

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

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The EU's General Pharmaceutical Legislation (GPL) proposal does not sufficiently consider the impact on the innovation ecosystem and how its impact may vary by company maturity. The legislation will lead to an increase in uncertainty for biotechnology companies, with effective reductions in protections and unguaranteed late-stage offsets.

There are some positive changes in the GPL. Streamlining regulatory processes will be beneficial, particularly for emerging, small, and mid-cap biotech companies needing help navigating the complex regulatory system. However, these benefits do not offset the negative elements of the rest of the GPL. Benefits from regulatory streamlining are outweighed by increased risks, particularly to emerging and small biotech, from changes on orphan medicines, regulatory data protection and classification of 'high unmet medical need' (HUMN).

Overall, reduced incentives will only exacerbate the impact of the challenges regarding the market access landscape, decreasing Europe's attractiveness for both investment and novel medicines development, leading ultimately to delay in European patients' access to novel treatments with consequences throughout the biopharmaceutical landscape, compared to patients from other parts of the world.

### **Reducing incentives and certainty for early programmes is a barrier to the delivery of innovative medicines through biotechnology**

A reduced baseline for regulatory data protection (RDP), with extensions based on a restrictive definition of unmet medical need (UMN), undertaking comparative clinical trials, and continuous supply across Member States, are seen by investors and companies as inherently uncertain, and, therefore, investment decisions by venture capital (VC) and mature biotech will be based on the baseline protections offered, reducing the attractiveness of the entire European landscape. This decrease will result in lower commercial valuations, fewer and reduced investments, and limited collaborations, particularly for smaller innovators and medicines at earlier stages.

### **Small innovators are at risk, and with them the EU's engine for novel medicines**

The biotech innovation landscape in Europe is falling behind, and the proposed GPL will only worsen the environment for emerging and small biotech companies, which have not been sufficiently considered in the development of the GPL to date. In particular, the GPL will lead to additional uncertainty, diminishing commercial value, and hindering investment prospects, especially in the orphan and ATMP space where small and mid-cap companies are pivotal innovators.

The report shows that proposed GPL changes hit smaller innovators hardest, with limits to orphan designation (OD), restrictive definitions for Unmet Medical Need (UMN) and High Unmet Medical Needs (HUMN), and reduced Regulatory Data Protection (RDP) and Orphan Market Exclusivity (OME) together with late stage conditionalities beyond the reach or control of companies. SME support proposed within the GPL is irrelevant, as small innovators grow past this definition before late programme support can be applied.

## **Rare disease goals are less likely to be met, especially through advanced therapies, impacting clinical trials and treatment options for patients**

Changes to the orphan medicine incentives in the GPL, such as the cap on orphan designation (OD) duration, disproportionately affect emerging and small companies. OD is an important enabler for attracting early investment, with a seven-year OD limit increasing investment risk and adding additional barriers to attracting capital. Given the role smaller companies play, this could affect a significant number of patients with rare diseases. The overall result is that the reduced security of OD and decreased perceived certainty regarding exclusivity, which are currently seen as an important differentiator for Europe to offset the challenging MA landscape, will decrease the attractiveness of Europe as an R&D hub or market target.

## **EU biotechnology companies are strongly inter-dependent for successful development of medicines. Proposed changes negatively impact partnerships and Europe's life sciences sector**

The current European innovation cycle is built on small biotech originators funded through VC investment; these companies subsequently partner with mature biopharma. In turn, mature companies commercialise the medicine and use the resulting profits to fund innovation in emerging and small biotech. The changes proposed in the GPL will damage this innovative cycle.

The study demonstrates that decreased collaboration across companies of all sizes will have knock-on impacts on translational research, clinical trials, and industrial partnerships as well as regional and biotech cluster development. The proposals will make it more challenging for small innovators to attract capitals and partners, reducing the overall attractiveness for mature companies, harming the innovation cycle and accelerating the offshoring of EU biotech excellence to other regions.

## **The EU must reprioritise biotechnology innovation and competitiveness and retain its significant life sciences sector**

Despite strategic recognition of the importance of biotechnology in Europe, the GPL significantly undermines the ability of European innovators to deliver biotechnology from Europe's own research base and sends a clear global message that Europe has deprioritised innovation for healthcare.

Changes to incentives which make obtaining capital more challenging for emerging and small companies will reduce the overall European attractiveness to mature companies, reducing collaboration and the transfer of expertise, which has been a driver for Europe's biotech delivery over the previous 30 years. This will harm the innovation cycle, reducing Europe's ability to innovate, accelerating the loss of talent and diminishing economic development.

In the worst case, global companies and investors will not consider Europe as a primary or even secondary territory to develop or launch innovative therapies, with reduced partnerships, investment, manufacturing and market authorisations. European innovators will struggle to start up and grow, with partners and investors focusing investment and market authorisation into other regions. Patients will not benefit from clinical trials of therapies developing within Europe and will be later recipients of therapies that have entered markets elsewhere, if and when it becomes economically viable to enter the European market.