MEA CODE OF PROMOTIONAL PRACTICES

2021

The Middle East & Africa (MEA)
Local Area Work Group (LAWG)

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Introduction

The Middle East Africa (MEA) LAWG is a representative body of the pharmaceutical industry in the Middle East and Africa. It is the goal of the MEA LAWG and its members to provide accurate, fair and objective information about medicinal products so that rational decisions can be made as to their use. With this in mind, the MEA LAWG has adopted the MEA Code of Promotional Practices (the "MEA Code"). The MEA Code is based on a premise of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise, consistent with international standards and practice.

The MEA Code is not intended to restrain the promotion of medicinal products in a manner that is detrimental to fair competition. Instead, the Code is founded on the following principles:

1

All marketing activities should be conducted in accordance with an enforceable code of marketing practices that is broad in scope, specific, consistent with highest ethical standards and is applicable to all pharmaceutical companies and all prescription medicines.

2

Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine or pharmacy. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

3

We should foster 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.

4

Companies have an obligation and responsibility to provide accurate, balanced and fair information about its prescription drugs to healthcare professionals.

5

The pharmaceutical industry derives its responsibility from its knowledge and experience in the development of these medicines.

6

Standards of ethical behavior shall apply equally to marketing of prescription medicines in all countries, regardless of the level of development of their economic and health care systems.

7

Companies have the obligation to maintain appropriate internal and external procedures to ensure full compliance with the specific guidelines of the MEA Code and other applicable codes of conduct.

8

Member companies are required to comply with applicable Data Privacy laws and regulations. A holistic approach must be followed when processing personal information from collection to use, storage, security, transfer, correction, erasure/deletion, retention, and matching.

"Personal Data / Personal Information" means any information relating to an individual that if used alone or in combination with any other information, can be used to identify or track back the identity of the individual.

Scope of the MEA Code

The MEA Code covers the promotion to healthcare professionals of prescription-only medicinal products.
"Promotion", as used in the MEA Code, includes any activity undertaken, organized or sponsored by a pharmaceutical company (directly or indirectly through third parties), which promotes the prescription, supply, sale, administration or consumption of its medicinal product(s).

The MEA Code covers promotional activity and communication directed not only to doctors but also those directed towards any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicine (each, a **healthcare professional**).

The MEA Code covers all methods of promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of medical sales representatives, internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and alike, and the provision of samples, gifts and hospitality.

The MEA Code is not intended to restrain or regulate the provision of non-promotional, medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription only medicines.

The MEA Code does not cover the following:

- The labeling of medicinal products and accompanying package leaflets;
- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- Factual, informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- Non-promotional information relating to human health or diseases;
- Activities that relate solely to non-prescription only medicinal products;
- Non-promotional, general information about companies (such as information directed to investors or to current/ prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the company and its products.

The MEA Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products. However those activities should be in line with local country regulations.

Within this MEA Code is Article 21, the "Implementation and Enforcement Procedures" which sets forth the framework for the implementation of the MEA Code, the processing of complaints and the initiation or administration of sanctions.

Applicability of Other Codes

The MEA Code sets out the minimum standards that the MEA LAWG considers must apply to promotional practices in the Middle East and Africa areas. In a manner compatible with applicable national laws and regulations, country associations must, at a minimum, implement the standards and the provisions contained in the MEA Code. Member companies must also comply, and must ensure that their respective subsidiaries comply, with other applicable codes and any laws and regulations to which they are subject. Country associations must establish adequate procedures for ensuring that their respective member companies comply with all applicable codes.

- In the event of a conflict between the provisions of other applicable codes, the more restrictive of the conflicting provisions shall apply.
  For the avoidance of doubt, the term "**company**" as used in this MEA Code, shall mean any legal entity that organizes or sponsors promotion that takes place within the Middle East and Africa, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization.
- To facilitate compliance with all applicable codes, each country association must establish adequate procedures for ensuring that each of its member companies complies with the requirements of such country association's national code. Additionally, member companies must be aware of or provide local advice on all international events (as defined in the MEA Code) in which their company is participating and occurring in their country.
- The spirit, as well as the letter of the provisions of the MEA Code must be complied with. For example, companies should apply consistent standards to their relationships with healthcare professionals, particularly with respect to gifts and hospitality.
  The MEA LAWG also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers Associations ("**IFPMA**") Code of Pharmaceutical Marketing Practices and the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**"), where applicable.

Provisions of the MEA Code of Promotional Practices

Overarching Principle:

Our relationships with healthcare professionals are regulated by multiple entities and are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.

Article 1

Marketing Authorization & Approved Labeling

Section 1.01

A medicinal product must not be promoted prior to the grant of the marketing authorization/regulatory approval allowing its sale or supply. In the absence of marketing authorization, prior approval from the relevant government authority must be obtained in order to medically & scientifically communicate product efficacy & safety within the submitted regulatory dossier (Communications under pre-license/ special license sales of medicinal products is prohibited unless it is explicitly allowed by the local law).

In such cases, medical and scientific communications that are allowed under local regulations should be limited to HCP's in hospitals/centers where the product is available/or as defined in the import license to ensure proper and safe use of the product.

Please refer to your local country regulations.

Section 1.02

Subject to applicable national laws and regulations, all advertising and promotional materials must be in accordance with the approved labeling in the concerned country.

Article 2

Promotion and its Substantiation

Section 2.01

Subject to applicable national laws and regulations, all promotional material must include the essential information consistent with the package insert, specifying the date on which such essential information was generated or last revised.

Section 2.02

Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 do not apply, provided that the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark.

Section 2.03

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 medicinal 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:

- The results of a study, which are contradicted or questioned by another scientifically valid and clinically relevant study, may not be cited without qualifications;
- 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;
- 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;
- 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 there in;
- 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 and;
- Particular care should be taken that essential information regarding pharmaceutical products' safety, for example, contra-indications, precautions, and side effects, is appropriately and consistently communicated, subject to legal, regulatory, and medical practices of each country.

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Section 2.04

Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from healthcare professionals. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. The words "safe" or "effective" should not be used without qualification.

Section 2.05

Promotion must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

Section 2.06

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. Sources of promotional statements shall be provided by the company within 15 days upon request.

Section 2.07

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

Section 2.08

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

A– Clearly indicate the precise source(s) of the artwork; and
B– Be authentically 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 artwork has been adapted and/or modified.

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 (for example by using incomplete or statistically irrelevant information or unusual scales).

Section 2.09

The word "new" must not be used to describe any product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

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Section 2.10

It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

Section 2.11

Substantiated information on serious and unexpected adverse reactions associated with pharmaceutical products should be reported to the appropriate national authority as a priority.

Section 2.12

Use of quotation in promotion.

