PCF 2010 Compliance Panel EMEA

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A maturing environment in EU…

Emerging Markets (15%)
Changing/Developing models

- Developing or fundamentally changing healthcare systems
- Information sources poor
- Pharma looking for sales deployment models and potentially leap-froging

Mature Markets (25%)
Some pressure for change

- Pharma in wait mode, not a burning platform for change
- Relationship selling, access not yet an issue
- Basic methodologies for sales deployment

Advanced Markets (60%)
Urgent need for change

- Prescriber access challenge
- Major ROI concerns
- Industry reputation
- Distribution complexity
- Increasing no. of stakeholders
- Shifting portfolio
- Potential data visibility issues

Japan
CEE
China
Turkey
India
Iber
L.A.
France
Italy
Nordic
USA
UK
Ger
Can
Benlx

Evolution

Source: IMS Health

European Union

- OECD Convention producing visible effects :
  - UK Bribery Act
  - Spain new legislation aligning public and commercial bribery (December 2010)
  - Legislation and new Code in Russia (Russia has not yet ratified the OECD convention)
- Devices, Eucomed on the move (appropriate locations)
- Restrictions appear on HCP sponsorships to Congress :
  - 50% co-payment in Sweden, planned exclusion of support Norway
- Increasing Due Diligence practice, Transparency and disclosure growing trends and expectations
- Education & Training:
  - IFPMA workshop Berlin, Healthcare Compliance Officer Curriculum
- **EFPIA Leadership Statement and related initiatives to regain trust and improve image**

EFPIA Leadership Statement…

A leadership statement was issued in June in order to :

- Face reputational challenges and regain momentum while moving to higher standards
  - Fair, accurate and objective information about our medicines to allow rational decisions to be made about their use.
  - greater transparency, accountability and ethical behavior within an industry framework of self regulation
- While closing the gap on ‘compliance basics’ for less advanced markets
  - Creation of National Ethics Groups in all local trade associations
  - Maximize Business Leaders impact for systematic implementation through company representation at local trade association level (ie roadmap for GMs)
- Work at EFPIA will be better structured and efforts better leveraged
  - Creation of a working group on Trust Reputation and Compliance,
  - Creation of Compliance Committee and of a Compliance Steering Group (that now include representation from Companies- before Trade Associations only)
  - JnJ represented in those three committees
- Twelve months to implement changes

Key areas of focus

- Educational events and exhibits
  - Assessment and rating system for international educational events in Europe (based on the spanish FarmaIndustria system)
  - Relates to both the educational part **and** exhibits
  - Is supplemented by EFPIA visits on congresses (pilot of ten on-going) to verify, establish a dialogue and assess 'on site' with the help of the local trade association
- Medical Representatives
  - Reps are 'ambassadors' of the firms and have a stake in the image
  - They should be trained by companies not only on rules, selling skills or on products but also on having an appropriate behavior in hospital, waiting rooms etc (partly based on observations in Russia and complains from authorities)
- Samples
  - Samples remains an issue in some markets, some companies simply advocate a ban on samples
  - Potentially, samples will only allowed up to a maximum of 4 units per physician for a period of two years
- Relationships to Patient Organizations
  - Next step beyond disclosing name of patient organization benefitting from support, disclosure of direct or indirect financial support granted and type of activities supported by the industry

Spain : code update
(General Assembly of Farmaindustria on Oct 26 2010)

- Article 10 “Gifts”
  - Maximum amount down from 30 to 10 Euros (‘unsignificant value’)
  - Positive list of office items that are tolerated
  - Positive exclusion of electronic PDAs that could be of dual use (personal and professional : laptops, i-pad, cell phones, notebooks, e-books…)
- Market Research 14.4:
  - Definition of criteria for Market research activities
  - Any other activity qualified as ‘promotional‘ (ie no remuneration)
- Fee for Service Art/ 16 y 17 :
  - Notification to employing entity
  - Notification to Farmaindustria’s Deontological Supervision Unit if more than 20 HCPs are remunerated as part of the same project

ABPI Code update / proposal
(to be reviewed approved on Nov 2nd 2010)

- The changes to the ABPI Code are to be considered by a meeting of the ABPI on 2 November so they are currently proposals.
- The proposals include a move to declare total amounts for certain fees for services and for sponsorship of health professionals to attend meetings organised by third parties.
- There are proposals to declare the amounts given to patient groups, publish results of non interventional studies and gifts and donations given to organisations.

Central Eastern Europe

- CEE still faces the challenges of the early days : samples, non-interventional studies, congresses and events, foundations + economic restrictions and challenges for the healthcare system
- Bad image of the industry, aggressive stance of authorities and legislators : ie Draft law “On the community health protection in the Russian Federation”(ban on gifts or payments above 100 USD, ban on calls during working hours, ban on sponsorships to congresses-see facilitated AIPM presentation)
- EFPIA willigness to address this through the LS statement
- Russia Trade association AIPM has an updated Code of Marketing Practices and becomes active within IFPMA’s Compliance Network

Middle East & Africa

- Middle East & Africa Local Area Working Group :
  - Code update : patient org, use of internet
  - Awareness campaign
  - Covers north africa
  - Negative list of cities/resorts
- South Africa Code :
  - Endorsed by mutliple segments stakeholders
  - supported by MOH
  - Has some teeth : breaches can lead to de-registration of a product
- Medical devices on the move :
  - MECOMED code = Copy pasting of the EUCOMED code
  - Consistency but like in Europe Implementation challenges

MEA Code Update – Why an 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 :

1. **Post Marketing / assessment studies**
2. **Grants and Donations**
3. **Pharmaceutical Industry and Patients Organization**
4. **Internet Usage**

New Articles Details

1. Post Marketing / assessment studies (Article 8)

- The Post Marketing assessments / studies was mentioned in the previous code but was very concise and did not give enough details
- There was a need to detail this section. So it was extracted from the EFPIA to have thorough details about how to handle this topic since it is a critical one and can be misused as disguised promotion.
- The new section clarifies the definition as well as the criteria of a good non interventional or post marketing study

2. Grants and Donations (Article 15)

This section was added to give guidelines on criteria for Grants & Donations. In fact, G&D are allowed only if:

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

New Articles Details

3. Pharmaceutical Industry and Patients Organization (Article 16)

- 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.
- This guidance Article covers relationships between member companies and their subsidiaries/contracted third parties and patient organizations.
- This article includes all criteria to be met in case of a partnering with a patient organization

4. Internet Usage (Article 17)

- One of the important responsibilities of the pharmaceutical industry is to transfer the available information concerning their products in an accurate and unbiased way, using the latest available communication techniques and according to the current principles of pharmaceutical promotion.
- Pharmaceutical firms (pharmaceutical manufacturers, importers and distributors) may create internet web sites 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
- Guidelines for company internet sites are given in this section

Existing articles that were updated …

1. Marketing Authorization and approved labeling (Article 1)

We have added a clarification that in case of SLS, medical and scientific communications about 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.

Other updates

1. Page 4 of the code:

Added one sentence:

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.

2. Page 6 of the code: Added the 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.

3. Page 28: Annex A1 – section A1.03.

Added the below sentence:

The CERB will maintain at a local level a registry of all member companies reported complaints & violations for the purpose of providing guidance for other member companies as well as monitoring trends in the market