European Federation of Pharmaceutical Industries and Associations

CURRENT INITIATIVES OF THE INDUSTRY ASSOCIATIONS

EFPIA Keynote






11th International Pharmaceutical & Medical Device Compliance Congress

Lisbon, 17 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

Ethics

Conflicts of interest

Gifts and entertainment

Financial controls

Tendering and contracting

Safe, Health, Environment & Quality

Information disclosure

Safeguarding information and assets

Employee relations

Legal compliance

Political activities

International operations

Drugs and alcohol

Harassment and intimidation in the workplace

EVOLVING EXPECTATIONS OF INDUSTRY

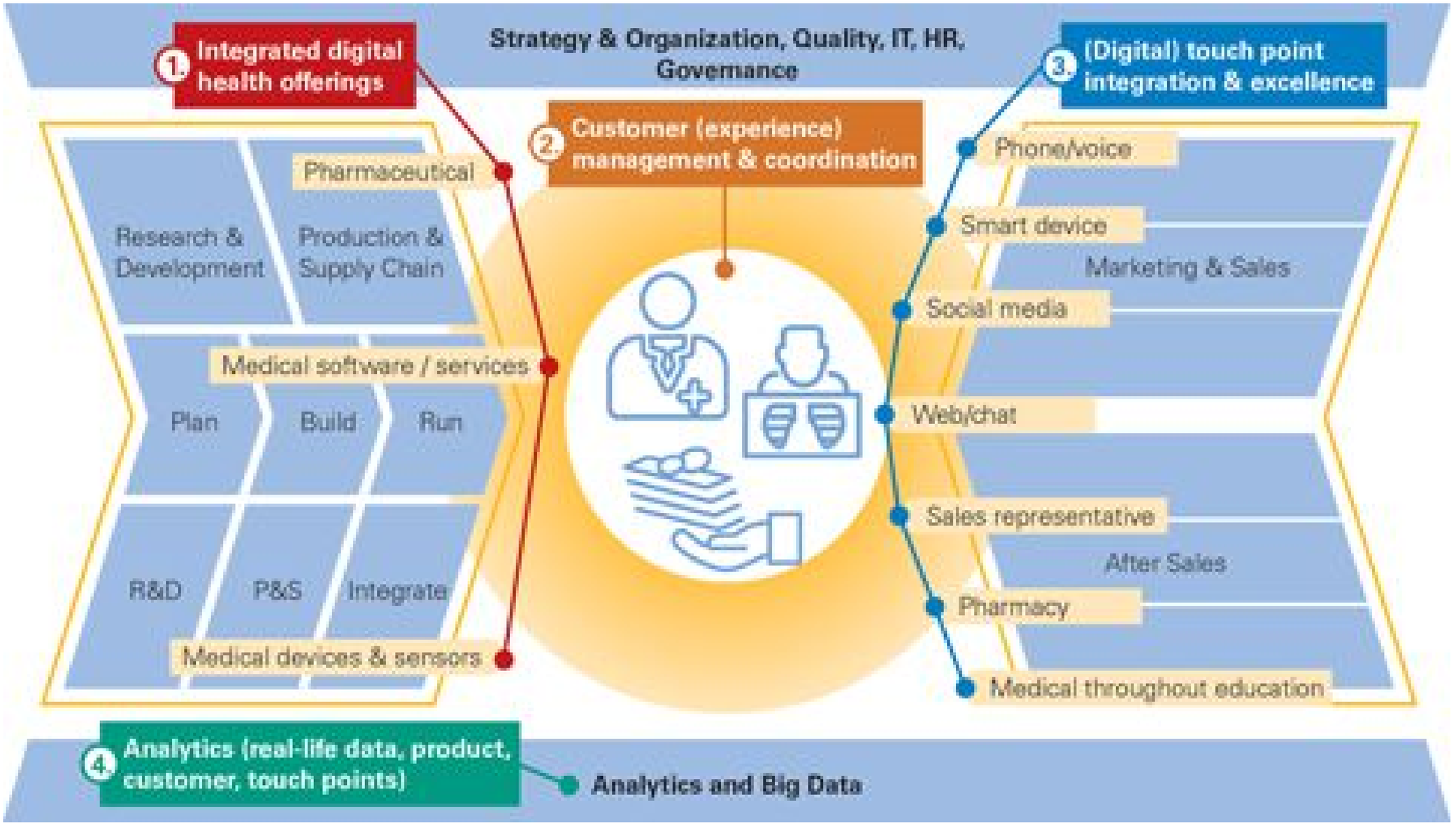
Times of transformation in the operating environment

