Key challenges and achievements in healthcare promotion and communication from various regional and national perspectives: EFPIA

IFPMA – PHAP Forum on Ethical Business Practices: Fostering Integrity and Good Governance in the Healthcare Sector
Hands-on Compliance Training
April 1st 2014, Manila, Philippines

Mr. José Zamarriego
Spanish Code of Practice Surveillance Unit Director, Farmaindustria
EFPIA’s “Transparency” Initiative

Increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level:

- Legal provisions: Denmark, France, Portugal, Slovakia
- Self-regulatory provisions: the Netherlands, UK
- Disclosure activities outside Europe: Japan, US

Different approaches are in place at national level re communication to public authorities and/or publication on publicly accessible websites.

By acting now, EFPIA has the opportunity to help encourage a consistent approach to data disclosure in Europe and help guide further action at national level.
Key challenges and achievements in healthcare promotion: EUROPE
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Issues relating to Codes

Codes Committee

Compliance Committee

National Ethics Groups

Bureau

Codes Steering Group

Ensuring effective oversight of industry standards, and implementation of the new guidance

Set up at national level by local operations

Transposition, implementation & enforcement of the EFPIA Codes
Role & mandate defined under the EFPIA Codes (including: HCP, PO & HCP/HCO Disclosure Codes)

Advising and promoting good practice and prevention of inappropriate behaviour (including monitoring) – Recommending interpretative rules and developing additional guidance in line with EFPIA Codes and “tone at the top”

Corporate Compliance Officers + Member Associations

CODES AUTHORITY (Member Associations & National Code Authorities)
The EFPIA HCP/HCO Disclosure Code was approved by the General Assembly on 24 June 2013

- Each member company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a HCP/HCO Recipient
- The first Reporting Period shall be the calendar year 2015 (first disclosures in 2016)
- Each member association shall transpose the provisions of this Code into its national code by 31 December 2013
- The Code sets out the minimum standards applicable to Member Associations, expect where it is in conflict with applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.
- The EFPIA Codes Committee shall assist Member Associations to comply with their obligations – scorecard
## Amendments to the HCP Code

<table>
<thead>
<tr>
<th>GIFTS</th>
<th>No gift or pecuniary advantage (in cash or benefit in kind) may be supplied, offered or promised to a healthcare professional.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Previously Article 10</strong></td>
<td></td>
</tr>
</tbody>
</table>
| INFORMATIONAL & EDUCATIONAL MATERIALS, and ITEMS OF MEDICAL UTILITY | 1. The transmission of informational or educational materials is permitted provided it is: (i) “inexpensive”; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients.  
2. Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are inexpensive and do not offset routine business practices of the recipient.  
3. EFPIA and Member Associations shall provide guidance on the meaning of the term “inexpensive”, as used in this Article 8. Companies must comply with any relevant guidance provided under this Section 8.03 or in connection with any Applicable Code(s). |
| **New Article** |                                                                                                               |
| HOSPITALITY | Member Companies shall not provide or offer any meals (food and beverages) to healthcare professionals, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold set by the relevant Member Association in its national code. Each Member Association shall set such monetary threshold in its national code by 31 December 2013, failing which EFPIA will set such threshold in lieu of such Member Association. |
| **Addition to Article 9** |                                                                                                               |
### Article 3 – Individual & Aggregate Disclosure

<table>
<thead>
<tr>
<th>Level of Disclosure</th>
<th>Disclosure Categories</th>
</tr>
</thead>
</table>
| **Aggregate**       | Research & Development ToV to HCPs/HCOs related to the planning and conduct of:  
a. Non-clinical studies (as defined in the OECD Principles of GLP)  
b. Clinical trials (as defined in Directive 2001/20/EC)  
c. 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, HCPs specifically for the study (cit Section 15.02 of the EFPIA HCP Code) |
| **Individual HCO**  | Donations & Grantees to HCOs  
Contribution to costs of events  
- Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event  
- Registration fees  
- Travel & accommodation  
Fee-for-service & consultancy  
- Fees  
- Related expenses agreed in the fees for service or consultancy contract |
| **Individual HCP**  | Contribution to costs of events  
- Registration fees  
- Travel & accommodation  
Fees for service & consultancy  
- Fees  
- Related expenses agreed in the fees for service or consultancy contract |

*Each company shall publish a note summarising the methodologies used in preparing their disclosures and identifying transfers of value for each category described above (Methodological Note).*
Transposition in national legislation & regulations

