

EuropaBio proposes how to increase competitiveness of biotechnology sector in the EU

PRESS RELEASE

EuropaBio response to the EU general pharmaceuticals legislation

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COVID-19 has shown that only science-based and high-risk research embedded in a strong life science industry ecosystem can bring the lasting solutions to health challenges. **“Revision of European pharmaceutical legislation creates an opportunity to create a future-proof and patient-oriented biotechnology sector in the EU.”, says Dr Claire Skentelbery, Director General of EuropaBio.**

Therefore, we caution against the current temptation to use the regulatory tools designed for medicines authorization to address availability issues that are clearly within the remit of Member States.

To regain EU’s global leadership, EU has to become a home for R&D, simultaneously ensuring that and a cutting-edge industry secures high-quality and affordable care for citizens. Improved access to accelerated innovation, long-term vision for the healthcare ecosystem and better coordination among Member States will enable the EU to respond to future health threats more efficiently.

EuropaBio, the association representing companies of all sizes, plus 15 national associations and their 1500 SMEs, cautions against (well-intentioned) interference into the remit of Member States and use of regulatory tools designed for medicines authorization to solve issues related to the availability of medicines.

Whilst equal access to medicines across the EU is a shared goal, members of EuropaBio believe that placing them on the market should not be linked with incentives. Utilising soft law policy instruments instead of legislative changes might be considered to enhance access to and uptake of medicines, in order to increase



application of novel agreements and attractiveness of clinical trials in the EU, to manage environmental risk and ensure security of supply.

‘No patient should be left behind or prioritised over another’, - says Bernard Grimm, Director of Healthcare Policy of EuropaBio. Health conditions with no treatment, and those with insufficient treatments where quality of life can be improved, should be both prioritised. Simplifying processes across Member States may improve access and availability of medicines significantly.’

The EU biotech sector, mostly made up of SMEs, relies on robust IP and targeted incentives that enable companies to raise risk capital. Many of the companies remain unprofitable until their scientific breakthrough become commercially viable. To keep pace with the rest of the world, future EU incentives should reflect the economic challenges of developing and bringing health innovation to patients.

The uptake of digital tools not only improves R&D, but also optimises diagnostics and treatments, while increasing cost-effectiveness of healthcare systems. An appropriate legislative framework is needed to ensure common EU standards for the collection, interoperability, access and use of data.

EuropaBio supports all initiatives aimed at enhancing security of medicine supply. Working together with manufacturers to ensure stable supply mechanisms is the most efficient way to achieve secure supply of medicines.

Reduced regulatory burden accelerated production of COVID 19 related products. Thus, easy to navigate, swift and up to date regulatory processes shall be applied in critical areas of unmet needs based on COVID-19 learnings. EU needs legislation to make GMO assessment process through an exemption scheme easier and faster. A flexible PRIME scheme with earlier access, capacity to provide rapid scientific advice and regulatory input extended to new indications of existing products would accelerate innovation. Fit-for-purpose RWE for regulatory benefit-risk assessment should be accepted to drive clinical development. Decentralised and single-arm clinical trials should be accepted to speed up access to novel technologies.

This result of this review is critical to the growth of the EU biotech industry and the health of European patients. EuropaBio is eager to work with the Commission to achieve an innovation supportive outcome.

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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 corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 1800 biotech SMEs. Read more about our work at www.europabio.org.

