وزارة الصحة ووقاية المجتمع

MINISTRY OF HEALTH & PREVENTION

Code of Ethical Practices for the Promotion and distribution Of Medical Products

United Arab Emirates

November 2017

Contents

I- OBJECTIVES:

This document provides the directives for ethical promotion and distribution of medical products in the United Arab Emirates. It covers the minimum standards that should govern the interaction between medical product companies or their representatives and the healthcare professionals and it aims at ensuring that all interactions between them are intended to advance healthcare practices and to benefit patients.

This document is not intended to restrain the promotion of medical products nor to limit interactions between medical product companies and healthcare professionals.

II- SCOPE:

This code is binding to:

- All entities involved in the promotion of medical products in UAE, including and not limited to: Marketing Authorization holders and whoever acts on their behalf, distributors, marketing consultants, etc. This will be referred to in the rest of this document by "medical products companies".
- All individuals and entities involved in the prescription, dispensing, purchase, enlisting and reimbursement of medical products in the private and governmental sectors (covering all medical and pharmaceutical facilities) …. This will be referred to in the rest of this document by "the healthcare professionals".
- For the purpose of this document, medical product refers to pharmaceutical products (originators, generics, herbal, biological, vaccines, etc.), medical devices and consumables, and medical equipments.

III- GENERAL PRINCIPLES:

Medical product companies and healthcare professionals share the responsibility of supporting the advancement of healthcare in the United Arab Emirates, and fostering an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients,

The medical products industry has as well the responsibility to provide accurate and updated information about its medical products to the healthcare community; such responsibility is derived from its extensive knowledge and experience in the development of these products,

Medical product companies have the obligation to ensure that all marketing activities for their products are applied with the highest standards of ethical behavior, and to maintain

appropriate procedures to ensure compliance with this code and other applicable codes of conduct.

IV- TERMS OF THE UAE CODE OF GOOD PROMOTIONAL PRACTICES:

1. MARKETING AUTHORIZATION AND APPROVED LABELING:

1.1. A medical product must not be promoted in UAE prior to the grant of the marketing authorization allowing its sale or supply in the country,

1.2. A medical product must not be promoted outside of its approved indications

1.3. All advertising and promotional materials must be in accordance with the approved labeling.

1.4. This provision is not intended to restrict a proper non promotional scientific exchange of appropriate technical information concerning a medical product non authorized in the UAE, including information on investigational findings, in a scientific setting or at medical conferences.

2. PROMOTIONAL MATERIALS - INFORMATION TO BE MADE AVAILABLE:

2.1. Promotional materials and advertisements, whether printed or electronic materials including audiovisual materials, must include the essential product information, in consistency with the approved insert leaflet, including:

1) Brand name and name of active ingredient
2) Name of the marketing authorization holder in UAE
3) A scientific reference to be cited in case of medical claim
4) Summary or short prescribing information: approved indications, dosage, administration, special precautions, contraindications and side effects.

2.2. In the case of a reminder advertisement, which is a short advertisement containing the name of the product; the abbreviated prescribing information (referred to in article 2.1) can be omitted.

3. PROMOTION AND ITS SUBSTANTIATION:

3.1. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medical product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. For example:

1) The results of a study, which are contradicted or questioned by another scientifically valid and clinically relevant study, may not be cited without qualifications;
2) A study should not be cited or presented in such a way that it could convey an incorrect or misleading impression of the nature, scope, results, implementation or importance of the study;
3) A study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical relevance of the investigation and its application in humans;
4) The report of such a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents and relevance of the report and the conclusions stated therein;
5) Statements of comparisons between different drugs or alternative treatments should be expressed in such a way as to make the statistical validity and clinical relevance clear; all comparisons must be scientifically appropriate and balanced;
6) Particular care should be taken that essential information regarding medical products' safety, for example, contra-indications, precautions, and side effects, is appropriately and consistently communicated.
7) The words "safe" or "effective" should not be used without qualification.

3.2. Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from healthcare professionals.

3.3. Promotion must encourage the rational use of medical products by presenting them objectively and without exaggerating their properties.