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

Article 3

Acceptability of Promotion

Section 3.01

Companies must maintain high ethical standards at all times. Promotion must:

- Never be such as to bring discredit upon, or reduce confidence in, pharmaceutical industry and;
- Be of a nature which recognizes the special nature of medicines and the professional standing of the recepient(s) and;
- Not be likely to cause offence.

Provisions of the MEA Code of Promotional Practices

Article 4

Distribution of Promotion

Section 4.01

Data privacy of healthcare professionals should be observed.

Section 4.02

The frequency and volume of communication of printed material to the healthcare professional should be reasonable. Promotion should only be directed at those whose need for, or interest in, the particular information can reasonably be assumed.

Section 4.03

Mailing, e-mail and similar contact lists must be kept up-to-date. "Requests by healthcare professionals to be removed from promotional lists must be complied with "but full mailing lists should be maintained in order to permit provision of important information concerning adverse reactions, precautions, warnings, etc.

Article 5

Transparency of Promotion

Section 5.01

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

Section 5.02

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.

Section 5.03

Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

Section 5.04

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

Section 5.05

Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a manner that is likely to mislead, confuse or disparage.

Section 5.06

Market research material, which need not reveal the company name, must nevertheless state that a pharmaceutical company is sponsoring it.

Section 5.07

Market research results should not be used in promotion. For 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.

Article 6

Direct to Consumer Communications

Section 6.01

Unless clearly prohibited by law; companies as well as health care providers are responsible to ensure that information directly provided to patients is accurate, balanced, precise and in accordance with the promotional standards of Article 2.

Section 6.02

Direct to consumer advertising of prescription medicine is not allowed in most of the MEA countries; however, some countries allow advertising of non-prescription medicine/OTC* products after approval of the respective ministries of health. Please check your local country regulations.

It is to be noted that the MEA Code applies to the promotion of OTC* products (as defined in local regulations) directed towards HCPs. However, the promotion of OTC* products to consumers is outside the scope of the MEA Code and must comply with local laws and regulations.

**OTC: Over the counter*

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Section 6.03

Despite the restrictions described in Section 6.02, companies are allowed to contribute with healthcare professionals to conduct public/patient disease awareness programs and other communication to meet growing demands of consumers/patients for more information and to enhance public understanding of disease prevention, signs and symptoms of medical conditions, illnesses, and available treatments. Yet, such activities must adhere to the highest standards of accuracy and fair balance, and complement the role of the health care professional. When properly conducted, disease education and awareness initiatives are not promotional.

In developing Disease Awareness Campaigns and other communication strategies addressed to the general public, companies should consider the following:

- The primary purpose must be informative (i.e. to increase awareness of a disease or diseases and to provide health educational information on that disease and its management). It should not promote the use of a particular medicinal product.
- Only the prescribing HCP is responsible to decide the appropriate treatment for each disease in consultation with the patient.
- Mentions of a product name: It might be appropriate to mention a product's generic name provided that all available therapies are equally covered (both medicinal and non-medicinal). Companies need to ensure compliance with local regulations.
- The communication must include information that is: accurate, up-to-date, substantial, comprehensive, balanced and fair, readable/accessible, and quoting the appropriate references.

Section 6.04

A pharmacy's promotion of prescription only medicines should follow applicable local regulations.

Section 6.05

The above guidelines apply to all communication channels (including but not limited to printed materials, audio visual materials, the internet, websites and social media etc).

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Article 7

Company-Sponsored Hotlines & Advice on Personal Medical Matters

Section 7.01

Company-sponsored call centers commissioned to communicate directly to patients should address disease education only and should not be used for promotion as direct to consumer promotion is prohibited by local laws. In addition, they should be adequately monitored and supervised by qualified medical persons.

Section 7.02

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

Article 8

Due Diligence on Third Party Intermediaries

Section 8.01

In many instances, member companies may engage individuals or companies that interact or transact business with other parties on companies' behalf, the latter category serves as an intermediary between company and another third party and therefore is considered a Third-Party Intermediary (TPI), in scope TPIs may include but are not limited to: Sales Intermediaries, Logistics intermediaries, Tender Intermediaries, Lobbyists, Clinical Research Organizations, Regulatory Consultants, Events & Travel agencies, Media Agencies, Market Research organizations. TPIs that interact or transact business with HCPs require additional due diligence measures, as the actions and activities of a TPI can be attributed to company that retained that TPI. Subject to applicable local laws it is recommended that due diligence is conducted periodically and is covering the following areas: business justification of the use a TPI, reputational check, ownership and management structure of a TPI, anticipated use of sub-intermediaries, fair market value of the TPI compensation. Each member company must provide TPIs with appropriate training and other communications concerning the MEA Code of Promotional Practices guidance and applicable Anti-Corruption Laws.

Section 8.02

When sponsoring or supporting scientific, educational or professional meetings, programs or initiatives conducted by either health care organizations comprised of or headed by HCPs or patient organizations, member companies are recommended to establish and maintain appropriate procedures to ensure only reputable organizations and programs that help to advance healthcare are benefitting.

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Article 9

Real World Evidence, Post Marketing Assessments/ Studies and Non-interventional Studies of Marketed Medicines

Real World Evidence (RWE) is Evidence used for clinical, access and payment decision-making that is generated from data not collected in conventional controlled clinical trials. Real World Data (RWD) is collected in circumstances where the observer has no control over the medical management of the patient, beyond observing the outcomes.

RWE can be generated by actively collecting new data (primary source) or by analyzing existing data (secondary source). It can be generated prospectively or retrospectively and can be collected from many sources including administrative claims databases, surveys, electronic medical records, registries, observational studies and post-marketing assessment studies.

Key Considerations for RWE Processing:

- Patient Privacy
- Data Quality and Scientific Rigour
- Data sharing
- Applicable Legal and Regulatory Frameworks

Quality methodology is essential for credibility of data and to avoid damage to the perceptions of the research field.

The following sections of the article focuses on **POST MARKETING ASSESSMENTS/STUDIES OR NON-INTERVENTIONAL STUDIES:**

Section 9.01

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. The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

Section 9.02

A non-interventional study of a marketed medicine is defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation.
The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients.

