Europe's Biotech Innovators at risk… the General Pharmaceutical Legislation must prioritise innovation

PRESS RELEASE

24 January 2024, Brussels - EuropaBio, the association representing Europe's biotechnology industry, has published research demonstrating the negative impact of the European Commission's draft General Pharmaceutical Legislation (GPL) for biotechnology innovation. This research highlights the consequences for EU patients and economies within a global race towards healthcare security and competitive positioning.

The study '**Impact of the EU's General Pharmaceutical Legislation on Europe's innovation ecosystem and biotechnology companies'** was conducted by Charles Rivers Associates, including interviews with investors, biotech companies, service providers and national biotechnology associations, supported by analysis of the impact of the GPL on companies across tiers from start up to mature.

It confirmed the GPL sends a clear global message to investors and innovators, that the EU has deprioritised innovation for healthcare. Reduced baseline incentives are a barrier for early-stage biotech programmes in companies of all sizes, with small innovators disproportionately impacted, which threatens the translation of Europe's powerful research base. Rare disease goals are less likely to be met, with the restrictions and reductions in incentives in turn impacting clinical trials and treatment options for patients within the EU. Proposed reductions also create a vicious circle for the essential collaboration in drug development, with reduced demand for partnership from mature companies for early-stage programmes, and restricted innovation flow into pipelines from small innovators.

Significantly, the study revealed that the positive changes introduced in the GPL do not offset the negative impact of the rest of the proposals or are ineffective, particularly for smaller companies.

EuropaBio Director General, Dr Claire Skentelbery said *"The GPL must be central to the EU's strategy for healthcare resilience through global biotechnology competitiveness. It has to empower Europe's innovators, especially small and growing biotechnology companies, and reprioritise our significant life science sector. We should increase rather than decrease baseline incentives, remove the seven-year time limit for Orphan Designation, increase Orphan Market Exclusivity and avoid definitions that restrict Europe's rare disease progress. This enables Europe to grow as a global hub for research excellence and be a home for novel medicines, with the beneficiaries being patients, economies and healthcare systems."*

Find out more at www.europabio.org

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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 biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions. Read more about our work at www.europabio.org.