European Federation of Pharmaceutical Industries and Associations

EFPIA feedback on the Roadmap for a European Partnership for Innovative Health

27 August 2019

EFPIA welcomes the roadmap for a "European Partnership for innovative health" under the Horizon Europe programme[1], and supports Option 2 (Institutional Partnership under TFEU Article 187) as an enabler to address the challenges, and deliver the expected beneficial impact on society, patients, healthcare systems, academia and the industry.

A novel multi-sector Partnership for health research and innovation will be instrumental to break the silos between different industries and their respective stakeholders. This will accelerate the development of safer and more effective healthcare innovation for patients, carers and citizens at large. It will enhance sustainability of both health industries and health systems in Europe.

The proposed level, depth and scale of multi-sector collaboration is unprecedented and unique at a European and global level.

Rationale: The Inception Impact Assessment reflects correctly the role that biomedical innovation can play and the challenges for its development, regulatory and economic evaluation and uptake in medical practice. The challenge of integrating products and technologies in a systematic and systemic way will require evolving well established R&D paradigms and defining a new pre-competitive multi-sector collaboration platform.

Policy options: The proposed level of "radical" collaboration, of integration between public and private sectors and the desired impact on medical practice, health systems and individual patients call for an Institutionalised Partnership under Article 187 TFEU (Option 2). Defining new boundaries for multi-sector precompetitive collaboration and/or pressure-testing traditional sector-specific regulatory frameworks against new R&D and business solutions requires an institutional and transparent platform. This platform would balance public health and business imperatives, and therefore bring together parties that would not be able to collaborate in less institutionalised frameworks.

Impact: In addition to the scientific, socio-economic and health impact described in the Inception Impact Assessment, the following is worth noting:

- the proposed Partnership would ensure filling an important **gap in translational research** in Europe for which funding mechanisms are scarce;
- the Partnership would accelerate the development of **regulatory sciences** that reflect the new integrated approaches to R&D and healthcare delivery that are transforming healthcare today and in the future;
- the Partnership would create **new businesses** placing Europe at the forefront of cross-sectorial benefits for citizens and patients;

[1] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972474_en

- The Partnership should **capitalise on past investments** and build on and connect with projects and results from the Innovative Medicines Initiative (IMI and IMI2) and ECSEL;
- This European Partnership should be **open to the world**: it should have a global footprint, allowing for global collaborations and impact.

To attract a wide range of industrial players from all sectors and deliver on its objectives, the Partnership would need to **operate in an efficient and flexible way**:

- **Flexible, time and cost-efficient processes**: the bureaucratic burden for applicants, funding members and the programme office should be reduced as much as possible. Shortening time from idea to project is critical to ensure the participation of the industry and SMEs. A flexible call process should allow a mix of bottom-up and top-down topics while ensuring openness to all stakeholders.
- **Schemes based on in-kind contribution** where the industry brings significant and diverse skills, expertise and industrial know-how, are an essential condition for impactful public-private collaborations. Blending public and private assets, know-how and research cultures accelerates translation and implementation of scientific ideas into research, development, regulatory and industrial standards. Valuation and eligibility of all types of resources will incentivise companies to contribute assets that are critical to the success and impact of the Partnership.
- **The Partnership must have the ability to attract resources at a global level.** Europe should benefit from synergistic collaborations with major industrial players in the pharmaceutical and medical technology sectors operating globally, as well as with international funding organisations and charities. This would enable global input and reach, resulting in the best possible science and innovation for the benefit of all citizens, as well as facilitate international knowledge transfers Such impact will only be achievable if in-kind contributions from all partners are eligible without limitation, irrespective of their origin.
- **A flexible legal framework** would be required for the management of intellectual property and research data, in order to incentivise the participation of multiple sectors and stakeholders with diverse research and innovation lifecycles and business models.
- **Mechanisms to ensure synergies & collaborations** between Partnerships would be required to avoid overlaps, especially with potential Partnerships on EU-Africa Global health[2], Healthcare systems, Personalised medicines and Rare diseases.

We believe that an Institutionalised Partnership under Horizon Europe would allow us to work towards our joint ambition to deliver tools, data and platforms, technologies and processes for innovative products and services for the benefit of citizens and patients. It would help us focus on learning healthcare systems predicting real needs, optimising the health journey for patients and de-risking innovation by providing solutions that enhance predictability. EFPIA welcomes engagement with EU institutions and stakeholders to further discuss the potential scope and features of such a Partnership.

[2] Please refer to feedback from EFPIA and Vaccines Europe on the EU-Africa Global health Partnership: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972489/feedback/F472672_en?p_id=5722447