3.4. When promotion refers to published studies, clear references should be given. Clinical data referenced to unpublished company sources should specify: "Data on file and available upon request." Sufficient information to permit evaluation of referenced data must be made available to recipients of promotional communications either as an integral part of the promotional communication, as a reference to a published report, or upon request.

3.5. Any comparison made between different medical products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

3.6. All artwork, including graphs, illustrations, photographs and tables taken from published studies and included in promotional material should:

1) Clearly indicate the precise source(s) of the artwork; and
2) Be authentically reproduced; except where adaptation or modification is required, it must be clearly stated that the artwork has been adapted and/or modified

3.7. Particular care must be taken to ensure that artwork included in promotion does not mislead about the nature of a medicine (for example whether it is appropriate for use in children) or mislead about a claim or comparison.

3.8. Use of quotations in promotion:

1) Quotation 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 code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.
2) Quotations from medical literature or from personal communications associated with medical literature shall not change or distort in any way the intended meaning of the author, clinical investigator or the significance of the underlying work or study.

4. DITRIBUTION OF PROMOTION:

4.1. Promotion should be in line with the healthcare facilities' approved policies, whenever such policies are in place, and should only be directed to those whose need for, or interest in the particular information, can reasonably be assumed.

4.2. Data privacy of healthcare professionals should be observed, and should not be distributed or shared with any party.

4.3. The use of fax, emails, automated calling systems, text messages and other electronic data communication tools for promotion requires the prior permission or request of the healthcare professionals,

4.4. Mailing, email or similar contact list must be kept up to date. While healthcare professionals' wish to be excluded from the promotional mailing list must be respected, full mailing list should be maintained to permit provision of important information concerning warnings, serious adverse reactions, product recall, etc.

5. TRANSPARENCY OF PROMOTION:

5.1. Programs shall not disguise or misrepresent their true promotional intent. Examples include market research studies and programs intended to promote a specific product.

5.2. Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter or be disguised as news or a third party report.

5.3. Material relating to medicines and their uses which is sponsored by a company must clearly indicate that it has been sponsored by that company.

5.4. Promotional material must not include any reference to registration authorities, unless the licensing authority specifically approves this.

5.5. Market research results should not be used in promotion. For the purposes of this Code, "market research" is any collection and analysis of information that is generated by non-scientific means and thereby not presentable in a medical or scientific forum or acceptable for use for medical or scientific purposes.

5.6. Medical products companies must ensure the transparency and adequacy of product information used in promotional materials.

6. EVENTS AND HOSPITALITY:

6.1. All promotional, scientific, educational or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, speaker training or investigator meetings for clinical trials and non-interventional studies, round table discussions) (each, an "event") organized or sponsored by or on behalf of a medical products company must be held in an "appropriate" venue that is conducive to the main purpose of the event. Hotels which are very well known as recreation locations - such as resorts, spas, golf hotels - reputed for entertainment are not acceptable under this code.

6.2. During those events, companies may only offer hospitality when such hospitality is appropriate,

6.3. Such events should also be:

1) Limited to relaying informative communication and providing scientific or educational value;
2) Focused on enhancing the knowledge of the attendees on the topic(s) being presented.
3) Attendees' selection must fulfill objective criteria demonstrating their eligibility to attend such events.

6.4. Companies may not organize or sponsor an event or the participation of healthcare professionals in events that take place outside the UAE (an "international event") unless:

1) Most of the attendees of the event are from outside the UAE
2) Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes more sense to hold the event in another country.

6.5. Hospitality extended in connection with promotional, professional or scientific events (international or domestic) shall be limited to travel, meals, accommodation and genuine registration fees.

6.6. Medical products companies may only pay for reasonable and actual travel. Travel provided to Healthcare Professional should not cover a period of stay beyond the official duration of the event.

6.7. For air travel, selection of the class of travel should be based on the policy set by the management of the authority or facility where the healthcare professional practices, if such policies exist. Otherwise, decision on the class of travel will be based on the duration of the flight and all medical products companies are expected to have preset thresholds for upgrading from economy to business and from business to first class.

6.8. Hospitality covers healthcare professionals only: Hospitality may only be extended to persons who qualify as participants in their own right. Inclusion of a healthcare professional's

spouse or other guests is not allowed. This applies not only to meals, but also to accommodation and any travel expenses.

