

IPCAA
Compliance / Regulatory Workshop
Frankfurt, 8 December 2010

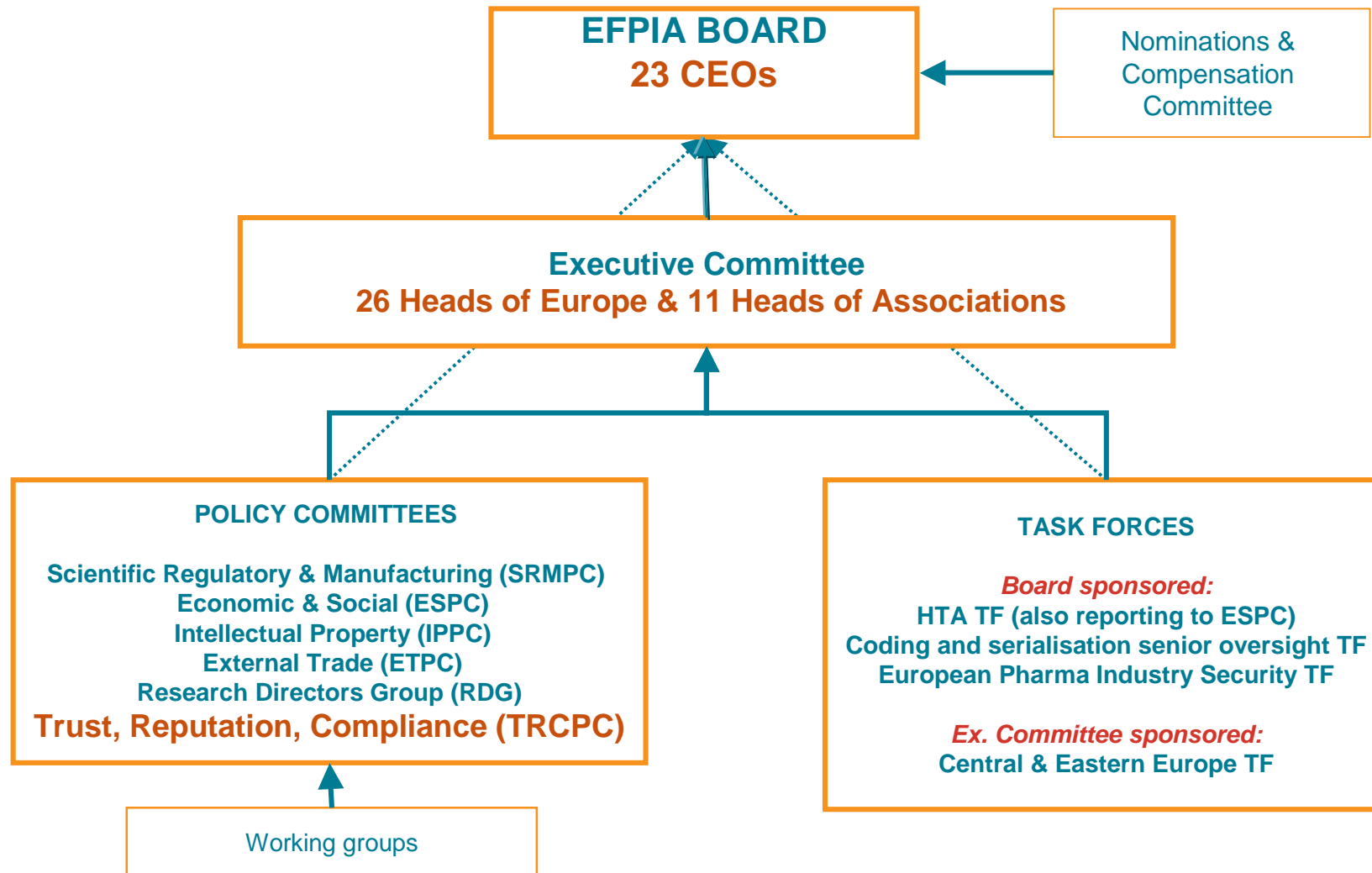
EFPIA Leadership Statement on Ethical Practices