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Section 9.03

Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

i. The study should be conducted in accordance to standard procedure with scientific objectives

ii. The study protocol must be approved and supervised by the company's scientific team and the execution of the study must be supervised by the company's scientific team or assigned third party organization. Each study protocol, based on the respective country regulations, guidelines and best practices to govern and regulate the conduct of non-interventional studies.

iii. Ethical Review Boards (ERBs) and/or Regulatory authorities are notified and approval is sought as required by local laws and regulations. Progress reports should be submitted to ERBs and regulatory authorities as required by local laws and regulations.

iv. These studies should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Pharmacoepidemiology Practices (GPPs) and applicable laws and regulations of the countries where the study is being conducted, as appropriate.

v. Local laws, rules and regulation on personal data privacy (including the collection and use of personal data) must be strictly adhered to;

Collecting patient information should follow the institutional procedure and should be documented as per the local policies. A formal consent to release information needs to be obtained from patients prior to the initiation of data abstraction.

vi. Implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure the Study can be conducted and data generated, documented, recorded and reported in compliance with the Protocol and applicable scientific standards;

vii. The study results must be analyzed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's scientific team, such service shall maintain records of the aforementioned reports for an adequate retention period, as applicable by local laws. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to respective industry regulatory bodies and/or committees, as per local guidelines.

viii. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority; and

ix. Agreements/contracts should outline that all parties shall conduct the Study in accordance with this Agreement, the Protocol, prescribing information and established clinical practice and in compliance with all Applicable Laws and Requirements, any condition required by an ERB and/or Regulatory Authority for all services rendered. Any remuneration provided is reasonable and reflects the fair market value of the work performed; immediately below, the basis for payment of those services.

x. Adverse Event Reporting - Due to the non-interventional nature of these studies, no pro-active safety data collection should take place. Only spontaneously mentioned safety events should be reported as required by the post-marketing pharmacovigilance regulations. Standard reporting standards should be followed when reporting any adverse drug reaction (ADR) related to an study drug regardless of whether the NIS specifies the drug or not according to the standard spontaneous reporting procedures for marketed products in their country. Such cases should be handled in the same way as any other post-marketing spontaneous report when received by Patient Safety departments and be reported to Regulatory Authorities within expedited timeframes as required.

Commercial teams should not be involved in the conduct of such studies. On exceptional basis, they may provide limited, blinded, administrative support.

Section 9.04

To the extent applicable, companies are encouraged to comply with section 9.03. For all other types of studies covered by section 9.02., including epidemiological studies and registries and other studies that are retrospective in nature.

Section 9.05

Collecting patient information should be done after consent from the patient. This provision also applies when companies are sending information to the patient.

Article 10

Events and Hospitality Congresses - Symposia - Medical Education

Section 10.01

Nature and venue of events

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each, an "event") organized or sponsored by a company must be held in 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,** can affect the image of the pharmaceutical industry, and therefore are not acceptable under the code although they might have proper business facilities. Hotels without such leisure offerings, but with adequate business facilities are considered appropriate venues.

During those events, companies may only offer hospitality when such hospitality is appropriate and complies with the provisions of any applicable code(s).

Such events should also be:

- Modest and simple in accordance to local standards;
- Limited to relaying informative communication and providing scientific or educational value.
- Primarily dedicated, in both time and effort, to promote scientific objective and educational activities and discourse (one or more educational presentations(s) should be a the core of the forum), and
- Focused on enhancing the knowledge of the attendees on the topic(s) being presented. Attendees' selection must fulfill objective criteria demonstrating their eligibility to attend such events.

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Section 10.02

Virtual International (Medical) Congress

In the context of virtual meetings, the notion of host country is no longer applicable, and this Section seeks to replicate the Codes' pragmatic approach in the virtual format.

A Virtual International (Medical) Congress is an International Congress where all activities are virtual/digital without an in-person event linked to it. Companies have the opportunity to participate in the form of virtual exhibition stands as well as virtual satellite symposia.

General Considerations for Virtual International (Medical) Congress

- Companies should consider the applicable industry Code of the geography from which the majority of delegates would be expected to come based on past experience. When there is no regional code, the MEA code applies.
- Companies should include a statement/disclaimer explaining to delegates when entering their virtual booth/exhibition to highlight that the content may not be applicable to their country.
- In collaboration with Congress Organizers:
  - Companies sponsoring/collaborating with a booth at the virtual exhibition area should be able to identify those wishing to view its booth (HCP or Non-HCP) and therefore determine what information will be appropriate and ensure that a process is in place to confirm participants' status as HCPs/Non-HCPs, reasonable efforts to restrict access to promotional material to HCPs only.
  - Companies should explore putting in place systems to appropriately address the situation where HCPs view promotional materials from countries other than their own.

Section 10.03

Location of events

Companies **may not** organize or sponsor an event or the participation of a healthcare professional in events that take place outside his home country (an **"international event"**) unless:

- Most of the invitees are from outside his home country and, given the countries of origin of most of the invitees, it makes much more sense to hold the event in another country; in other words, meetings should be held in the country where majority of the participants come from.
- 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. However, this should be limited to specific cases –for example, if the objective of the meeting is visiting facilities like a state-of-the-art hospital or clinic, an R&D facility or manufacturing plant in another country.

Provisions of the MEA Code of Promotional Practices

- When famous speakers/experts are not willing to travel to a specific country due to security concerns, and when the company is not able to find other speakers. Under this sole condition; it is acceptable to hold the meeting in an appropriate location outside of that country.
- Meetings held in the MEA region:
  In case of a large regional meeting with participants from different countries in MEA, the meeting can take place in any country in MEA from where the participants come from. However, the meeting can take place in any country in MEA even if no participants from that country are involved, should security or travel considerations hinder the meeting from taking place in one of the participants' countries. The same shall apply if there is a need to hold the meeting in a more central location due to travel considerations.

Section 10.04

Expenses reimbursement

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

Reimbursement of expenses and costs shall be made upon submission of receipts of actual expense incurred. Per diems shall not be provided unless otherwise required by local law. It's not allowed to pay honoraria to non-faculty or non-speaker participants in meetings, except under conditions described in Article 14 related to consultants.

Section 10.05

Hospitality covers HCPs 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 accomodation and any travel expenses. Additionally, companies should not facilitate, organize or assist any logistics of accompanying persons travel or participation into events whether company sponsored or independent, taking place in the country or outside it.

To prevent occasions where HCPs come to the company sponsored meeting with accompanying persons like sposes or kids, all companies need to explicitly discourage them from doing so in their invitation letter, the following can be used as an example:

"We would like to remind you that this is a personal invitation for one invitee. As per the MEA Code of Promotional Practices for pharmaceuticals; spouses, relatives or other guests in relation with health care professionals cannot be invited or included in any promotional, professional or scientific event."

Section 10.06

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.

Section 10.07

Hospitality provided during virtual events

Member Companies cannot provide hospitality for the Healthcare Professionals attending individually a virtual third-party organized event as well as the company organized events. The hospitality provided to a group of Healthcare Professionals attending a virtual event together, organized by member companies, in the presence of company representative (including scientific agency representative) could be assimilated to a face-to-face meeting.

