European Federation of Pharmaceutical Industries and Associations

Medical Education Activities

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BioMed Alliance

Brussels, 9 November 2016

MCP 07-11--2016

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.

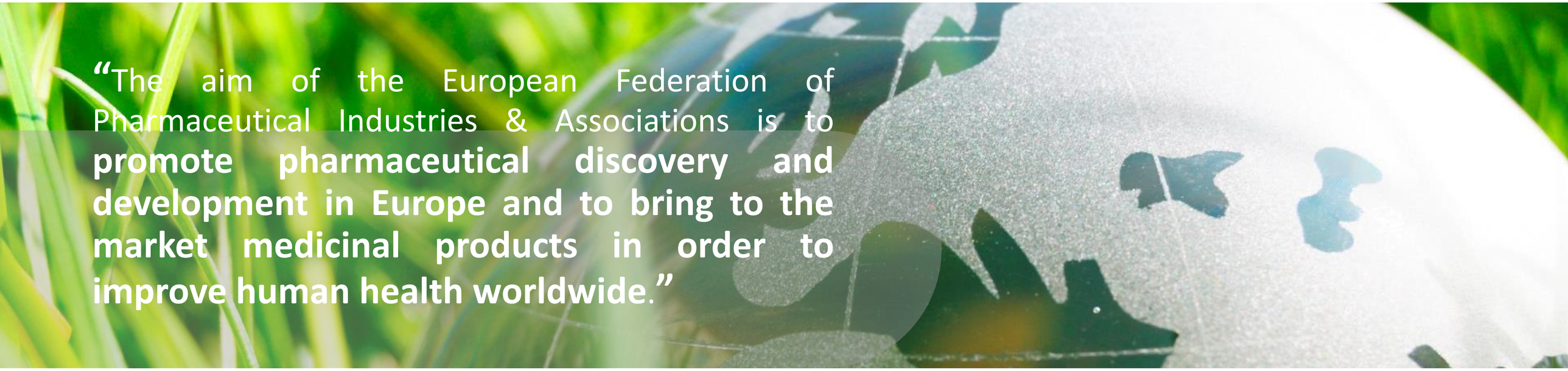
  In 2015, she was asked to take the role of **Ambassador to the Medical Communities**, coordinating EFPIA's relationships with medical & scientific societies, including learned societies, also through professional communities within the pharmaceutical companies that interact with medical communities.

- 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.

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.

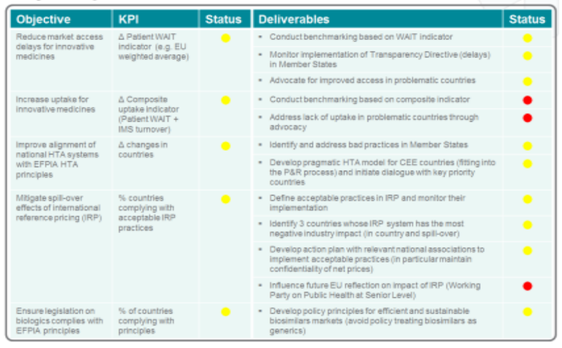
“Partners in Research” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 15+ members.

Outline of EFPIA's Vision & Key Priorities

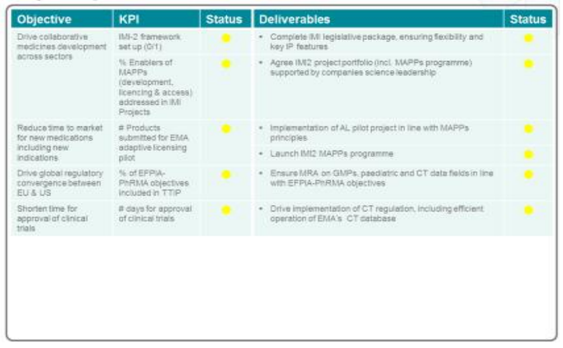
Vision

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

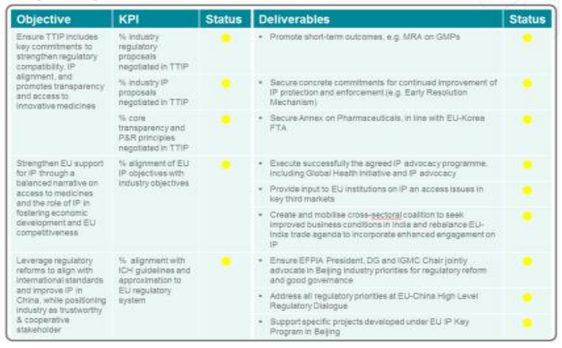
Patient Access	Innovation	International	Ethics & Compliance