6.9. Nature of hospitality: All forms of hospitality offered to healthcare professionals shall be reasonable and strictly limited to the main purpose of the event. As a general rule, hospitality must not exceed what healthcare professional recipients would normally be willing to pay by themselves.

6.10. No entertainment or other leisure or social activities should be provided or paid by medical product companies. Only secondary entertainment/hospitality linked to the main purpose of the event is considered appropriate provided it is modest in nature and in conjunction to meals. However, the Secondary entertainment should not dominate or interfere with the overall scientific content or the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the event

6.11. Informational discussions/meetings between medical representatives and a group of healthcare professionals may take place in meeting rooms in the healthcare facility that is the working place of the healthcare professional. In this case, the healthcare facility must not charge space rental fees or any other fees related to the use of the facilities to the medical product company.

6.12. Information provided during these meetings should be transparent and capable of substantiation and should be in line with all the provisions stated in articles 3 and 5.

6.13. Internal medical products companies' meetings, that are limited to company staff, are out of the scope of these provisions and are managed as per the company's policies and regulations.

7. GIFTS AND OTHER ITEMS:

7.1. No gift, monetary advantage or benefit may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medical product.

7.2. Educational items and/or gifts must not be given in the form of cash or cash equivalents (E.g. Debit cards, Gift cards, vouchers, loyalty cards and Gift certificates or any similar items). Any cash or cash equivalent items are strictly forbidden.

7.3. Promotional aids of minimal value and quantity may be offered to healthcare professionals if relevant to the practice of the healthcare professional. A promotional aid is a non-monetary item given for a promotional purpose. Possible examples of acceptable inexpensive promotional aids include: pens, note pads, convention bags, calendars, paperweights, mouse pads, portfolios, laser pointers, prescription pad, or business card holders. These items need to be of minimal value and quantity. Promotional aids branding should be limited to the name, logo of the company and of the medical product, its international nonproprietary name when applicable, or its trademark.

7.4. Informational or Educational Materials and Items of Medical Utility can be provided to healthcare professionals provided it is: (i) “inexpensive”; (ii) directly relevant to their practice; and (iii) directly beneficial to the care of patients.

7.5. Companies must not provide any gift to Healthcare Professionals engaged as consultants or speakers in lieu of a professional fee for their services.

8. DISTRIBUTION AND COMMERCIALIZATION OF MEDICAL PRODUCTS:

8.1. Medical products companies and their distributors can offer a quantity of free of charge goods (bonus) up to 15% of the invoiced quantity to pharmacies.

8.2. Apart from this, no monetary benefit or equivalent such as additional bonuses, discounts or any other forms of financial benefit may be offered to pharmacies or healthcare facilities for the execution of regular business activities such as and not limited to: allowing medical representatives’ access to the facility, visits to healthcare professionals, enlisting products in formularies, making products available on the shelves, etc.

8.3. This provision is not intended to deny the right of government funded institutions to negotiate orders and prices of medicines and medical products with medical product companies and their distributors, this process continues to follow the normal tendering and purchasing channels relevant to each institution.

8.4. This provision (article 8.1) does not cover not priced (freely priced) medical products whose prices and commercial conditions are set as per the agreements between the medical products companies, their distributors and the pharmacies.

8.5. Pharmacies and Hospitals in the private sector have the obligation of making registered medicines available for their patients based on patients’ needs and physicians’ prescriptions. Linking medicine availability in any pharmacy to the provision of free of charge goods, enlisting fees, any monetary benefit or profit considerations is strictly prohibited.

8.6. The permitted quantity of free of charge goods (bonuses) indicated in article 8.1 can be amended by increase, decrease or nullification via a decree issued by H.E. the Minister of Health and Prevention, whenever such amendment is needed.

8.7. Trade agreements between marketing authorization holders and their distributors are out of the scope of this code.

8.8. Should the marketing authorization holder or his local distributor decide to partner with a wholesaler to provide services such as storage and distribution that are beyond the capabilities of the local distributor, reasonable fees should be paid to the wholesaler in compensation for his services. In this case, a trade agreement should be put in place and it should state accurately the responsibilities and duties of each party.

