European Federation of Pharmaceutical Industries and Associations

EFPIA PRE-CONGRESS WORKSHOP

The Privilege of Self-regulation – Compliance & Enforcement






11th International Pharmaceutical & Medical Device Compliance Congress

Lisbon, 15 May 2017

www.efpia.eu

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 EFPIA's **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.

EFPIA Mandate

EFPIA, which has no profit-making purpose, pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

EFPIA’s represents the pharmaceutical industry operating in Europe. Its direct membership includes **33 national associations** and **40+ leading companies**. Two specialised groups within EFPIA represent vaccine manufacturers – **Vaccines Europe - VE**, with 12 member companies and **European Bio-pharmaceutical Enterprises – EBE** with 50+ member companies.

“Partners in Research” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 15+ members.

The many faces of Business Conduct Policies


VISION
MISSION
VALUES
STRATEGY

EFPIA CHARTER

Setting general principles for membership *2015*

ETHICAL PRINCIPLES

Patients at the heart of what we do – Integrity – Respect – Transparency *2016*

Values and standards behaviour in collaboration and relationships…

… with Healthcare Professionals & Organisations	… with Patients & Patient Organisations	… with Public Authorities & Regulators
HOW we are working together		
HCP Code + Disclosure Code *1992/2004/2007/2010 + 2013*	PO Code, incl. Disclosure *2004/2007/2013*	EU Institutions Code of Conduct, incl. transparency
CPME-EFPIA JOINT DECLARATION 2005 – *being review*	**EPF-EFPIA JOINT STATEMENT** *In development*	**GENERAL PRINCIPLES FOR GOOD GOVERNANCE IN THE PHARMA SECTOR** *2012*
BioMed Allicance Code *2016*		EU Transparency Register *2008 & subsequent updates*
WHY are we working together		
Knowledge dissemination and scientific exchange Optimal use of treatments developed by pharma	Improved understanding of patient needs Optimising outcomes a.o. through concordant use of medicines	Improving policy decision making Smarter law making and adaptive pathways keeping pace with scientific & medical innovation


CODES
RULES
STANDARDS
GUIDELINES
COMPLIANCE

Legal & Self-regulatory background

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

- **Self regulation background** – complementing legal provisions in place at national level
  - 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) – *under review*
  - 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 Pharmaceutcial Companies to Healthcare Professionals and Healthcare Organisations (2013): ***HCP & HCO Disclosure Code***
  - Principles for Responsible **Clinical Trial Data Sharing** – joint PhRMA-EFPIA Principles (2013)

EFPIA HCP Code

EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals

- Marketing authorisation
- Information to be made available – reference documents
- Promotion and its substantiation
- Use of quotations in promotion
- Transparency of promotion
- No advice on personal medical matters

- Informational & educational materials, and items of medical utility
- Events & hospitality
- Donations & Grants that support healthcare of research
- Fees for Service
- Sponsorship of HCPs
- The use of consultants
- Non-interventional studies for marketed medicines
- Medical Samples

- Prohibition of gifts

EFPIA PO Code

EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations

- Non-promotion of prescription-only medicines

- Written agreements
- Use of logos and proprietary materials
- Editorial control

- Transparency

- Contracted services

- Single company funding

- Events and hospitality

EFPIA HCP/HCO DISCLOSURE Code

EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

- **Disclosure Obligations**
- **Form of Disclosure**
- **Individual and Aggregate Disclosure**
- **Enforcement**
- **Amendments to, and Guidance regarding Compliance with, the Code**

- Definitions
- Template
- Implementation and Procedural Rules

Minimum Standards at European Level

The EFPIA Codes set **minimum standards** which EFPIA considers must apply to all EFPIA Member Associations in all member states.

All EFPIA Member Associations were required to **transpose the Code into their national codes in full, except where its provisions are in conflict with applicable national laws or regulations**, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

Member Companies shall be bound by the relevant EFPIA Member Association's code in each country in Europe in which they operate (whether directly or through its relevant subsidiary)

EFPIA's CODES COMMITTEE regularly reviews the transposition of the EFPIA Codes into national codes. Applicable codes are posted on the EFPIA website (in English).

Setting Standards at European level
Transposition, Implementation and Enforcement in the Countries

Promotion of Medicines to and Relationships with HCP	Relationships with PO (including disclosure)	Disclosure of Transfers of Value to HCPs/HCOs
EFPIA HCP CODE	EFPIA PO CODE	EFPIA HCP/HCO DISCLOSURE CODE
Transposition	Transposition	Transposition

In line with national laws & regulations


JUST BECAUSE IT'S
RIGHT
DOESN'T MAKE IT
LEGAL


JUST BECAUSE IT'S
LEGAL
DOESN'T MAKE IT
RIGHT


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CASE STUDIES

HCP CODE – Article 10: Events and Hospitality

e4ethics assessment process illustrated

Declaration of Interest

- **José Zamarriego** has a PhD on Economics & Business Studies by Universidad Complutense de Madrid, MBA on Business Administration by the University of Wales (Aberystwyth) and General Management Program in IESE Business School.

- Since January 2004, he has been working as Director of the Code of Practice Surveillance Unit, one of the control bodies of FARMAINDUSTRIA Self – Regulation System. FARMAINDUSTRIA is the National Trade Association of the Spanish based pharmaceutical industry.

- He is Chair of the EFPIA's Compliance Committee. He is also Chairman of IFPMA's Code Complaint Procedure Adjudication Group and Member of the eBIC. He has actively participated in several modifications of the EFPIA, IFPMA and FARMAINDUSTRIA Codes.

Case Studies 1 – EVENTS & HOSPITALITY

Article 10 – HCP Code

Section 10.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar **events … organised or sponsored by or on behalf of a company** must be held in an **"appropriate" venue** that is conducive to the main purpose of the event and may only offer hospitality when such **hospitality is appropriate** …

Section 10.02. No company may organise or sponsor an event that takes **place outside its home country** unless:

a. most of the **invitees are from outside of its home country** and, given the countries of origin of most of the invitees, **it makes greater logistical sense to hold the event in another country**; or
b. given the location of the **relevant resource or expertise** that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

Section 10.03. …

Section 10.04. **Hospitality** extended in connection with events shall be **limited to travel, meals, accommodation and genuine registration fees**.

Section 10.05. Member Companies shall not provide or offer any **meal (food and beverages)** to healthcare professionals, unless, in each case, the value of such meal (food and beverages) does **not exceed the monetary threshold** set by the relevant Member Association in its national code. …

Section 10.06. Hospitality may only be extended to persons who qualify as **participants in their own right**.

Section 10.07. All forms of hospitality offered to healthcare professionals shall be **"reasonable"** in level and strictly limited to the main purpose of the event. …

Section 10.08. **Hospitality shall not include sponsoring or organising entertainment** (e.g., sporting or leisure) events. Companies should **avoid using venues that are "renowned" for their entertainment facilities or are "extravagant"**.

Section 10.09. Member associations shall provide guidance on the meaning of the term: **"reasonable" – "appropriate" – "renowned" – "extravagant" venues**

Educational Events & Ethical Evaluation
www.efpia-e4ethics.eu

The purpose of e4ethics is to serve as a reference for the EFPIA members. Companies belonging to the **EFPIA membership are encouraged to consult the e4ethics Events Database** and should **be mindful of the rules and provisions that apply** when deciding to sponsor, participate or collaborate in an event.

It is however the company's individual decision to decide to sponsor / participate in the event.

The pre-assessment reports posted on the e4ethics website are **without prejudice to full compliance with laws and regulations applicable**. It is recommended to check the rules prevailing under applicable national codes.

PRE-ASSESSMENT PROCESS

The EFPIA Codes Secretariat assesses **each event in regard of the 5 areas**:

1. Scientific Programme Schedule/Structure;
2. Venue;
3. Hospitality Provided (Directly or Indirectly) to HCPs;
4. Other Activities;
5. Accompanying Persons;

and submits the draft pre-assessment reports to:

- The **assessors' team** appointed by the EFPIA Codes Committee;
- The **Member Association of the event hosting country**.

The pre-assessment report validated by the assessors' team is **shared with the Learned Society (or the event organiser, where applicable)**.

Following completion of the pre-assessment process the **final reports posted on the e4ethics public website are shared with EFPIA members and other interested parties** including IPCAA, Medicines for Europe and MedTech.