Section 10.08

Entertainment

No entertainment or other leisure or social activities should be provided or paid by member companies. However, entertainment/hospitality is allowed if modest in nature, of reasonable duration and in conjunction to meals.

As a general guideline, more than 70% of the time of an event (working hours/day) should be spent on scientific and educational activities.

Section 10.09

The provisions above apply to all promotional, scientific or professional meetings, congresses, conferences, symposia, advisory board meetings, speaker training or investigator meetings and any other similar event. Companies must comply with guidance concerning the meaning of the term "reasonable", as described in this Article 10, as provided in, or in connection with, any applicable code(s).

Article 11

Education & Sponsorship of Healthcare Professionals

Section 11.01

Continuing medical education or other third party scientific and educational conferences or professional meetings can contribute to the improvement of patient care. Therefore, sponsorship of healthcare professionals by member companies is permissible.

Companies should ensure that:

- Selection of healthcare professionals for sponsored attendance at conferences or other educational events is not offered or promised as an inducement to prescribe, supply, sell or administer a medical product.
- All payments are reasonable in nature and relate to actual out-of-pocket expenses, incurred in connection with the specified event and covers only amounts that are allowable under this Article 11.
- No payments are made to compensate healthcare professionals for time spent attending the event.

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Section 11.02

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

Section 11.03

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when:

i– The participants receive extensive training on the company's drug products and on compliance with regulatory requirements for communications about such products.

ii– This training will result in the participants providing a valuable service to the company, and

iii– The participants meet the criteria for consultants *(as described in Article 14)*.

Section 11.04

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Section 11.05

Payments made directly 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.

Section 11.06

Companies have an obligation to disclose to participants in conferences that have an appearance of independence any direct or indirect sponsorship by the company of informational and educational activities. Sponsorship shall be disclosed to attendees prior to educational activities in brief statements in conference materials such as, but not limited to, brochures, syllabi, exhibits, poster sessions, and also in post-meeting publications, clinical reports or supplements to third-party journals.

Section 11.07

Financial support for meals or receptions may be provided to conference sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting. *(refer to section 10.07 for hospitality provided during virtual events)*

Article 12

Gifts and Other Items

Section 12.01

No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medcinal product.

Section 12.02

Prohibition of Cash and Personal Gifts

Providing or offering cash, or cash equivalents (such as gift certificates (even if limited to a medical gift, vouchers, etc.) or personal services to healthcare professionals either directly or indirectly through clinics and institutions is prohibited. Personal services are considered any type of services unrelated to the healthcare professional's profession and that confer a personal benefit to the healthcare professional. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered. Cultural courtesy gifts (such as birthday presents, condolence payments, gifts for opening a medical practice etc.) to healthcare professionals are also prohibited.

Section 12.03

Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Article 1 & Article 2). Providing or offering them to HCPs in relation to the promotion of prescription only medicines is prohibited. Examples of these prohibited items include post-its, mouse pads, calendars, plasters, lanyards, bookmarks, etc. As an exception, pens and notepads can only be provided to healthcare professionals in the context of company events for the purpose of taking notes during the meeting, provided they are company branded only, of minimal value and distributed in necessary quantity for the purpose of the event.

Section 12.04

Reprints of scientific and medical articles, when used as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are proactively presented to a HCP together, with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

Provisions of the MEA Code of Promotional Practices

Section 12.05

Informational or Educational Materials

In accordance with local laws and regulations, informational or educational materials may be provided to healthcare professionals or medical institutions (hospitals, clinics etc.) for the education of healthcare professionals or for the education of patients on disease and its treatments, provided the items are primarily for educational purposes and do not have independent value. The items must be relevant to the practice of medicine or pharmacy and beneficial to the care of patients.

Some examples of permitted informational or educational items include but are not limited to: patient education materials, medical education CD, VCD or DVD, scientific books, journal subscriptions and their electronic equivalents, or memory sticks pre-loaded with educational or informational data, if the storage capacity is commensurate with the materials provided. However, a tablet computer may have an independent value for the healthcare professional and must not be provided, even if they could be used to deliver education to patients.

Informational and educational items provided to healthcare professionals for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The books and subscriptions must be of reasonable market value. Other informational or educational items must be of modest value. Consideration should be given both to the cost of an individual book or subscription as well as the overall benefit to an individual healthcare professional in a given year and on an ongoing basis.

Section 12.06

Items of Medical Utility

In accordance with local laws and regulations, items of medical utility may be provided to healthcare professionals or medical institutions (hospitals, clinics etc.) if they are of modest value, do not offset routine business practices of the recipient and are beneficial to enhancing the provision of medical services and patient care.

Examples of acceptable medical utility items include but are not limited to: anatomical models for use in an examination room, inhalation device (without active ingredient), devices intended to assist patients to learn how to self-inject, software or mobile apps (e.g. BMI-calculator), diagnostic kits, side effects management kits for patients. However, items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses which are expected to be covered by the healthcare professionals themselves or their employers.

Items of medical utility should not be offered on more than an occasional basis, even if each individual item is appropriate.

Article 13
Samples

Section 13.01

In accordance with applicable national laws and regulations, product samples, clearly identified as such, may be supplied without charge in moderate quantities to healthcare professionals who are qualified to prescribe that medicinal product to familiarize them with the product, either spontaneously or upon request. Samples shall not be given for the sole purpose of covering a patient treatment. The quantity of samples should always be limited and defined annually.

Section 13.02

Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. 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.

Section 13.03

Each sample must be clearly marked 'Free Medical Sample – Not For sale' or words to that effect 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.

Section 13.04

Companies must have adequate systems of documentation, control of, accountability for, tracking and monitoring of samples which they distribute, and for all medicines handled by its authorized representatives. Member companies are encouraged to observe the following:

- 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.
- Member associations shall have a clearly defined process to prevent theft and possess the ability to report theft to the relevant authorities to avoid the potential misuse of lost quantities.

Section 13.05

No samples of the following medicinal products may be supplied, unless allowed by local law:

- Medicinal products which contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971; and
- Any other medicinal products for which the supply of samples is inappropriate, as determined by competent authorities, from time to time.

Article 14
Consultants

Section 14.01

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

A– 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, subject to clause (g) below, the basis for payment of those services;

B– A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;

C– The criteria for selecting consultants are directly related to the identified need and the persons responisble for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

D– The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

E– The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;

F– The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product and;

G– It is appropriate for consultants 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. Token consulting or advisory arrangements should not be used to justify compensating health care professionals for their time or their travel, lodging, and other out-of-pocket expenses.

Provisions of the MEA Code of Promotional Practices

Section 14.02

In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligations of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

Section 14.03

Limited market research, such as one-off phone interviews or mail/internet questionnaires are excluded from the scope of Article 14, provided that the healthcare professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal. Member associations shall provide guidance on the meaning of "minimal" in connection with any Applicable Code(s).