Objective	KPI	Status	Deliverables	Status
Reduce market access delays for innovative medicines	Δ Patient WAIT indicator (e.g. EU weighted average)		• Conduct benchmarking based on WAIT indicator	
			• Monitor implementation of Transparency Directive (delays) in Member States	
			• Advocate for improved access in problematic countries	
Increase uptake for innovative medicines	Δ Composite uptake indicator (Patient WAIT + IMS turnover)		• Conduct benchmarking based on composite indicator	
			• Address lack of uptake in problematic countries through advocacy	
Improve alignment of national HTA systems with EFPIA HTA principles	Δ changes in countries		• Identify and address bad practices in Member States	
			• Develop pragmatic HTA model for CEE countries (fitting into the P&R process) and initiate dialogue with key priority countries	
Mitigate spill-over effects of international reference pricing (IRP)	% countries complying with acceptable IRP practices		• Define acceptable practices in IRP and monitor their implementation	
			• Identify 3 countries whose IRP system has the most negative industry impact (in country and spill-over)	
			• Develop action plan with relevant national associations to implement acceptable practices (in particular maintain confidentiality of net prices)	
			• Influence future EU reflection on impact of IRP (Working Party on Public Health at Senior Level)	
Ensure legislation on biologics complies with EFPIA principles	% of countries complying with principles		• Develop policy principles for efficient and sustainable biosimilars markets (avoid policy treating biosimilars as generics)	



Objective	KPI	Status	Deliverables	Status
Drive collaborative medicines development across sectors	IMI-2 framework set up (Y/)		• Complete IMI legislative package, ensuring flexibility and key IP features	
	% Enablers of MAPPs (development, licencing & access) addressed in IMI Projects		• Agree IM2 project portfolio (incl. MAPPs programme) supported by companies science leadership	
Reduce time to market for new medications including new indications	# Products submitted for EMA adaptive licensing pilot		• Implementation of AL pilot project in line with MAPPs principles	
			• Launch IMI2 MAPPs programme	
Drive global regulatory convergence between EU & US	% of EFPIA-PhRMA objectives included in TTIP		• Ensure MRA on GMPs, paediatric and CT data fields in line with EFPIA-PhRMA objectives	
Shorten time for approval of clinical trials	# days for approval of clinical trials		• Drive implementation of CT regulation, including efficient operation of EMA's CT database	



Objective	KPI	Status	Deliverables	Status
Ensure TTIP includes key commitments to strengthen regulatory compatibility, IP alignment, and promotes transparency and access to innovative medicines	% industry regulatory proposals negotiated in TTIP		• Promote short-term outcomes, e.g. MRA on GMPs	
	% industry IP proposals negotiated in TTIP		• Secure concrete commitments for continued improvement of IP protection and enforcement (e.g. Early Resolution Mechanism)	
	% core transparency and P&R principles negotiated in TTIP		• Secure Annex on Pharmaceuticals, in line with EU-Korea FTA	
Strengthen EU support for IP through a balanced narrative on access to medicines and the role of IP in fostering economic development and EU competitiveness	% alignment of EU IP objectives with industry objectives		• Execute successfully the agreed IP advocacy programme, including Global Health Initiative and IP advocacy	
			• Provide input to EU institutions on IP an access issues in key third markets	
			• Create and mobilise cross-sectoral coalition to seek improved business conditions in India and rebalance EU-India trade agenda to incorporate enhanced engagement on IP	
Leverage regulatory reforms to align with international standards and improve IP in China, while positioning industry as trustworthy & cooperative stakeholder	% alignment with ICH guidelines and approximation to EU regulatory system		• Ensure EFPIA President, DG and IGMC Chair jointly advocate in Beijing industry priorities for regulatory reform and good governance	
			• Address all regulatory priorities at EU-China High Level Regulatory Dialogue	
			• Support specific projects developed under EU IP Key Program in Beijing	

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

Modernise the research, development and regulatory model to restore Europe's competitiveness and speed up access to medicines

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

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.

