Medical Education Activities

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BioMed Alliance
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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.
EFPIA Mandate

“The aim of the European Federation of Pharmaceutical Industries & Associations 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, 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.
Outline of EFPIA’s Vision & Key Priorities

**Vision**
Shift the healthcare policy debate from a transactions focus to an outcomes focus

**Patient Access**
- Develop EU and national competitiveness policies for the pharma industry, focusing on patient access for new products

**Innovation**
- Modernise the research, development and regulatory model to restore Europe’s competitiveness and speed up access to medicines

**International**
- Secure improved market access conditions, high regulatory and IP standards in international growth markets

**Ethics & Compliance**
- Enhance ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector

EFPIA Charter
MEDICAL EDUCATION ACTIVITIES

Background

- **Collaboration between industry and health professionals benefits patients.** It is a relationship that has delivered numerous innovative medicines and treatments and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway.

- HCPs are relied upon as **partners** to the pharmaceutical industry. Yet, criticism of the industry by HCPs impacts on the **quality of the long-standing collaboration**, which (may) undermine(s) trust in the pharmaceutical industry beyond the HCP community.

- At the same time, the industry finds increasing failures in HCPs’ **recognition/acknowledgment of the role of R&D-based companies** in the scientific advances and the development of new treatments.

- **Creeping mistrust could ultimately lead to skepticism about the value of new and innovative therapies.** Regaining HCPs trust and esteem for the innovative industry’s contribution to improved health outcomes is essential to ensure that the industry-HCPs relationship operates to the best benefit of patients.

- HCPs have also expressed disappointment about the way EFPIA had one-sidedly imposed its self-regulatory principles on its partners, whilst **co-constructed self-regulation** would have been better accepted. Without EFPIA compromising on its belief in highest ethical standards, a collaborative approach may be more effective.
Medicines lifecycle

Dissemination of knowledge and collaborations between stakeholders are essential to scientific and medical progress that builds up throughout the medicines lifecycle.

Innovation cycle and continuous improvement of treatments

Investment to bring a successful new medicine to market

~ 10 Years

ROI

Competition for real return on investment

~ 10 Years

Marketing Authorisation defining label – SmPC, EPAR

Regular updates of Marketing Authorisation based on further development, taking into consideration Pharmacovigilance – PRAC

~ 10 Years

Patients on current ‘gold standard’ therapy attract next generation clinical trials

Health system savings from generic competition

Generic competition post loss of exclusivity

++ Years
Knowledge Exchange & Areas of Collaboration

- Clinical Trials
- Return of results
- Regulatory engagement
- Information
- Outcome measures
- Appropriate Use
- Setting the research agenda
- Pharmacovigilance
- Using healthcare data
- HTA engagement
- Guideline development
- Defining outcomes
PHARMA COMPANIES’ ROLE in MEDICAL EDUCATION ACTIVITIES
Medical Education activities are “educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession”.

The current heterogeneous universe of Medical Education with accredited (independent) CME in some countries, for-profit training organizations offering services, medical societies developing their own training network and industry-led initiatives have led to questions about the health sectors role in Medical Education activities and calls for clarification of EFPIA’s position.

Pharmaceutical companies have a legitimate role in Medical Education activities: knowledge dissemination and scientific exchange with HCPs enhance medical practice to the benefit of patients. As owners of scientific knowledge and experts in medicinal products, pharmaceutical companies can be a unique resource to the healthcare systems and providers, which will ultimately benefit the patients, as they will benefit from better informed clinical decisions and appropriate use of medicines.

Whatever the approach, industry is committed to the delivery of high quality Medical Education activities, and other parties to these activities have the same responsibilities.

EFPIA will work with iPACME to reach other stakeholders in order to share the principles of a high quality Medical Education.
Consensus Statement of the European Medical Organisations on CPD

Luxembourg, 18 December 2015

7. The pharmaceutical industry and suppliers of diagnostic and medical devices, must be attentive to the needs of patients and of the profession for objective information and education not tied to promotion of products. CPD events have to be clearly separated from commercial activities and must be designed and held in ways that the integrity of the medical profession cannot be questioned. National or international codes of ethics must always be respected.

EFPIA reads this as EMOs recognising that there is a role for pharma industry, provided basic principles and ethical standards are complied with.
The BioMed Alliance has adopted a “Code of Conduct” reinforcing the core principles that help to maintain professional independence, objectivity and scientific integrity. It also helps to ensure that the Alliance’s interactions and collaboration with the healthcare sector will be for the benefit of patients and for the improvement of scientific standards and medical care in its respective specialty fields.

The BioMed Alliance “Code of Conduct” include General Guidelines that should apply to among others CME/CPD activities.

EFPIA acknowledges the BioMed Alliance “Code of Conduct” reflecting the ethical values of HCP and Scientific Organisations.
European CME Forum is a not-for-profit organisation dedicated to bringing together all stakeholder groups with an interest in European Continuing Medical Education. It facilitates multi-channel discussion in an independent and neutral environment to promote the advance of high quality CME in Europe.