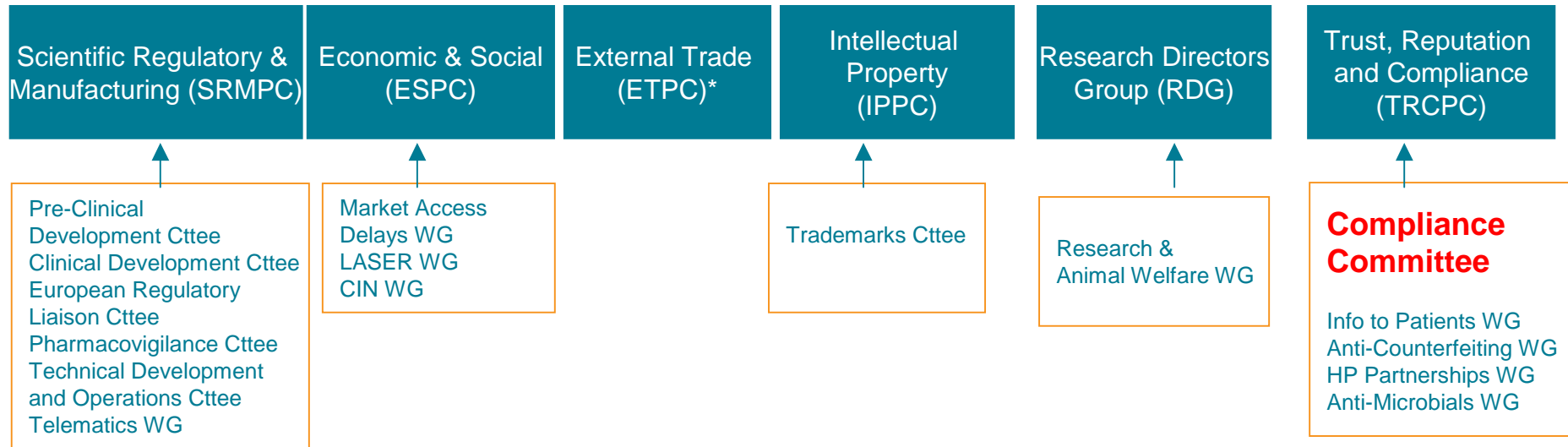
Marie-Claire PICKAERT
Deputy Director General

The aim of the European Federation of Pharmaceutical Industries & Associations, which has no profit-making purpose, is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.

EFPIA 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 31 national associations and 40 leading companies. Two specialised groups within EFPIA represent vaccine manufacturers – EVM, with 9 member companies) and emerging biopharmaceutical companies – EBE with 65 member companies.





* Including Regulatory Support virtual network

GENERAL MANAGEMENT

Brian Ager – *Director General*
Maria Curatolo – *Personal Assistant*

Marie-Claire Pickaert – *Deputy Director General*
Fabienne Muylle – *Executive Secretary*

ECONOMIC AFFAIRS

François Bouvy – *Director*
Anthony Barron – *Assistant Manager*
Edith Frenoy – *Assistant Manager*
François Lamerant – *Assistant Manager*
Fabienne Muylle – *Executive Secretary*

COMMUNICATION & PARTNERSHIP

Colin Mackay – *Director*
Erica Poot – *Manager (Patient Relations)*
Philomène Bouchon – *Assistant (Media)*
Amelia Kossi – *Secretary*

EXTERNAL TRADE

Louis-Nicolas Fortin – *Director*
Fabienne Muylle – *Executive Secretary*

EUROPEAN VACCINE

MANUFACTURERS – (EVM)

Magdalena Rodriguez de Azero –
Executive Director
Julien Patris – *Assistant Manager*
Anne Meynaerts – *Secretary*

ADMINISTRATION

Andreas Walter – *Administrative/IT
& Conference Manager*
Stéphane De Molling – *Administrative/IT
Assistant Manager*
Anita Colin – *Assistant*
Pina Avola – *Receptionist*

LEGAL AFFAIRS

Ann Robins – *Director*
Irène Suzuki – *Secretary*

MULTILATERAL AFFAIRS AND HEALTH POLICY

Brendan Barnes – *Director*
Mary-Rose VanRollegem – *Secretary*

CEE REGION AND ANIMAL WELFARE

Magda Chlebus – *Director*
François Lamerant – *Assistant Manager*
Catherine Lecerf – *Assistant Manager*
Mary-Rose VanRollegem – *Secretary*

GOVERNMENT AFFAIRS

Andreas Preising – *Director*
Fadwa Sibai – *Assistant Manager*
Angela Piedra-Hernandez – *Secretary*

SCIENTIFIC, TECHNICAL & REGULATORY AFFAIRS

Christine-Lise Julou – *Director*
Isabelle Clamou – *Assistant Manager*
Elisa Siviglia – *Assistant Manager*
Sandra Rodrigues – *Secretary*

