



EFPIA Transparency rules – opportunities and challenges

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WHY WE DO IT?



WE HAVE NOTHING TO HIDE

Did you know?



- According to a global survey of over 114,000 people, 45% believed medical and health services to be corrupt or extremely corrupt.
- According to another survey an estimated 10-25% of global spending on health public procurement was lost to corruption.

First disclosures in 2016

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

Are we already transparent?

Country	Aggregate/individual	To authorities/public	Limited scope
Slovakia	both	To authorities, public disclosure only by HCPs	✓
Estonia	individual	authorities	✓
UK	aggregate	public	✓
France	individual	public	
Croatia	individual	authorities	✓

Current understanding of future reporting requirements

Most countries expect to adopt EFPIA code 1:1

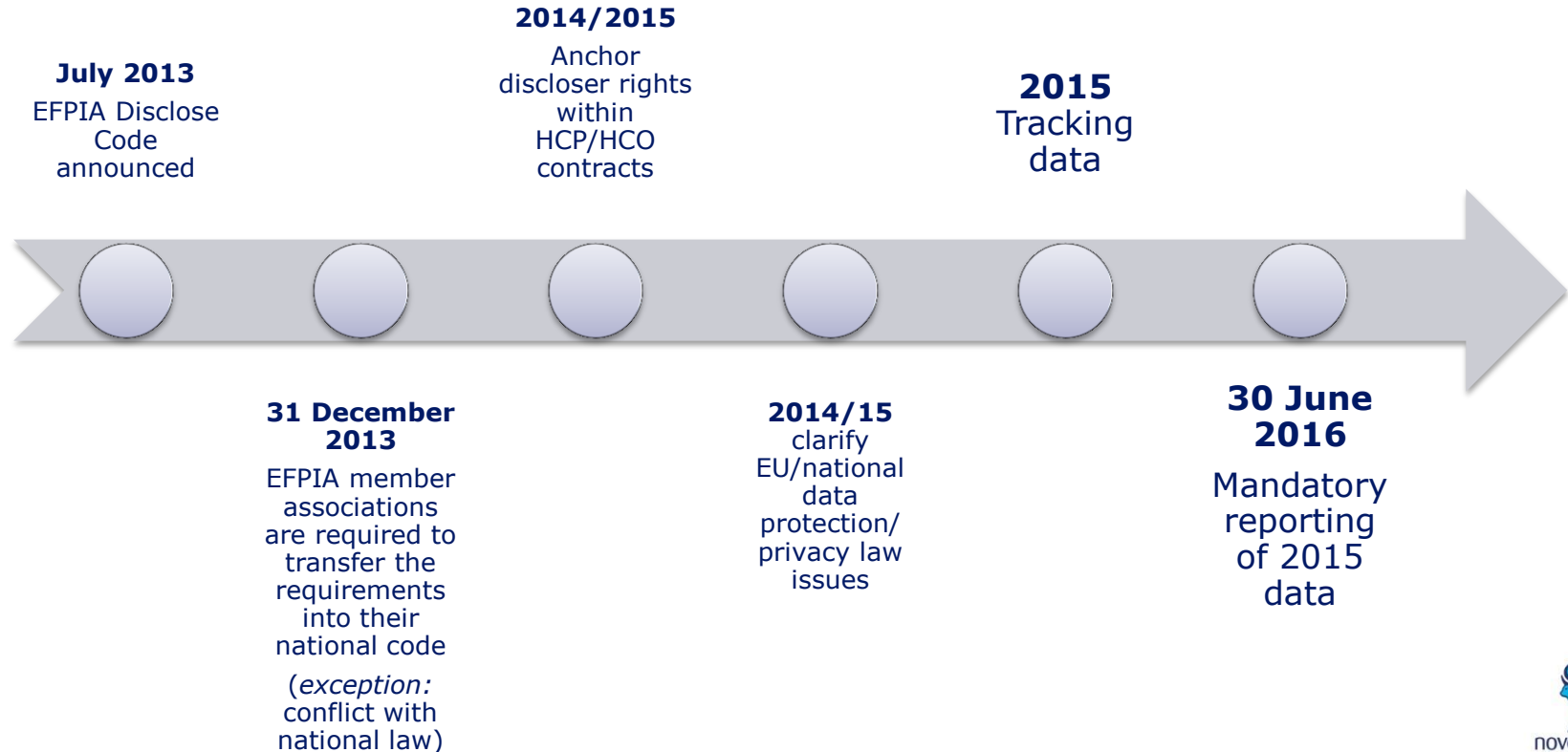
	Existing		Future expectation		
	Legal requirements to disclose some value transfers	Self-regulatory requirements to disclose some value transfers	Legal requirements	EFPIA requirements adopted 1:1	EFPIA requirements adopted with deviations
Denmark	✓	✓	✓	—	✓
UK	—	✓	—	✓	—
Germany	—	—	—	✓	—
Spain	—	—	—	✓	—
Italy	✓	✓	✓	✓	—

Based on initial EFPIA reports, at least 18 out of 23 countries will adopt EFPIA code 1-to-1

But there are deviations....

EFPIA is completing the mapping of each national code with the EFPIA Code, and has asked that Member Associations clearly reference **legal and regulatory provisions that would justify deviations.**

EFPIA – disclosure timeline



Challenges

- What if HCPs say that they do not want this?
- How will this affect wider relations with the professions?
- Company platform vs. central platform?
- Are national differences in implementation going to be a problem?
- Can we successfully defend the extent of HCP-industry relations?
- Is the public ready for the disclosure? Will it know how to interpret it?

Get ready



- Learn the (local) EFPIA regulation
- Clarify EU/national data protection/ privacy law issues
- Find out all types of HCP/ HCO interaction in your company
- Anchor discloser rights within HCP/HCO contracts
- Consider how to simplify processes/ find benefits for your organisation
- Prepare PR responses

Any Questions?