PRE-ASSESSMENT PROCESS

Selection of Events

- Multinational events in Europe
- Attendance from at least 5 countries
- Significant number of delegates *(5,000)*

- *Ad hoc, upon request*

6 months prior to event

Preliminary pre-assessment, prepared by EFPIA

- Information available on events' dedicated website
- 5 criteria

Validation, by EFPIA Assessors' Team

- with input from organizing society
- Additional comments by Member Association in the event's host cou

10 days for validation

Final pre-assessment report posted on the e4ethics platform

- Colour-code for each of the 5 areas

- Where applicable, Member Association comment added preceded by attention sign 

Final pre-assessments reports are sent to:

- Congress organisers
- All EFPIA members (corporate & associations)
- Pharma communities: IPCAA, IFAPP, etc.
- Other life science associations: MedTech, Medicines for Europe

MAY BE REVIEWED

PRE-ASSESSMENT PROCESS

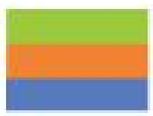
Selection of events
Multinationals events taking place in Europe, i.e. Events in which HCPs from more than 5 countries may take part, and which are expected to attract a significant number of participants

Preliminary pre-assessment
Versus Art. 10 of the EFPIA HCS Code
- Scientific Programme Schedule/Structure
- Venue/Exhibition Area
- Hospitality to HCPs
- Other activities
- Accompanying persons

Based on the event's website

Validation
Versus Art. 10 of the EFPIA HCS Code
By EFPIA's Assessors' Team

FINAL PRE-ASSESSMENT REPORT POSTED ON e4ethics
Observations' Index



Pre-assessment reflected by a colour-code for each of the 5 areas
+
National Code Provisions

If the information available in the congress website(s) is added or modified, the pre-assessment may be reviewed.

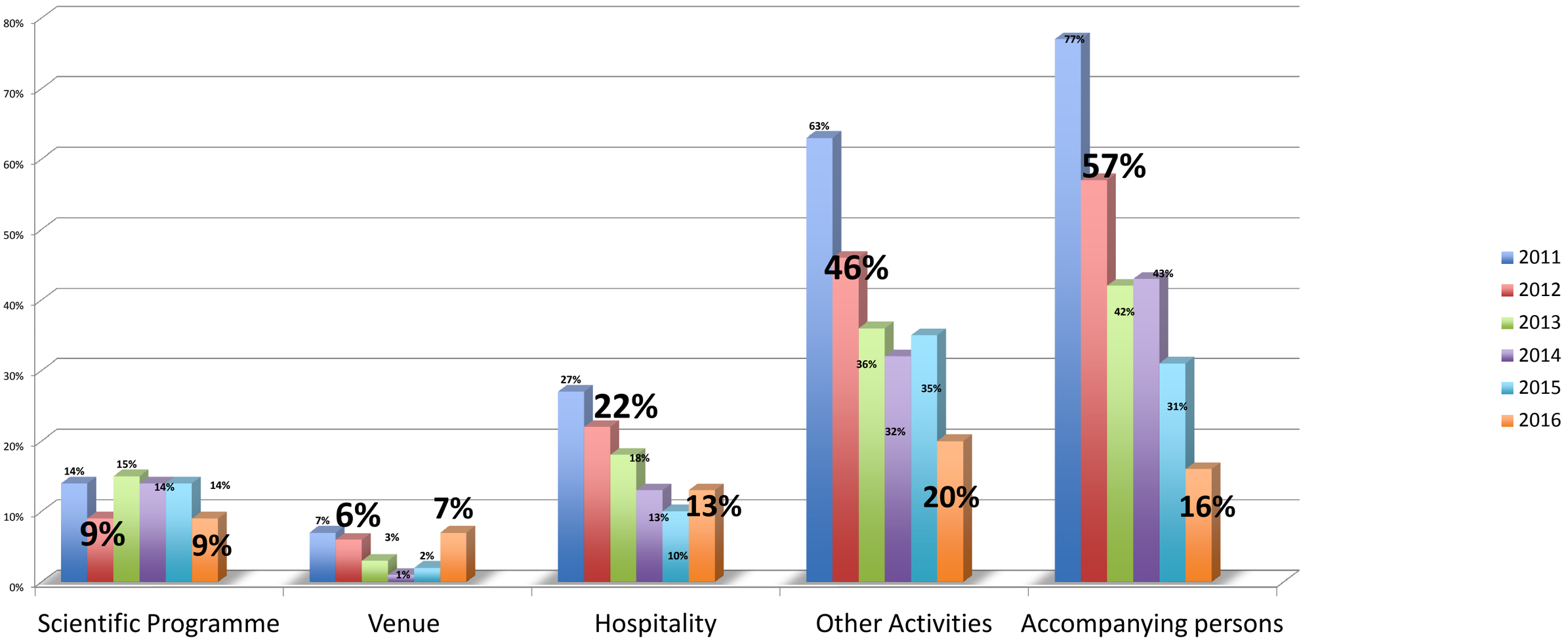
For input from the organizer
By the relevant scientific & medical society

For additional comments with regard to national provision, where appropriate
By Member Association of the Event hosting country

10 working days
tacit consent in the absence of objection

Electronically generated message informing of the final pre-assessment report to:
Congress organisers + all EFPIA members, including:
33 member associations + 40 corporate members + EBE members + VE members
cc IPCAA + IFAPP + Medicines for Europe

Elements that may raise concern



All Green: may not raise concern

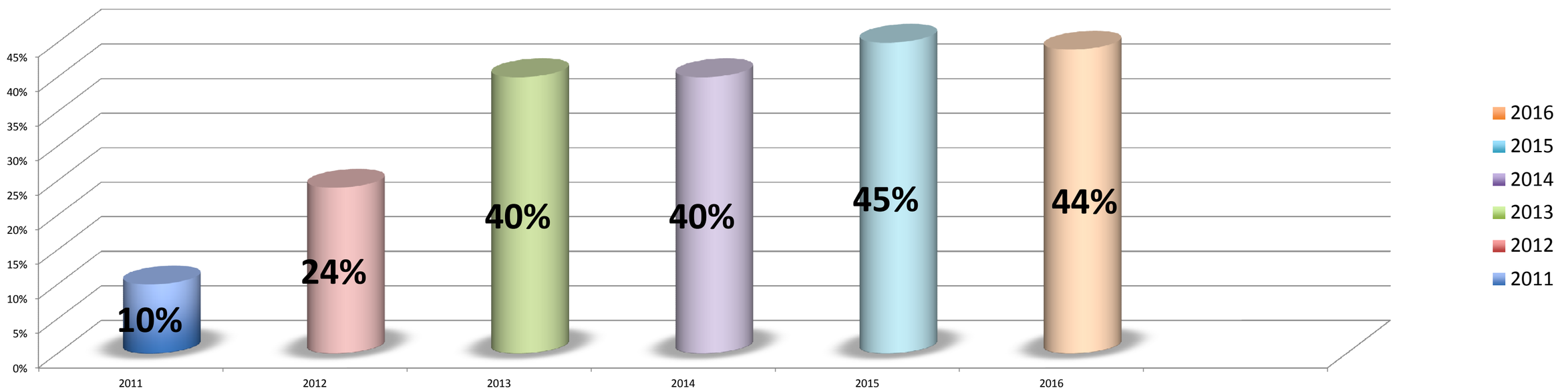


ILLUSTRATION & DISCUSSION

Euroanaesthesia 2017 (ESA)
concern regarding "other activities" (social evening live music performance)

European Hematology Association (EHA) 22nd Congress National Code provision regarding 5* Hotels

http://www.edtna-erca.com/resource/edtna/files/EDTNA2017_2nd_Announcement.pdf

And after discussion with the organisers they changed the brochure taking out the accompanying people section:

http://www.edtna-erca.com/resource/edtna/files/EDTNA2017_2nd_Announcement_Final_20170303.pdf

European Society of Human Reproduction and Embryology
Clarifying "Networking event"

CASE STUDIES

Perception and Reputation

Addressing reputational damage resulting from activities that are not supported by pharma companies

ADDRESSING REPUTATIONAL DAMAGE

How should we handle situations where activities not supported by pharma companies are not aligned with industry standards?

