pharmaceutical companies/plants are sharing responsibility with health care providers to furnish the patients with the same information.
3. The continuous of education and availability of the information are essential to understand the appropriate usage of prescribed medication.
4. All promotional activities and practices should be done in accordance with clear standard that can be gauged.
5. The promotional information should be designed in a way that can help the health care providers to offer a better health service. In addition, this information should be done in conformance with the relevant laws and regulations and the companies should be committed to maintain internal and external regulations to ensure its conformance with the general basis of this Code.

Introduction :

This Code is considered as an ethical code for the practicing of pharmaceutical promotion in the Kingdom of Saudi Arabia. All pharmaceutical companies/plants working in the Kingdom of Saudi Arabia and how working in health sector , physician , and Pharmacists either working at private or Governmental sectors and should adhere to this code.

Objectives :

1. Organizing the marketing practices in line with ethics profession of medicines and Pharmacy.
2. Provide accurate, fair, and objective information about the pharmaceutical products to the health care providers, In order to reach the correct decisions about the usage .
3. Create suitable and healthy environment for virtuous competition between the pharmaceutical companies.
4. Developing and organizing the pharmaceutical companies/plants relationships with health sectors professionals through providing accurate and reliable information about the pharmaceutical products for patient benefit.

- 2-3** The Pharmaceutical product recalling announcement should include simple information about the product, with referring to the possibility of contacting the marketer company.
- 2-4** All promotional materials should be approved by a scientific and medical qualified official person inside the company
- 2-5** The study should not presented or published in a way that could give Incorrect or misleading impression to the nature, results, scope, application, summary, or significance of those studies
- 2-6** If (in-vitro) study or study on animals Is available, It should not be presented in a way that might be leading to incorrect impression or misleading on the possibility of linking these medical results and applications on the human.
- 2-7** Usage of the word safe or effective should not be used unless it is supported by documented and published medical information
- 2-8** Any comparison between many products or similar generics, should be presented in a statically form which helps implement it medically. Also, this comparisons should be supported with scientific and medical proofs.
- 2-9** When giving an information from medical source, you should not distorted or misinterpreted the meaning of this medical source which presented by author or investigator,.
- 2-10** The reference of any medical information should be mentioned when It is requested by any person. overall, these information must be referred so the public can evaluate them.
- 2-11** Any comparison between different pharmaceutical products should be based on comparison points that relevant to the product. The advertising and comparison should not be misleading or gives a dishonest impression about the other products.
- 2-12** The information about pharmaceutical product should be submitted upon request from the advertiser, not later than (30) days from the date of request.
- 2-13** Any promotional program should not be presented in a way that could give dishonest impression about the other products or promote for different product.
- 2-14** The advertisement or promotion of pharmaceutical product In general should be in conformance with the Islamic Sharia , social traditions, ethical, and cultural fundamentals for this society.

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

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 labeling materials of the pharmaceutical product should be in conformance with the uses that approved by Saudi Food and Drug Authority.

2-2 The Advertisement pharmaceutical product should include the following :

- A. The trade name of the product.
- B. Generic name.
- C. Name and address of the company or the Agent responsible for marketing the product.
- D. For any medical claim published in any advertisement, a scientific reference should be mentioned and to be supported officially with publicized information for this claim.
- 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.

3-2 pharmaceutical companies/plants and health care providers are both responsible for the education of public with the accurate and balanced Information that related to drugs and diseases, which complies with this code .

Article (4)

The use of 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 Quotations from medical literature or from personal communications that associated with medical literature shall not changed or distorted the intended meaning which presented by author, clinical investigator or the significance of the underlying work or study

Article (5)

Post Communications:

5-1 The repetition and average of literature (newsletters) should be of reasonable, when sending them to the medical Society through post

5-2 The desire and request of the health professional to delete his name from the Post list of the advertising materials should be respected.

5-3 The list should remain complete and updated to send the information that related to particular precautions or new contraindication or side effects to all health professionals.

Article (6)

Samples :

6-1 In accordance with article 15 in the executive roles of pharmaceutical products and institutions law , recognized samples may be supplied in small quantities to health care professionals who are qualified to prescribe, in order to make them familiar with these kinds of products.

2-15 No cash payments to be offered by any means to the health care providers to stimulate them to prescribe or give the medication.

2-16 Gifts in kind can be offered to health care providers in symbolic form maximum SR (50) subject to be linked with medical field or has medical concept to get use of it in their work.

2-17 These gifts should hold the trade name of the product which will be promoted.

2-18 Donation can be offered to government and private hospitals excluding individuals in form of support for furnishing a Division or apparatus.

2-19 Books, scientific sources, Information, anatomical skeletons, or other similar educational materials can be offered to the health care providers If It has absolute scientific objective subject to be of reasonable price.

2-20 Promotion should be based on encouragement on moderate usage of medicinal pharmaceuticals to be presented logically and without exaggeration about its characteristics and the inspiration of particular medicinal product or its active ingredient which have privilege or quality or special characteristic is not permissible unless this can be proved..

2-21 Suspicion of effectiveness or quality of product registered in the Kingdom of Saudi Arabia or submission of information in this respect is not permissible by all means.

2-22 It is not permissible to announce that a particular product has no side effect or toxicant or addiction risk etc. without supporting evidence

2-23 Priority should be given to SFDA informing them about the unexpected serious side effects relevant to the pharmaceutical product.

Article (3)

Direct contact with consumer :

3-1 pharmaceutical companies/plants and health care providers are both responsible to ensure that these information which directly provided to patients are accurate, balanced, true and in conformance with the promotional standards of Article (2).