9. SAMPLES AND/OR DEMONSTRATION PRODUCTS:

9.1. Product samples, clearly identified as such, may be supplied without charge in moderate quantities to the healthcare professionals who are qualified to prescribe that medical product to familiarize them with the product, either spontaneously or upon request.

9.2. The distributed quantity of samples should be limited. Each company should define a cap for samples distribution that should be reviewed annually.

9.3. No person may sell, purchase, trade or offer to sell, purchase or trade samples. Samples should not be used for commercial purposes or as part of a Post-Marketing Study.

9.4. Each sample must be clearly marked with non-erasable ink by 'Free Medical Sample – Not For sale' in Arabic and in English on both the outer pack and the inner pack and must be accompanied by a copy of the package insert. Each sample shall be no larger than the smallest available presentation or unit on the market.

9.5. Companies must have adequate systems of documentation, control of, accountability for, tracking and monitoring of samples which they distribute, directly or through their authorized representatives,

9.6. Samples must be transported and stored in a manner that is consistent with the storage conditions required by the product label and Quality Assurance requirements.

9.7. Provision of Demonstration Products and/or Samples must not improperly induce and/or encourage Healthcare Professionals and/or Healthcare Organizations to purchase, lease, recommend, prescribe, use, supply or procure medical products companies' products or services.

9.8. Medical products companies may provide examples (demo or product demonstration items) of their products to Healthcare Professionals and/or Healthcare Organizations in the form of mock-ups (such as unsterilized single use products) that are used for Healthcare Professionals and patient awareness, education and training.

10. SUPPORT FOR EDUCATION:

10.1. Continuing medical education of healthcare professionals can be sponsored by medical product companies for the sole purpose of improving patient care.

10.2. Sponsorship of education must not be offered or promised as an inducement to prescribe, purchase, sell, administer, enlist or reimburse a medical product.

10.3. All payments made within the scope of sponsorship of an educational event must relate to the expenses incurred in connection with the event. No payments are made to compensate healthcare professionals for time spent in attending the educational event.

10.4. Any payment or contribution made to a conference sponsor should in no way be tied to the relinquishment of control by the sponsor over the selection of content, faculty, educational methods, materials, and venue. Content of the educational conference must remain fair and unbiased to any particular product.

10.5. In the event where a medical products company wishes to sponsor healthcare professionals' participation in an educational event, selection of individual healthcare professionals to participate is the responsibility of the management of the medical facility.

11. CONSULTANCY SERVICES:

11.1. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel.

11.2. It is permitted for medical product companies to develop consultants through including healthcare professionals in programs intended to recruit and train speakers for company sponsored speakers' bureaus. In this case, healthcare professionals will be given extensive training on the company's medical product and on the compliance and regulatory requirements for communication on such products.

11.3. The hiring of the healthcare professional to participate in or provide such consultancy service as mentioned in 11.1 and 11.2 must not be done as an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medical product

11.4. The arrangements that cover these genuine consultancy services must, to the extent relevant to the particular arrangement, fulfill the following criteria:

1) A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
2) A legitimate need for the services has been clearly identified in advance of requesting the services,
3) The criteria for selecting consultants are directly related to the identified need

11.5. It is appropriate for consultants as described in 11.1 and 11.2 who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.

11.6. Healthcare professionals working as consultants for a medical products' company have the obligation to declare that he/she is a consultant to the company whenever he/she writes, speaks in public or contribute to a therapeutic committee about a matter that is the subject of the agreement or any other issue relating to that company.

11.7. Medical products companies shall maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.

12. CLINICAL RESEARCH INCLUDING POST MARKETING ASSESSMENT STUDIES:

12.1. Clinical assessments, post-marketing surveillance, experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

12.2. All clinical studies in UAE must abide by the regulations set by the relevant authorities.

12.3. Any remuneration provided to a healthcare professional participating in a clinical trial must be reasonable in accordance with the fair market value of the work performed.

12.4. Medical product companies should also comply with section 12 for the implementation of registries, epidemiological studies and other retrospective studies.

