Public health aspects of biotechnology and life sciences

2025/2087(INI) - 19/12/2025 - Committee report tabled for plenary, single reading

The Committee on Public Health adopted the own-initiative report by Margarita DE LA PISA CARRIÓN (PfE, ES) on the public health aspects of biotechnology and life sciences.

Exploring the potential of biotechnology in healthcare

The report highlighted the need for **long-term strategic investment** in biotechnology research, given that biotechnological therapies (CAR-T cell or mRNA therapy, CRISPR therapy) and other advanced therapy medicinal products (ATMPs) are transforming healthcare and prevention for many serious or previously incurable diseases.

The EU's competitiveness in the life sciences must encompass a strong patient perspective, ensuring that research and innovation translate into timely access to effective treatments and medicines across the EU.

The report emphasised that biotechnological innovation can play a major role in reducing and replacing animal testing. It highlighted that new applications of biotechnology can provide solutions to antimicrobial resistance, as well as the need to increase genome sequencing capacity to facilitate early diagnosis and screening. Members stressed the importance of biotechnology research and development in addressing unmet medical needs, particularly in the treatment of rare and paediatric diseases. They called for public funding to be directed towards these priorities.

Shaping the future EU Biotech Act

The report called for EU Biotech Act to **review, simplify and optimise the regulatory framework for biotechnology** in healthcare so as to foster innovation, including off-patent-led developments, while maintaining **high standards of safety, quality, efficacy and ethical compliance**, as well as public health and environmental protection. Members stressed the need for a science-based clinical trials framework coherent with evolving EU legislation and tailored to the specific characteristics of different biotechnologies (orphan drugs and advanced therapy medicinal products), to promote innovation and improve patient access to treatments.

Members called for a harmonised, streamlined, and science-based **clinical trials framework** to increase efficiency, transparency, and cross-border collaboration, including by reducing authorization times to **30 days** through risk-based assessments. They advocated for greater use of multi-country clinical trials is key to unlocking the value of the single market and positioning the EU as a global leader in clinical research.

The Commission is invited to explore the establishment of a **centralised coordination mechanism** for clinical research governance, with the European Medicines Agency (EMA) potentially playing a coordinating role in this structure. The report also highlighted the need to streamline and make more predictable the work of national ethics committees in approving clinical trials, including cross-border clinical trials and to simplify, align and better coordinate clinical approval processes across the EU.

Members reiterated their support for the use of next-generation **regulatory sandboxes** and health technology assessments to test emerging biotechnologies in a secured, controlled and adaptable framework that complies with EU standards.

Noting the **growing role of AI** in healthcare, particularly in personalised medicine, diagnostics, treatments, and clinical research, the report called on the Commission to develop sector-specific and harmonised ethical guidelines for the use of AI across the life cycle of medicines, ensuring coherence with the AI Act. It called for targeted support for initiatives such as the **European Virtual Human Twins** to enable low-cost early-stage therapeutics and improve translational readiness.

Members stressed the need for the European life sciences strategy and the EU Biotech Act to **make Europe a leading destination** for investment in biotechnology R&D, manufacturing and clinical trials, while ensuring tangible benefits for citizens.

Promoting innovation, investment and financing

The report called for structured EU support to help excellent biotechnology innovation districts in the EU grow and ensure that they have sufficient capacity, resources and scientific edge to promote new groundbreaking biotechnology discoveries, innovation and commercialisation.

Members stressed the need to increase **public and private investment** in biotechnology across the entire value chain, with a focus on the early stages of development, where funding gaps for startups remain greatest.

They advocated for increased private investment to complement public funds, alongside faster and more agile financing mechanisms, simplified regulatory and operational frameworks and stronger interconnected value chains, in order to close the innovation gap.

The report also highlighted the need:

- to **promote career opportunities** in life sciences and address brain drain by offering better working conditions to retain skilled workers and researchers in the EU and attract others to the Union;

- to put in place flexible support and financing models to **assist SMEs**, from early research to commercialisation and to improve SMEs' access to private investment in research, development and innovation;

- to consider the creation of an **EU biotech innovation fund** to support researchers, universities, start-ups and SMEs conducting R&D and innovation in healthcare biotechnologies;

- to ensure **strong ethical oversight** in the field of biotechnology, including for AI-based tools.