Section 14.04

If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Article 10 shall apply.

Section 14.05

Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to companies and ultimately to patients if these individuals choose to serve as speakers or commercial consultants for companies. To avoid even the appearance of impropriety, companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company. Upon disclosure, healthcare professionals who serve as speakers or consultants for companies should be required to follow the procedures set forth by the committee of which they are a member.

Article 15

Pharmaceutical Company Staff

Section 15.01

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 medicinal products (each a **"medical sales representative"**) are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide complete information about the medicinal products they promote.

Section 15.02

Medical sales representatives must comply with all relevant requirements of the applicable code(s) and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

Section 15.03

During each visit, and subject to applicable laws and regulations, medical sales representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present.

Section 15.04

Medical sales representatives must transmit to the scientific service of their companies any information they receive in relation to the use of their company's medicinal products, particularly reports of side effects.

Section 15.05

Medical sales 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, do not cause inconvenience.

Section 15.06

Medical sales representatives must not use any inducement or subterfuge to gain an interview. 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.

Section 15.07

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 the applicable code(s) and relevant laws and regulations.

Section 15.08

Every company must establish a scientific service in charge of information about its medicinal products. This scientific service must include a doctor or, where appropriate, a pharmacist who will be 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 the applicable code(s) 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.

Section 15.09

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 the applicable code(s) are met.

Article 16

Grants and Donations

Section 16.01

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

- They are made for the purpose of supporting healthcare or research;
- They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
- They are documented and kept on record by the donor/grantor;
- They are made to institutions only and not individuals.

Company sponsorship of healthcare professionals to attend international events is covered by Article 11.

Provisions of the MEA Code of Promotional Practices

Article 17

Pharmaceutical Industry & Patient Organisations

Section 17.01

The pharmaceutical industry recognizes that it has many common interests with patient organizations, which represent and/or support the needs of patients and/or caregivers.

Section 17.02

This guidance Article covers relationships between member companies and their subsidiaries/contracted third parties and patient organizations. Patient organizations are defined as not-for-profit organizations (including the umbrella Organizations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

Section 17.03

Member companies and their subsidiaries/contracted third parties are prohibited to engage patient organization(s) to advertise prescription-only products.

Section 17.04

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organizations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company should have an approval process in place for these agreements.

Section 17.05

The public use of a patient organization's logo and/or proprietary material by a pharmaceutical company requires written permission from that organization. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Section 17.06

Pharmaceutical companies must not seek to influence the text of patient organization material they sponsor in a manner favorable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

Section 17.07

Transparency

Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset. Member companies must ensure that their sponsorship or grant to a patient organization is always clearly acknowledged and apparent from the outset. Any sponsorship or grant provided by member companies to a patient organization must be transparent and accurately recorded and disclosed, as applicable.

Section 17.08

No company may require that it be the sole funder of a patient organization or any of its major programs.

Section 17.09

Member companies may engage patient organizations as experts and/or advisors to obtain expert information and/or advice on matters relating to their business, marketed products, patient needs or disease areas. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- A legitimate need for the services must be clearly identified and documented;
- The criteria for selecting services must be directly related to the identified need;
- The extent of the service must not be greater than is reasonably necessary to achieve the identified need;
- The contracting member company must maintain records concerning the services;
- The engaging of patient organizations must not be an inducement to recommend a particular medicine or marketed product; and the compensation for the services must be reasonable and not exceed the fair market value of the services provided.

Section 17.10

Events and Hospitality

All provisions from Article 10 apply.

Section 17.11

Enforcement

Upon complaint about member companies in breach of the provisions of this Article 17, "Implementation and enforcement procedures" detailed in Article 21 will be followed and sanctions will be applied accordingly.

Article 18

Improvement in Patient Care Through Educational and Medical Programs

Patient Support Programs are programs designed to improve patient care through educational or medical programs. They must be in the interest of patients whilst maintaining patient care at its core, and must not be provided to individuals for their personal benefit nor be construed as merely a gift, benefit in kind, donation or some other non-promotional or promotional commercial practice.

Provisions of the MEA Code of Promotional Practices

Section 18.01

Where human resources are involved, member companies must use appropriately qualified and designated staff, or a third party service provider or other appropriately qualified persons contracted to implement such programs i.e. a registered nurse.

Section 18.02

Outcomes of such programs must be clear, measurable and treatments must be in line with nationally accepted clinical guidance (where such guidance exists).

Section 18.03

Such programs must not constitute an inducement to health professionals or administrative staff to prescribe, supply, recommend, buy or sell any medicine. It must therefore always be ensured that all of the benefits of joint working with a third party service provider do not go to individuals but to organizations or institutions and alike.

Section 18.04

Pharmaceutical companies practicing in such programs must ensure that patient confidentiality is maintained at all times and that local data protection legislation is complied with. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of this Code.

Section 18.05

Service providers must take reasonable steps, when engaging a patient in an interview, or when seeking an appointment, to ensure that they do not mislead patients regarding their identity or that the service company they represent, along with the purpose of contact.

Section 18.06

Any printed material designed for use in relation to the provision of medical and educational goods and services in such programs must be non-promotional, and must abide by the pertinent provisions in the MEA Code. It is not appropriate for such materials to promote the prescription, supply, sale or administration of the member company's medicines. All printed materials must clearly identify the member company.

Section 18.07

Material relating to the execution and implementation of such patient centered programs for provision of medical and educational goods and services (including, but not limited to: internal instructions, external instructions, the written protocol for recipients and other printed material, including material related to therapy reviews) must be certified as per the Code and the internal policies of member companies.

Section 18.08

Companies are encouraged to partner with relevant parties such as health authorities, health boards, scientific associations and primary care organizations for their activities under such programs. There are advantages to this partnership: involvement of partner input, identification of proper objective, target audience and content, shared resources (e,g, financial or logistical), increased visibility and credibility of the Patient Support Program; ensuring long-term viability of the Program.

Article 19

Internet Usage

Section 19.01

One of the important responsibilities of the pharmaceutical industry, in addition to manufacture of high quality and reliable medicines for the community and contribute to their rational use, is also to transfer the available information concerning these products in an accurate and unbiased way, using the latest available communication techniques and according to the current principles of pharmaceutical promotion.

Section 19.02

Pharmaceutical firms (pharmaceutical manufacturers, importers and distributors) may create internet websites to serve the purpose, to give information about their firms, product lists, prices, product monographs and patient information leaflets approved by the Ministry of Health, health issues related to their product lines and developments in medicine, as well as information about their pipelines to the target groups in conformity with Code.

Section 19.03

Companies must comply with rules imposed by the State to internet usage and verdicts of the tribunals and international good practices about internet usage. Guidelines for company internet sites are given below.