13. GRANTS AND DONATIONS:

13.1. Donations, grants and benefits in kind to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research are only allowed if:

1) They are made for the purpose of supporting healthcare, patients need or research; third party organized educational events, Healthcare Professional participation at third party organized educational events, scholarships, fellowships, or public awareness campaigns;
2) They are documented and kept on record by the donor/grantor;
3) They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medical products.
4) They are made to institutions only and not individuals.
5) Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient.

14. IMPROVEMENT IN PATIENT CARE THROUGH EDUCATIONAL AND MEDICAL PROGRAMS

14.1. Patient support programs are designed to improve patient care through educational or medical support.

14.2. All patient support programs must be in the interest of the patient and should not be commercial or promotional in any way.

14.3. All patient support programs in the UAE must be approved by the competent health authorities.

14.4. Where human resources are involved, medical products companies must use appropriate third party service providers or qualified persons who would be contracted to implement such programs.

14.5. The medical product company sponsoring the program must have no influence on patients' enrollment.
14.6. Confidentiality and privacy of patients participating in such programs must be maintained at all times.
14.7. Such programs must not constitute an inducement to healthcare professionals to prescribe, supply, recommend, enlist, reimburse, buy or sell any medical product.
14.8. A method for the measurement of outcomes including and not limited to medical, financial and patient satisfaction indicators must be determined prior to the start of the program. These indicators should be reported periodically to the concerned health authority.
14.9. Any printed or digital materials used for patient support programs must be non-promotional and must abide by the regulations set by the Ministry of Health and Prevention. Such materials should not promote the prescription, supply, recommendation, enlisting, reimbursement, purchase or sale of any medical product.
14.10. Medical products companies and contracted parties must take necessary steps to ensure that patients receive clear and transparent information on the program, its purpose and the identity of the sponsoring company and contracting party.

15. COMPANY STAFF:

15.1. Each company shall ensure that its sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medical products (each, a "medical sales representative") are familiar with the relevant requirements of this applicable code, and all applicable company codes and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medical products they promote.
15.2. Medical representatives must approach their duties responsibly and ethically and they must comply with all relevant requirements of this code, and all applicable codes and regulations, and companies are responsible for ensuring their compliance.
15.3. During each visit, medical sales representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medical product they present.
15.4. Medical representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's medical products, particularly reports of an adverse drug reaction.
15.5. Medical representatives must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, are in line with the facilities' policies and do not cause any inconvenience or interruption to patient care.

15.6. Medical representatives must not use any inducement or subterfuge to gain an interview with a healthcare professional. In an interview, or when seeking an appointment for an interview, medical sales representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

15.7. All company staff, and any personnel retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of this code and relevant company codes and regulations.

15.8. All company staff and any personnel retained by way of contract with third parties must respect patients' rights in maintaining their privacy and confidentiality of information.

15.9. Every company must establish a scientific service in charge of information about its medical products. This scientific service must include a doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before 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 the requirements of this code and any applicable advertising laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine.

15.10. Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of this code are met and should be able to submit to the Ministry of Health and prevention, upon request, all necessary documentations to prove compliance with the terms of this code.

16. ENFORCEMENT PROCEEDURE:

16.1. Medical product companies, pharmacies and all healthcare facilities must ensure awareness and education of their relevant staff on this code and provide them with training and guidance on the implementation of its terms.

16.2. Local Health Authorities will escalate to MOHAP any identified violations to the term of this code in healthcare facilities under their jurisdiction and MOHAP will coordinate with the health authority to take necessary corrective measures.

16.3. Ministry of Health and Prevention reserves the right to audit medical product companies, pharmacies and healthcare facilities to ensure compliance with the terms of this code.

16.4. Any incompliant practice will be investigated by the Pharmaceutical Licensing Committee of the Ministry of Health and Prevention and necessary corrective measures will be taken against any culpable party.

V- REFERENCES:

1. IFPMA* code of practice 2012
2. Middle East Code of promotional Practices – PhRMAG 2016
3. Gulf Code of pharmaceutical Practices in the GCC – 2011
4. Code on interaction with healthcare professionals – PhRMA 2009
5. EFPIA** code on the Prescription-only medicine to and interaction with Healthcare Professionals 2007
6. Saudi Code of Pharmaceutical Promotional Practices