Europe Update

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Living up to expectations

The R&D-based pharmaceutical industry is committed to **working in partnership with all stakeholders** to improve healthcare across Europe.

Industry is conscious of the importance of **providing accurate, fair and objective information** about its medicines to allow rational decisions to be made about their use. As such, industry fully respects the role that (EU) legislation plays in regulating interactions between pharmaceutical companies and healthcare professionals.

In the same spirit, **industry is committed to working towards greater transparency, accountability and ethical behaviour within an industry framework of self-regulation**.

Therefore, EFPIA will continue to develop additional guidance around areas where **industry's credibility** is engaged.

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Demonstrated history of transparency

- Notification of all clinical trials when started
- Posting of summary results from clinical trials after completion
- NEW: Disclosure of all financial relationships to be disclosed from 2015
- NEW: Enhanced clinical trial data sharing

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Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

Relations with HCPs

Level of Disclosure	2016 *based on 2015 data*
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 *(cfr Section 15.02 of the EFPIA HCP Code)*
Individual HCO ***"following the money"***	**Donations & Grants 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
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Each company shall publish a note summarising the methodologies used in preparing their disclosures and identifying transfers of value for each category described above.

Frequently asked questions

- Scope of gift ban
- Options for disclosure platforms
- HCPs vs HCOs
- Scope of R&D aggregate disclosure
- HCP consent, or not?
- Dynamic effect: impact on HCP behaviour and response from CME organisers

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