MEDIPRESS SERVICES SA
Avenue G. Demey, 57
1160 Auderghem
Tel : +32 (0)2 352 07 80
Fax : +32 (0)2 354 59 17
Mail : info@mpsservices.be

QUI SOMMES-NOUS ?
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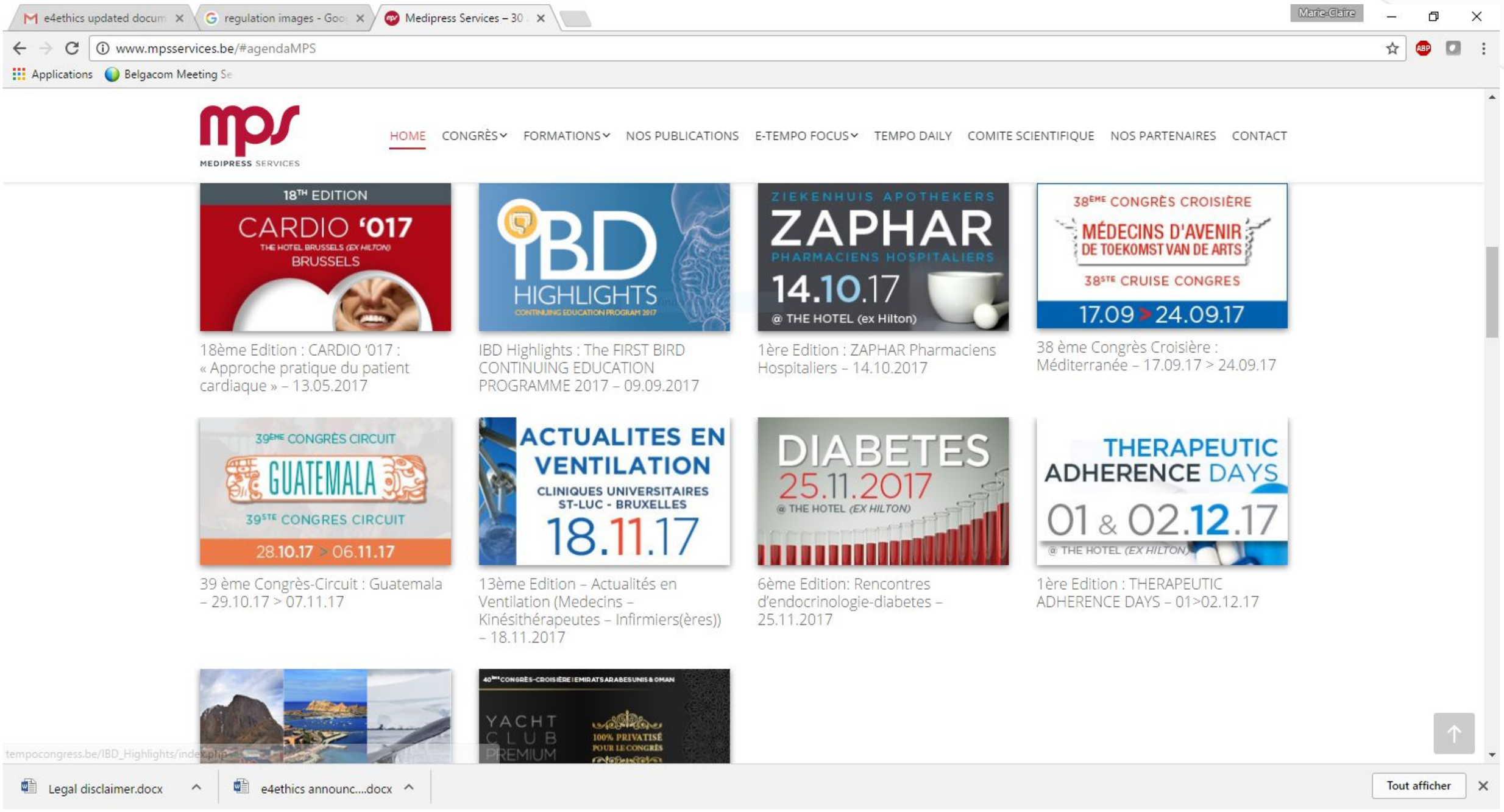


www.medipress.be

COLLABORATIONS WITH PATIENT ORGANISATIONS

Perception becoming reality

Declaration of Interest

- **Holger Diener** has been **Managing Director** of the Association of Voluntary Self-Regulation for the Pharmaceutical Industry (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. – **FSA**) since January 2012.

- Holger previously worked in the legal department of the German Association of Research-based Pharmaceutical Companies (Verband der forschenden Arzneimittelindustrie e.V. – vfa.

- He is Vice Chair of the Codes Committee and member of the Ethics and Compliance Committee at EFPIA. Holger is also a Vice Chair of the IFPMA Ethics and Business Integrity Committee (eBIC). Moreover, he is a Member of the International Society of Healthcare Ethics and Compliance Professionals (ETHICS).

- Holger holds a law degree and a Ph.D. from the Phillips University of Marburg.

PATIENT ORGANISATIONS ASSESSING THE PHARMA INDUSTRY AND ITS COMPANIES

2016 Findings – *Source: PatientView, 21st March 2017*

Making high-quality useful products

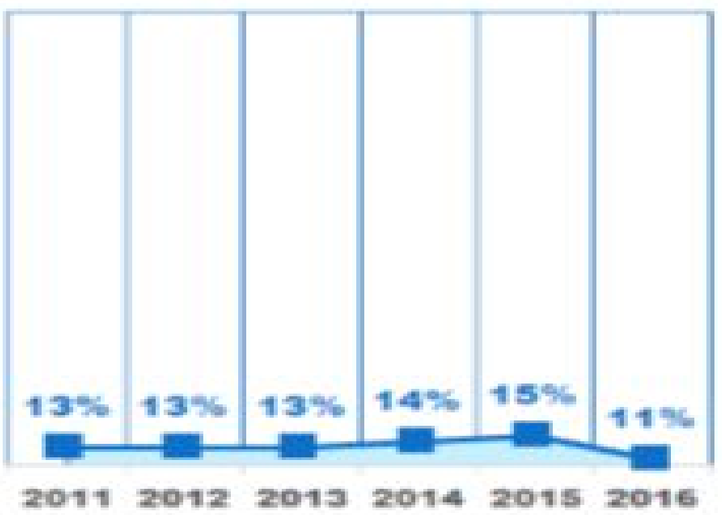
Access to clinical trials

Transparency

Being innovative

Ethical marketing

Fair pricing



Patient Groups Challenged on Pharma Ties

The role of patient advocates in shaping regulations and policy has put attention on financial and operational links between drug companies and independent health organizations.

In PharmTech, 6th April 2017

Toward a Healthier Patient Voice
More Independence, Less Industry Funding
JAMA, March 2017

Conflict of Interest for Patient-Advocacy Organisations
The New England Journal of Medicine – 2nd March 2017

… subpoenas were related to groups that help cover patient co-payments for prescription drugs. … As aggressive price hike for certain prescription medications have drawn the ire of politicians and the healthcare industry, **concerns have grown that donations made by pharmaceutical companies to patient assistance groups may be contributing to the price inflation**.
Source: Reuters (US) – 27 February 2017

…, **a charity that tried to force the NHS to buy more of an expensive … treatment, has taken GBP 200,000 in grant funding from … drugs giant … since 2014**. Last year, it had unsuccessfully taken NHS England to court for restricting access to the medicine on cost grounds. In 2016, the … charity brought a High Court action against NHS England to try to force it to reconsider a controversial decision to limit a new cure … . *Source: BBC (UK) – 1 March 2017*

European Federation of Pharmaceutical Industries and Associations

EFPIA CODE OF PRACTICE ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

Initially approved in 2007
Amended by decision of the General Assembly in June 2011

FSA. Konsequent. Transparent.

Kontakt Mitgliederlogin

Der FSA | Verhaltenskodizes | Schiedsstelle | Bezugsgruppen | Presse | Service

- Auf einen Blick
- Geschäftsstelle
- Vorstand
- Mitgliedschaft
- Seite drucken
- Als PDF speichern

Der FSA

Zum Wohle der Patienten: Wirksame Maßstäbe für Ethik und Transparenz in der Pharma-Industrie

Zu nichts weniger haben sich 55 namhafte Pharma-Unternehmen im Verein „Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." (FSA) zusammengeschlossen. Der Verein wurde am 16. Februar 2004 von den Mitgliedern des Verbands Forschender Arzneimittelhersteller gegründet. Der FSA überwacht die korrekte Zusammenarbeit von pharmazeutischen Unternehmen und Ärzten, Apothekern sowie weiteren Angehörigen der medizinischen Fachkreise und den Organisationen der Patientenselbsthilfe. Hierzu hat der FSA

FSA-Transparenzkodex

Umfassende Informationen zum FSA-Transparenzkodex finden Sie unter www.pharma-transparenz.de.

Aktuelles

Aktuelle Nachrichten des FSA per @ oder erhalten.

