

## EuropaBio response to the public consultation on the Roadmap for an EU Pharmaceutical Strategy

July 2020

EuropaBio sees the Pharmaceutical Strategy as a crucial chance to strengthen the EU life sciences & biotechnology ecosystem; protecting citizens' health and enhancing EU's competitiveness vs US and China. COVID-19 has revealed the critical role of innovation in dealing with health emergencies. Of utmost importance is nurturing the bio-science sector and stimulating innovation to meet patient needs.

The research-based biotechnology industry is a core EU industrial sector. EuropaBio calls on the Commission to align its Pharma Strategy with the Industrial Strategy. Within the existing regulatory framework, all objectives of the Roadmap can be achieved. Increased collaboration of EU, Member States, public and private stakeholders will create solutions for value-based innovations.

### Access & availability

- Improved access to new treatments (ATMPs, OMPs) should be prioritised. A series of challenges relating to HTA and reimbursement must be overcome.
- R&D of novel biotherapeutics requires streamlined regulatory processes: rapid centralised scientific advice procedures, continuous dialogue and re-evaluation for additional requirements, e.g. GMO. Flexible regulatory pathways used for COVID-19 medicines should be applicable to better address unmet medical needs: faster approval, rolling reviews, labelling flexibility, increased interactions with regulators.
- The OMP legislation increased investors' interest in biotechnology but more supportive measures are vitally important to drive future medicine development for rare diseases. Its framework should be preserved as only 5% of existing rare diseases have a treatment available.
- The definition of unmet need should better incorporate the needs of patients.

### Affordability & health systems sustainability

- Affordability measures should be balanced against the need for both sustainable health systems and a viable, competitive biotechnology ecosystem.
- Cost-effectiveness or therapeutic value should be considered through systematic patient feedback to fill evidence generation gaps (ATMPs).

- Early interaction between health authorities, HTA bodies and payers along with evidence generation in consultation with these stakeholders can lead to better access.
- Financial schemes or performance-based agreements should be considered.
- Procurement through the Most Economically Advantageous Tender (MEAT) can be useful in exceptional cases of cross-border threats. It remains undesirable if used only for cost containment.

#### Innovation for unmet needs via digital & emerging technologies

- IP & incentives are critical to encourage long-term investments in high-risk, complex research & diversified product development (ATMPs, OMPs). Access to capital remains a challenge when compared to the US and China. Caveating incentives or building in conditionalities will not increase patient access and will jeopardise European research competitiveness.
- The EU needs a strong collaborative network involving EMA and national agencies with sufficient resources and the right expertise to anticipate increasing complexities linked with breakthrough innovation.
- Consideration should be given for continued use of non-legislative approaches to emerging technology which have proven effective in responding to COVID-19.
- Timely access to standardised data sets and streamlined GDPR implementation will enhance data use for cross-border scientific collaboration.
- High-quality RWD & AI must be harnessed as part of the planned EU Health Data Space. RWE should be supported by EU-wide measures.

#### EU competitiveness & less dependence on non-EU manufacturing

- Flexibility and funding must be improved for innovative biotechnology SMEs.
- Supply chains of innovative treatments are global by necessity. A strategic approach to support innovative manufacturing in the EU will ensure reliable supply and create high-skilled jobs for the future.

Long-term investment is key to create a competitive and innovative EU life sciences & biotechnology ecosystem.

[Read the full response here](#)

---

### **About EuropaBio**

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a bio-based and zero-waste economy. EuropaBio represents 81 corporate and associate members and 15 national biotechnology associations and bioregions.

Read more about our work at [www.europabio.org](http://www.europabio.org).

EuropaBio *aisbl*  
Avenue des Arts 53, 1000 Brussels

+32 2 735 03 13  
[www.europabio.org](http://www.europabio.org)

VAT: BE0477520310

