

Supporting small biotechs in the revision of EU Pharmaceutical Legislation

Disruption for innovation: the role of small biotech companies

Small biotech companies play a crucial role in medicines discovery and development. Characterised by a focus on breakthrough scientific discoveries and emerging technologies, and their willingness to take risks and pursue innovative approaches to drug development, small biotechs have developed many successful and transformative therapies and technologies in the life sciences sector.

Collaboration is critical for small biotechs success. Together with academia and large companies, they overcome challenges in development, access funding, expertise, and regulatory knowledge. Collaboration with large companies also doubles the likelihood of success, from setting up clinical trials to gaining access to larger markets.

The EU Pharmaceutical Legislation has enabled a thriving ecosystem of small biotechs to emerge and fill pipelines, especially in the rare disease space. In the last 20 years, small biotech companies' share of the global R&D pipeline grew from around 30% to 60%.

The new Pharmaceutical Legislation should strengthen Europe's innovation ecosystem upon which small biotechs depend for success.

Helping small biotechs grow in Europe improves patient access

Research & development: improving collaboration in the pre-competitive space, better access to registries, and greater use of health data will help small biotechs move into clinical development faster.

Regulatory improvements: reducing administrative burden, increasing support from EMA, greater acceptance of novel clinical trial designs and real-world data, and increasing coordination between regulators will help small biotechs bring their therapies to patients faster.

Access to funding: maintaining the stability and predictability of regulatory incentives is critical to attract and retain private investment flows. Improving access to public funding at EU and national level and more diverse funding sources will help small biotechs become more resilient.

Market access: Streamlining pricing and reimbursement and HTA procedures, especially for rare and very rare diseases, will help small biotechs enter the market more quickly.

The growing footprint of biotech in Europe

- Healthcare biotech is a **highly efficient and capital intensive industry** with a labour productivity higher than the telecommunications and financial sectors.
- Healthcare biotech industry has seen **consistent growth** in the past 20 years improving people's lives.
- The biotech industry creates **high-quality jobs** throughout the EU from R&D to manufacturing and business. In **2021**:

€34.5 bn
added value

€48.8 bn
exports

224,600
jobs

3%
annual
growth

- In **France**, over 800 biotech companies create over **46,000 jobs** with an annual GDP contribution of **€10 billion** (2021).
- In **Belgium**, over 300 companies create over **35,000 jobs** with a total added value of **€11.6 billion** (2022).
- In **Germany**, over 700 companies create over **44,000 jobs** with **€26.3 billion** in annual revenue (2021).
- In **Poland**, the biotech sector creates more than **12,000 jobs** in the whole biotech sector with almost **1,5 billion PLN** spent on R&D per year (2019).
- In the **Netherlands**, over 500 companies create over **41,000 jobs** with a GDP contribution of around **€4 billion** in 2017 (2021).
- In **Spain**, over 800 companies create over **30,000 jobs** with a GDP contribution of **€10.3 billion** (2021).
- In **Denmark**, close to 200 companies create over **30,000 jobs** with a total added value of **64 billion DKK** (2021).