

EuropaBio welcomes the EU strategy on Covid-19 therapeutics

PRESS RELEASE

Brussels, 27 May 2021

EuropaBio believes that, beyond the short-term targets by the year end, more innovation needs to originate from the EU through an ambitious life science and biotechnology ecosystem.

New medicines, vaccines and treatments derived mostly from biotechnology have helped to tackle some of the leading causes of diseases and life-threatening illnesses. Advanced therapies, such as cell-based and gene therapies, are paving the way for new promising treatments. Covid-19 has confirmed the critical role of biotechnology in the response to the pandemic with the unprecedented development of mRNA based vaccines.

In a period of such rapid change and innovation, EuropaBio maintains that long-term investment in a strong EU life sciences and biotechnology sector is critical to achieve the goals of its biotechnology and biopharmaceutical industry in ensuring leadership on the global stage and addressing patient unmet needs..

The proposed strategy covers a number of key areas critical for biotechnology companies.

Research, development, and innovation

We welcome the creation of a “therapeutics innovation booster” to support the most promising therapeutics from preclinical research to market authorisation.

The rich biopharmaceutical innovation pipeline of transformative cell-based and gene-based therapies came to exist as a result of the remarkable convergence of modern biotechnology and digital sciences. These developments should be supported by the innovation booster and the European Health Emergency Preparedness and Response Authority (HERA) with the right financial instruments.



Access to and swift approval of clinical trials

EuropaBio believes that clinical trials with innovative therapies can be best supported by a world-class regulatory framework. The mRNA vaccine platform would not have existed without the pre-existing long-term investment in science and clinical trials.

Innovating clinical research should be the priority if we do not want to lose out to other regions in the world. The areas for collaboration should include complex clinical trials and the acceptance and support for new types of trials by the EU network of medicine agencies, including de-centralised and single-arm clinical trials. Alignment on RWE, related methodologies, and its use and acceptance are priority areas for collaboration. The Clinical Trial Regulation (CTR) and infrastructure will need to accommodate submission of such trials and address properly the resources needed at European and Member State level. EuropaBio welcomes a broader role for the EMA in providing universal advice and coordination and facilitation of multinational clinical trials in the EU. This will help the life sciences and biotechnology sector to streamline and accelerate clinical trials of investigational treatments.

Scanning for candidate therapeutics

The goal of establishing a portfolio of ten potential treatments and identifying the five most promising ones by June 2021 is reliant on the underlining strengths of a pipeline developed over years. Mapping therapeutics development, manufacturing capacities and supply chains can only be as effective as the robustness of a pre-existing pipeline of potential treatment options that has emerged over years of efforts and has been embedded in a strong and predictable IP system.

Supply chains and delivery of medicines

Increasing manufacturing capacity in Europe is not necessarily the only solution to ensure continuity of supply for biotechnology-based treatments. It is the diversification of manufacturing sources that lowers the risk of local dependency. Many of our EuropaBio members have built international manufacturing networks that ensure medicines supply worldwide. Building on the experience of the EU Task Force for Industrial Scale-up of Covid-19 vaccines, it is these diversified global supply chains that have assured continuity of supply when the Covid-19 crisis emerged. The proposed “matchmaking” events should fully consider solutions integrating efficient international supply chains built in the past that could be enhanced by targeted local investments to accelerate production processes and capacities where needed.

Regulatory efficiency

The EMA has been conducting rolling reviews for Covid-19 vaccines allowing the EMA to check data from ongoing studies as they become available and is planning



to follow similar processes for new Covid-19 treatments. Beyond the current emergency situation, all lessons should be taken from the implemented processes during the Covid-19 period to reflect on what can be improved across the board to accelerate and allow for more flexible regulatory processes in the future. The Commission should consider all possibilities based on this experience to accelerate regulatory approvals in the future with a long-term vision to optimise regulatory pathways. Maintaining the possibility of the EMA conducting staged assessment of incoming scientific product information is one example of a good and working practice.

Joint procurement and financing

The Commission is considering using advance purchase agreements or new innovative partnership procurement procedures to increase speed and flexibility of these new types of agreements. We welcome any initiative streamlining general processes, reducing the administrative burdens required and avoiding parallel procurement initiatives for the same products or resources that could be counterproductive.

International cooperation

EuropaBio fully supports the Commission intention to expand its engagement with international partners on the development and fair distribution of Covid-19 treatments. All solutions should aim to make sure all countries including low- and mid-income countries have the best access to innovative vaccines and treatments.

In conclusion, EuropaBio maintains that investing for the long run in a strong EU life sciences and biotechnology sector, from basic research to effective product development, should be fully prioritised if we were to achieve the goal to deliver new therapeutics treatments for Covid-19 and address proactively other potential pandemic threats in the future.

ENDS

Media contact

Dovilė Sandaraitė, Communications Manager

Email: d.sandaraitė@europabio.org

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy.



EuropaBio represents corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 2500 biotech SMEs. Read more about our work at www.europabio.org.

EuropaBio aisbl
Avenue des Arts 53, 1000 Brussels

 +32 2 735 03 13
www.europabio.org
VAT BE0477520310

