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Gulf Code of Pharmaceutical Promotional Practices in the GCC

Members of
the Gulf Central Drug Registration Committee

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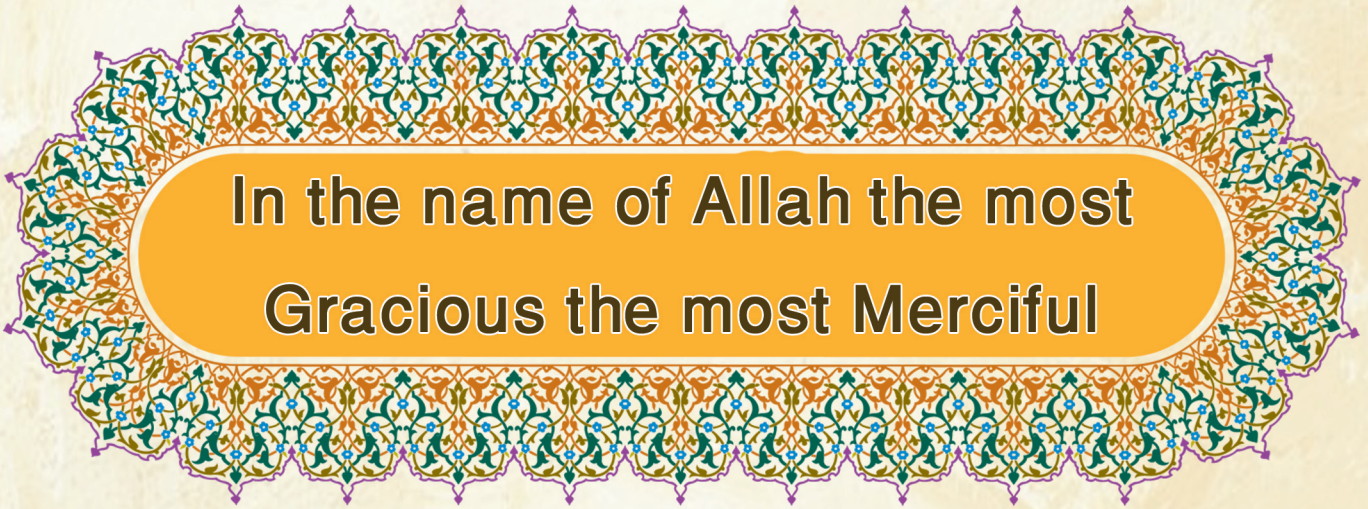

INTRODUCTION

Our first and last invocation is that all praise to Allah, the Lord of the worlds and peace and blessings on the messenger of Allah our Prophet Mohammad and on his Companions.

The pharmaceutical industry is witnessing a great competition in marketing products, whether the big international companies or the generic ones. Success of pharmaceutical companies depends on marketing and promotion of their products.

The Gulf arena is witnessing practices of some of the companies by their agents and sales representatives through visiting physicians, pharmacists and decision makers to promote for the companies and their products. Some commit un-ethical and non-competitional practices through provision of gifts and other benefits.

Some others provide fallacious information supporting the use of their products and doing wrong to the competitor product. There are over promotion on the part of some of the companies not based on evidence as well as having wrong information.

Therefore, the relation between these pharmaceutical companies regarding marketing as well as the relation between these companies and the practitioners should be organized. This is to keep the principle of honorable competition, and thus not harming the health of the patient.

We must give to the community its full right to exercise the conventional drug marketing ethics and those internationally agreed upon principles.

The community has the right to be well informed about the drugs used and there should be full transparency in this respect.

On the other hand, the drug control responsible bodies should strictly monitor giving effect to the drug marketing ethics taking into consideration that the role of the media is pivotal in this regard, and should comply to and confirm with these constitutions professional ethics and patient rights. We emphasize that we should act together towards achieving health security and safety of beneficiaries of this vital industry.