Section 19.04

General Conditions

- Company internet websites are within the scope of the Code.
- Companies are responsible for the websites created by them or on their behalf.

Provisions of the MEA Code of Promotional Practices

Section 19.05

Transparency of Website, Origin, Content and Purpose

- Each website should have a home page, and clearly identify:
  - The identity and physical and electronic addresses of the sponsor(s) of the website;
  - The identity and physical and electronic addresses and contact numbers of the website owner and site designer;
  - The source(s) of all information on the website, the date of publication of the source(s) and the identity and credentials including the date credentials were received) of all individual/institutional providers of information included on the website;
  - The purpose or objective of the website and the target audience of the website (e.g. healthcare professionals, patients, caretakers and the general public, or a combination thereof).
- Information included in the website shall be regularly updated and shall clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.
- Information figuring on the website directed to healthcare professionals and to the general public should be prepared under the supervision of the scientific service of the company.
- Home page of the website should not feature information of promotional nature.
- Information and links directed to general public should appear on the home page.
- The homepage should bear the message "information given on this site is not substitute of a consultation of a physician or pharmacist".

Section 19.06

Content of the Website

Examples of the information that may be included in a single website or in multiple websites are:

i– General information on the company;

ii– Health education information;

iii– Information intended for healthcare professionals, including any promotion;

iv– Non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

Provisions of the MEA Code of Promotional Practices

Section 19.06.01

General Information on the Company

Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programs, discussion of regulatory developments affecting the company and its products, information for prospective employees, Human Resources links, company press releases, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising as long as they are not of a nature to be interpreted to contain product promotion.

Section 19.06.02

Health Education Information

Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to treatments, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioral change and other interventions that do not require use of medical products.

Each page of website containing health education information must always advise persons to consult a physician or pharmacist for further information.

- Information available on internet accessible to general public should conform to Article 19 of the present Code.
- Information directed to general public including references to diseases should have clear ad accessible reference sources.
- The content and level of the information provided should be tailored to the targeted audience.

Section 19.06.03

Pages of Healthcare Professionals

- The selections prepared for physicians/pharmacists and for patients/caretakers should be distinct from each other. The section prepared for physicians/ pharmacists should bear the sign “The part is prepared for physicians/pharmacists”.
- It is suggested to limit access to the website sections directed to healthcare professionals by a password or preventive warning.
- Any information on websites directed to healthcare professionals that constitutes promotion must comply with the Code. Such information must clearly be identified as information for healthcare professionals.
- Promotion activities and information contained in these pages should comply with this Code.

Provisions of the MEA Code of Promotional Practices

- The access to promotional materials related to prescription-only medicines and other products not legally permitted to be promoted to the general public should be limited to healthcare professionals.
- Information in conflict with the SPC approved by the Ministry- even if it approved in other countries- should not be used in product promotion.
- It is the responsibility of the pharmaceutical company owner of the site to update product related information.

Section 19.06.04

Non-Promotional Information for the Patients and the General Public

- Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company.
- For each product that is discussed, the website must contain full copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the unedited copy of any public assessment report issued by the Ministry of Health.
- Brand names should be accompanied by international non-proprietary names.
- The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organizations, patient organizations websites, etc. The website must always advise persons to consult a healthcare professional for further information.

Provisions of the MEA Code of Promotional Practices

Section 19.07

E-mail Enquiries

In communications with patients or members of the general public, discussion of personal medical matters must be avoided. Where appropriate, replies shall recommend that a healthcare professional be consulted for further information. If personal medical information is revealed, it must be held in confidence.

Section 19.08

Links with Other Websites

- Links may be established between company sponsored websites; to a company sponsored website from websites sponsored by other persons, or vice versa; but companies should not establish and not permit the establishment of links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals.
- User should be made aware that they are leaving a company website through a link to another website not related with the company.
- Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the linked website.
- When a user is linked to another website from a company website there should be a warning that the content of the link is not under the responsibility of the company and that it may contain information not in line with approved texts by the Ministry and may not conform to the applicable laws and regulations.

Section 19.09

Website Addresses in Packaging

Subject to any applicable law and regulation, uniform resource locators (URLs) of company sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

Section 19.10

Content Compliance

Companies should ensure that scientific and medical information in their websites is reviewed for accuracy and compliance with the Code. The scientific service established within the company may perform this function, or it may be entrusted to other appropriately qualified persons or institutions.

Section 19.11

Privacy

Data collected from visitors should be kept confidential. The website must conform to national and international legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.

Article 20

Guidelines on Interactions with Pharmacists

Interactions with Pharmacists are in the scope of the MEA Code articles.
The below is intended to reinforce applicable principles for those interactions.

Section 20.01

Product Discussions with Pharmacists

When a pharmacist is not allowed to prescribe medication as per the local laws, and is only allowed to dispense the medication prescribed by a physician, the below guideline should be adhered to:

Product discussions that occur as part of an interaction with company representatives and pharmacy personnel should always encourage the appropriate and legally authorized channels of dispensing prescription medications. Company representatives must never encourage, assist, or lend tacit support to any pharmacy personnel to engage in a behavior that violates local requirements (that would encourage product switching or product prescription).

Educational messages are permitted if they meet the below criteria

- To educate the Pharmacist, that the medication may only be dispensed when accompanied by a valid prescription.
- To educate and preserve/protect the validly issued medication prescription, and neither to switch nor influence the original prescribing decision, and nor to encourage a Pharmacist as a Dispenser to deliver a medication without a prescription.
- To educate about disease states, efficacy, drug-drug interactions, the medication's mode of action, dosing, and safety profile to help the Pharmacist respond to a patient's questions and/or to refer the patient back to his treating physician.

Section 20.02

Additional Considerations For Interactions with Pharmacists

While legitimate interactions with pharmacists and pharmacies are permissible, no arrangements that may be deemed to be an inappropriate influence on pharmacists in the fulfillment of their obligations may be concluded.

Each arrangement must fulfill all the following criteria

- It must have a legitimate business justification that is clearly described, documented, and approved;
- It should include rationale for the services to be provided;
- It should reflect an appropriate fair market value compensation for the services, when applicable;
- It is to be documented in a written agreement with the pharmacy that outlines the specific terms and requirements for the program and the payment;
- To ensure payment is not issued prior to confirming the delivery of contracted services and in a manner consistent with the documented terms.

Article 21

Implementation and Enforcement Procedures

Section 21.01

CERB Review Board Composition, Nominations (Refer to Annex A)

- Nomination procedures to the CERBs are at the discretion of the Local Association Executive Committee. However, each association member company shall have the opportunity to nominate members to the CERB and an equal representation of European and American companies should be maintained, if possible.
- The CERB chairman will be a member of the Local Association Executive Committee.
- The number of CERB members is at the discretion of the Local Association Executive Committee. However, the composition of the CERB should include compliance officers of member companies.

