2005 – 2010
Looking at our Achievements and the Way Forward

MIDDLE EAST & AFRICA

CODE OF PROMOTIONAL PRACTICES

The 5th pharmaceutical compliance congress &
best practices forum
Istanbul - Turkey

2011

What was accomplished since launch of MEA code in 2005 ?

- Increased understanding and alignment to the “spirit” of the code
- Aligned vocabulary & standards
- Platform for sharing: Compliance is a systematic agenda topic in all MEAC meetings and in country LAWG meetings
- Training material & Q&A constantly updated
- HCPs and external stakeholders increasingly aware of industry promotional & ethics standards
- Update of the code in July 2010

2010: Why Update

- A lot of changes and developments have taken place since the launch of the MEA code in 2005
- Changes to the code were based on:
  - Changes/updates and experiences from EFPIA, PhRMA and IFPMA codes.
  - Incorporating the learning's from the code implementation since its launch
  - Incorporating the Q&A in the code

New Articles added to the code :

- Post Marketing / assessment studies
- Grants and Donations
- Pharmaceutical Industry and Patients Organization
- Internet Usage

Existing articles that were updated …

1. Marketing Authorization and approved labeling (Article 1)

We have added a clarification that in case of SLS, promotion of the product subject to SLS should be limited to the hospitals / centers where the product is available

2. Distribution of promotion (Article 4)

We have added one sentence: Data privacy of health care professional should be observed

3. Direct to Consumer Communications (Article 6)

We have added more details about Disease Awareness Campaigns addressed to the public and some of the considerations to take into account.

4. Company sponsored hotlines or call centers (Article 7)

Company sponsored cal centers to communicate to patients should address disease education only and should be adequately monitored by medical personnel

5. Events and hospitality (Article 9)

We have added more details about:

1- Nature and venue of events (Hotels which are acceptable)

2- Location of the events: should be in location where majority of attendees are from

3- Hospitality covers HCPs only!

4- No entertainment allowed – 70% of the time should be spent on scientific / educational activities

5- The above article applies to all kind of meetings with HCPs

Existing articles that were updated …

6. Gifts and inducements (Article 11)

Added more details about acceptable gifts (Promotional items and items of medical utility) as well as unacceptable items.

Added a subsection about cultural courtesy gifts

7. Samples (Article 12)

Slight additions about quantities to be delivered, presentation of samples and that hey should not be linked to any inducement to prescribe, purchase… medicinal products. Samples should not be used for commercial purposes.

8. Consultants (Article 13)

This section was extracted from the latest EFPIA version. It is a very important section highlighting the following:

1- What are the criteria of a genuine consultancy arrangement?

2- In the written contracts, companies are encouraged to include provisions regarding the obligation of the consultant to declare that he is a consultant to the company whenever he writes or speaks in public about a matter that is subject of the agreement

3- Limited market research are excluded for the scope of this article

4- If an HCP attends an event in his consultant capacity, article 9 shall apply (events & hospitality)

5- To avoid 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.

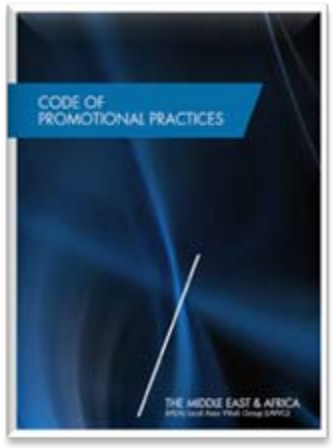
Communications Campaign

- Communications Objectives
  - Raise awareness of the MEA Code among key stakeholders both internal and external
  - Build up the industry's credibility and strengthen their confidence in the pharmaceutical industry
  - Encourage compliance from all international and regional pharmaceutical companies based in the Middle East and Africa
  - Build key strategic partnerships with endorsers who will add credibility to the MEA Code
- Internal audience: employees & partners
- External audience: governments & medical associations followed by HCPs and Public / Media

CRITICAL SUCCESS FACTORS

CSF #1: Secure endorsement of the MEA Code from Government bodies and Medical Associations	• By successfully meeting with key officials in each health ministry in key markets • By successfully meeting with one to two medical associations in each key markets
CSF #2: Increase the number of Healthcare Professionals or Medical Educators acting as Key Influencers who will actively support the MEA Code	• By obtaining buy-in of key messages and toolkit from KOLs
CSF #3: Encourage compliance with the MEA Code within the industry	• By conducting internal communication programs to encourage compliance and vigilance within the organizations • By increasing awareness among the public through a strong PR campaign and media relations

Communications Toolkit



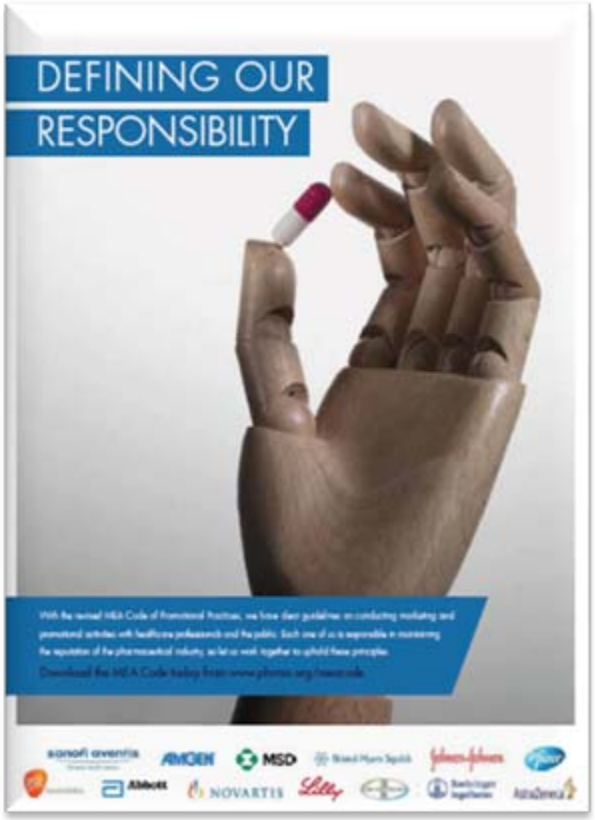
A guide book to deliver a clear and consistent communication program

Guidance and tools and templates for Phase 1 & 2

To be distributed to all members in each of the 6 priority markets

Rolled out in UAE and Jordan

Internal Rollout



Government Meetings

- UAE
  - Workshop with key government officials in UAE in May
    - Preliminary meetings with top 3 officials
- Jordan
  - Meetings with Minister and Jordan FDA Head
- Next meetings in the pipeline
  - Kuwait, Lebanon, Saudi Arabia, Egypt

What are the remaining challenges ?

- Self Regulation & Enforcement
- Broader endorsement outside of Phrma member companies
- External stakeholders endorsement
- Variable application depending on country association activity