- Ageing society requiring rethink of organisation of multi-generational solidarity
- Prescribers model focus on rapid increase to specialty care
- Evolving role of payers in a financial zero-growth scenario
- Digital transformation and “big data” opportunities (and challenges)
- Gaining credibility in the emerging debates

Classical Organisation of Pharma in Healthcare

Source: Arthur D. Little, in SCRIP Intelligence, 24 February 2016

Key Factors determining FUTURE Success in Healthcare



Source: Arthur D. Little, in SCRIP Intelligence, 24 February 2016

Where is the business model / innovative treatment portfolio taking us?

- Current **norms and standards** considered to adequately cover the current **business model**
- Need to step up the **educational enforcement**
- Push towards improved **transparency,** not only from Member Companies, but from **all interested parties** (including HCPs) – NGOs focused on life science industry, should also direct attention to other stakeholders
- **Mounting diversification** through **combination treatments and data packages**, where different (un)regulated universes will be coming together
- **Blurring lines** between health technologies, where **“commercial” activities** (heavily regulated) and **“scientific” development** (where peer-to-peer prevails), will attract additional attention (convergence)
- **Evolving (higher) societal expectations** of pharma/life-science sectors – similar attention to all stakeholder communities

The relationships will continue to evolve

- In recent years, companies have increased their focus on providing opportunities for **peer-to-peer interactions** with company's research and medical departments. This reflects the rapidly advancing science, driving a wave of new innovative medicines and the HCPs need to keep up-to-date with the latest information.

- The **enhanced role of patients / patient organisation** in disease management and their involvement in the development of health policies offer additional opportunities for improved patient care as patients are becoming more health literate. Patient organisations propose innovative ways of rethinking healthcare systems while safeguarding a high-level of patient safety and equitable access to high-quality healthcare.

- Yet, requirements for all aspects of the interactions between industry and health professionals / patient organisations are clearly defined, and serve to protect clinical independence and patient-centred decision-making. These **requirements continue to evolve over time as the nature of healthcare, medical science and societal expectations change.**

Anticipating new models of collaboration

- **Self-regulation is a fast-moving area** – anticipating upcoming political debates:
  - ✓ IP and Access
  - ✓ Pricing and Access

- **Be prepared – multi-stakeholder platforms reflecting on:**
  - ✓ What needs regulated
  - ✓ What can be self-regulated

- **Gaining credibility in the emerging debates:**
  - ✓ Increased transparency changes roles of stakeholders (ex. Regulators are losing their importance as “gatekeepers”)
  - ✓ “Alternative facts” are gaining importance
  - ✓ Perception becomes reality

- **Retaining pharma sector’s legitimacy in activities across all areas:**
  - ✓ R&D and scientific development
  - ✓ Knowledge dissemination and scientific collaboration
  - ✓ Commercial and promotional activities

Where do we want to stand (in a 5-10-year perspective)

- **ANTICIPATE: prepare for future challenges**
- **SELF-REGULATION: use our ability to set standards and rules**
- **(EU) REGULATION: being ahead of the curve of legislative initiatives**


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

KEY ETHICAL PRINCIPLES

EFPIA's Charter aims a.o. at enhancing ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector

First and foremost, the **PATIENTS ARE AT THE HEART OF WHAT WE DO**. We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to make high quality medicinal products and to encourage their appropriate and rational use in the care pathway.

We act with **INTEGRITY**, interact in a responsible manner and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We interact with all our stakeholders with **RESPECT**. We commit to approach our stakeholders in an open manner, with a responsive, constructive and learning attitude and mutual respect. We value the importance of independent decision making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly.