German PO Code 2008/2009

2005

ABO SHOP AKADEMIE JOBS MEHR ▾ E-PAPER AUDIO APPS ARCHIV ANMELDEN

ZEIT ONLINE

Suche

Politik Gesellschaft Wirtschaft Kultur ▾ **Wissen** Digital Campus ▾ Karriere Entdecken Sport Spiele mehr ▾ ZEITmagazin

Pharmaindustrie

Geben und einnehmen *„Give and collect“*

Selbsthilfegruppen sind für Schwerkranke ein letzter Halt dabei arbeiten sie oft mit Pharmakonzernen zusammen und riskieren ihre Glaubwürdigkeit

Von **Martina Keller**

19. Mai 2005, 14:00 Uhr / Editiert am 28. November 2007, 13:59 Uhr / Quelle: (c) DIE ZEIT

http://www.zeit.de/2005/21/Pharmafirmen_neu

2016

FSA. Konsequent. Transparent.

Kontakt Mitgliederlogin

Der FSA | Verhaltenskodizes | Schiedsstelle | **Bezugsgruppen** | Presse | Service

Ärzte & Apotheker

Patientenorganisation

- Transparenzliste
- **Zuwendungen**

Einrichtungen im Gesundheitswesen

Seite drucken

Als PDF speichern

Leistungen der Mitgliedsunternehmen an Patientenorganisationen für das Jahr 2016

Die Mitglieder des Vereins Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA) veröffentlichen bereits seit 2009 jährlich sämtliche Leistungen an Patientenorganisationen. Neben der Transparenzliste stehen die Daten der Pharmaunternehmen über Empfänger, Höhe und Zweck der Leistungen in einer Datenbank zur Verfügung. Nachfolgend finden Sie die durchsuchbare Datenbank. Diese erhebt keinen Anspruch auf Vollständigkeit, denn nicht alle FSA-Mitgliedsunternehmen haben direkte Patientenkontakte. Die entsprechenden Daten beruhen auf den Angaben der Unternehmen.

Filtern nach: **Unternehmen** Filtern nach: **Patientenorganisation**

Unternehmen	Empfänger	Datum	Betrag	Zweck
Bayer	PHA (European Pulmonary Hypertension Association), Österreich	05.05.2016	100000 €	Unterstützung der PO bezüglich Organisation des "World PH Day 2016"
Boehringer Ingelheim GmbH	Stroke Alliance for Europe (SAFE), London, UK	2016	95000 €	1. Regional SAFE meetings with member organisations 2. SAFE presence with stand at ESO congresses 3. Preparation Burden of Stroke report
AbbVie	European AIDS Treatment Group	20.10.2016	91275 €	Mitgliedschaft 2016 (100.000 USD)

Mehr Transparenz für Patienten

Von Jennifer Evans, Berlin / Die Zuwendungen der Pharmaindustrie an Patientenorganisationen

aerzteblatt.de

Pharmaindustrie zahlt an Patientenorganisationen 5,8 Millionen Euro

Donnerstag, 31. März 2016

Transparenz gefragt

Niemand lässt sich gern in die Karten schauen. Kein Wunder: Am Spieltisch könnte das schließlich den Sieg kosten. Auch die Pharmaindustrie setzt gern ihr Pokerface auf, vor allem wenn andere Juni sollen nun auch Zahlungen an Ärzte, Apotheker und andere Vertreter von Gesundheitsberufen offengelegt werden (lesen Sie dazu Seite 6). Die vom FSA gestellten Kodizes sollen schutzgründen nur anonymisiert oder zusammengefasst veröffentlichen. Im Moment tun sich die Pharmafirmen mit der Transparenz also leichter als die Ärzte. Sie können damit immerhin dem

Das Fachmagazin für Gesundheitsmarken

FSA: Pharmaunternehmen zahlen knapp 5,9 Millionen Euro an Patientenorganisationen

FSA. Konsequent. Transparent.

Pharmaunternehmen in Deutschland zahlten im vergangenen Jahr insgesamt 5,87 Millionen Euro an Patientenorganisationen. Das ergibt sich aus der neuen Zuwendungsdatenbank des Vereins Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA), Berlin. In der nach Unternehmen und Patientengruppen filterbaren Datenbank stehen ab sofort die

Pharmaindustrie zahlt an Patientenorganisationen 5,8 Millionen Euro

BERLIN (dpa-AFX) - Pharmaunternehmen haben in vergangenen Jahr die

über Empfänger, Höhe und Zweck der Zuwendungen.

Der Verein überwacht seit 2004 die Zusammenarbeit zwischen Pharmaun-

PHARMAZEUTISCHE PZ ZEITUNG online

Neue Datenbank: Mehr Transparenz in der Pharmaindustrie

Der Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA) hat die Zuwendungen seiner Mitgliedsunternehmen an Patientenorganisationen erstmals in einer Datenbank zusammengefasst. Damit seien laut FSA-Geschäftsführer Holger

PHARMA ADHOC vom 04.04.2017

Autor: Marion Schneider
Seite: online
Ressort: Märkte
Gattung: App
Jahrgang: 2017

Pharma veröffentlicht Spenden an Patienten

Healthcare Marketing | Online | 04.04.2017

HEALTHCARE MARKETING

Pharma förderte Patientenorganisationen 2016 mit fünf Millionen Euro

FSA. Konsequent. Transparent.

Der Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA) hat die 2016 erbrachten Zuwendungen an Patientenorganisationen veröffentlicht. Mit rund fünf Millionen Euro Förderwert unterstützten demnach die Pharmaunternehmen, die in der Transparenzinitiative Mitglied sind, die Verbände und Vereine in ihren Betroffenen-Zielgruppen. Die Offenlegung erfolgte zum zweiten Mal in

rung stattfinden und seien ohne die
nterstützung der Unternehmen nicht

Pharma Relations

pharma RELATIONS

FSA veröffentlicht Zuwendungen an Patientenorganisationen

05.04.2017 15:21

Bereits seit 2009 veröffentlichen die Mitglieder des Vereins „Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.“ (FSA) jährlich sämtliche Zuwendungen an Patientenorganisationen. Neben der Transparenzliste mit den Verlinkungen zu den Veröffentlichungen der einzelnen Unternehmen steht in diesem Jahr zum zweiten Mal zusätzlich eine Datenbank zur Verfügung, in der die Daten der Pharmaunternehmen nach Empfänger, Höhe und Zweck der Zuwendungen nutzerfreundlich durchsuchbar sind.

ÄRZTE ZEITUNG vom 05.04.2017

Seite: 11
Ressort: Wirtschaft
Gattung: Tageszeitung
Jahrgang: 2017
Nummer: 66
Auflage: 48.227 (gedruckt) 5.119 (verkauft) 48.010 (verbreitet)

ÄRZTE ZEITUNG

Industrie veröffentlicht Zuwendungen aus 2016

BERLIN. Der Verein "Freiwillige Selbstkontrolle für die Arzneimittelindustrie" (FSA) hat die Zuwendungen Das seien "deutlich weniger als zehn Prozent der jährlichen Zuwendungen, die die Organisationen beispielsweise jährlich die Firmen-Zuwendungen an Patientenverbände und Selbsthilfe. *(cw) Geberfirmen, Empfänger, und konkrete*

FSA Press Release, 3 April 2017

FSA. Konsequent. Transparent.

FS Arzneimittelindustrie e.V.

Dr. Holger Diener - Geschäftsführer
Daniela von Arnim - Assistentin

Grolmanstr. 44-45
10623 Berlin

d.arnim@fsa-pharma.de
Tel.: 030 88728-1700
Fax: 030 88728-1705

Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.

03.04.2017

Pharmaindustrie ist Vorreiter bei nachhaltiger Transparenz - FSA veröffentlicht erneut Zuwendungen der Mitgliedsunternehmen an Patientenorganisationen für 2016 nutzerfreundlich in Datenbank

Berlin, 3. April 2017 – Bereits seit 2009 veröffentlichen die Mitglieder des Vereins „Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) jährlich sämtliche Zuwendungen an Patientenorganisationen. Neben der Transparenzliste mit den Verlinkungen zu den Veröffentlichungen der einzelnen Unternehmen steht in diesem Jahr zum zweiten Mal zusätzlich eine Datenbank zur Verfügung, in der die Daten der Pharmaunternehmen nach Empfänger, Höhe und Zweck der Zuwendungen nutzerfreundlich durchsuchbar sind.

