European Federation of Pharmaceutical Industries and Associations

CURRENT INITIATIVES OF EFPIA
Code Compliance, Ethical Principles, Business Integrity

Author: **Marie-Claire PICKAERT –** EFPIA Deputy Director General



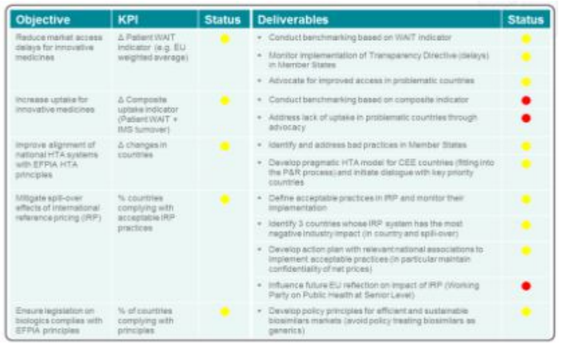


11th International Pharmaceutical & Medical Device Compliance Congress
CLOSING SESSION
Lisbon, 17 May 2017

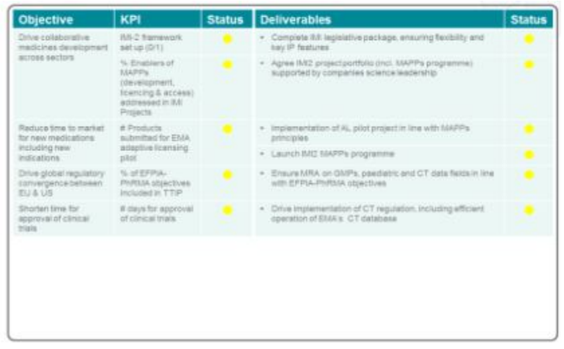
Outline of EFPIA's Vision & Key Priorities

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

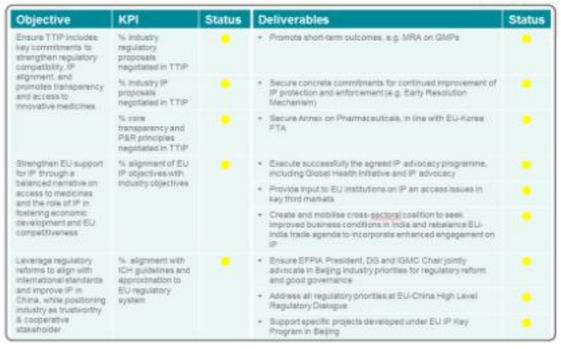
Patient Access	Innovation	International	Ethics & Compliance



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 (Q1)		• Complete IMI legislative package, ensuring flexibility and key IP features	
	% Enablers of MAPPs (development, licencing & access) addressed in IMI Projects		• Agree IMI2 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

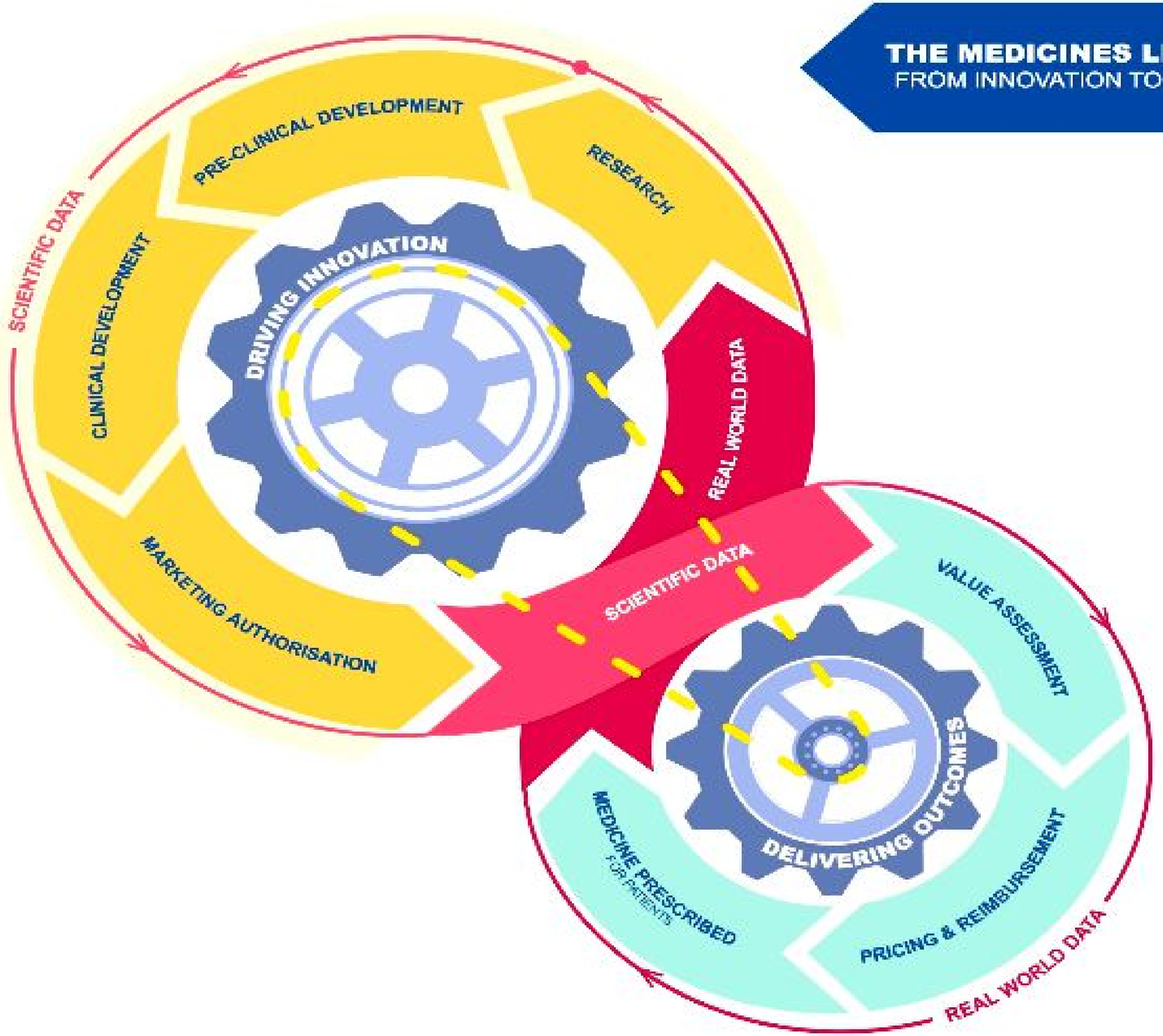
Secure improved market access conditions, high regulatory and IP standards in international growth markets