We are committed to ensure that **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

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

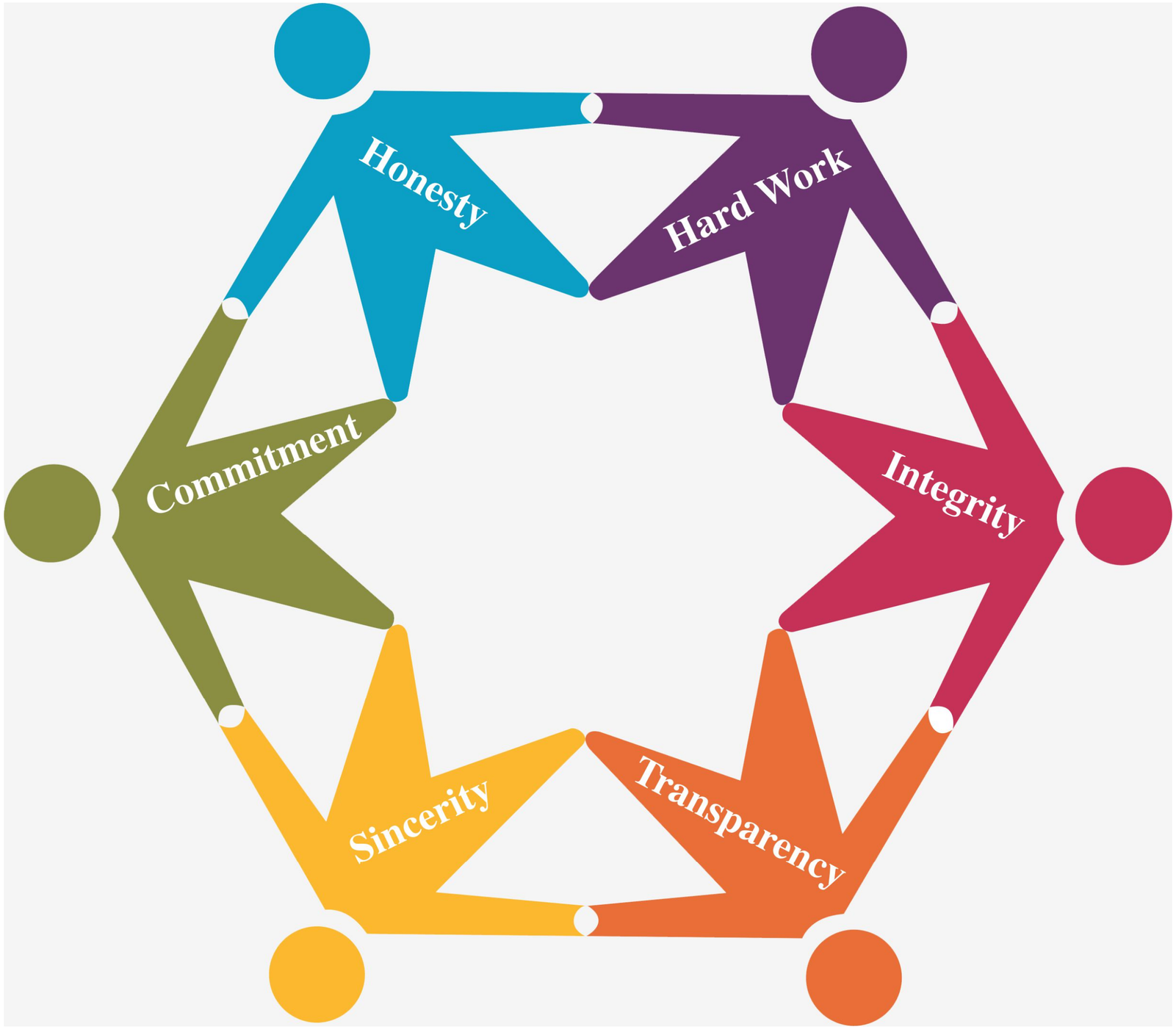
In line with national laws & regulations

Leadership's Statement on WHAT GOOD LOOKS LIKE

Any practice that might create confusion about the real (scientific and educational) purpose of interactions between healthcare professionals and pharmaceutical companies shall not be tolerated.