Provisions of the MEA Code of Promotional Practices

In the event that a compliance officer function is not available in the country for a member company, then membership of their Medical Director or appointed compliance liaison is encouraged);

- CERB members will serve for a period of two years, which can be renewed.
- The nomination of substitute members, observing that no company is represented with more than one member, may be appointed and participate as observers at CERB meetings.

Section 21.02

Review Board Composition, Nominations
(Refer to Annex A)

- At a minimum, the LERB will meet annually and will have three additional teleconferences.
- The number of LERB members is at the discretion of the MEA LAWG Executive Committee. However, the composition of the LERB should at a minimum include:
  - Chairman: MEA LAWG Executive Committee Member
  - Secretary: MEA Representative (non-voting member)
  - Regional Compliance Officers of member companies
  - Local legal council will be consulted when needed.

Nomination procedures to the LERB voting members are at the discretion of the MEA LAWG Executive. Regional compliance officers from each company are encouraged to participate in the LERB. No restriction is in place on the number of members eligible from the same company, however when voting, all members from the same company shall be allowed to issue one vote only per company.

- The election procedures for the LERB Chairman is at the discretion of the MEA LAWG Executive. However, the LERB Chairman should embody the values to be promoted and adhered to by the Association.
- LERB members will serve for a period of two years, which can be renewed.

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Section 21.03

Reporting Structure

- The CERB will provide minutes of regular sessions and a quarterly written report of activities to the LERB through the LERB Secretary (MEA representative).
- The CERB will maintain at a local level a registry of all member companies reported complaints and violations for the purpose of providing guidance for other member companies as well as monitoring trends in the market.
- The LERB Chairman will present a summary of activities to the MEA LAWG as part of the regular bi-annual session.

Section 21.04

Enforcement Procedure

Section 21.04.01

General Procedures

- Majority of the entire membership form the quorum for the CERB and the LERB.
- The CERB meets as business requires, but not less than quarterly.
- Voting is by absolute majority of the voting members.
- The Chairman of the LERB and CERB can invite substitute members to form the quorum. Substitutes for company representatives can also be invited to each meeting and can participate in each session. The substitutes can express their opinions on the subject under discussion but they have voting rights only in case permanent members are missing. At the beginning of each meeting, the Chairman minutes the names of the substitute members with voting rights.
- Members who do not participate to three consecutive meetings without a legitimate reason will be eliminated from permanent membership and replaced by the appointed substitute.
- If within 30 days in three scheduled consecutive meetings, the committee cannot achieve quorum or cannot come to a decision related to a complaint, the committee will refer the complaint to the next higher level.
- The Chairman may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but have no voting rights.
- LAWG General Secretary shall provide the necessary administrative support to CERB.

Provisions of the MEA Code of Promotional Practices

Section 21.04.02

Levels of the Enforcement Procedure

Level I –
Company to Company (Refer to Annex A)

- Complaints between MEA LAWG member companies should first be sought to be reconciled amicably between local country management in accordance with any applicable laws.

- A courtesy phone call to local country management should precede any formal written correspondence.

- In countries where a company doesn't maintain a local corporate presence, complaint should be addressed directly to the company's regional headquarters; or where the company has no regional office, to corporate headquarters.

- Formal correspondence should provide adequate information to make a proper assessment of the complaint and be presented with all relevant supporting material and information including the following:

  - Name and address of the complainant company;
  - Name and address of the respondent company;
  - Documentary proof that the compainant already fulfilled the first action mentioned above;
  - Material subject to the complaint(s): The complaint should be detailed and submitted; copies of any advertisements and/or promotional material, and/or any other material (such as invitations, agreements, correspondence, etc.) which may be relevant.
    If the complaint is a scientific issue, supporting literature and any studies relied on.
  - Date of complaint;
  - Date, and for events, place of the breach of the Code;
  - Summary of the Complaint: Summary should include the breached Code article numbers and a detailed summary of the breach.

- The company alleged to be in breach of the Code should provide a formal written response to the complainant and any corrective action taken.

- If within two (2) weeks, the complainant does not receive a satisfactory response, the formal complaint procedure to Country Ethics Review Board (CERB) or to LAWG Ethics review Board (LERB) should be implemented.

Provisions of the MEA Code of Promotional Practices

Level II –
Country Ethics Review Board (CERB)

- If the response is not satisfactory or a mutually agreeable solution is not found at the company to company level within the two (2) week timeline, the complainant may forward a written complaint and supporting documents to the CERB.

- The company alleged to be in breach of the Code has the opportunity to provide a formal written response to the CERB. If no reply is submitted from the company alleged to be in violation of the Code, a ruling will be made based solely on material supplied by the complainant.

- The review is to be handled in a strictly confidential manner. The identities of the concerned parties should be kept confidential, pending the CERB recommendation.

- When the written complaint reaches the CERB, the following points are checked:

  - The complaint matter is under the Code, taking into consideration interpretations and guidance provided by the MEA Regional Code;
  - The information in the complaint letter is sufficient to establish the case;

- In case the file is incomplete, the complaint is considered not valid until completion of the complaint file.

- Majority of the entire membership forms the quorum and voting is by absolute majority.

- The CERB has three (3) weeks to contact the concerned parties, complete a review of the complaint and issue a corrective action where appropriate or recommendation for penalty sanctions to the LERB (See Sanctions).

- The decision is announced in writing to both the complainant and the respondent companies, irrespective whether there is a sanction or not. If there is breach of the Code, corrective measures shall be asked to be taken to correct the situation.

- The respondent company shall have seven (7) days to provide a written undertaking that the breaching activity will cease forthwith and that all possible steps will be taken to avoid similar breach of the code in future. This undertaking must be signed by the senior country management and compliance officer and must contain detailed evidence of the implementation.

- In all cases, the complainant and the respondent company may appeal against the ruling within ten (10) days of the written notification of the ruling, accompanied by reasons as to why the ruling is not accepted. These reasons will be circulated to the LAWG Ethics Review Board (LERB), which will then provide a secondary review.

Provisions of the MEA Code of Promotional Practices

Level III –
LAWG Ethics Review Board (LERB)

If the complaint or alleged Code violator is not satisfied with the recommendation of CERB (or the CERB is unable to render a judgment within three (3) weeks), the two parties reserve the right to request a review by the LERB. In countries where no IFPMA member association exists, complaints can also be submitted to IFPMA for adjudication, if it is believed that a breach of the IFPMA Code of Practice has taken place.