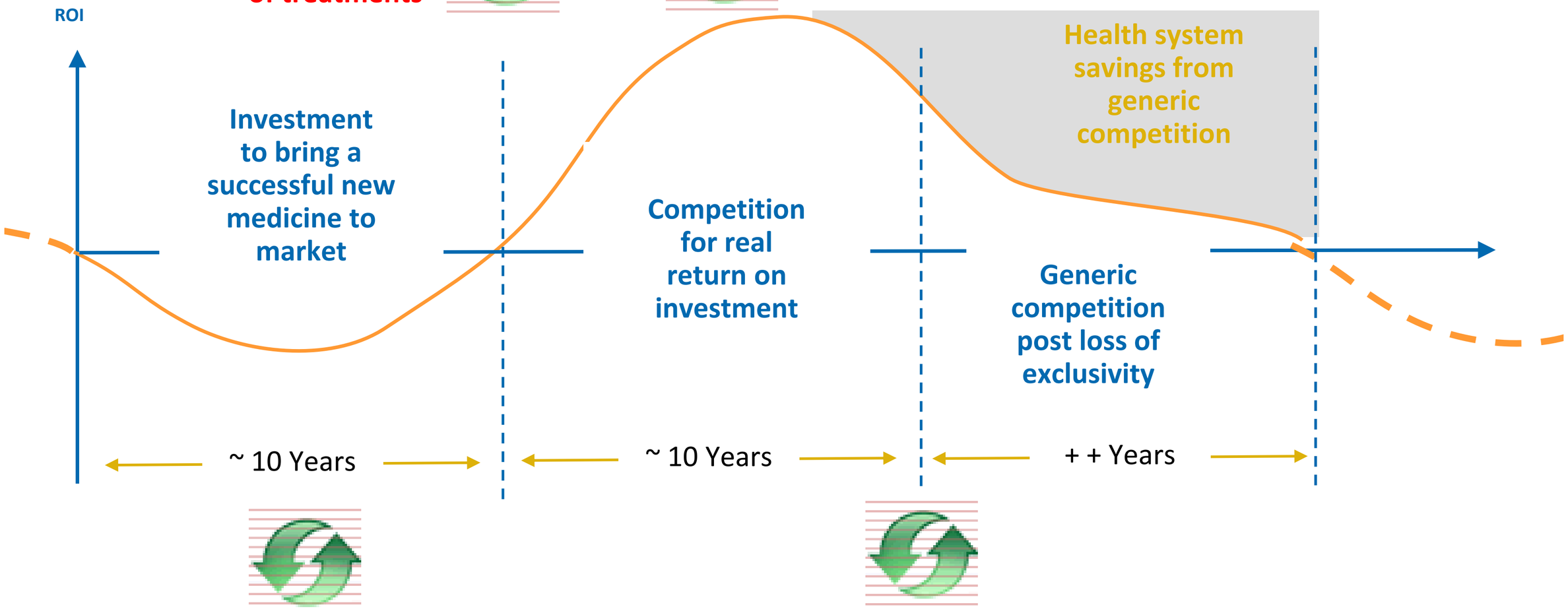
- HCPs have also expressed disappointment about the way EFPIA had one-sidedly imposed its self-regulatory principles on its partners, whilst **co-constructed self-regulation** would have been better accepted. Without EFPIA compromising on its belief in highest ethical standards, a collaborative approach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

Patients on current 'gold standard' therapy attract next generation clinical trials