RESEARCH DIRECTORS GROUP

Titta Rosvall-Puplett – *Director*
Anders Colver – *Assistant Manager*
Tatiana Kirpitchenok – *Secretary*

EUROPEAN BIOPHARMACEUTICAL ENTERPRISES – (EBE)

Emmanuel Chantelot – *Executive Director*
Piers Allin – *Manager, Regulatory Affairs*
Audrey Claeys – *Assistant Manager*
Joëlle Baruti – *Executive Assistant*

EFPIA's work programme is aligned with its commitment, as shown in the list of key projects for 2010-12:

- Securing fast and wide access – HTA
- The Innovative Medicines Initiative (IMI)
- Maintain industry's ability to conduct animal studies
- Entrenching IP framework in Europe and beyond
- Antibiotics and neglected tropical diseases
- Sales and marketing practices**
- Information to patients
- Counterfeit and patient safety – coding & serialisation
- External trade and emerging markets
- National developments – implications of the financial and economic crisis

Setting **new standards** for **congresses, exhibits & other meetings**

Monitoring and key **learnings** of **European events** – results from ESC, EADS, ESMO, ...

Working with medical and scientific societies to raise awareness

What does the Leadership Statement say

Setting **new standards** for congresses, exhibits & other meetings
→ **developing common standards for meetings organised / sponsored by industry and attended by HCP**

Monitoring and key **learnings** of European events – results from ESC, EADS, ESMO, ... → **monitoring of congress activities – including the monitoring of exhibitions at congresses (with particular attention to venues and exhibitions)**

Working with medical and scientific societies **to raise awareness** → **working with medical & scientific societies to raise awareness of high ethical standards applying to interactions between medical doctors and pharmaceutical companies**

LEADERSHIP STATEMENT

June 2010

General statements of industry leaders

- Full respect for the role that **EU legislation** plays in regulating interactions between pharmaceutical companies and healthcare professionals
- Commitment to working towards **greater transparency, accountability and ethical behaviour** within an industry framework of **self-regulation**
- Adherence to **EFPIA Codes** establishing standards for appropriate behaviour in companies relations with healthcare professionals and patient organisations is essential – **breaches should not be tolerated**
- Establishment of **National Ethics Groups** in EFPIA's member associations
- Inviting **non-member companies** to adhere to self-regulatory rules and guidance adopted by the R&D-based pharmaceutical industry
- Developing additional guidance around 5 areas to ensure that EFPIA membership continues to uphold the highest standards

EFPIA was asked to develop additional guidance around the following areas:

1. Provision of information – general policy

Additional guidance to be issued

... representatives
... principles
... and other meetings, including exhibitions at congresses

5. Relationships with patient organisations – for discussion in the afternoon

EFPIA P.O.
Code Review

Reference

- EU Directive 2001/83 – areas to be addressed are covered by EU provisions – i.e. the so-called “PROMOTION” Directive, included in EU Pharmaceutical Legislation
- National regulation – implementing EU provisions; national legislation may be more restrictive / prescriptive
- EFPIA “Healthcare Professionals” (HCP) / “Patient Organisations” (PO) Code – national codes may be more restrictive; in some areas, EFPIA Codes require specific action from membership
- Joint Declaration of CPME and EFPIA on the Cooperation Between the Medical Profession and the Pharmaceutical Industry (June 2005)*

Additional guidance should:

- protect EFPIA and its membership from anti-trust accusation
- include enforcement / monitoring mechanisms
- evolve towards more restrictive rather than less restrictive prescriptions

Objective:

Building on existing legal obligations and industry standards, developing guidance for defining standards and housekeeping rules for medical sales representatives

Deliverables:

- Defining **scope**, which may need to take into consideration the evolution in the role of “sales representatives” and technology; also addressing functions under different departments
- Identifying **areas** to be covered by housekeeping rules, including areas that raise reputational issues in practice – guidance should be conducive to medical education, and provide adequate support to doctors in their continued medical development
- Developing **standards** that are effective and practical; enhancing **training**
- Reflecting on **monitoring mechanisms**

Objective:

Supporting (self-)regulation moves towards the “4 X 2” standard – i.e. Each healthcare professional should receive, per year, no more than 4 samples of a particular medicine he / she is qualified to prescribe; and sampling should not extend beyond the two years after the product is first launched

Deliverables:

- Restating the limitation to sampling under the EU Directive
- Clarifying conditions under which samples can be given to healthcare professionals
- Preventing sampling taking place outside the strict “exceptional” cases allowed under EU legislation
- Providing clear guidance to the member associations in evolving towards the “4 x 2” standard

Objective:

Developing common standards for meetings organised / sponsored by industry and attended by healthcare professionals

Deliverables:

- Reviewing the standards applicable, and clarifying scope
- Reviewing implementation required by the EFPIA HCP Code (defining “reasonable”; providing guidance on “appropriate”; “renowned”; and “extravagant” venues) – identifying room for common guidance and improved consistency
- Addressing overshadowing exhibitions and reducing the *arms’ race*

Objective:

Setting up an on-line platform to pre-assess events in regard of the EFPIA HCP Code

Deliverables:

- Criteria for the pre-assessment of events
- Setting up a process for the promotion of compliance with industry highest standards, the prevention of inappropriate behaviour
- Sponsoring corrective actions through leveraging corporate compliance officers role

Codes Steering Group – member association representatives

CSG-MAR

Objective:

Exerting peer review pressure through site visits at congresses

Deliverables:

- Reporting on visits of selected congresses in Europe – organisers and scientific societies advised of EFPIA's plan to visit
- Improving understanding of industry's rules applying to their relations with healthcare professionals
- Sharing findings with the Compliance Committee and prevent inappropriate behaviour, including reducing the *arms' race* at exhibitions
- Looking for pragmatic solutions to issues arising with congress organisers and scientific societies

Mandatory disclosure of support to patient organisations

Objective:

Requiring companies to disclose the amount of support provided to patient organisations – this mandatory requirement needs a review of the EFPIA "PO" Code

Deliverables:

- Defining the total amount of support provided, which should include: (i) the amount of financial support; (ii) the amount of cost invoiced to the sponsoring company for significant non-financial support; (iii) for significant indirect support not covered by invoices and for significant non-financial support, the company will provide its best estimate established in good faith of costs incurred
- Providing guidance as to the format in which the total amount of support should be disclosed
- Identifying legal and practical issues arising (also from PO's point of view)

**Developing common standards for
meetings organised / sponsored by
industry and attended by HCP**

Article 94

1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.
2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than HCP.
3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under § 1 or contrary to § 2.
4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by §§ 1, 2 and 3.

Article 95

The provisions of Article 94(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than HCP.

Article 9 – Events & Hospitality

1. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar meetings, ... 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 and otherwise complies with the provisions of any Applicable Code(s).

2. 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 make greater logistical sense to hold the event in another country (an “international event”).

3. Promotion information which appears on exhibition stands or is distributed to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses) which are not registered in the country where the event takes place, or which are registered under different conditions, so long as:
 - i. Any such promotional materials (excluding promotional aids) is accompanied by a suitable statement indicating the countries in which the product is registered and makes clear that the product or use is not registered locally; and
 - ii. Any such promotional material which refers to the prescribing information (indications, warnings, etc.) authorised in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally.
4. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and genuine registration fees.
5. Hospitality may only be extended to persons who qualify as participants in their own right.

6. All forms of hospitality offered to HCP shall be “**reasonable**” in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.
7. 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**”.
8. Member Associations shall provide guidance on the meaning of the terms “**reasonable**”, as used in this Article 9. Member Associations shall also provide guidance on “**appropriate**”, “**renowned**” and “**extravagant**” venues, as used in Section 9.01 and Section 9.07. Companies must comply with any relevant guidance provided under this Section 9.08 in connection with any Applicable Code(s).

MEETINGS ORGANISED OR SPONSORED BY INDUSTRY

9. Pharmaceutical companies may arrange or sponsor meetings for doctors. Such events must have a clear educational content. The information rendered at any meeting should be based on scientific and medically relevant data.
10. Activities, which form part of systematic continuing professional development (CDP) should be reviewed and certified by relevant bodies.
11. In the announcement the purpose of the event should be clearly stated. Where appropriate, it will also be indicated whether the event is reviewed and certified.
12. The venue of the meeting should be appropriate for the scientific purpose of the meeting, and should not involve travelling beyond what is needed.

13. Industry may pay for lecturers, study material and facilities that are needed for the meeting. It can also pay for travelling and lodging for participants but not for any accompanying persons.
14. Hospitality during the meetings should be generally acceptable, reasonable and strictly limited to the purpose of the event. Sponsoring or organising of sporting or entertainment events is prohibited.
15. The principles of this declaration shall apply also for activities taking place outside EU, EFTA and EEA countries when EU, EFTA and EEA doctors are involved.

CONGRESSES AND OTHER MEETINGS, INCLUDING EXHIBITIONS AT CONGRESSES

Promotional, scientific or professional meetings include – but are not limited to – congresses, conferences, symposia, advisory meetings, training meetings, investigator meetings for clinical trials and non-interventional studies, etc.