- In the event that the CERB is not operational, the complainant company may address the complaint directly to the LERB.
- The LERB has a four (4) week duration to review the complaint through telecon and may convene anemergency session of the LERB depending on the particular nature of the code violation. The LERB has four (4) weeks to contact the concerned parties, complete a review of the complaint and issue a corrective action where appropriate.
- Upon review by the LERB, sanction penalties (See Section 20.05) may be recommended to the MEA LAWG Executive Committee for review.

Level IV –
MEA LAWG Executive

- The MEA LAWG Executive Committee (Executive), composed of senior industry Executives, is the sole Code enforcement body capable of imposing penalty sanctions. (See Section 20.05).
- The Executive will review sanction recommendations from the LERB within four weeks after submission by the LERB.
- The MEA LAWG Executive Committee decision is final.

Section 21.04.03

Case Reports

- At the conclusion of any case under the Code, the complainant is advised of the outcome and CERB or the LERB shall prepare a written report summarizing the findings and the agreed corrective actions including sanction recommendations, if any.
- A copy of the report is made available to both the complainant and respondent company. The CERB or LERB Chairman considers any suggested amendments.
- Copies of all case reports shall be submitted on a calendar quarter basis to the LERB Secretary (MEA Representative) for inclusion in the regional MEA case file.

Provisions of the MEA Code of Promotional Practices

Section 21.05

Sanction Authority & Administrative Actions

- The MEA LAWG Executive Committee has the sole authority to issue penalty sanctions for violations. The CERB and LERB may issue corrective measures in the form of administrative actions and may recommend penalty sanctions to the higher authority as part of the summary findings issued.

- Where the Country Ethics Review Board (CERB) or LAWG Ethics Review Board (LERB) concludes that there has been a violation of the Code, an appropriate corrective action shall be administered against the breaching company. Corrective actions shall be commensurate to the severity level and frequency of occurrence.

- The CERB and LERB are authorized to impose corrective measures in the form of administrative sanctions which may include but are not limited to the following internal industry actions:

  - Removal of a detail aid from the market;
  - Formal request to breaching company (senior country management and compliance officer) to cease the violation;
  - Recommendation to the higher authority for penalty sanctions;

- Upon the recommendation of the LERB, the MEA LAWG Executive Committee is authorized to impose corrective measures in the form of penalty sanctions, which may include but are not limited to the following **external industry** actions:

  - Forward a formal written communication to company headquarters.
  - To reprimand the company and publish details of that reprimand.
  - To request the company to publish a corrective statement.
  - To present to the MEA LAWG Membership through the Steering Committee the proposal of suspending the company from the MEA LAWG.
  - Notification of respective national and international industry associations such as PhRMA, IFPMA and EFPIA.

Annex (A) Reporting Structure & Implementation and Enforcement Procedure

Level 4 Complaint

Owner: MEA LAWG
(MEA Local Area Work Group)

Penalty Sanctions

Unresolved

Level 3 Complaint

Owner: LERB (Local Ethical Review Board)
Complaint should be sent to the LERB Chairman. The LERB Chairman: MEA LAWG Executive Committee Member

Admin Sanctions

Unresolved

Level 1 to Level 3 directly if the CERB is not functional

Level 2 Complaint*

Owner: CERB (Country Ethical Review Board)
Complaint should be sent to the CERB Chairman. The CERB Chairman: Country LAWG Executive Committee Member

Admin Sanctions

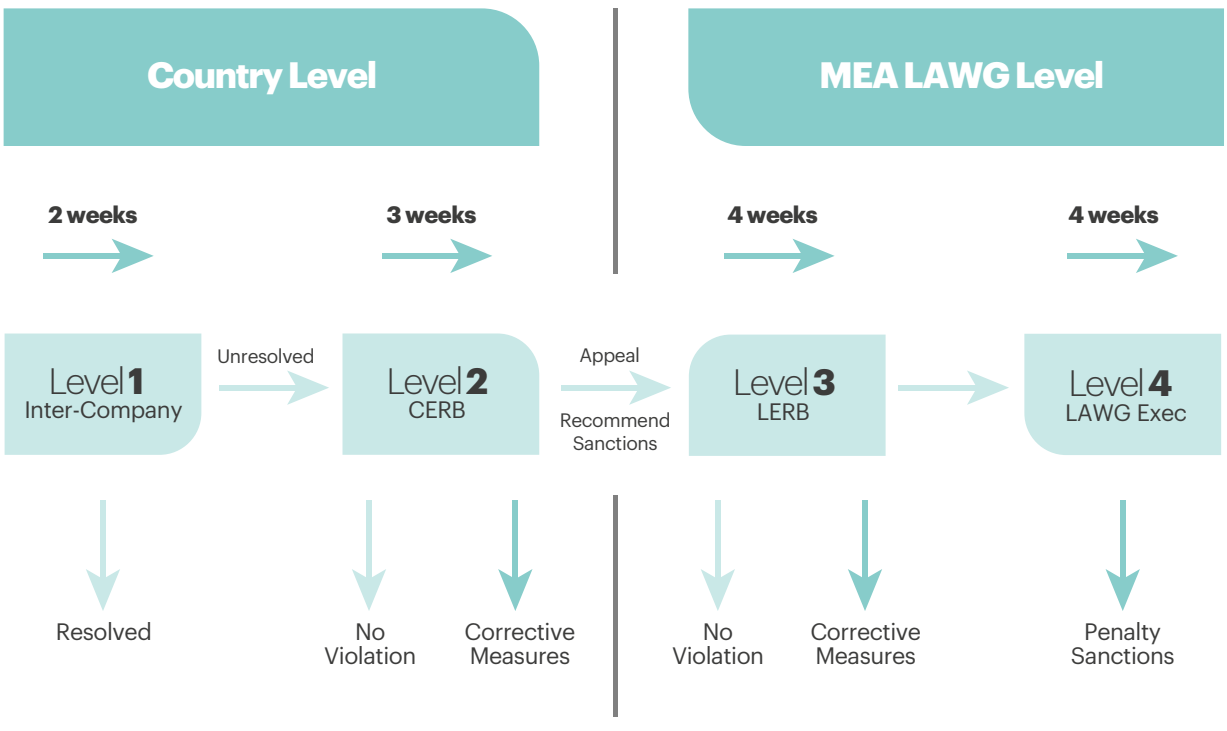
Unresolved

Level 1 Complaint

Owner: Company to company

** In countries where no IFPMA member association exists, complaints can also be submitted to IFPMA for adjudication, if it is believed that a breach of the IFPMA Code of Practice has taken place.*

Annex (B) Implementation and Enforcement Procedure



Note: Corrective Measures: Administrative (e.g. Changes to detail aid)
Penalty Sanctions: Issued only by LAWG Exec (Suspension)