Marketing Authorisation defining label – SmPC, EPAR

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

efpia

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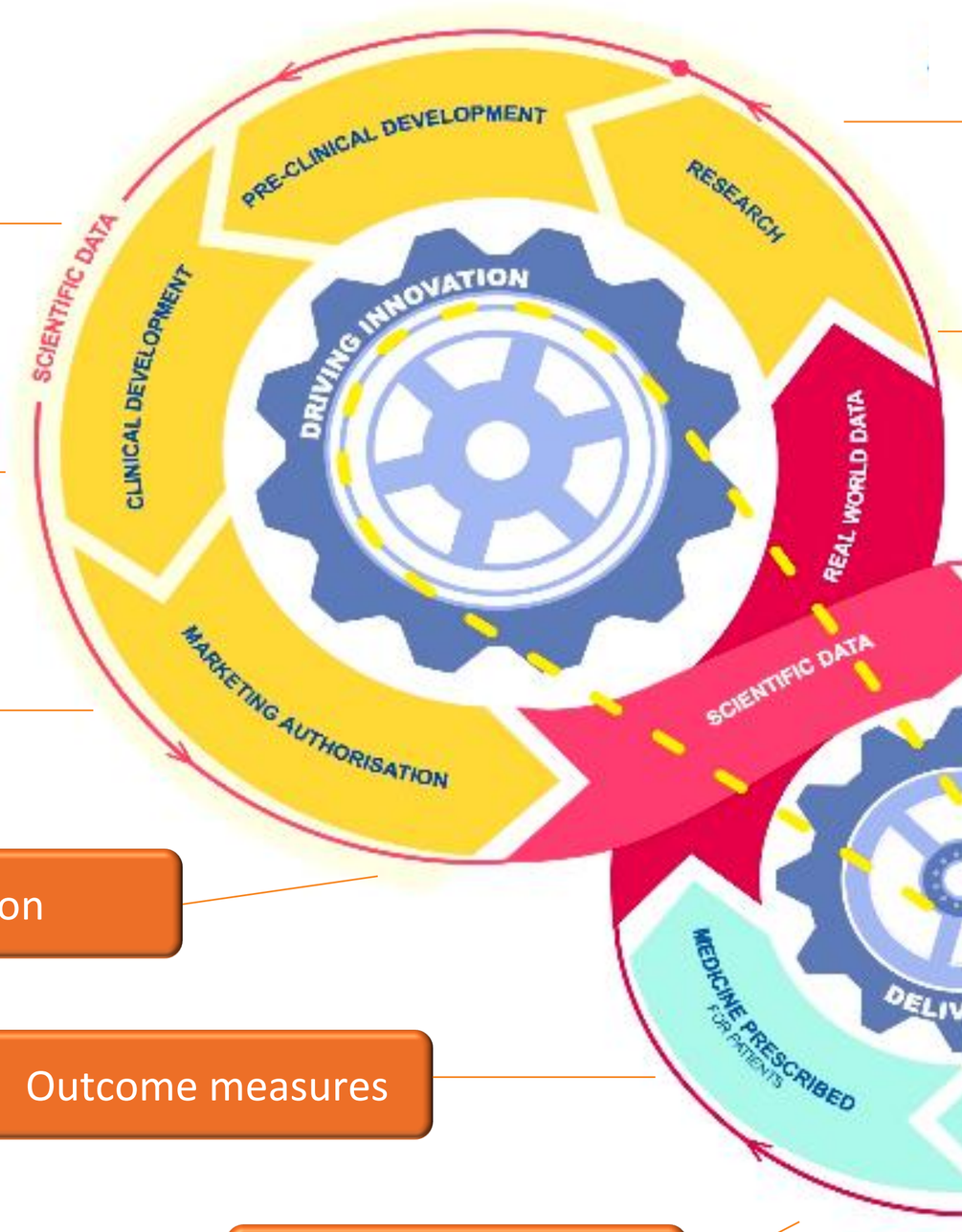
Knowledge Exchange & Areas of Collaboration



Setting the research agenda

Clinical Trials

Pharmacovigilance

Return of results

Using healthcare data

Regulatory engagement

HTA engagement

Information

Guideline development

Outcome measures

Appropriate Use

Defining outcomes

PHARMA COMPANIES' ROLE in MEDICAL EDUCATION ACTIVITIES

EFPIA'S VISION

Executive Committee – Luxembourg, 4th June 2015

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.

Learned Societies positioning

Biomed Alliance “Code of Conduct”

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.

