ERS EUROPEAN RESPIRATORY SOCIETY
every breath counts

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Reaction of Respiratory Community to Commission proposal on Biotech Act

We hope that the elements around speeding up clinical trials and creating incentives for the most innovative players in the life sciences sector will keep Europe at the cutting edge. We support efforts to accelerate innovation and simplify regulatory pathways, provided this does not compromise rigorous clinical validation, transparent risk assessment, and public health safeguards. Europe's respiratory burden is too large, and advancing biotechnology is part of the solution in getting it under control.

For the Biotech Act to work, clinicians must be able to rely on robust evidence, clear regulatory guidance, and practical implementation support to integrate biotech innovations safely and effectively into care. The Commission should support collaboration between biotech developers, clinical societies, and health systems should therefore be encouraged to co-develop evidence-based guidelines and training.

In the inter linkage with the pharmaceutical legislation, equitable access should be a core principle of the Act. Persistent inequalities in respiratory care across Europe underline the need for EU-level coordination to promote pricing transparency, reduce fragmentation between Member States, and ensure timely access to biotech innovations, particularly for people living with chronic and rare respiratory diseases. The Act should support the development of targeted diagnostics, innovative vaccines, advanced therapies, and digital biotech tools, including AI-enabled solutions.

Strengthening the biotech workforce, ensuring access to high-quality and ethically governed health data, and promoting the use of real-world evidence and post-market monitoring are essential to support safe and effective deployment of biotech products. Patients should be actively involved throughout the biotech lifecycle, from research and clinical development to evaluation and post-market follow-up, with patient-reported outcomes playing a central role.

Finally, the Biotech Act should align with the EU's broader research and innovation framework, including Horizon Europe, to ensure sustained investment in respiratory research and the translation of scientific advances into equitable benefits for patients across Europe.