It is extremely important to provide the appropriate environment for ethical drug promotion to assure drug safety and safe use of drug on the part of the individuals in the community.

This code of practice is an initiative from the Health Ministers' Council for Cooperation Council States and its Executive Office to organize this relation, and I do hope and look forward to see the pharmaceutical companies fully commit themselves to this Gulf Code of practice & in the meantime the Council States should monitor its implementation to protect the society against an unjust marketing or fallacious promotion.

I do pray to Almighty Allah that this code proves to be useful to all workers in health and pharmaceutical services, and to be a good help to them in the practice of honorable marketing and gives them the chance to provide the best services to serve the community.

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Gulf Code of Pharmaceutical Promotional Practices in the GCC

Introduction :

This Code is considered as an ethical code for the practicing of pharmaceutical promotion in the GCC. All companies working in the Kingdom of Saudi Arabia , Doctors, 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..

General Principles :

1- The Pharmaceutical industry 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 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.**

Terms of Gulf Code of Pharmaceutical Promotional Practices.

Article (1)

Marketing Authorization and Approved Labeling

1.1. A medicinal product must not be promoted for sale or supply before issuing the marketing authorization license In The GCC.

1.2 According to the national laws and regulations, all advertising and promotional materials must be in approved and certified by the Executive Board of the Health Ministers› Council.

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 GCC Authority.

2.2 The Advertisement 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.

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 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 This information 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 In general should be in conformance with the religious, social traditions, ethical, and cultural fundamentals for this society.

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 GCC or submission of information in this respect is not permissible by all means as this is the role of Executive Board of the Health Ministers› Council by giving analysis results etc.

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 Executive Board of the Health Ministers› Council informing them about the unexpected serious side effects relevant to the pharmaceutical product.

Article (3)

Direct contact with consumer:

3.1 Companies 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).

3.2 Companies and health care providers are both responsible for the education of public with the accurate and balanced Information that related to drugs and diseases.

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 the by laws of the Central Registration System for the drug companies registration, 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.

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 Companies 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 medicinal products must not supplied :

(a) Medicinal products which used in psychotropic or contain a narcotic substances and defined by the executive role of narcotics and psychotropic's law in the member states.

(b) Any other medicinal products that prohibited by the Executive Board of the Health Ministers› Council.

Article (7)

Symposium , Meetings and Medical Education Events:

7.1 All promotional, scientific or professional meetings, congresses, conferences, symposium, and other similar events (each an "event" that organized or sponsored by a company must be held in an appropriate venue that is conducive to the main purpose of the event. Such hospitality is appropriate and can be offered if It complies 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 (one or more educational presentation(s) should be the highlighted issue of the meeting).

(d) Increase knowledge of the attendees about the presented topics.

7.2 Hospitality which provided in promotional, professional or scientific events (whether it was 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.

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 appropriate.

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.

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 clearly subordinate in terms of time and emphasis.

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 Companies are committed to inform to all participants directly or indirectly about its sponsoring for the scientific and educational activities. Also, the companies should make an announcement about those activities through brochure, exhibition, Posters, pamphlets and advertisements which distributed at the end of this meeting.

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 Advertizing 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 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 medicinal 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, must not cause any inconvenience or disturbing to them.

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 board which will be responsible about company›s medicinal products. This scientific board must include on a doctor or, where appropriate, 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.

Article (11)

Enforcement roles:

11.1 Each company must have a specified procedures to monitor and observe any infringements to this codes.

11.2 The chambers of commerce and industry will form a committee, in cooperation with Executive Board of the Health Ministers› Council , which include the company›s representative, in order to ensure their commitment to this Code in the Gulf country .

11.3 Any complains about the implementation of this code should be presented to the committee , so it can study It and take a decision about the company and inform it about its infringement.

11.4 If the company didn't comply to committee decision, the committee must inform the Executive Board of the Health Ministers› Council Authority to take an appropriate action to the company›s infringements.

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