

Impact of the EU's General Pharmaceutical Legislation on Europe's Innovation Ecosystem and Biotechnology Companies

EuropaBio Solutions

24/01/2024

An EU General Pharmaceutical Legislation to Deliver the Future of Healthcare through Biotechnology Innovation

Biotechnology is the future of healthcare, enabling treatment of more complex diseases, introducing personalised healthcare, and advancing current therapies, improving patients' outcomes and quality of life. It is also a high impact sector for the EU economy, outperforming the EU average through high productivity, gross value added, skills and employment. For over 40 years, it has been part of EU and national strategies to grow successful clusters, manufacturing capacity and centres of excellence, with added benefits of enhanced health sovereignty and resilience when facing health crises.

Higher risk and long development timelines characterise the translation of biotechnology into therapies, with smaller companies being the primary vehicle for translation of Europe's research into development pipelines. The pathway to patients is a highly collaborative process between companies of all sizes. Innovators, especially emerging and small companies, are highly reliant on a strong and predictable incentives framework to secure early investment for long term programmes.

EuropaBio believes the revision of the EU General Pharmaceutical Legislation (GPL) is an opportunity to leverage biotech innovation for patients, economy, and resilience. The study demonstrates that in their current form, the proposals will:

- Create barriers to the delivery of innovative biotechnology medicines by reducing incentives and certainty for innovators.
- Weaken the EU's engine for novel medicines by disproportionately impacting small innovators.
- Put the EU rare diseases goals at risk and negatively impact access to clinical trials and treatment options for rare diseases patients.
- Negatively impact collaboration and partnership opportunities between innovators and weaken the EU's life science sector.
- Send the message that the EU is deprioritising its life science sector at a time of global scientific arms race to leverage innovation for competitiveness and resilience.

How Europe can solve this: use the GPL as a force for growth in EU biotechnology innovation and patient benefit

1. ***Europe succeeds when innovation can grow***

Increasing baseline incentives and certainty for innovative biotechnology helps more companies secure investment into early stage and novel programmes, giving innovators at all stages a clear view to market authorisation. This offsets Europe's challenging market and investment landscape compared to other global regions.

2. ***Patients and healthcare systems are the beneficiaries from breakthrough biotechnology***

Removing the seven-year time limit to Orphan Designation, increasing Orphan Market Exclusivity and avoiding definitions that restrict research, gives Europe the advantage needed, to enable innovators in rare diseases to develop breakthrough medicines for patients, and focus clinical trials in Europe.

3. ***As the primary vehicle for translation of Europe's research into therapies, the GPL must enable risk taking small biotechnology companies to thrive and attract investment without restriction***

The GPL should empower Europe's small and growing biotechnology innovators rather than restrict them, through increased baselines for incentives, no restrictions on viability of early programme innovation through definitions of High Unmet Medical Need and elimination of late programme modulation linked to unachievable conditions. It should also recognise that the SME definition is irrelevant for late programme support, given the long time and company growth required for a successful medicine.

4. ***The EU delivers for patients, economy and its long-term resilience through high levels of biotechnology innovation and partnerships***

The GPL must be positioned as a mechanism within the EU's strategy to achieve resilience in healthcare through global biotechnology competitiveness. It must enable, without limit, innovators in industry to address complex diseases and technologies, create growth, critical mass of expertise, manufacturing capacity and pathways from R&D through to market authorisation and to patients.

See the full study

