European Federation of Pharmaceutical Industries and Associations

EFPIA presentation for EFSPI meeting

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6 July 2022

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe.

EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. **Our vision** is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

About EFPIA


49
staff members
39
member companies
36
member associations
14
SMEs
35
partners in research
Vaccines Europe
An industry for healthy lives

Organogram

EFPIA Board

Innovation BSC

RSC

CREG (Clinical Research Expert Group)

EU CTR

Data Sharing & Transparency

Innovative Clinical Trials

ICH & global convergence

Patient engagement subgroup

Digital Health Technologies subgroup

EFPIA 2022 priorities

I. DEFEATING COVID-19 & BUILDING BACK BETTER

I.1 Ensuring resilient and **innovative manufacturing and supply** chains in Europe and globally

I.2 Proactively shaping the EU framework for **pandemic preparedness**

II. MAKING EUROPE A WORLD LEADER IN LIFE SCIENCES

II.1 Ensuring robust **incentives** for private R&D in the EU and globally

II.2 Proactively shaping the EU **regulatory framework** and enable **global regulatory convergence**

II.3 Building a positive innovation eco-system in Europe, including through health data

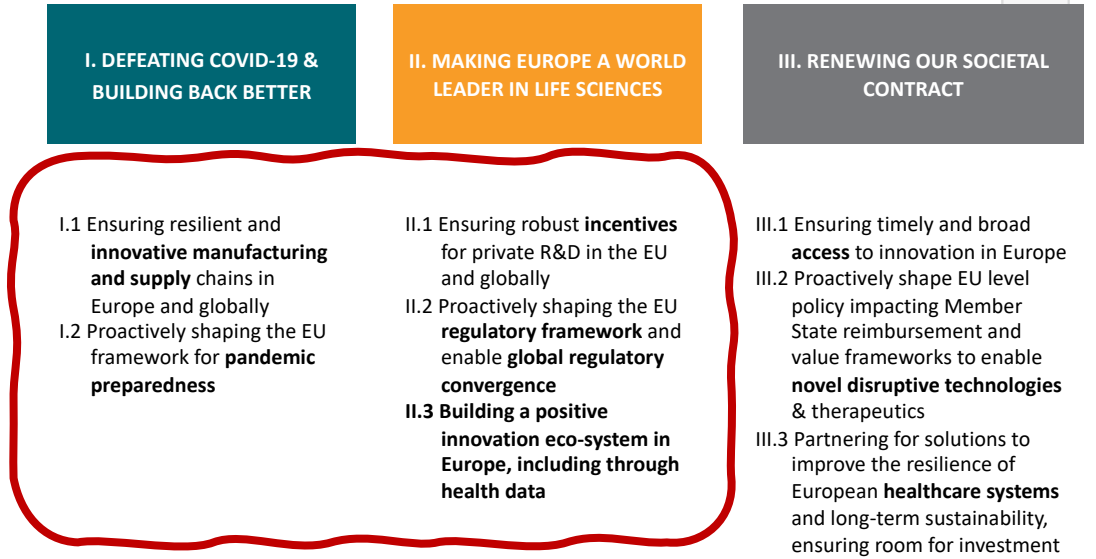
III. RENEWING OUR SOCIETAL CONTRACT

III.1 Ensuring timely and broad **access** to innovation in Europe

III.2 Proactively shape EU level policy impacting Member State reimbursement and value frameworks to enable **novel disruptive technologies** & therapeutics

III.3 Partnering for solutions to improve the resilience of European **healthcare systems** and long-term sustainability, ensuring room for investment in innovation

EFPIA 2022 priorities



Innovation BSC priorities 2022

Tier 1: Core pharma review

- Incentives (OMP, Paeds, IP, AMR) (II.1)
- Regulatory modernisation (II.2)

Tier 2: Innovation ecosystem

- European Health Data Space (II.3)
- Research and Innovation (II.3)
- Licence to Operate (II.3)
- Biopreparedness (I.2)

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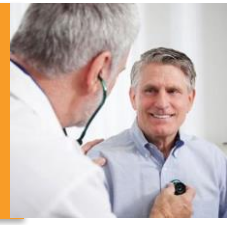
Regulatory Strategy Committee priorities 2022






