



Conflicts of interest – industry view

Richard Bergstrom
EFPIA Director-General

Principles



- * Important to separate personal from institutional relations
- * "Expert witness" is a great concept (cf US FDA)
- * Some relations are no "conflicts", such as clinical research
- * Medicines development is a public-partnership; different from most sectors
- * Important with visible whistle-blower function
- * Industry will contribute by introducing "sunshine" provisions from 2015/2016: disclosure of payments (ToV: transfers of value) to health care professionals (HCPs) and health care organisations (HCOs)

First Disclosures in 2016

Level of Disclosure	2016 <i>based on 2015 data</i>
<p><u>Aggregate</u></p>	<p>Research & Development ToV to HCPs/HCOs related to the planning and conduct of:</p> <ul style="list-style-type: none"> a. Non-clinical studies (<i>as defined in the OECD Principles of GLP</i>) b. Clinical trials (<i>as defined in Directive 2001/20/EC</i>) 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 (<i>cfr Section 15.02 of the EFPIA HCP Code</i>)
<p><u>Individual HCO</u> <i>“following the money”</i></p>	<p>Donations & Grants to HCOs Contribution to costs of events</p> <ul style="list-style-type: none"> ➤ Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event ➤ Registration fees ➤ Travel & accommodation <p>Fee-for-service & consultancy</p> <ul style="list-style-type: none"> ➤ Fees ➤ Related expenses agreed in the fees for service or consultancy contract
<p><u>Individual HCP</u> <i>“following the money”</i></p>	<p>Contribution to costs of events</p> <ul style="list-style-type: none"> ➤ Registration fees ➤ Travel & accommodation <p>Fees for service & consultancy</p> <ul style="list-style-type: none"> ➤ 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.



efpia*

EFPIA Brussels Office

Leopold Plaza Building
Rue du Trône 108
B-1050 Brussels - Belgium
Tel: +32 (0)2 626 25 55

www.efpia.eu