Through such events, pharmaceutical companies contribute to continuous medical education of HCP and scientific information exchange between the attendees and between these and industry representatives.

Any practice that might create confusion about the real scientific and educational purpose of these events should not be tolerated.

We, leaders of the industry, have asked EFPIA to develop common standards for meetings organised / sponsored by industry and attended by HCP.

EFPIA Board
23 CEOs

**Monitoring of congress activities –
including the monitoring of exhibitions at
congresses (with particular attention to
venues and exhibitions)**

- **Site Visits at Congresses** – with special attention to exhibitions
- **Pre-assessment of events** – EFPIA's on-line platform

Objective

Considering that congresses are a vital forum where R&D-based pharmaceutical companies can present data and interact with scientific experts, it is critical that *exhibitions at congresses do not over-shadow the main purpose of scientific events.*

Site Visits

- Prior notice was given to the President of the Medical & Scientific Society organising the congress: “... *With these visits we hope to be better positioned to enhance code compliance through awareness building and education. ...*”
- Copy to corporate compliance officers of companies included in the list of exhibitors
- Visits coordinated with the member associations of the country where the congress took place.

European Society of Cardiology – ESC Congress 2010
Stockholm, 28.08-01.09.10

European Respiratory Society – ERS Annual Congress 2010
Barcelona, 18-22.09.10

European Association for the Study of Diabetes – EASD 46th Annual Meeting
Stockholm, 20-24.09.10

European Federation of Neurological Societies – EFNS 14th Annual Congress
Geneva, 25-28.09.10

European Society for Medical Oncology – ESMO Congress 2010
Milan, 8-12.10.10

United European Gastroenterology Federation – 18th UEGW
Barcelona, 23-27.10.10

The visits planned focused on the **exhibition areas**, more particularly on gifts and activities in the booths. The reports cannot be interpreted as a judgment regarding the event, and compliance with the provisions of any Applicable Code(s). EFPIA's preventive activities do not exclude actions taken by (national) code authorities to suspect breaches with the relevant codes.

EFPIA committed to prepare a short report following the visits, and to share the report with the congress organisers and the relevant EFPIA members. Reports will not be made public. As yet, reports have not been shared with congress organisers. Findings presented at this Workshop are shared in confidence for the sake of discussion.

EFPIA noted willingness of medical & scientific societies involved to discuss the observations made and recommendations EFPIA can give with regard to future meetings. Follow-up contacts are being planned in view of 2011 events.

CALL FOR ACTION

- EFPIA was asked to develop common standards for meetings organised / sponsored by industry and attended by HCP
- Any practice that might create confusion about the real scientific and educational purpose of these events should not be tolerated.

- EFPIA should pursue its **programme of “peer pressure”**:
 - Focusing on major congresses – 9 medical specialities areas would cover a large part of the HCP population
 Anaesthesiology (surgery), Cardiology, Diabetes (Endocrinology), Gastroenterology, Infectious diseases, Oncology, Neurology, Nephrology, and Respiratory / Pulmonary diseases
 - Collaboration with member associations of the countries where congresses take place enhances stepping up standards
 - Reaching out to scientific & medical societies has proven beneficial, and should be followed-up – several Societies welcome EFPIA’s input to their guidelines to industry’s participants in their congresses
 - EFPIA will continue to reach out to companies individually (and in confidence) to suggest changes in behaviour that may harm the reputation of industry as a whole

Objective:

Setting up an on-line platform to pre-assess events in regard of the EFPIA HCP Code

Deliverables:

- Criteria for the pre-assessment of events
- Setting up a process for the promotion of compliance with industry highest standards, the prevention of inappropriate behaviour
- Sponsoring corrective actions through leveraging corporate compliance officers role