Transparenzliste und Datenbank sind unter folgendem Link erreichbar:
http://www.fsa-pharma.de/bezugsgruppen/patientenorganisation/

Für FSA-Geschäftsführer Dr. Holger Diener ist die praktizierte Transparenz der entscheidende Faktor: „Der FSA steht für nachhaltige Transparenz. Diesen Weg gehen wir konsequent mit unseren Mitgliedern – zum Wohle der Patienten. Die Offenlegung und Nachvollziehbarkeit der Daten schaffen Vertrauen und bekämpfen Misstrauen."

Bereits 2008 haben die FSA-Mitglieder im FSA-Kodex Patientenorganisationen verbindliche Regeln für die Zusammenarbeit mit dieser Gruppe beschlossen. Basierend auf diesem Kodex informieren die Mitgliedsunternehmen des FSA seit 2009 die Öffentlichkeit jährlich über alle Zuwendungen an Selbsthilfeorganisationen in Form und Höhe. Dazu zählen etwa finanzielle

(…)

Dr. Martin Danner, Managing Director of BAG SELBSTHILFE, also welcomes the transparency requirements of the FSA from the view of the patient organization: "The work of self-help organizations of chronically ill and disabled people is supported above all by the voluntary commitment of those affected. However, many support and advisory services could not be realized without a sufficient financial basis. It is to be welcomed that, in addition to the public sector, statutory health insurance funds and other sponsors, the pharmaceutical companies are also involved here. It is important that the cooperation takes place on the same level and is clear from the outside. Disclosure promotes this confidence building and secures the neutrality and independence of the organizations."

(…)

CODE ENFORCEMENT

Learning from case handling

Corrective actions can move the needle

Conoce el Código de Buenas Prácticas de la Industria Farmacéutica

Ir al Código

Descargar

Caso práctico: REUNIONES CIENTÍFICAS

Caso práctico: REUNIONES CIENTÍFICAS

TRANSPARENCY IS AN ASSET

Anticipating societal expectation of the pharma sector and addressing conflict of interest

Declaration of Interest

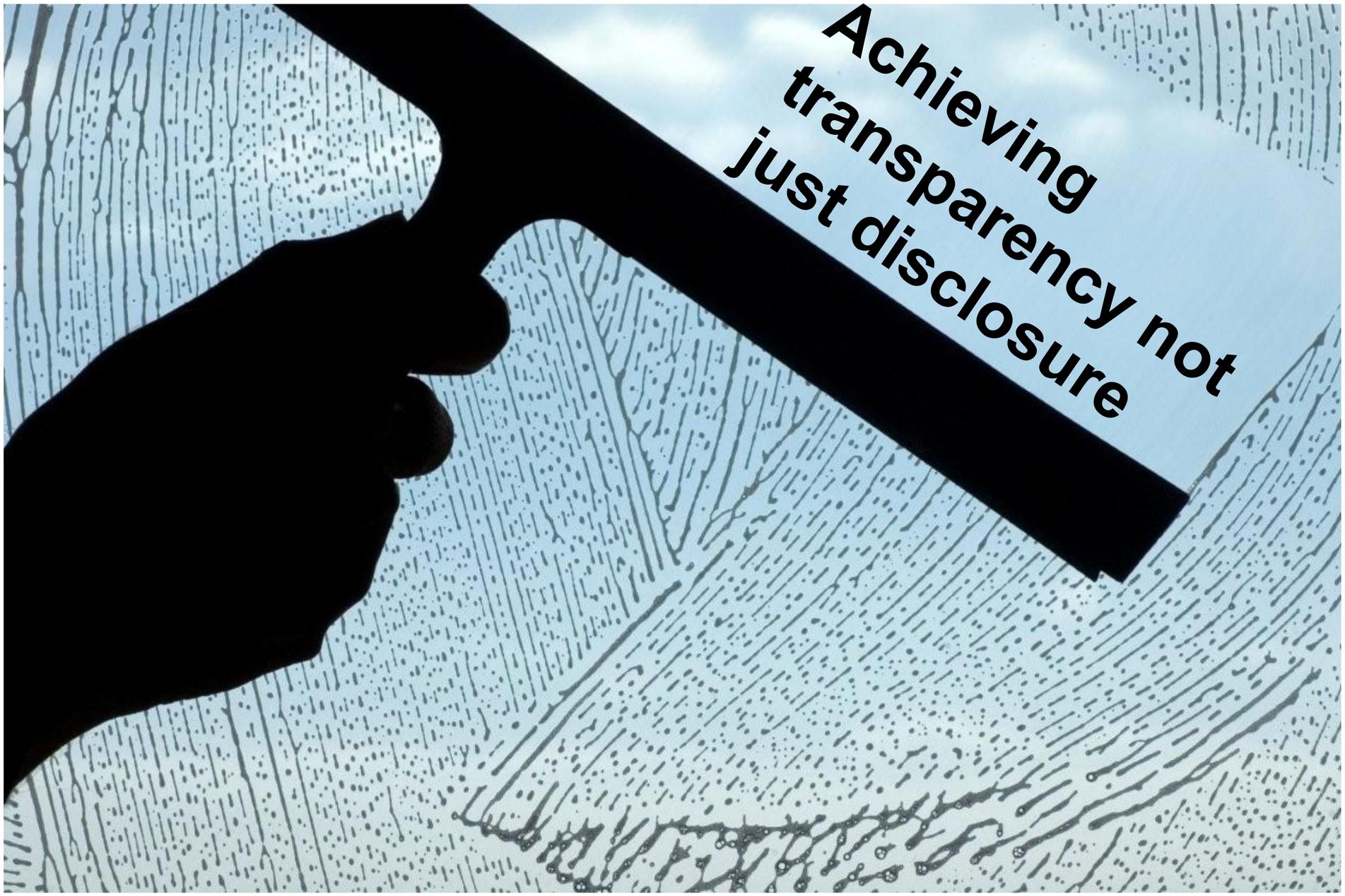
- **Heather Simmonds** is the Director of the Prescription Medicines Code of Practice Authority (PMCPA).

- Heather chairs the **Code of Practice Panel**, which considers complaints submitted under the **ABPI Code** in the first instance, and is responsible for the overall running of the organisation.

- Heather also works with IFPMA and EFPIA in relation to their codes of practice.

- Heather has a degree in pharmacology and joined the ABPI in 1984. Heather has been working full time on the Code of Practice since 1989 and has been Director of the Authority since 1997.