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

EFPIA Charter

THE MEDICINES LIFE-CYCLE
FROM INNOVATION TO OUTCOMES

CREATION



USAGE

Conceptualising Convergence of Interests

01
- Prevent disease and maintain wellbeing
- Provide access to optimal and affordable care
- Provide access to disease and health information

02
- Increase/maintain QoL, health & wellbeing
- Provide access to optimal and affordable care
- Mitigate risk

03
- Maintain a competent medical workforce
- Address existing medical needs and resolve gaps
- Prevent/avoid disease
- Standardize and improve efficiency
- Mitigate risk

04
- Ensure cost effectiveness and cost containment
- Drive competitive differentiation
- Improve effectiveness of treatment

05
- Stay abreast and competent
- Achieve excellence in practicing medicine
- Avoid errors
- Maintain license or get CME/CPD credits

06
- Ensure safe and appropriate use of products
- Foster awareness, contextualization, and adoption of new scientific data and concepts
- Effectively manage disease and resources in healthcare

EFPIA's ETHICS & COMPLIANCE STRUCTURE

Codes Committee CodCom	**Ethics & Compliance Committee** E&CC	**National Ethics Groups**
Strategy Group Chairs & Vice-Chairs of CodCom and E&CC		
Transposition, implementation & enforcement of the EFPIA Codes Role & mandate defined under the EFPIA Codes (including: HCP, PO & HCP/HCO Disclosure Codes)	Contribute to enhanced ethical behaviour within a self-regulation (industry) framework Increase reputation and credibility of the pharmaceutical sector for the benefit of patients Anticipating implications of the evolving landscape	Ensuring effective oversight of industry standards, and implementation of the new guidance Promoting ethical standards in partnership with national Stakeholders Enforcing Codes following consistent interpretation and establishing a culture of self-regulation
CODES AUTHORITY (Member Associations & National Code Authorities)	• Corporate Compliance Officers • Corporate members representatives (responsible for Ethics & Compliance) • Member Association representatives	Set up at national level by local operations Member Associations Ethics Working Groups

EFPIA Codes Committee (CodCom) Work Programme

Goal: Completing the Codes Committee mandate following the EFPIA Codes, ensuring consistent and coherent transposition and implementation of the EFPIA Codes *in full*

Transposition of the EFPIA Codes	Implementation and Enforcement	Best Practice *2010 Leadership Statement*	Complaints lodged with EFPIA
CODE CONSISTENCY	MEMBERSIHP COMMITMENT TO THE NATIONAL CODES	SITE VISITS AT CONGRESSES	PROCEDURE / SOP
DEVIATIONS	ANNUAL CODES REPORT	e4ethics PLATFORM	CASE HANDLING
SUPPORT TO MEMBER ASSOCIATIONS	CONVERGENCE OF CODES	DISCLOSURE CODE (#3)	MEMBER ASSOCIATIONS SUPPORT

EFPIA Ethics & Compliance Committee (E&CC) Work Programme

Goal : Contribute to enhanced ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector for the benefit of patients.

Key Ethical Principles	Patients Interactions	Stakeholders Interactions	New Areas of Interaction
EFPIA CHARTER	CLARIFYING TERMS OF INTERACTIONS	STAKEHOLDERS MAPPING	SOCIAL MEDIA
DISSEMINATION	COLLABORATION WITH THE PATIENT THINK TANK	AWARENESS RAISING	e-/m-HEALTH
PROMOTING ETHICAL CULTURE WITHIN ORGANISATION		JOINT EFPIA-CPME DECLARATION	REAL-WORLD DATA
		ETHICS WATCHERS / NGOs	MEDICAL APPs

UPDATE: 01-02-2017

Room for Convergence in Self-regulation

A mid-term ambition (2020-programme)

3. "Life Science Circle"
Aligning standards in areas covered in respective codes

- EFPIA Codes – *R&D-based industry (POM)*
- Medicines for Europe Code – *Generics & bio-similars industry (POM)*
- CPME Guidelines on the Transparency of Relationships between Physicians and the Healthcare Industry – *Doctors*
- BioMed Alliance Code of Conduct – *Learned societies*
- EFPIA-CPME Joint Declaration – *R&D-based industry and Doctors*
- MedTech Code – *Medical devices and Diagnostics*

1. "Inner Circle"
Towards one common pharma code

2. "Medical Circle"
Mirroring standards in Codes of Conducts of Medical Communities

European Federation of Pharmaceutical Industries and Associations

* marieclaire.pickaert@efpia.eu
* julie.bonhomme@efpia.eu
* versina.bregu@efpia.eu





EFPIA Brussels Office
Rue du Trône 108
B-1050 Brussels * Belgium
Tel: + 32 (0)2 626 25 55
www.efpia.eu * info@efpia.eu