CCMI FACTSHEET:

EUROPEAN BIOTECH ACT AND ACCOMPANYING DIRECTIVE ON GENETICALLY MODIFIED MICRO-ORGANISMS

(CCMI/257)

The European Biotech Act, adopted on 16 December and announced in the Political Guidelines for the European Commission 2024–2029, aims to create a robust framework that enables biotechnology products to move seamlessly from the laboratory to industrial production and ultimately to the market, while maintaining high safety and ethical standards. By setting a clear vision, the Act aims to strengthen Europe's position as a global leader in sustainable and innovative biotechnology.

The EESC calls for stronger investment, regulatory coherence, and strategic autonomy to unlock the full potential of health biotechnology in the EU, emphasizing a coordinated, forward-looking approach that drives innovation, competitiveness, and responsible development across the sector. The opinion underscores the importance of collaboration across stakeholders, strategic planning, and alignment with broader European priorities to ensure that biotechnology delivers tangible benefits for health, society, and the economy.

KEY FACTS: THE URGENCY TO ACT

EU industrialization of biotech is slowed by **fragmented regulations, weak clusters, and unstable long-term policies**.

Global biotechnology market reached **€720 billion in 2021**, growing **18% annually**; the EU accounts for only **12%**.

EU venture capital represents just **7%** of global biotech investment; US: **63%**, China: **14%**.

Current EU supplementary protection certificates (SPCs) have **restrictive conditions**, limiting innovation incentives.

Between 2013–2023, EU's share of commercial clinical trials **halved from 22% to 12%**, while China's **tripled to 18%**.

EU multinational clinical trials take **113 days** on average for approval, nearly **double** the 60 days in the US and China.

Of 67 EU biotech firms listed (2019–2025), **66 listed outside the EU**, highlighting regulatory and market limitations.

Despite strong research institutions, a **'translation gap'** hinders turning EU into market-ready biotech products.

RECOMMENDATIONS FROM EESC OPINION

- **Invest in EU health biotech:** Increase targeted EU investment in research, innovation and production, while strengthening clusters, scale-up tools and coordination across EU initiatives.
- **Increase funding and collaboration:** Maintain and expand financial tools like the 'capital booster', encourage university-industry partnerships, and harmonise EU investment regulations.
- **Establish a single licensing authority:** Make the EMA as the single EU authority for pharmaceutical licensing and use regulatory sandboxes to test innovation, including social acceptability aspects.
- **Incentivise local production:** Extend one-year supplementary protection certificates (SPCs) to reward innovative medicines produced in the EU with new mechanisms of action, ensuring equivalent safety and effectiveness.
- **Integrate digital and AI tools:** Implement simple, harmonised frameworks for AI and digital tools in biotech, while keeping human decision-making central.
- **Strengthen biosafety and oversight:** Control sensitive technologies, ensure traceability, and license end users of high-risk products to prevent misuse, while applying the precautionary principle for genetically modified micro-organisms.
- **Support preventive health innovation:** Reinforce vaccine research infrastructure and enable faster and inclusive clinical trials for paediatric and rare diseases.
- **Maintain safety and ethical standards:** Ensure all biotech applications are independently evaluated, safeguard workers and the environment, and improve ethics coordination across Member States.

ALIGNMENT WITH EU COMMISSION POLITICAL GUIDELINES (2024-2029)

- Both the opinion and the Guidelines emphasise fostering **innovation**, **research**, and **industrial capacity** in biotechnology to strengthen the EU's **strategic autonomy**.
- The opinion calls for **resilient EU biotech capabilities**, aligning with the Commission's goal of reducing **dependency** on external political and economic developments.
- The opinion highlights the need for targeted **financial instruments** and **capital support**, echoing the Guidelines' commitment to mobilise **public and private investment** for innovation.
- The opinion stresses **harmonised**, **predictable frameworks**, supporting the Guidelines' objective to create **clear**, **efficient EU rules** that enable business and innovation.
- Both documents highlight the importance of integrating **digital tools** and **AI** into biotech, while ensuring **human oversight** and **safety**.
- The opinion underlines **biosecurity**, **traceability**, and **ethical oversight**, reflecting the Guidelines' principle of **responsible** and **sustainable innovation**.
- The opinion calls for broad **dialogue** and **public awareness**, in line with the Guidelines' emphasis on **inclusive policymaking** and **citizen trust**.