



European Federation of Pharmaceutical
Industries and Associations

INDUSTRY AND CORPORATE STANDARDS

Consolidation, Harmonisation, and Implementation

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VISION

- Supporting a regulatory and political environment which stimulates R&D, rewards innovation and speeds up patient access to innovative therapies.
- Establishing patient-centred approaches and take into account patient needs in pharmaceutical (company) policies.
- Ensuring healthcare professionals are fully informed of potential benefits of treatments available.
- Empowering patient groups to be involved, informed and sustainable in the long-term.

CHALLENGES

- Supporting industry's legitimacy as a reliable source of information – accurate, balanced, fair, objective, complete; based on up-to-date evaluation of all relevant evidence; not misleading by distortion, exaggeration, undue emphasis, omission; scientifically substantiated
- Supporting industry's legitimacy to collaborate / support patient organisations
- Enhancing ethical behaviour in companies' communications – with healthcare professionals and the public at large.

ENABLERS

- **TRUST** – Strengthening the reliability and confidence in industry self-regulation of marketing and information
- **CONFIDENCE** – Increasing the efficiency and operation of the Codes of Conduct
- **TRANSPARENCY** – Increasing the Codes of Conduct transparency, both within and between European countries

Industry
Ethical Framework

EFPIA-CPME
Principles

**Relations
with Patient
Organisations**
Code

**Medicine Promotion
to Healthcare
Professionals.**
Code

**Information to
Patients**
Principles ▶ Code

Cooperation between doctors (healthcare professionals) and pharmaceutical companies

- Is important and necessary
 - ❖ to exchange knowledge
 - ❖ to secure safety of patients
 - ❖ to support efficacy of therapy
- Must be based on high ethical standards
 - ❖ respecting both parties' independence
 - ❖ guaranteeing the rights of patients
 - ❖ answering expectations of society
- Requires full transparency
 - ❖ to ensure credibility
 - ❖ « disclosure of interest »

Joint Declaration EFPIA / CPME – June 2005

- **Product information and promotion of approved medicines**
- **Meetings organised or sponsored by industry**
- **Consultancy and affiliation**
- **Covered by EFPIA's HCP Code (latest reviewed 2007)**
- **Clinical research**
- **Disclosure of information through clinical trial registries and clinical trials results database**

Self-regulation at European level = CONSOLIDATION

- Background

- ❖ EFPIA Code of Conduct for the Promotion of Medicines (1992)
- ❖ Implementing Rules / Procedural Rules (1992)
- ❖ Guidelines for Internet websites (2001)

- Code re « Healthcare Professionals » - HCP Code

- ❖ Interpretation of Code provisions (2003 / 2004)
- ❖ Revision of EFPIA's Code (2004)
- ❖ Deepening of EFPIA Code provisions (2007)

- Code of Practice on Relationships with Patients Organisations – P.O. Code (2007)

Health Information accessible to the public

- Enhanced access to health and medicines information – improving disease awareness and compliance
 - Quality information from multiple sources, including pharmaceutical companies
 - Regulatory developments based on best practice – optimal and safe use of medicines
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- Industry is a legitimate provider of information
 - The provision of information should not be inhibited by bureaucratic controls
 - Self-regulatory mechanisms should be able to enhance best practice

Scope / Applicability of EFPIA Codes

- EFPIA's Codes are applicable to:
 - ▶ EFPIA member companies
 - ▶ their subsidiaries
 - ▶ any company affiliated with EFPIA member companies or their subsidiaries if such affiliated companies have agreed to be bound by the Code
 - ▶ Third parties: (i) if commissioned to act on behalf of member company (company is responsible); (ii) if not commissioned, member company must take reasonable steps

- Adhering to national codes:

Member companies & their subsidiaries to join codes of member associations to which they belong OR agree in writing with each national association in countries where they conduct activities

- **SGA of 14 May 2009 decided to clarify Codes' compliance as a Statutory obligation**

Implementation = HARMONISATION

- Transposition of Codes – all 31 EFPIA member associations have confirmed that EFPIA Codes provisions have been included into their Codes
 - EFPIA's Codes provide minimum standards; national codes may include more strict provisions
- Mapping EFPIA Codes' provisions versus national codes provisions – under review by EFPIA's Codes Steering Group
 - Divergencies bigger among HCP codes provisions than among P.O. codes provisions
- Mapping EFPIA corporate membership with membership of member associations
 - Full sign off by affiliates to be completed

Enforcement = PRACTICAL IMPLEMENTATION

- **Reporting**

EFPIA's Annual Report – based on activities reports from Member Associations

- ✓ Statistical report
- ✓ Summary of the most significant cases

➤ Reporting remains different from country to country, and is not capable of capturing the functionality of the Codes

- **Independent report**

Based on formalised interviews with representatives of member associations, healthcare professionals, as well as companies' compliance officers

➤ Qualitative analysis and fact finding

EFPIA's Codes Steering Group – Mandate

- **Richard Bergström, Marie-Claire Pickaert, Heather Simmonds and José Zamarriego**
 - Monitoring the implementation and enforcement of the EFPIA Codes
 - Enhancing credibility through coherent enforcement, and recommending interpretative rules, where appropriate
 - Providing informal guidance and pre-advice to the membership, third parties and other stakeholders
 - Supporting EFPIA in preparations of activities reports and Codes meetings
 - Ensuring necessary coherence / interaction with other industry Codes
- + **« Patients Relations Network » Group** – inputting on P.O. Code issues
- **Fiona Brownlie and Erica Poot**

Publication – www.efpia.eu

- EFPIA Codes
- National Codes of member associations, translated into English