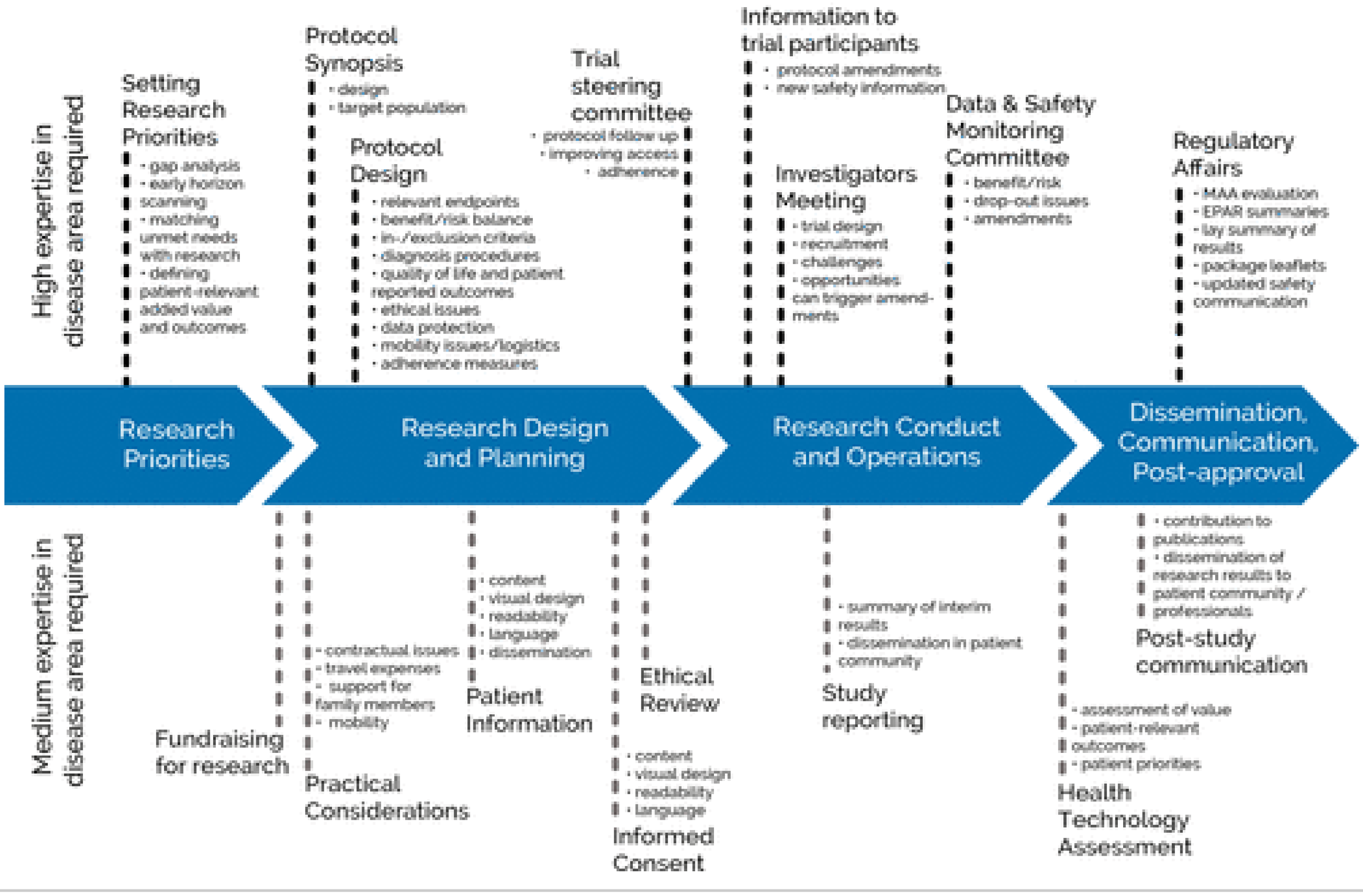
Corporations have a responsibility towards the communities in countries where they operate, and recognise that society has particularly high expectations of our industry.