The Good CME Practice group (gCMEp) is a membership organisation for European continuing medical education (CME) providers. The Group is an initiative of the European CME Forum, which has a wider stakeholder base. gCMEp are available on www.goodcmepractice.eu

The degree of importance attached to robust and relevant CME in Europe continues to grow. Many countries are developing regulations, accreditation schemes or guidelines to encourage participation in continuing medical education and thus improve clinical practice and outcomes. Consequently there is a clear need for ensuring that accredited activities:

- are developed by independent, qualified, scientific educators
- meet identified participant needs
- are free from bias and
- are of high quality.
Links between providers of continuing medical education and scientific communications. Solid arrows indicate the preferred channels of communication; dotted arrows are those links where an added impartial expert commentary could be useful.
The convergence of interest model*  
Areas for appropriate (commercial) engagement in Medical Education

**Commercial Needs**
- Establishing novel & most appropriate treatments
- Dissemination of new or emerging concepts or data
- Providing value to the healthcare community

**Patient Needs**
- Prevalence & Incidence
- Mitigate risks
- QoL, health & wellbeing
- Treatment options
- Learning from each other & building communities
- Access to healthcare

**HCP Needs**
- Staying abreast and competent,
- Evolve in practicing medicine
- Avoiding errors
- Maintaining license or getting CME/CPD credits

**Healthcare System Needs**
- Maintaining the medical workforce
- Addressing existing medical needs & resolving gaps
- Prevention/disease avoidance
- Standardization & efficiency
- Risk mitigation

**Payor Needs**
- Cost effectiveness & cost containment
- Competitive differentiation
- Effectiveness of treatment

* Modified from Saxton, 2009 – by Thomas Kellner (UCB), 2016 (edited)
**EFPIA’s Work Programme** on building a step-by-step engagement with stakeholders involved in Medical Education

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<th>DESCRIPTION</th>
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| **Survey on Levels of Engagement** – documenting and assessing industry’s levels of engagement is a pre-requisite to EFPIA’s engagement in discussions on further involvement of pharma companies in Medical Education activities | Q3-2016  
*Survey results available by year-end* |
| **Policy Paper on “Convergence of Interest Models”** – building on EFPIA’s storyline “From Innovation to Outcomes”, translating general public policy principles into their relevance to medical education, and vice versa | Q4-2016 |
| **Outcomes-based management** – based on Survey outcomes, establishing quality assessment criteria and develop a grid for impact assessment based on concrete examples | Q1-2017 |
| **Pilots for collaborations** – developing concrete programmes that illustrate pharma industry’s contribution to Medical Education, and the criteria that any participant to each type of engagement should comply with | from Q4-2016 to Q1-2017 |
| **Collaborative opportunities** – responding to invitations to take part in reflections on the future framework of Medical Education, Life-long Learning and Professional Development | **In parallel**: in collaboration with learned societies and CME providers |
| **EMC Workshop** (1-day off-site) – in conclusion of the workshop, EMC will be asked to agree the quality standards and further collaborative programmes | Q2-2017 |

* This Work Programme was developed with support of the iPACME Industry Team.
The Medical Information departments of pharmaceutical manufacturers have robust scientific and clinical information regarding their products. They are staffed by health care professionals who are trained and skilled in the function of medical information.

Medical Information departments operate within the “safe harbor” of peer to peer scientific exchange utilizing published and internal information to respond to unsolicited inquiries from the medical and healthcare community. Medical Information departments have the most current, accurate, and scientifically balanced information about their respective products. Yet, HCPs access to information available from companies’ websites is not as straightforward as it should be.

HCPs may or may not know a product’s manufacturer and therefore how to contact them – and, where they exist, each manufacturer’s website works differently. There is evidence that HCPs frequently use websites, such as Google, Wikipedia and the eMC, that provide easy access to information about many products. It is important that HCPs make decisions based on the most accurate and up-to-date information about a product. The Manufacturers have this information.

EFPIA has decided to coordinate the creation of a GATEWAY to pharma companies medical information to provide HCPs with an efficient access to the most accurate and balanced, current product medical information.
Sharing Knowledge and Communicate

1. Analyse state of the art
2. Gain political commitment
3. Stakeholder involvement
4. Prioritize and involve: Intake Workshop
5. The Transformation Agenda
6. Area Development
7. Monitor & improve

Source: taken from the web through Google (free source)
Background

• Members include employees of global and regional pharmaceutical companies with responsibility for medical education grants and programming; iPACME gathers 27 professionals of 17 companies worldwide
• Provides a forum for members interested in advancing innovation in CME/CPD, define quality standard internationally and define and leverage the value proposition of industry involvement
• Allows for exchange and sharing of best practices (appropriately allowed within the law) between industry representatives actively engaged in the CME/CPD

Vision
Pharmaceutical industry wants to be recognized as a valued and trusted partner for the provision of high quality education that complements existing activities and meets the educational needs of HCPs in improving patient care

Key Initiatives
• Provide an online forum to discuss key issues (including through networking)
• Develop a Global Lexicon for Medical Education
• In 2014, the European iPACME members formed a subcommittee to develop a guidance document to set standards and processes for the industry in Europe. It outlines ways for improving the quality of medical education, it describes ethical behavior as well as explores how industry in Europe could be a meaningful partner in the medical education space.