Corporate members will be encouraged to request EFPIA assessments at early stage

Objective

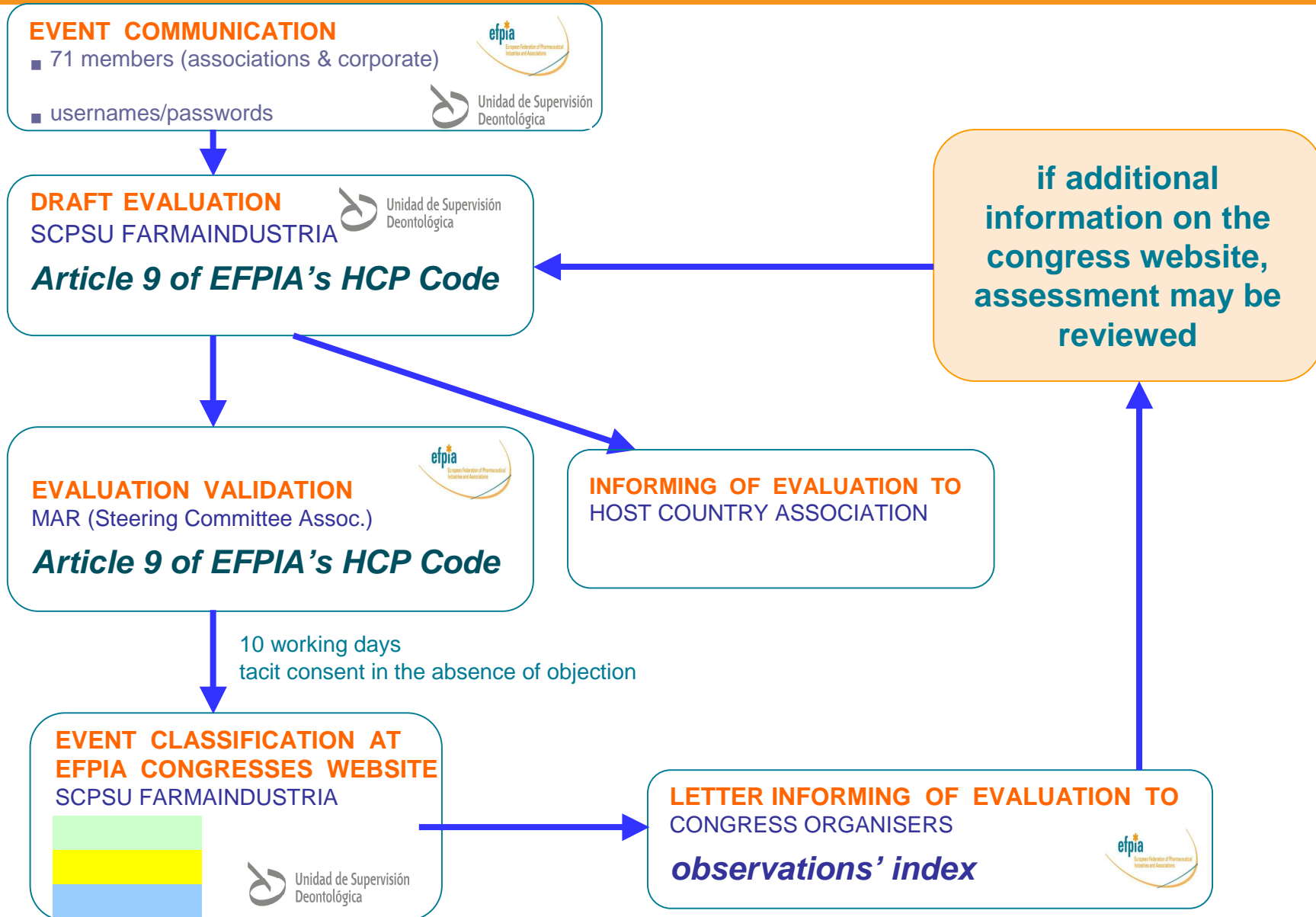
Pre-assessing events in regard to EFPIA's HCP Code

EFPIA's on-line platform – PROGRESS

Developed in collaboration with Codigo – building on Spain's 5-year experience

- **General structure** – EFPIA webpage and link to the database developed by Codigo for EFPIA
- **Criteria & process** – for discussion
- **“Appropriate venue”** – at the request of the Executive Committee, EFPIA was asked to provide additional guidance on what should be considered “appropriate venues

- EFPIA will focus on **major international events taking place in Europe or organised by European organisations outside Europe** – the EFPIA database will include events in which more than **2,500** participants of more than **5** countries take part. *Upon request of member companies, EFPIA may also assess other European events.* – estimation: 300-500 events per year
- Each event will be assessed in regard of **common standards** applicable, in particular in regard of provisions included in the **EFPIA HCP Code Article 9**. *The member association of the country where the event takes place will be given the opportunity to comment during the assessment process.*
- As soon as EFPIA will have completed its assessment, the **organisers of the event** and the **member association of the country** where the event takes place will receive an electronically generated message informing them of the conclusions of EFPIA's assessment.
- EFPIA corporate members will be encouraged to **consult the database before deciding** about sponsoring, participating or collaborating to an event. The comments included in the database are intended as a means to provide members with potentially relevant information for their own autonomous decision as to whether to support the event.



