The 13th International Pharmaceutical and Medical Device Compliance Congress, Athens 04/19

MEA CODE OF PROMOTIONAL PRACTICES

BECAUSE PATIENTS COME FIRST

THE MIDDLE EAST AND AFRICA (MEA) LOCAL AREA WORK GROUP (LAWG)

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Outline

- MEA Code Revisions
- Guiding principles
- MEA Code provisions highlights
- MEA Code Enforcement
- Next level Partnerships



MEA CODE REVISIONS

2005

- First written by PhRMA, MEA LAWG and LERB members, in line with IFPMA and EFPIA
- · Enforceable among all pharmaceutical companies in the MEA region
- · Aligned with international standards and practices

2010

First Revision.

- <u>Sections added</u>: Post Marketing studies, Grants and Donations, Patients Organization, Internet Usage...
- <u>Sections revised:</u> Marketing Authorization and approved labeling ,Direct to Consumer Communications , Events and hospitality...

2014

- Revision to align with the IFPMA Code update, at a minimum
- · Revision of Events and hospitality and Gifts sections
- · Special focus on Appropriate location of meetings

2016

- Revision of different articles: Samples, Implementation and Enforcement Procedures etc..
- · Added new articles:
 - > Improvement in patient care through educational and medical programs
 - > Guidelines on Interactions with Pharmacists

2019

RWD, Data Privacy, Third parties Assurance, Interactions with POs, Gifts, Entertainment, Enforcement

MEA Code Signatories (22 companies)

































BAYER

Bristol-Myers Squibb









Guiding Principles

- The Code is broad in scope, specific, consistent with highest ethical standards and is applicable to all pharmaceutical companies and all prescription medicines.
- Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine or pharmacy.
- We should foster an environment where the general public can build trust and confidence in the industry.
- Companies have an obligation and responsibility to provide accurate, balanced and fair information about its prescription drugs to healthcare professionals.

Guiding Principles

- The pharmaceutical industry derives its responsibility from its knowledge and experience in the development of these medicines.
- Standards of ethical behavior <u>shall apply equally</u> to marketing of prescription medicines in <u>all MEA countries</u>.
- 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.

MEA Code Provisions

PROVISIONS OF THE MEA CODE OF PROMOTIONAL PRACTICES

•	Article 1	. MARKETING AUTHORIZATION & APPROVED LABELING
•	Article 2	. PROMOTION AND ITS SUBSTANTIATION
•	Article 3	. ACCEPTABILITY OF PROMOTION
•	Article 4	. DISTRIBUTION OF PROMOTION
•	Article 5	. TRANSPARENCY OF PROMOTION
•	Article 6	. DIRECT TO CONSUMER COMMUNICATIONS
•	Article 7	. COMPANY-SPONSORED HOTLINES AND ADVICE ON PERSONAL MEDICAL MATTERS
•	Article 8	. POST MARKETING ASSESSMENTS/STUDIES OR NON-INTERVENTIONAL STUDIES OF
	MARKETED MEDICINES	
•	Article 9	EVENTS AND HOSPITALITY - CONGRESSES - SYMPOSIA - MEDICAL EDUCATION
•	Article 10	EDUCATION AND SPONSORSHIP OF HEALTHCARE PROFESSIONALS
•	Article 11	GIFTS AND OTHER ITEMS
•	Article 12	SAMPLES
•	Article 13	CONSULTANTS
•	Article 14	PHARMACEUTICAL COMPANY STAFF
•	Article 15	GRANTS AND DONATIONS
•	Article 16	PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS
•	Article 17	IMPROVEMENT IN PATIENT CARE THROUGH EDUCATIONAL AND MEDICAL PROGRAMS
•	Article 18	INTERNET USAGE
•	Article 19	GUIDELINES ON INTERACTIONS WITH PHARMACISTS
•	Article 20	IMPLEMENTATION AND ENFORCEMENT PROCEDURES
•	ANNEX A	REPORTING STRUCTURE & IMPLEMENTATION AND ENFORCEMENT PROCEDURE
•	ANNEX B	IMPLEMENTATION AND ENFORCEMENT PROCEDURE

GIFTS AND OTHER ITEMS

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- No gifts, pecuniary advantage or benefit may be supplied, offered or promised to a HCP as an inducement to prescribe, supply, sell or administer a product.
- Prohibition of Cash and Personal Gifts: Payments in cash or cash equivalents (such as gift certificates (even if limited to a medical gift), phone cards, etc.) must not be provided or offered to healthcare professionals either directly or indirectly.
- Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.
- Cultural courtesy gifts must not be provided or offered to healthcare professionals.
- Any gift offered to a HCP must be directly related to practice of medicine or benefit the HCPs patients or to serve a genuine educational or medical function, such as: promotional aids of minimal value and quantity, informational or educational materials and items of medical utility.

Always refer to local laws and regulations.

MEA Code Article 11 provides more details on permissible gifts

IMPROVEMENT IN PATIENT CARE THROUGH EDUCATIONAL AND MED PROGRAMS

IMPROVEMENT IN PATIENT CARE THROUGH EDUCATIONAL AND MEDICAL PROGRAMS

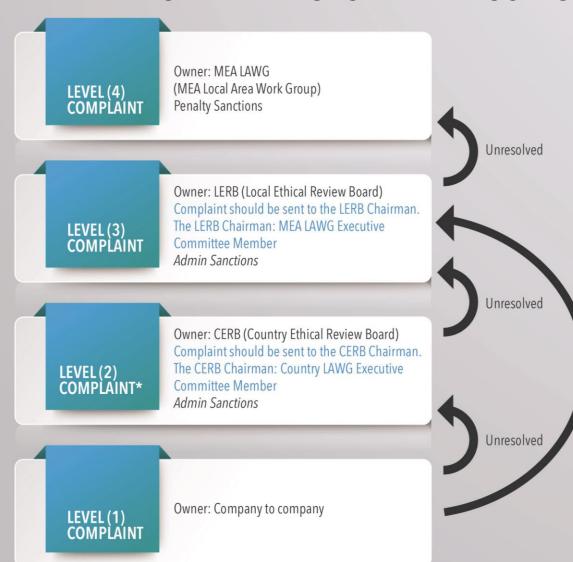
Patient Support Programs are programs designed to improve patient care through educational or medical programs.

- Outcomes of such programs must be clear, measurable and treatments must be in line with nationally accepted clinical guidance (where such guidance exists).
- Such programs must not constitute an inducement to health professionals or administrative staff to prescribe, supply, recommend, buy or sell any medicine.
- Respect of patient confidentiality and data protection.
- Material relating to the execution and implementation of such programs must be certified as per the MEA Code and the internal policies of member companies.
- 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.

IMPLEMENTATION AND ENFORCEMENT PROCEDURES

ANNEX B

IMPLEMETATION AND ENFORCEMENT PROCEDURE



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.

Level 1 to Level 3 directly if CERB is not functional



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Successful Partnership



Shared Purpose



Better Together



Impact on priorities



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THANK YOU