

Press Release

EuropaBio Statement on the EU Pharmaceutical Strategy

Setting the EU on course for future-proof & and patient-oriented biotech innovation

Brussels, 25 November 2020 - Today, the European Commission has launched its ambitious Pharmaceutical Strategy to improve and accelerate patients' access to safe and affordable medicines and to support health innovation in the EU pharmaceutical industry. The strategy aims to address the life cycle of medicines from R&D to authorisation and patient access, how Europe can better translate scientific and technological advances into practice, how to tackle unmet needs for European citizens, and to implement lessons learnt from COVID-19 pandemic on how to better prepare for future health crisis.

EuropaBio's Director General, Dr. Claire Skentelbery, stated today: *"It is a privilege to start my new role in EuropaBio just as the publication of the Pharmaceutical Strategy is sending a wave of anticipation throughout the life sciences and biotechnology community. Today, the European Commission has delivered a long-awaited strategy that will underpin the next generation of European intellectual, economic, and patient benefits. EuropaBio looks to engage in a concerted effort for successfully establishing HERA, creating a European Health Data Space, achieving better regulatory efficiency, in particular in the area of gene and cell therapies, and sharpening the EU's competitive edge through strong incentives for innovation. The strategy offers the potential for the EU to reclaim its position as a leader in life sciences and enable it to respond quickly and strongly to future health threats and contribute to a healthy society in Europe."*

The COVID-19 pandemic has revealed the critical role of innovation for citizens and patients, particularly through SMEs using biotechnology, in dealing with health emergencies. Over the last months, nearly 75% of the 800 R&D programmes launched for COVID-19 come from small and medium-sized biotechnology companies, indicating the sheer potential of the EU biotech sector – all COVID-19 vaccines about to be approved are based on biotechnological modalities.

The European biotech and biopharmaceutical sector, mostly represented by SMEs, relies on a robust and competitive intellectual property framework and a set of targeted incentives that enable companies to raise financing in order to develop new treatments,



even with the prospect of remaining unprofitable for years. It is thanks to this set of incentives that Europe has retained its ability to be a source of cutting-edge innovation along with the US, Japan and increasingly China.

Commenting on the Commission's vision for market incentives, Dr. Skentelbery added: *"We would like to invite the European Commission to assess possible refinements of this framework against their potential impact on the rate of innovation and on EU's standing against global competitors. We should remember that the highly novel medicines and vaccines developed today, and in the future, heavily rely on these incentives, and access is always preceded by high-risk innovation."*

The creation of an EU Health Emergency Authority (HERA) is a unique opportunity to create new R& D approaches to which EuropaBio is eager to contribute.

In terms of initiatives around regulatory efficiency, Dr. Skentelbery commented: *"We welcome the Commission's plan to streamline the application of GMO requirements for the conduct of clinical trials with life-transforming gene therapies and strongly recommend that a full exemption scheme is considered."*

Improved regulatory convergence and global harmonisation in international standards, as well as a more supportive approach to innovative clinical trial designs, combined with sound and simpler regulatory approval processes, will help to achieve enhanced EU life science and biotech competitiveness.

The acceleration of a European Health Data Space, assuring timely access to standardised data sets and streamlined GDPR implementation across the EU, would enhance data use for cross-border scientific collaboration in the vibrant life sciences and biotechnology innovation ecosystem. High-quality Real-World Evidence and Artificial Intelligence must be harnessed as part of the planned EU Health Data Space.

Dr. Skentelbery continued to underline: *"We expect a holistic strategic approach supporting a long-term vision and increased investment for Europe's effective world-class life sciences and biotechnology innovation ecosystem. This is a sine qua non for achieving a healthy future of the EU citizens and economy."*

EuropaBio looks forward to working closely with the European institutions to ensure the Pharmaceutical Strategy delivers for European patients and establishes a framework that enables a successful life sciences sector for the medium to long-term.

ENDS

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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 75 corporate members and 17 national biotechnology associations and bioregions.

Read more about our work at www.europabio.org.

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