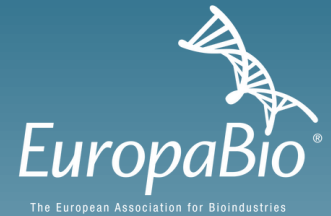


THE EU GENERAL PHARMACEUTICAL LEGISLATION



In the last 20 years, **biotech has transformed the pharmaceutical industry**. It is increasingly becoming the **primary source of new therapies**, making treatments for previously untreatable diseases possible and transitioning from 'manage' to 'cure', thereby improving quality of life for patients, their families, and healthcare systems.

The revision of the EU General Pharmaceutical Legislation (GPL) is vital to enable the faster approval of health biotech innovations that can bring high added-value to EU patients, society, and economy in the coming decades.

A recent study demonstrated that the GPL will **negatively affect the EU biotech ecosystem**, with smaller companies most at risk by the proposed changes.

WHAT IS THE EU GENERAL PHARMACEUTICAL LEGISLATION?

The Parliament adopted its position on 10 April 2024. New Rapporteur and Shadows will need to be named before trilogues start

The Commission adopted its proposals in April 2023. The proposals aim to **modernise the EU framework** and enhance resilience against shortages, while promoting innovation and ensuring timely and equitable access to safe, effective, and affordable medicines within the EU. The legislation would also apply to medicines for rare diseases and advanced therapies (ATMPs).

The Commission proposed measures to reduce and conditions incentives for innovative medicines, simplify the regulatory framework, address medicine shortages, enhance environmental protection, tackle antimicrobial resistance, and create a regulatory sandbox for cutting-edge therapies.

EUROPABIO'S POSITION

EuropaBio firmly believes that a **supportive and forward-looking GPL** is essential to unlock the full potential of health biotech innovations and address health challenges. EuropaBio supports the Commission's objectives for revising the GPL but has concerns about the approach. With biotech designated a critical technology, We remain convinced that the GPL is an **opportunity to improve on the current regulatory framework** and give the EU the effective tools to once again be an innovation leader and secure faster access to innovative medicines for the European patients.

EuropaBio welcomes the Parliament's improvements but remains concerned the voted version will not be positive on Europe's biotech ecosystem and most likely will lead to decreased investment potential for European innovation, reduced innovation maturation through collaboration and partnership. More important, it will also, probably lead to decreased and delayed patients access to innovative treatments when compared to other regions.