Presentation

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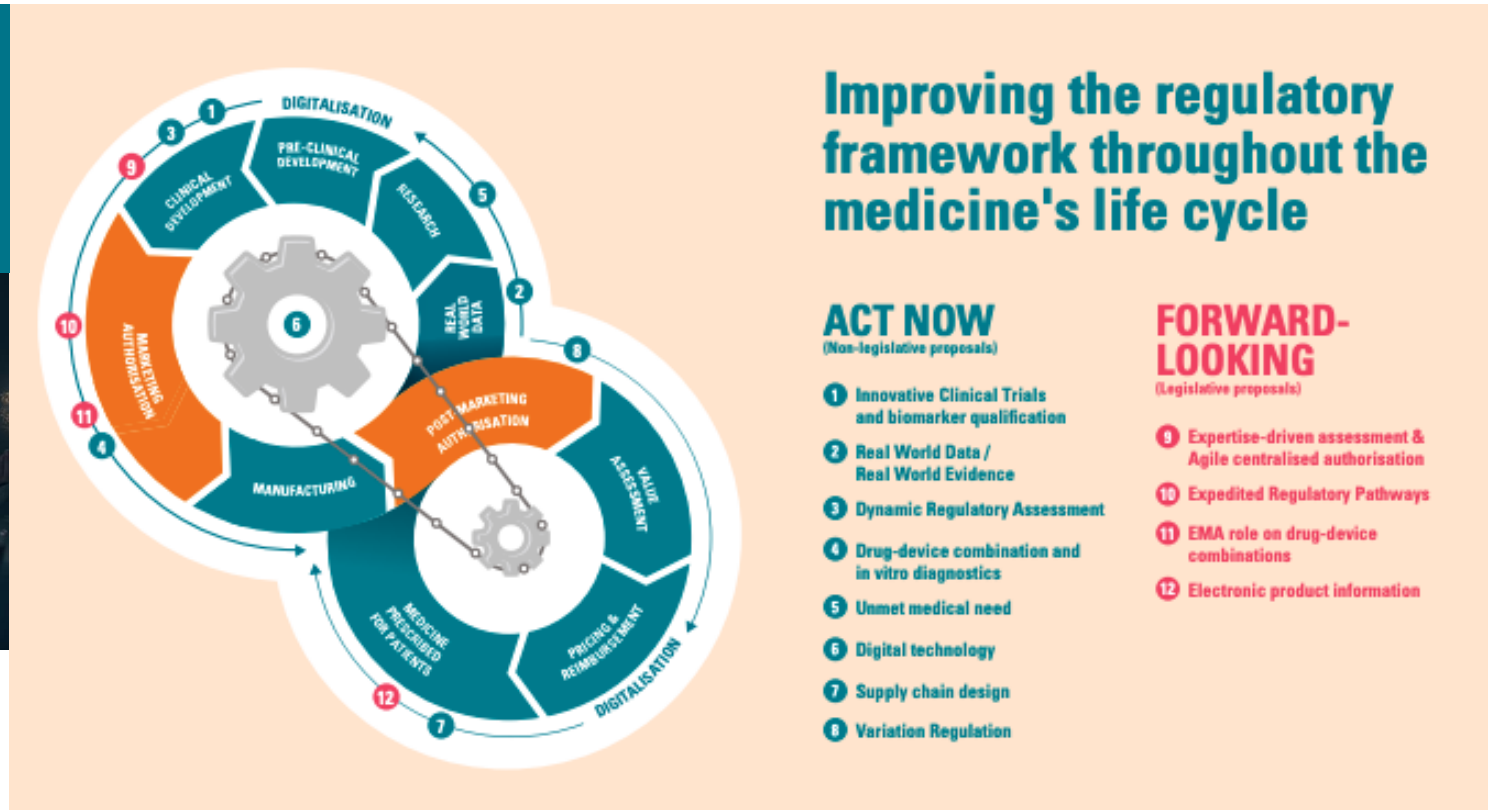
Regulatory Road to Innovation – Implementing EFPIA's regulatory strategy



Link to EFPIA website: https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/efpia-regulatory-road-to-innovation/#:~:text=The%20Regulatory%20Road%20to%20Innovation,with%20no%20guarantee%20of%20success.

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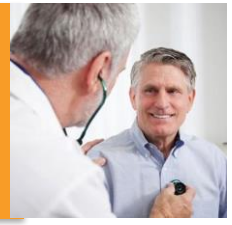
Clinical Research Expert Group priorities 2022





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Headline EFPIA Priority:
I.2 Proactively shaping the EU framework for bio-preparedness

Headline Objective(s)	Key actions/deliverables
Regulatory flexibilities and liability questions addressed as part of the preparedness and response "toolkit". Implementation of supply rules for pandemic crisis aligned with EFPIA principles.	Implement lessons learned from COVID crisis management/ regulatory flexibilities, incl. clinical

Headline EFPIA Priority:
II.2 Proactively shaping the EU regulatory framework and enable global regulatory convergence

Headline Objective(s)	Key actions/deliverables
Ensure a competitive, world-leading and future-proof regulatory framework by including EFPIA legislative and non-legislative proposals in the EU pharma legislation review	Clinical research modernisation including transparency, complex CT design, patient centricity, equity and clinical trial regulation implementation and related IMP manufacturing • Work with EMA, MS (CTCG) and other stakeholders to ensure the implementation and further development of the CT information System supports clinical trials conduct and transparency in Europe • Responsible Transparency of clinical research to cover patients and public interests, foster innovation and meeting regulatory requirements while ensuring data privacy • Work with EMA, HMA and EC on ACT (Accelerating Clinical Trials) initiative published in Jan 2022
	Contribute proactively to the advancement of the EU Regulatory Science community (including through implementation of EMA Regulatory Science Strategy and Network strategy) as an enabler for RRI • Ongoing input to address arising issues affecting clinical trials that impact EU operations including COVID-19, and transparency • Inter-association analysis of introduction of regulatory flexibilities for COVID-19

Headline EFPIA Priority:
II.3 Building a positive innovation eco-system in Europe, including through health data

Headline Objective(s)	Key actions/deliverables
IHI initiatives contribute to addressing scientific and regulatory gaps in areas covered by the pharmaceutical strategy	Launch of IHI initiatives to support regulatory modernisation and outcomes strategies
	Maximise regulatory opportunities across IMI portfolio • Explore opportunities for IMI projects on new approaches in Complex Clinical Trials and patient centricity
Operating environment for pharmaceutical companies and SME's that foster continued investments in Europe and a thriving innovation eco-system, including through avoiding or mitigating undue burden from regulation in chemicals, environmental protection and animal welfare	Advocacy and communication on the innovation eco-system in Europe vs other regions (the "innovation problem statement"), including relating to SMEs (including CT footprint)
	Advocacy to address arising regulatory issues outside of RRI that impact EU operations

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Thank you