



European Federation of Pharmaceutical  
Industries and Associations

# UPDATES ON GLOBAL CODES – the EFPIA Codes

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# Legal & Self-regulatory background



## \* Legal background

- EU Directive 2001/83 (*including the 1992 Directive*)
- National law & regulations

## \* Self regulation background

- Code of Conduct for the Promotion of Medicines (1992)
  - Update - Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (2007): **HCP Code**
  - Guidelines for Internet websites (2001 - incorporated to the HCP Code in 2007)
- Code of Practice on Relationships between the Pharmaceutical Industry and Patients Organisations (2004 – updates in 2007): **PO Code**
- Joint Declaration between CPME and EFPIA (2005)
- European Commission Guiding Principles Promoting Good Governance in the Pharmaceutical Sector (2011)
- Pre-assessment Platform **e4ethics** (2012)
- Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (2013): **HCP Disclosure Code**
- Principles for Responsible **Clinical Trial Data Sharing** – joint PhRMA-EFPIA Principles (2013)

# The **subsidiarity principle** applied to self-regulation

EFPIA Codes set general standards

National standards may be stricter

Code compliance is a membership obligations

Member Associations are required to transpose the EFPIA Code **in line with national laws** & regulations, and ensure enforcement in the countries

EFPIA corporate members are submitted to applicable codes in the 33 EFPIA countries where they operate, whether they have joined EFPIA's member associations or not.

# The EFPIA Charter

EFPIA principles applicable to organisations that are within EFPIA membership – September 2015

Member Companies and Associations, including members of Specialised Groups, are required to:

- 1. subscribe to the aim of EFPIA;**
- 2. support EFPIA in attaining its objectives**, and refrain from actions that undermine EFPIA’s ability to attain its objectives;
- 3. defend the views expressed by EFPIA on core topics;**
- 4. implement high and transparent standards of conduct in dealings with external stakeholders;**
- 5. treat as confidential any documents so marked issued by EFPIA**, and comply with the EFPIA “Data Collection and Information Sharing Guidelines”;
- 6. promote consistency and alignment within the sector**, by:
  - a. cascading EFPIA decisions faithfully to local operations and others within the member’s organisation;
  - b. ensuring that EFPIA’s public policy positions are faithfully represented at public debates;
- 7. abide by the EFPIA Statutes and Internal Rules.**

The Board may issue further guidance on the **interpretation of the above Principles**.

The Board may consider that non-compliance with the EFPIA Principles jeopardises the attainment of the aims pursued by EFPIA, and may therefore decide to exclude organisations that impede EFPIA’s general policy following the provisions laid down in the Statutes.

**High level principles** supported by all stakeholders:

Industry, Healthcare Professionals, Healthcare Providers, Patient Organisations, Consumers, Government Officials (Member States)

➤ Facilitated by the EU Commission

Integrity

Governance

Respect

Accountability

Responsiveness

## Disclosure & Transparency

**Topic-related** standards, as needed:

Substantiation of claims; congresses & events; hospitality; support to CME; support for associations; gifts; clinical trials; non-interventional studies; good practices for education and enforcement;...

National stakeholder platforms for education & enforcement



# EFPIA Key Ethical Principles

Work in progress



**We keep patients at the heart of what we do**

**We act with integrity**

**We act with respect**

**We are transparent about our actions**

**We believe in what we do**



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