

## ***Pre-Conference - Track III:***

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### ***European Transparency & Global Compliance Monitoring Evolution***

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European Federation of Pharmaceutical  
Industries and Associations

# European Transparency & Compliance Monitoring Evolution

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**PRECONFERENCE III**  
**Pharmaceutical & Medical Device**  
**Compliance Congress**  
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# Declaration of Interest

- Marie-Claire Pickaert is a full-time employee of EFPIA, holding the position of **Deputy Director General** and is a member of its **General Management**.
- Since 2008, Marie-Claire is coordinating EFPIA's ethics and compliance activities. She is acting as the **Chief Ethics & Compliance Officer** at EFPIA.

In 2015, she was asked to take the role of **Ambassador to the Medical Communities**, coordinating EFPIA's relationships with medical & scientific societies, including learned societies, also through professional communities within the pharmaceutical companies that interact with medical communities.

- Marie-Claire Pickaert declares having **no direct / indirect financial interest** in any life science company.
- This slide deck includes **EFPIA public policy positions**, unless otherwise indicated.
- When expressing **personal opinions**, Marie-Claire will clearly indicate so.



**EU Medicines Regulation**

Directive  
65/65

EU  
Regulation  
2001/83

**Regulation of Promotion & Information**

Directive  
94/25  
PROMOTION  
OF MEDICINES

Directive  
2001/83  
PROMOTION &  
INFORMATION

**European Self-Regulation**

EFPIA  
Code of  
Conduct  
1992

EFPIA Codes:  
PROMOTION,  
INFORMATION  
&  
RELATIONSHIPS

# 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 in the relevant countries or not.

# Adoption of “Disclosure” Codes

**Board (CEOs) decision** that EFPIA will adopt a “Transparency” Code

June 2013: EFPIA **General Assembly adopts the “Disclosure” Code**

Q4-2013/Q1-2014, Member Associations **transpose** the EFPIA “Disclosure” Code, in line with national law and regulations

**DEVIATIONS:** where national law prevents transposition *in full*

**VARIATIONS:** where stricter rules apply

Member Companies **implement in line with applicable codes**

First disclosure period: May-June 2016, reporting 2015 ToV



## Sunshine ACT

## EU DIRECTIVE\*

- NATIONAL LAWS & REGULATIONS
- SELF-REGULATION AT EU & NATIONAL LEVELS

**Legalistic approach** – self-regulation “underdeveloped” in the area of promotion of medicines to and relationships between pharma industry and HCPs

**Established tradition of self-regulation** – laws and regulations of promotion of medicines has often followed adoption of Codes (first codes adopted in the 1950s)

The goal of the law is to increase the transparency of **financial relationships** between healthcare providers and suppliers of healthcare products and to uncover potential conflicts of interest.

EFPIA’s Disclosure Code is a response to the growing expectation that **interactions** between corporations and society are not only conducted with integrity but are also transparent.

American Medical Association acting as an active advocate of implementation of the Sunshine Act

CPME (Medical Communities) and BioMed Alliance (Learned Societies) supporting transparency, but not uniformly followed by individual HCPs.

“First follower” (after Australia)

“Next adopter” – advantage: **benefitting from US learning**

Complex reporting approach, including the need to compute accounting data

Aiming at simplicity, which is conducive of coherence and consistency

**No direct sponsorship** of HCPs in Medical Education

**Direct sponsorship** of HCPs in Medical Education

\* A directive is a legislative act of the EU, which requires Member States (MS) to achieve a particular result without dictating the means of achieving that result.

# Learning & Challenges

- \* FAQ on the compatibility of the EFPIA "Disclosure" Code with applicable laws and regulations:
  - **competition laws** – EFPIA has gained sufficient comfort as to conformity of the Code with applicable EU legislation.
  - **personal data protection laws** – companies have the responsibility to conform to legal provisions applicable; the scope of personal data protection shall not be extended to HCOs, unless imposed by law.
  - **balancing legitimate interests** – Data Protection regulations should not be an obstacle to transparency of pharma industry's relationships with HCPs. Our ability to reach the right balance requires good understanding of the purpose of disclosure provisions and the value of organising transparency through self-regulation.
  - **protection of trade secrets** and on **contract laws** – EFPIA's Codes do not require revealing "trade secrets"; confidentiality clauses in contracts shall not operate as circumventing Code provisions.
- \* **National authorities positioning:**
  - **Reluctance** to transparency organised through self-regulation
  - **Legislative initiatives**



# PERSONAL DATA ISSUES HAVE TO BE ADDRESSED AT NATIONAL LEVEL

## Each competent authority will make their own assessment of the balance of legitimate interests

Several national Data Protection Agencies – including the French Data Protection Agency (CNIL), the Dutch Data Protection Agency (CPB), and now the Spanish Data Protection Agency (AEPD) – have confirmed that **the balance of interest is in favour of public interest for transparency**, not necessarily on the same basis. and considering that it would be convenient to implement **additional measures**.

In addition, our Greek Member Association (SfEE) has taken legal opinion on the Greek Law 4316/2014 requiring disclosure of ToVs on company and the Medicines Agency (EOF) websites, which also confirms that public interest outweighs individual interests.

EFPIA Legal Counsel recommended that **local operations (through the national Member Association) reach out to and confirm with the relevant Member States' data protection authorities if their approach is robust enough in each country**.

# Spain: Data Protection Agency defines the balance of legitimate interest



Farmaindustria has made a **formal request (consultation)** to the **Spanish Data Protection Agency (AEPD)**, for them to take a stance on the balance between the legitimate interest of the general public and the individual interests of HCPs inquiring if companies can make their disclosures of personal data without consent of the data subject.

The AEPD's response to Farmaindustria confirmed that **the balance of interest is in favour of "transparency"** and therefore agreed to a **"blanket waiver"** to the collection of individual consent of each Recipient HCP.

In order to prevent a further processing of data which might deviate from the original purpose of the Code, the AEPD considers that it would be convenient to implement **additional measures**. The Spanish Data Protection Agency refers to additional measures such as applying protocols to the website hosting the publication of the data, preventing its indexation through search engines, and stating clearly in the website that the final purpose of the publication is the one indicated in the Code, and that **the publication does not grant a general permission for those accessing the website to undertake additional processing of the HCPs' data, such as crossing the data with information published on other websites**.

# Greece: DPA's Interpretation of the Law

Greek Law 4316/2014 requires disclosure of ToV on company and EOF websites. As prescribed by law, prior consent of data subject to publication is not required, but the Greek data protection authority (DPA) should fix the conditions under which the data can be published.

On 29 June, the Greek DPA allowed disclosure of **ToVs to HCPs relating to promotional activities** without prior consent, subject to:

- Tax Number and social security number of the doctors is not disclosed;
- Security measures are taken (no profiling, no search from google, etc.);
- The Methodological Note must refer to the Opinion 5/2016;
- The duration of the disclosure will be 3 years.

The DPA also considers that **university doctors and doctors serving in the public sector are outside the scope** of the legislation, as disclosure is already covered in the DIAVGEIA .

# Clarifying the Scope of Consent

- \* Consent is given to allow Member Companies to comply with the objectives of the self-regulatory codes.
- \* Legal obligations to disclosure and “exemptions” allow Member Companies to disclose without prior consent, but Data Protection Agency may impose additional measures with a view to ensuring **proportionality** and **prevent use of published data beyond the purpose of the Code**.



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