7-3 Hospitality may only be provided to qualified persons as participants who attend such meetings, a healthcare professional's spouse or other guests is not allow .

7-4 All forms of offered hospitality to the health care professionals shall be reasonable in level and strictly limited to the main purpose of the event. Generally, the provided hospitality must not exceed what healthcare professional recipients would normally be prepared to pay by themselves.

7-5 Hospitality shall not include sponsoring or organizing any entertaining activities (e.g. sporting or leisure events). Companies should avoid using venues that are renowned for their entertainment facilities.

7-6 Companies must comply with guidance which concerning the meaning of the term “reasonable”, as used in this Article 7 as provided in, or in connection with, any applicable code(s).

Article (8)

Consultants

8-1 It is appropriate for healthcare professionals who provide consulting services to companies to be offered reasonable compensation for those services and to be offered reimbursement for travel, lodging, and meal expenses incurred as a part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts under this Code can be acceptable for consultants when it is related to their consulting arrangements. Simple consultations or advisory arrangements should not be used to justify the compensating of healthcare professionals for their time, their travel, lodging, and their allowances. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- A. A written agreement specifies the nature of the services to be provided and the basis for payment of those services.
- B. Identifying the need for services in advance of requesting these services and begin the arrangements with perspective consultants. The criteria of selecting consultants are directly linked to the identified purpose and the persons responsible for selecting the consultants who have the expertise necessary to evaluate whether the particular health care professionals meet those criteria.
- C. To achieve the identified purpose, the number of healthcare professionals who will be agreed should reasonable.
- D. The retaining company should keep the records which related to services and take the advantage of the services that provided by consultants.

6-2 Each sample must be marked by the phrase “free medical sample, not for resale” or similar words. Also, a copy of the package leaflet must be attached .

6-3 pharmaceutical companies/plants must have adequate systems of control and accountability for samples, which they distribute, and for all medicines handled by its representatives.

6-4 The samples of the following pharmaceutical products must not be supplied :

- A. Pharmaceutical products which are used in psychotropic or contain narcotic substances and defined by the executive role of narcotics and psychotropic’s law issued with royal decree number M/39 dated 8/7/1426 H.
- B. Any other pharmaceutical products that are prohibited by the Saudi Food and Drug Authority.

Article (7)

Symposium , Meetings and Continuous Health Education :

7-1 All promotional, scientific or professional meetings, congresses, conferences, symposium, and other similar events (each an “event” that is organized or sponsored by a company must be held in an appropriate venue that is conducive to the main purpose of the event. And should comply with the provisions of any applicable code(s). Also, such events should:

- A. Be modest according to the local standards.
- B. Updated in a manner that can provide both scientific and educational value.
- C. Dedicated both time and effort to promoting scientific objects and educational activities
- D. Increase knowledge of the attendees about the presented topics.

7-1 Hospitality which is provided in promotional, professional or scientific events (whether it is international or domestic) shall be limited by travel, meals, accommodation and genuine registration fees. Reimbursement of expenses and costs shall be made upon submission of receipts of actual expenses.

precise and complete information about the medicinal products which they promote.

10-2 Medical sales representatives must comply with all relevant requirements of the applicable code(s), all applicable laws and regulations. Companies are responsible about their representative compliance.

10-3 During each visit, with application of laws and regulations, medical sales representatives must provide a summary of the product characteristics for each pharmaceutical product they present to the visited person

10-4 Medical sales representatives must notify the scientific services department of their companies about any information they receive in relation to the use of their company's medicinal products, reports of side effects.

10-5 Medical sales representatives must ensure that the frequency, timing and duration of their visits to health care professionals, pharmacies, hospitals or other health care facilities.

10-6 Medical sales representatives must not use any inducement or subterfuge to get an appointment for interview. During the interview or when seeking an appointment for an interview, medical sales representatives must take all practical steps to ensure that they do not mislead and provide a false information about their identity or the company they represent.

10-7 All company staff, and any personnel retained thorough a third parties, who are concerned with the preparation and approval of promotional material or other activities, must be fully conversant with the requirements of the applicable code(s), relevant laws and regulations.

10-8 Every company must establish a scientific office which will be responsible about company's pharmaceutical products. This scientific office must include on a physician or a pharmacist who will be responsible for approving any promotional material before their release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with requirements of the applicable code(s), any applicable advertising laws and regulations in consistent with the summary of product characteristics. In addition, the summary must be presented fairly and truly.

10-9 Each company must appoint at least a senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the applicable code(s) are met.

- E. The venue and circumstances of any meeting with consultants must be focusing on the consulting services and activities that related to the services are, and any social or entertainment events are prohibited .

Article (9)

Lecturer :

9-1 The selection and supporting of the lecturer should be based on his/her qualifications and the evaluation of scientific value of the information which he/her will address. Also, the appropriateness of the information to the attendees is included in the selecting process.

9-2 These lectures should focus on the educational programs and balanced, in order to include scientific , medical, and pharmaceutical information.

9-3 Pharmaceutical companies/plants are committed to inform to all participants directly or indirectly about its sponsoring for the scientific and educational activities.

9-4 Some expenses can be paid or reimbursed (e.g. lecturer travel expenses). Such expenses must be appropriate and not exaggerated, also the companies should express their relationship with the lecturer.

Article (10)

Sales and Marketing Representative :

10-1 Each company shall ensure that its sales representatives, including retained personnel through a third parties, and any other company representatives who visits the health care professionals, pharmacies, hospitals or other health care facilities in connection with the promotion of medicinal products (each, a “medical sales representatives”) are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations. Furthermore, the companies must insure that all of its representative are adequately trained and have sufficient scientific knowledge to provide