Consent of the Data Subject
Article 29 WP opinion (data protection authorities’ consensus view)
Where ToV to a HCP occur in the context of a contract, the contract provides a ready mechanism to obtain the data subject’s consent to the processing of his/her personal data for the purpose of meeting that member’s obligations under the Code → as a matter of good practice, data controllers should create and retain evidence showing that the consent was indeed given

Legitimate Interests of the Data Controller
A company (as a data controller) may have legitimate interest in disclosing data – for instance: to promote confidence in its relationships with HCPs. This legitimate interest must be outweighed by the data subject’s interests → the legal basis is significantly strengthened when a data controller can say that consent had been obtained

Data Privacy Requirements must be checked at national level (including: legislation, regulations and jurisprudence)
COMPETITION LAW CONSIDERATIONS

EFPIA’s Code has been drafted with support of and reviewed by Legal Counsel
Legal Counsel advice gives EFPIA sufficient comfort to adopt the Code

Member Associations will be required to transpose the EFPIA Code into national codes
- Each association will take the necessary legal opinions as to applicable laws & regulations in their countries – in principle, these should not be different, although there may be a matter of judgement.
- In some countries, self-regulation needs to be submitted for approval by national competition authorities

The Codes Committee will collect comments re national legal advice that may raise issues with transposition of the EFPIA HCP/HCO Disclosure Code

Companies’ disclosures
Each company will make its own decisions regarding its disclosures, also taking into account “commercially sensitive data”.
Each company will develop a Methodological note
Key challenges and achievements in healthcare promotion: EUROPE
Mr. José Zamarriego, Spanish Code of Practice Surveillance Unit Director, Farmaindustria

EFPIA CODE ON DISCLOSURES OF TRANSFERS OF VALUE TO HCP & HCO
Junio 2013

CÓDIGO ESPAÑOL DE BUENAS PRÁCTICAS
Enero 2014

PNT, CÓDIGOS INTERNOS, CONTRATOS, IT...
Mr. José Zamarriego, Spanish Code of Practice Surveillance Unit Director, Farmaínndustria
### Disclosure Template

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Healthcare Profession (HCP): city of principal practice</th>
<th>Country of Principal Practice</th>
<th>Principal Practice Addresses</th>
<th>DNI / CIF</th>
<th>Employment (Art. 15.3.1.a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr. José Zamarriego</td>
<td>Spanish Code of Practice Surveillance Unit Director, Farmaindustria</td>
<td></td>
<td></td>
<td>XXXX123456X</td>
<td></td>
</tr>
</tbody>
</table>

#### Disclosure Information

**Indirect Transfer of Value to HCPs (Art. 15.3.1.b & 15.3.1.d):**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an Event</td>
<td>Yearly Amount</td>
<td>Optional</td>
</tr>
<tr>
<td>Registration Fees</td>
<td>Yearly Amount</td>
<td>Optional</td>
</tr>
<tr>
<td>Travel &amp; Accommodation Fees</td>
<td>Yearly Amount</td>
<td>Optional</td>
</tr>
<tr>
<td>Total</td>
<td>Yearly Amount</td>
<td>Optional</td>
</tr>
</tbody>
</table>

**Aggregate Disclosure:**

- **Transfers of Value related to Research & Development (Art. 15.6):** Yearly Amount €

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**Key challenges and achievements in healthcare promotion:**

**EUROPE**

Mr. José Zamarriego, Spanish Code of Practice Surveillance Unit Director, Farmaindustria
EFPIA focuses on **major international events taking place in Europe** – the EFPIA database mainly includes international events (European Society or at least 5 organising countries) in which more than 1,000 participants take part.

Each event is assessed in regard of **common standards** applicable, in particular in regard of provisions included in the **EFPIA HCP Code Article 10**. *The member association of the country where the event takes place and the scientific society organising it are given the opportunity to comment during the pre-assessment process.*

As soon as EFPIA completes its pre-assessment, the **organisers of the event** and **EFPIA membership** receive an electronically generated message informing them of the conclusions of EFPIA’s pre-assessment.

EFPIA corporate members are encouraged to **consult the database before deciding** about sponsoring, participating or collaborating to an event. *The comments included in the database are intended as a means to provide members with potentially relevant information for their own autonomous decision as to whether to support the event.*
Key challenges and achievements in healthcare promotion: EUROPE
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The pre-assessment of events provided on e4ethics cannot, under any circumstance, be interpreted as a judgement on the quality or content of the scientific programme, or on the quality of the speakers.

It is the company’s individual decision to decide to sponsor / participate in the event. Companies belonging to the EFPIA membership should be mindful of the rules and provisions that apply when deciding to sponsor, participate or collaborate in an event.

It is always recommended to check the rules prevailing under applicable national codes.

