MEA Code of Promotional Practices - update
The Middle East and Africa Code of Promotional Practices is a set of guiding principles that are developed and enforced by the pharmaceutical companies to self-regulate marketing and promotional practices.
BACKGROUND ON THE MEA CODE

- First edition was created in 2005, revised in 2010
- Developed by PhRMA, MEA LAWG and LERB members
- Aligned with IFPMA and EFPIA (Does not include 2012 updates)
- Enforceable among all pharmaceutical companies in the region (13 companies)
GUIDING PRINCIPLES

• The code is broad in scope, specific, consistent with highest ethical standards
• Support and enforce ethical behaviors
• Foster an environment where the general public can be build trust and confidence in the industry
GUIDING PRINCIPLES

• Industry obligations and responsibility to provide accurate, balanced and fair information about its prescription drugs to healthcare professionals.
• The Code applies equally to marketing of prescription medicines in all MEA countries
• Obligation to maintain appropriate internal and external procedures to ensure full compliances
WHAT DOES THE CODE REGULATE?

- provides guidance on below topics:
  - Promotion
  - Events and Hospitality
  - Education and Sponsorships of HCPs
  - Gifts and Inducements
  - Non interventional studies of marketed medicines
  - HCPs paid services (speaking, advisory board)
  - Pharmaceutical staff practices
  - Relationships between member companies and patient organizations
  - Internet usage
  - Grants and Donations
  - Samples distribution
WHY UPDATE THE CODE?

• lots of changes and developments in the industry since the launch in 2005

• Changes are made to update the code based on:
  – Changes/updates and experiences from PhRMA, EFPIA, and IFPMA codes.
  – Incorporating the learning's from the code implementation since its launch
  – Incorporating a Q&A document to address frequently asked questions about the Code

• Additions and Revisions: Some Articles were revised and below articles were added
  – Post Marketing / assessment studies
  – Grants and Donations
    Pharmaceutical Industry and Patients Organization
ADDITIONS & REVISIONS

- Post Marketing / assessment studies
- Grants and Donations
- Pharmaceutical Industry and Patients Organization
- Internet Usage e.g. Social Media
REVISIONS & UPDATES

- Marketing Authorization and approved labeling (Article 1)
- Distribution of promotion (Article 4)
- Direct to Consumer Communications (Article 6)
- Company sponsored hotlines or call centers (Article 7)
- Events and hospitality (Article 9)
COMPANIES COMPLIANCE OFFICERS ROLE

• Compliance officers have a responsibility to ensure that all employees of their respective companies are aware of and are in compliance with the Code.

• Compliance officers have the duty to address all violations brought to their attention by your team and escalate the complaint, if necessary.
Reporting Structure & Implementation and Enforcement Procedure

**Level 1 Complaint**
Owner: Company to company

**Level 2 Complaint**
Owner: CERB (Country Ethical Review Board)
Complaint should be sent to the CERB Chairman.
The CERB Chairman: Country LAWG Chair.

**Level 3 Complaint**
Level 3 Owner: LERB (Regional Ethical Review Board)
Complaint should be sent to the LERB Chairman.
The LERB Chairman: MEA LAWG Executive Committee Member

**Level 4 Complaint**
Owner: MEA LAWG (MEA Local Area Working group)
Penalty Sanctions

Unresolved

Unresolved

Unresolved

Level 1 to Level 3 directly if CERB is not functional
MEA Code – 2012 Progress so Far...

**MEA Code Update**
- Finalized in 2011
- Copies printed and distributed to different LAWG chairs in different countries

**Toolkit Rollout**
- Completed in UAE, Jordan, Lebanon and Saudi Arabia
- Egypt and Kuwait are in the pipeline

**Member Companies Rollout**
- Completed: UAE and Saudi Arabia
- Next steps: Jordan, Lebanon, Kuwait and Egypt

**Government Rollout**
- In progress. LAWG Chairs will be responsible in leading the campaign with stakeholders in respective countries
MEA Code – 2012 Enforcement Updates

- LERB is expanding to include members from multinational companies
- 8 companies represented so far and we encourage other companies to have their Compliance Officers as members
- Conference call every 2 months to discuss hot topics and issue required guidance to be shared with all companies via steering committee. Minimum One face to face meeting yearly.
- Enforcement Procedure of the code was updated to make it more understandable and easier to implement
THE LAUNCH PLAN OF THE NEW CODE

INTERNAL COMMUNICATIONS PLAN

EXTERNAL STAKEHOLDERS OUTREACH
• Meeting with Government and Medical Associations
• Raising awareness of the Code among HCPS
Toolkit Packs

Toolkit CD that you will be receiving includes:
• PDF versions of the MEA Code
• Complete Toolkit and Guidance
• Templates and tools that can be customized
• Posters Visuals to use for internal roll-out
Internal Tools

Customizable Internal Memo

Detailed Presentation
Visuals
Government Outreach

Tools

Customizable Invitation and Appointment Letter

Detailed Presentation

RAISING THE STANDARDS

MIDDLE EAST AND AFRICA CODE OF PROFESSIONAL STANDARDS

HOW DOES IT WORK?

- Level 1: Owner: MEA Code of Professional Standards
- Level 2: Owner: CERB Code of Professional Standards
- Level 3: Owner: CERB Code of Professional Standards

HOW DOES THE CODE IMPACT THE INDUSTRY?

- Quality of healthcare
- Evidence-based practices
- Patient safety

PARTNERSHIP

- The MEA Code will complement your existing ethical codes [Include when relevant]
- Through your endorsement and support the Code will ensure all promotional practices are aligned with international ethical codes
- Your support will add credibility, encouraging non-member and local pharmaceutical companies to adopt the Code
  - [Include additional points relevant to Government official or Medical association]
WHAT DOES THE CODE REGULATE?

- The code provides guidance to the below topics which can be done but under specific conditions described in the code:
  - Promotion
  - Events and Hospitality
  - Education and Sponsorships of HCPs
  - Gifts and Inducements
  - Non-interventional studies of marketed medicines
  - HCP's paid services (speaking, advisory board)
  - Pharmaceutical staff practices
  - Relationships between member companies and patient organizations
  - Internet usage
  - Grants and Donations
  - Samples distribution
Media Outreach Tools

Press Release Template and Media Factsheet
So far LERB are composed of 9 Members from the following companies:

Sanofi, Eli Lilly (2), Amgen, Novartis

Astra Zeneca, Johnson & Johnson, Pfizer, Abbott