Our next challenge? …



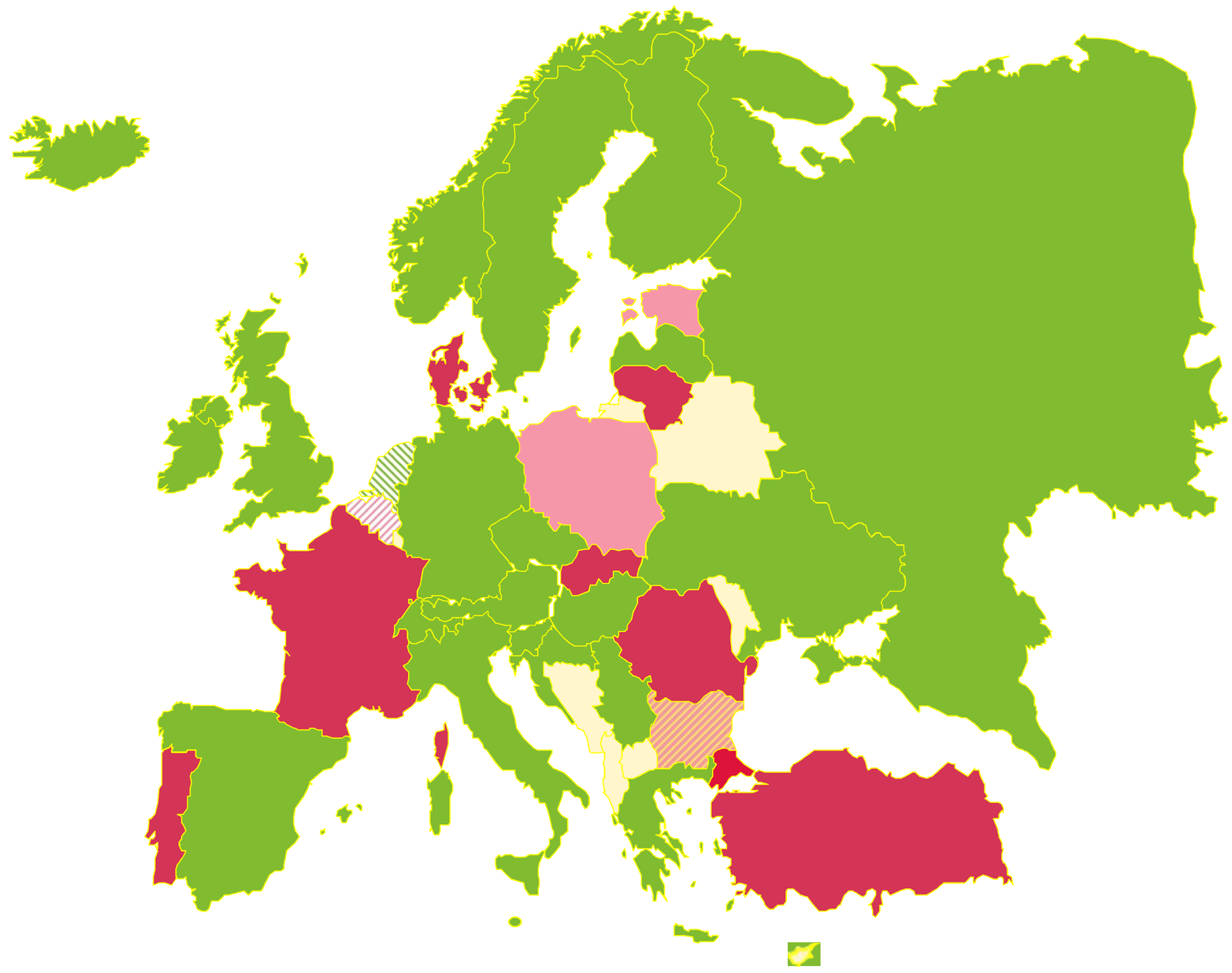
Legislation versus Self-Regulation

Self-regulation

Multi-stakeholder self-regulation

Legislation expected
- Belgium
- Bulgaria

Legislation
- Denmark
- Estonia
- France
- Lithuania
- Poland (limited scope)
- Portugal
- Romania
- Slovakia
- Turkey

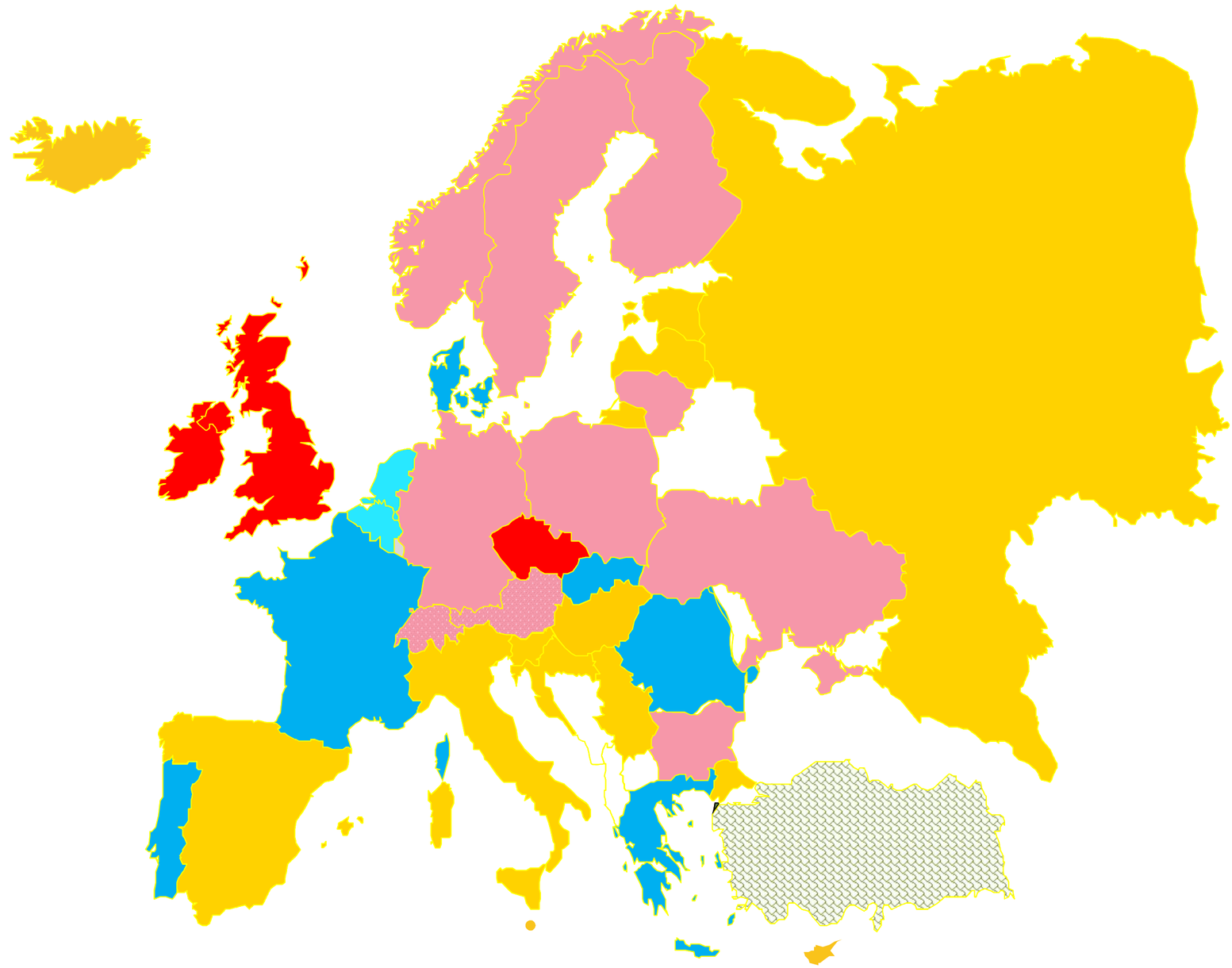


FORMS OF DISCLOSURE

Company Websites / Government Platforms / Member Association Central Platforms / Member Association Gateways

Several types of **"Central Platforms"** have been implemented :

- **Association platform:** Czech Republic, Ireland, UK
- **Association "gateways" in place**: Bulgaria, Finland, Germany, Lithuania, Norway, Poland, Sweden, Ukraine
- **Association "gateways" planned**: Austria and Switzerland
- **Government platform**: Denmark, France, Greece, Portugal, Romania, Slovak Rep.
- **Multi-stakeholders platform**: Belgium (and Luxembourg), the Netherlands



CLAUSE 24 Transfers of Value to Health Professionals and Healthcare Organisations

- Companies must document and publicly disclose certain transfers of value made directly or indirectly, whether in cash or kind, to health professionals other relevant decision makers and healthcare organisations located in Europe
- The transfers of value covered are those made in relation to:
  - Medical and educational goods and services
  - Joint working
  - Contracts with organisations or individuals
  - Sponsorship/subsistence/travel for meetings

CLAUSE 24 Transfers of Value to Health Professionals and Healthcare Organisations

Disclosure is on a central platform.

The template which to be used is available to download from the Authority's website (www.pmcpa.org.uk).

Disclosure UK

Click here to download a full transcript of the video.

The relationship between the pharmaceutical industry and healthcare professionals (HCPs) and healthcare organisations (HCOs) plays a vital role in the development and delivery of life-enhancing and life-saving medicines.

It is a relationship that we are proud of. At the core of the relationship is sharing knowledge to improve outcomes for patients. We want to ensure that patients and others have confidence that this relationship is open and transparent and this is why the pharmaceutical industry is taking the lead on disclosing details of payments and other benefits in kind made by industry to HCPs and HCOs.

This information will be published on the database - Disclosure UK.

Disclosure UK is part of a Europe-wide initiative to increase transparency between pharmaceutical companies and the doctors, nurses, pharmacists and other health professionals and organisations it works with.

Related links

Links

ABPI reputation with stakeholders

Industry commitment to disclosure

Press

Majority of healthcare professionals continue to support pharmaceutical industry drive for greater transparency

Pharmaceutical industry takes another stride towards greater transparency of financial relationships with healthcare professionals

Pharma and transparency: actions speak louder than words

Disclosing payments from drug companies should be mandatory for doctors, says academy

ABPI to work with IMS Health and C&C Group to deliver disclosure database

Resources

Disclosure UK: FAQs

HCP's survey on transparency - infographic

How will it work?