CODES
RULES
STANDARDS
GUIDELINES
COMPLIANCE


Honesty
Hard Work
Commitment
Integrity
Sincerity
Transparency

Collaborating with Patients & Patients Organisation

Patient involvement in medicines R&D



PATIENT ORGANISATIONS ASSESSING THE PHARMA INDUSTRY AND ITS COMPANIES

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

Making high-quality useful products

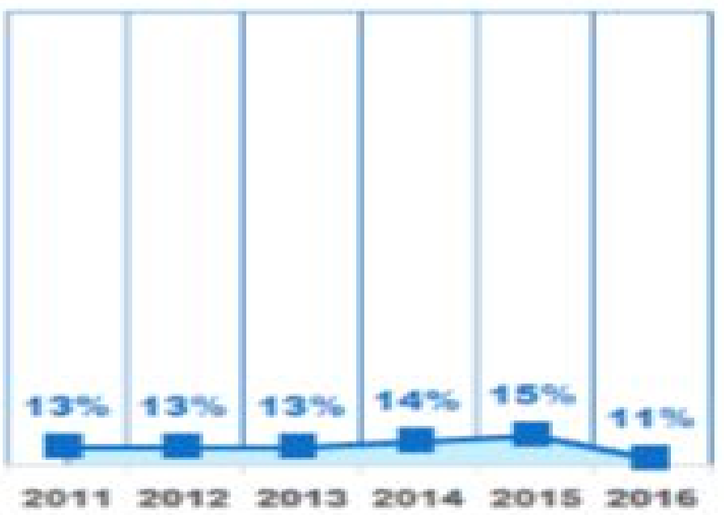
Access to clinical trials

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*

Collaborating with Healthcare Professionals & Organisations

Re-engaging with Medical Communities

- 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, recent disruption with high-profile 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 their 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.

"We should **reward companies that admit to having broken the law**, especially when they come up with remedies to make the markets more competitive, or companies that provide evidence voluntarily," said EU Commissioner Vestager.
In Compliance Alerts, 3rd February 2016

For companies, the 'return on investment' is clear…**the benefits of an effective compliance program far outweigh the costs of the program** and help mitigate government enforcement and compliance-related risks.
In Corporate Compliance Insight, 15th January 2016

"A recent OECD review of successful corruption prosecutions cites **involvement by senior management or Chief Executive Officers in more than 50 percent of global anti-corruption cases** to date — revealing deliberately unethical decision making by executives who decisively outrank Chief Compliance Officers."
In Compliance Wave, 8th January 2016

Research integrity—have we made progress?
Compared with 20 years ago there is undoubtedly more discussion and awareness of research misconduct, but there is still a long way to go to strengthen research integrity and publication ethics.
In The Lancet, 8th May 2017

US: FCPA Enforcement Refocuses on Life Sciences Industry

… the globalization of healthcare is increasing the enforcement risks for companies outside of the pharmaceutical and medical device manufacturing space, including clinical research organizations, hospitals and providers.

EU: Watch out, Pharma: The committee also touched on the impact of unlawful practices of the medicines industry on citizens' well-being, before the public hearing about what the EU has done well on health. The European Commission is preparing a report on recent competition cases in the pharmaceutical sector,

China: **Anti-corruption Efforts** Working, No Letup in 2017


STORM
AHEAD

Il Gazettino, 7 May 2017

Italian anti-corruption police make 19 arrests in wide-scale investigation involving doctors and pharma industry

The anti-corruption police from Parma have carried out actions against a suspected large-scale corruption ring involving doctors and employees of pharmaceutical and medical devices producers…

The actions took place on 7 May and resulted in the arrest of 19 doctors and individuals involved in the marketing of medicines and medical devices in seven Italian regions, with another 75 people reported to be under investigation.

The accused face charges of bribery, money laundering, activities involved with clinical trials, and the dissemination of scientific information to promote the commercial activities of domestic and foreign companies, the source has added. The alleged corruption ring was focused on pain therapies and palliative treatments.

PLAYING BY THE RULES

TRY is great

CONVERTING is better

European Federation of Pharmaceutical Industries and Associations

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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)*

1. "Inner Circle"
Towards one common pharma code

- 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*

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

- MedTech Code – *Medical devices and Diagnostics*

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