Under no circumstance can the observations included in the EFPIA database be interpreted as pertaining to the quality or content of the scientific programme, or to the quality of the speakers.

● **YELLOW:** based on information available from the event’s website, arrangements (may) raise concern with regard to provisions of the EFPIA HCP Code

● **GREEN:** based on information available from the event’s website, arrangements do not raise concern with regard to criteria assessed. However, EFPIA membership should check application of laws, regulations and codes that may apply in the country where the event takes place and/or rules of the jurisdiction where healthcare professionals carry out their profession.

● **BLUE:** EFPIA’s assessment process ongoing – conclusions will be posted within 15 days of inclusion of the event to the current list of events.

The comments included in the database are intended as a means to provide members with potentially relevant information for their own autonomous decision as to whether to support the event.

RELEVANT PROVISIONS – *assessment criteria*

- 1. Scientific purpose** – the programme should show that the event has a genuine scientific purpose; the programme posted on the web-site of the event will be used for reference
- 2. Venue** – the venue must be conducive to the main purpose of the event (scientific / professional), avoiding venues that are renowned for their entertainment facilities or shall not be extravagant
- 3. Hospitality to healthcare professionals** – hospitality extended in connection with events shall be limited to travel, accommodation, genuine registration fees and meals, but cannot be extended beyond the official duration of the event; hospitality offered shall be reasonable in level and strictly limited to the main purpose of the event – as a general rule, the hospitality provided must not exceed what HCP recipients would normally be prepared to pay for themselves

RELEVANT PROVISIONS – *assessment criteria*

4. **Hospitality extended to non HCP** – hospitality must not be extended beyond persons who qualify as participants in their own right
5. **Social programme** – hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure) events

All events will be assessed against these 5 criteria. Information available on the events' website will serve as a reference.

Communication of the EFPIA conclusions to the congress organisers will be generated automatically. Standard observations are listed in the **observations' index**, clarifying the criteria in the 5 areas, following the provisions of Article 9 of the EFPIA HCP Code.

CSG recommended that EFPIA revise the “observations index” following comments collected at the meeting.

Draft being finalised

CALL FOR ACTION

The EFPIA Executive Committee has asked that EFPIA reflect, and where appropriate provide additional guidance, on what should be considered “appropriate venues” for events organised / sponsored by pharmaceutical companies and attended by HCP.

- Additional guidance regarding “appropriate” venues issued by Member Associations
 - **Location renowned for entertainment** – venues mainly promoted as a sport resort, theme park, wine hotels, etc. should be excluded
 - **In the season when the event takes place, locations renowned as a destination for vacation** – sky resort in winter; beach in summer months; etc. – are not appropriate venues

- Reflecting on “congress destinations” within medical & scientific societies – AC Forum
 - **Are there principles we can share?**

Working with medical & scientific societies to raise awareness of high ethical standards applying to interactions between medical doctors and pharmaceutical companies

Objective

- To promote compliance with industry standards
- To raise awareness of the high ethical standards applying to interactions between medical doctors and pharmaceutical companies

Deliverables

- Reporting on visits of selected congresses in Europe – organisers and scientific societies advised of EFPIA's plan to visit
- Improving understanding of industry's rules applying to their relations with healthcare professionals
- Sharing findings with the Compliance Committee and prevent inappropriate behaviour, including reducing the *arms' race* at exhibitions
- Looking for pragmatic solutions to issues arising with congress organisers and scientific societies

BACK-UP SLIDES

DG ENTR initiative: Corporate Responsibility in the field of Pharmaceuticals

The process on corporate responsibility in the field of pharmaceuticals will be set up to initiate a momentum among the Member States, industry and other relevant stakeholders by considering in a balanced approach societal and industrial challenges. Given the experiences of the G10 process and of the HLPF, the Process on corporate responsibility in the field of pharmaceuticals should facilitate discussions on ethics and transparency of the sector but also on non-regulatory conditions for better access to medicines after their MA.