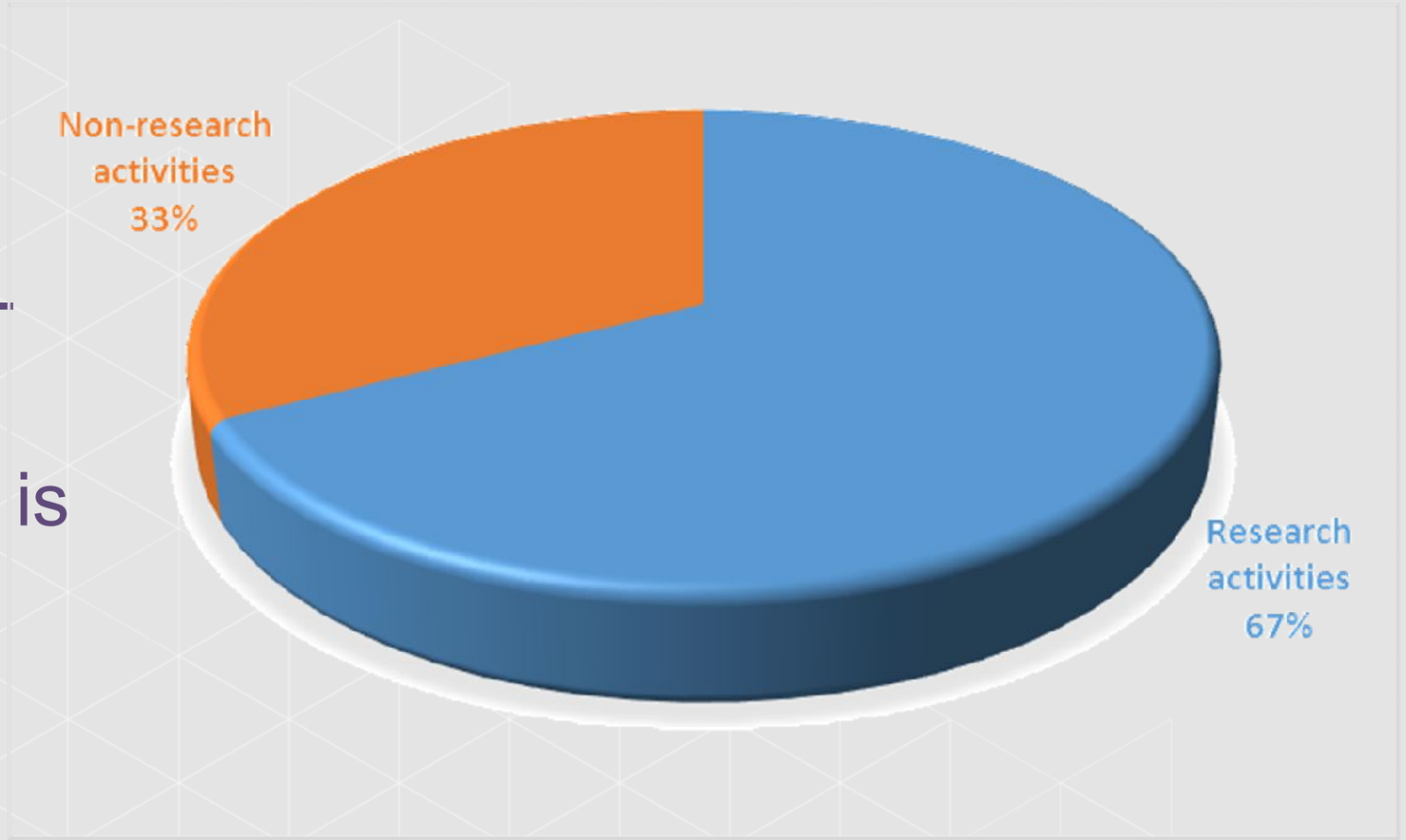
Understanding the value of HCP and pharma interaction

Public disclosure of payments to HCPs leaflet

Video: Disclosure of payments to healthcare professionals 2015

Disclosure UK - high-level analysis*

- Total transfer of value disclosed for 2015 is **£340.3 million**, including research activity and non-research activity
- 2/3 **£229.3 million (67%)** is research activity spend in 2015
- 1/3 **£111 million (33%)** is non-research activity spend in 2015



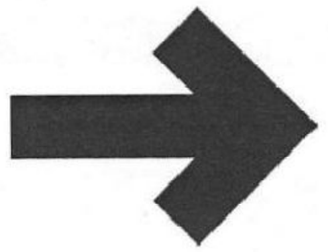
* **Data analysed 24 June**

* **109 companies (54 ABPI members, 55 non-members)**

NHS England

Managing Conflicts of Interest in the NHS

Guidance for staff and organisations



Publications Gateway Reference: 06419

Hospitality

NHS England

What are the issues?	Delivery of services across the NHS relies on working with a wide range of partners (including industry and academia) in different places and, sometimes, outside of 'traditional' working hours. As a result, staff will sometimes appropriately receive hospitality. Staff receiving hospitality should always be prepared to justify why it has been accepted, and be mindful that even hospitality of a small value may give rise to perceptions of impropriety and might influence behaviour. Hospitality means offers of meals, refreshments, travel, accommodation, and other expenses in relation to attendance at meetings, conferences, education and training events, etc.
Principles and rules	Overarching principles applying in all circumstances: • Staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement. • Hospitality must only be accepted when there is a legitimate business reason and it is proportionate to the nature and purpose of the event. • Particular caution should be exercised when hospitality is offered by actual or potential suppliers or contractors – these can be accepted if modest and reasonable but individuals should always obtain senior approval and declare these. Meals and refreshments: • Under a value of £25 - may be accepted and need not be declared. • Of a value between £25 and £75* - may be accepted and must be declared. • Over a value of £75* - should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept. • A common sense approach should be applied to the valuing of meals and refreshments (using an actual amount, if known, or an estimate that a reasonable person would make as to its value). *The £75 value has been selected with reference to existing industry guidance issued by the ABPI http://www.pmcpa.org.uk/thecode/Pages/default.aspx

6. Transparency: Maintenance and publication of register(s)

NHS England

Maintenance of Register(s)

6.1. Organisations must ensure that a nominated team or individual collates and maintains up to date organisational register(s) of interests. An interest should remain on the register(s) for a minimum of 6 months after the interest has expired. Organisations should retain a private record of historic interests for a minimum of 6 years after the date on which it expired.

6.2. Template declaration of interests and register of interests forms for organisations to use are provided at Annex C and D. They should always contain:

- The returnee's name and their role with the organisation
- A description of the interest declared (reflecting the content of section 5 of this guidance for common situations)
- Relevant dates relating to the interest
- Space for comments (e.g. action taken to mitigate conflict)

6.3. Using the common format in the templates will help minimise burdens on staff who might need to submit returns to multiple organisations.

Declaration of interests template

Publication

6.4. All staff should declare interests and, as a minimum, organisations should publish the interests of decision making staff at least annually in a prominent place on their website. Organisations without websites should maintain registers locally, available for inspection on request.

6.5. The format of published registers should be accessible and contain meaningful information. Adopting the templates and advice on content in this guidance will assist organisations in this task.

6.6. Organisations should put in place processes for staff to make representations that information on their interests should not be published. This will allow for, in exceptional circumstances, an individual's name and/or other information to be redacted from any publicly available registers where the public disclosure of information could give rise to a real risk of harm or is prohibited by law.

6.7. As well as taking these steps, organisations should seek to ensure that staff who are subject to wider transparency initiatives such as the ABPI Disclosure UK scheme are aware of and comply with them: http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx

Register of interests template

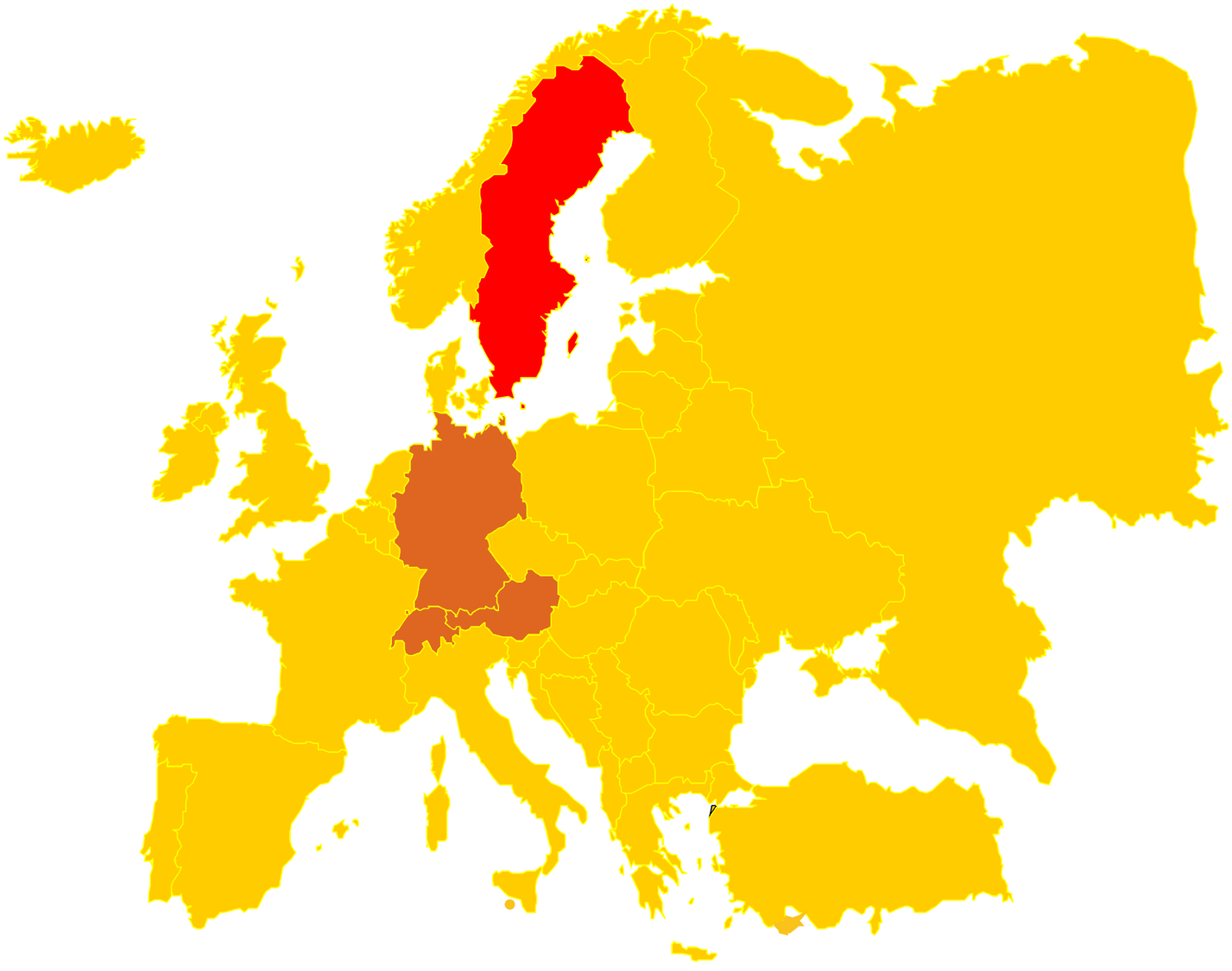
FROM DISCLOSURE TO TRANSPARENCY

Leaving it to third parties / media or taking credit for it

Germany:
Disclosure reports on companies' websites accessible through the **FSA Gateway**

CONNECTIV!
Replicated the re-organisation of data in Switzerland and Austria

Recently, similar approach applied to Sweden



14 July 2016

Database of Spiegel Online and Correctiv.org was published

CORRECT!V

RECHERCHEN ÜBER CORRECTIV COMMUNITY

EUROS FÜR ÄRZTE ÖSTERREICH

Wieviel Geld hat Dein Arzt/

Pharmaindustrie erhalten?

1010

Suche nach Personen und Organi

Deine Suche ergab fo

Name
Österreichische Gesellschaft für G
Wien, Österr. Krebshilfe-Krebsges
Österreichischer Verband der Impf

Wir decken Missstände auf. Wir sind unabhängig und nicht gewinnorientiert. CORRECTIV UNTERSTÜTZEN

CORRECT!V

RECHERCHEN ÜBER CORRECTIV COMMUNITY

GELD FÜR ÄRZTE SCHWEIZ

Wieviel Geld hat Dein Arzt/Heilberufler im vergangenen Jahr von der Pharmaindustrie erhalten?

1010 Suchen

Suche nach Personen und Organisationen in der Schweiz

Deine Suche ergab folgende Treffer

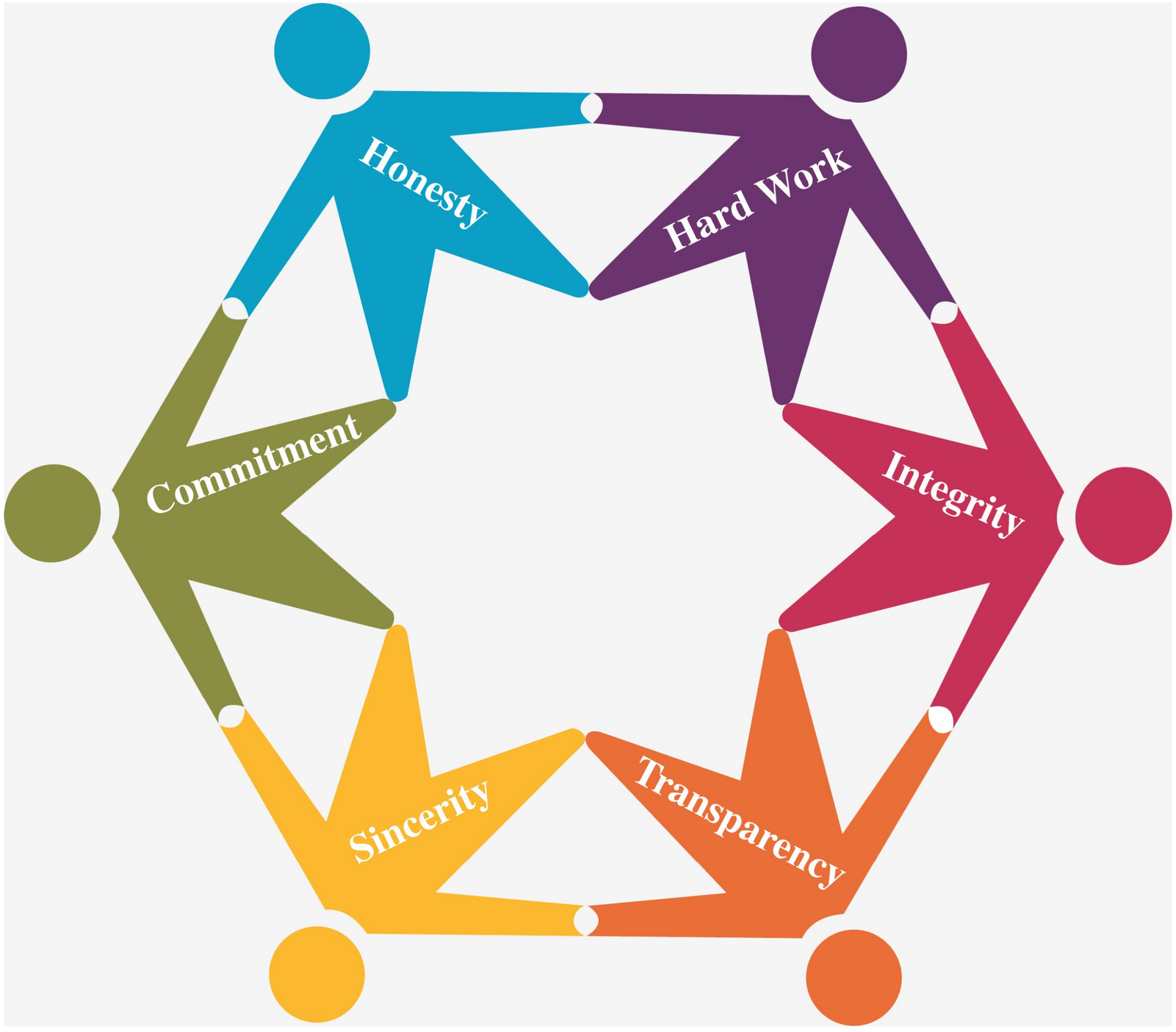
Name	Adresse	Gesamtbetrag
Anne Stucki	Lausanne 1010 Lausanne	CHF 2'133.00
Vincent Jéquier	Cabinet medical FMH Medecine interne generale Routed'Oron 1 1010 Lausanne	CHF 1'250.00
Rodrigo Da Graça	Praz-Berthoud 19	CHF 1'208.00

Other disclosure requirements – mixture of IFPMA Code, EFPIA codes and principles and national codes

- Companies must disclose details of clinical trials in accordance with IFPMA, EFPIA, PhRMA and JPMA positions and include on homepage of their website information as to where details of their clinical trials can be found
- Detailed requirements for prospective non interventional studies
- EFPIA PhRMA data sharing principles
- Patient organisations

CLOSING REMARKS

One-line comment from the PANELLISTS
Take away messages from the AUDIENCE


Honesty
Hard Work
Commitment
Integrity
Sincerity
Transparency

European Federation of Pharmaceutical Industries and Associations

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