Positioning of (professional) CME providers

Europe CME Forum

Manchester, 11-13 November 2015

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

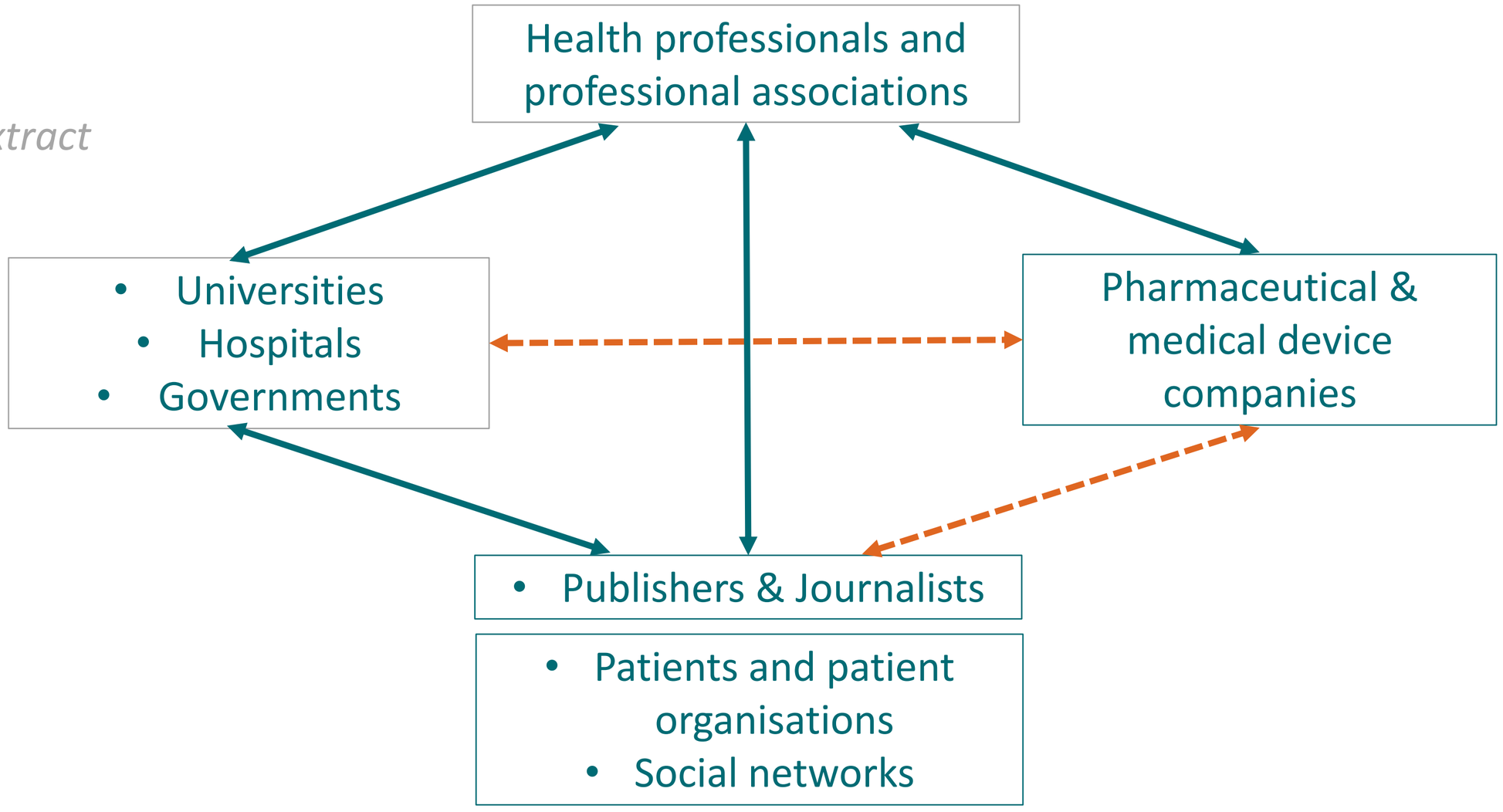
The degree of importance attached to robust and relevant CME in Europe continues to grow. Many countries are developing regulations, accreditation schemes or guidelines to encourage participation in continuing medical education and thus improve clinical practice and outcomes. Consequently there is a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

ESC Policy Statement on Industry & CME

in European Heart Journal (2012) **33**, 666-674

Extract



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.

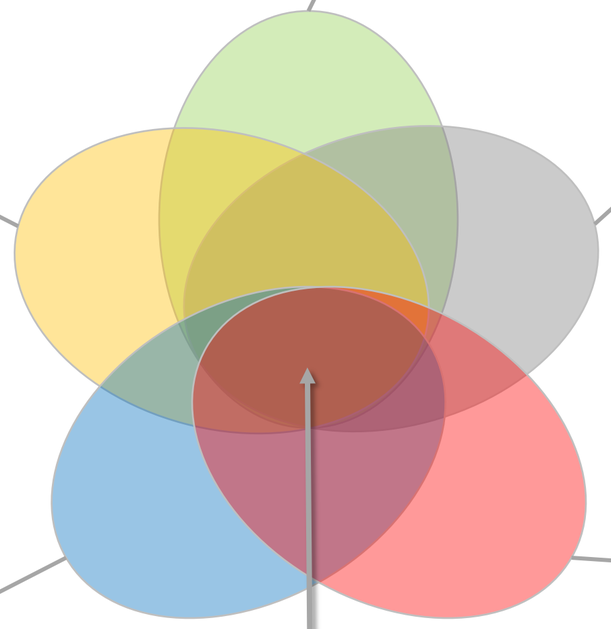
The convergence of interest model*

Areas for appropriate (commercial) engagement in Medical Education

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

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

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



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

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

Areas for engagement

* 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

DESCRIPTION	TIMELINES *(tbc)*
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.

MEDICAL INFORMATION

eMIG Project: Purpose

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

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

European Federation of Pharmaceutical Industries and Associations

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iPACME

International Pharmaceutical Alliance for Continuing Medical Education

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.