The Process will comprise 3 independent platforms:

- A. Transparency and ethics in the sector
- B. Access to medicines in Africa
- C. Access to medicines in Europe, in the context of pricing and reimbursement

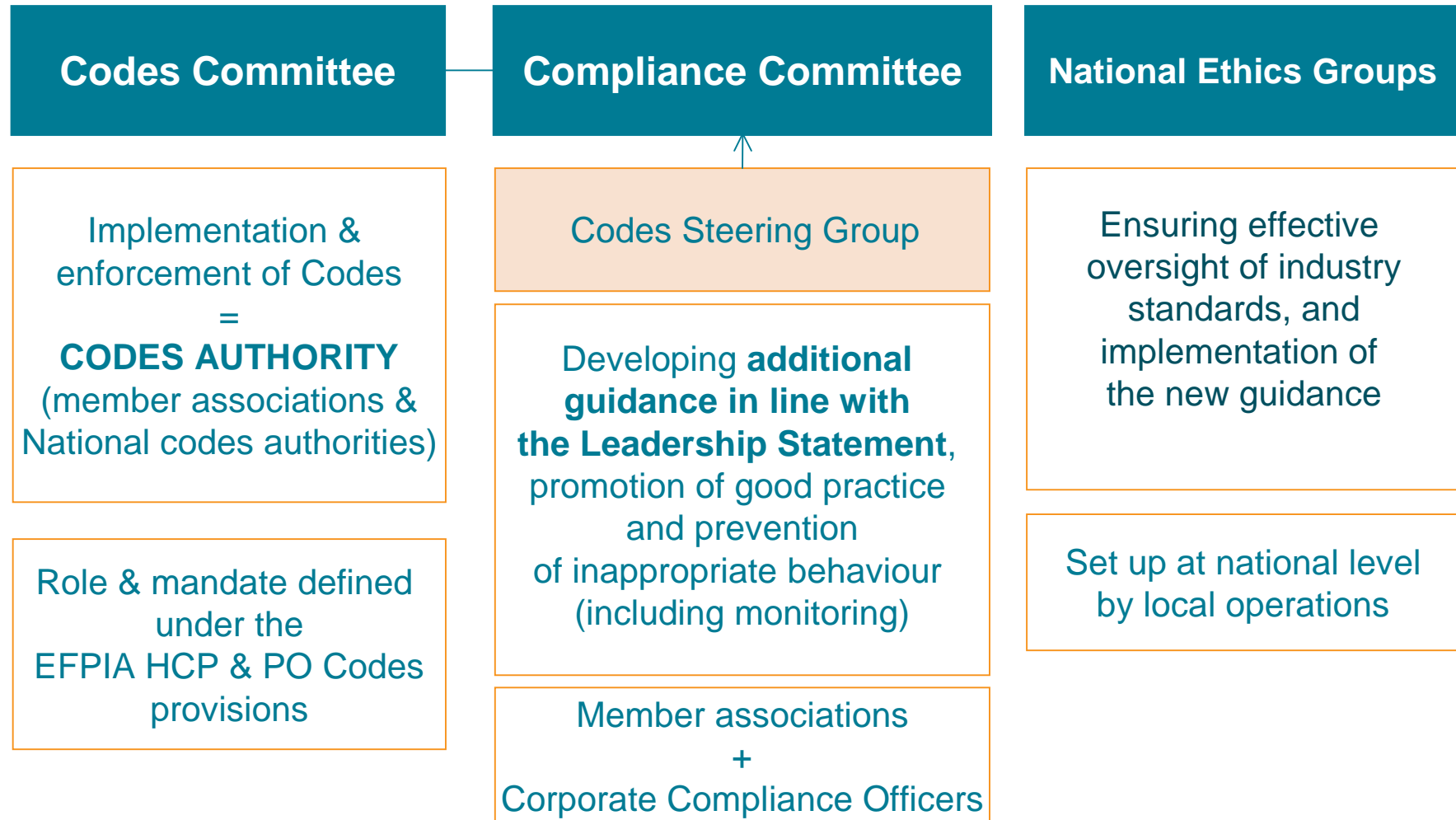
Ref. MEMO/10/442 – 24 September 2010

Objective

“The objective of the platform on ethics and transparency will be to exchange information and potentially achieve a common understanding in terms of best practices.”

Deliverables

- Outlining a scoping document for discussion with the Commission, clarifying what input EFPIA can provide to DG ENTR’s CSR Initiative
- Suggesting a frame for the 4-5 month feasibility phase – following the Commission’s plan to share the general outline of the initiative with the “Pricing & Reimbursement” Committee in April 2011
- Identifying key issues under the 3 work streams:
 - i. Relationships with physicians – *the Commission targets physicians, not HCP*
 - ii. Relationships with patients
 - iii. Relationships with government officials



CALL FOR ACTION

- Leaders of industry called for the establishment of National Ethic Groups in each of the EFPIA 31 member associations.
- These Groups should further ensure effective oversight of industry standards, as well as implementation of the new Guidance within one year of its issuance.

Member Associations asked for clarification of the role / mandate of the NEG, and their role versus national code authorities.