EXHIBITIONS – please read carefully the provisions of the EFPIA HCP Code and the additional guidance.
**Key challenges and achievements in healthcare promotion: EUROPE**

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**Ev4Etics Web Events Database**

Events sorted out by:

- Name of the event (alphabetically ordered)
- Dates of the event (from nearest in time to the distant)
- Organizer (Acronym)
- Country
- 15 Last Days (events being updated in the last 15 days)

<table>
<thead>
<tr>
<th>Date</th>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17/09/2014</td>
<td>EUGMS</td>
<td>10th Congress European Union Geriatric Medicine Society</td>
</tr>
<tr>
<td>07/05/2014</td>
<td>EADO</td>
<td>10th Congress of the European Association of Dermato-Oncology</td>
</tr>
<tr>
<td>20/05/2015</td>
<td></td>
<td>10th European Congress of Menopause and Andropause</td>
</tr>
<tr>
<td>04/12/2014</td>
<td></td>
<td>10th International Congress on Non-Motor Dysfunctions in Parkinson's Disease and Related Disorders</td>
</tr>
<tr>
<td>21/10/2015</td>
<td></td>
<td>11th Congress of the European Society of Gynecology</td>
</tr>
<tr>
<td>22/05/2014</td>
<td>EADV</td>
<td>11th EADV Spring Symposium (European Academy of Dermatology &amp; Venerology)</td>
</tr>
<tr>
<td>07/06/2014</td>
<td>EGS</td>
<td>11th EGS Congress (European Glaucoma Society)</td>
</tr>
<tr>
<td>29/06/2014</td>
<td></td>
<td>11th European Congress on Epileptology</td>
</tr>
<tr>
<td>09/10/2014</td>
<td></td>
<td>11th Meeting of the European Association of NeuroOncology</td>
</tr>
<tr>
<td>06/07/2014</td>
<td>ESPRAS</td>
<td>12th Congress of the European Society of Plastic Reconstructive and Aesthetic Surgery</td>
</tr>
<tr>
<td>09/11/2014</td>
<td></td>
<td>12th International Congress of Neuroimmunology</td>
</tr>
<tr>
<td>02/11/2014</td>
<td></td>
<td>12th International Congress on Drug Therapy in HIV Infection 2014</td>
</tr>
<tr>
<td>12/06/2014</td>
<td></td>
<td>12th Congress of the European Society for Pediatric Dermatology (ESPD)</td>
</tr>
<tr>
<td>28/05/2014</td>
<td>ESC</td>
<td>13th Congress Of The European Society Of Contraception &amp; Reproductive Health</td>
</tr>
<tr>
<td>11/09/2014</td>
<td>EURETINA</td>
<td>14th EURETINA Congress</td>
</tr>
<tr>
<td>05/11/2014</td>
<td></td>
<td>14th International Forum on Mood and Anxiety Disorder</td>
</tr>
<tr>
<td>25/06/2014</td>
<td>EAES</td>
<td>14th World Congress of Endoscopic Surgery</td>
</tr>
<tr>
<td>11/06/2014</td>
<td></td>
<td>15th Annual European Congress of Rheumatology EULAR 2014</td>
</tr>
<tr>
<td>07/09/2014</td>
<td></td>
<td>15th Congress of the International Society for Peritoneal Dialysis</td>
</tr>
<tr>
<td>04/06/2014</td>
<td></td>
<td>15th EFORT Congress (European Federation of National Associations of Orthopaedics and Traumatology)</td>
</tr>
<tr>
<td>24/05/2014</td>
<td>ESTES</td>
<td>15th European Congress of Trauma and Emergency Surgery (ECTES)</td>
</tr>
</tbody>
</table>

[www.efpia-e4ethics.eu]
Key challenges and achievements in healthcare promotion: EUROPE

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RESULTS PRE-ASSESSMENT EVOLUTION 2011 - 2013

ELEMENTS THAT MAY RAISE CONCERN

- Scientific Programme
- Venue
- Hospitality
- Other Activities
- Accompanying Persons

<table>
<thead>
<tr>
<th>Year</th>
<th>Scientific Programme</th>
<th>Venue</th>
<th>Hospitality</th>
<th>Other Activities</th>
<th>Accompanying Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>14%</td>
<td>7%</td>
<td>27%</td>
<td>63%</td>
<td>77%</td>
</tr>
<tr>
<td>2012</td>
<td>9%</td>
<td>6%</td>
<td>22%</td>
<td>46%</td>
<td>57%</td>
</tr>
<tr>
<td>2013</td>
<td>15%</td>
<td>3%</td>
<td>18%</td>
<td>36%</td>
<td>42%</td>
</tr>
</tbody>
</table>

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