

EuropaBio: Revision of the EU general pharmaceuticals legislation for a healthier tomorrow

PRESS RELEASE

Brussels, December 22, 2021 – yesterday, EuropaBio, the European Association for Bioindustries, submitted responses to the [open consultation on the revision of the EU general pharmaceuticals legislation](#), and the [targeted survey supporting the revision](#). Our members highlighted their belief that leveraging the full potential of biotechnology is fundamental to reposition the EU as a global leader in cutting-edge medicine R&D.

“In the context of global challenges and accelerated science, the ambition of the pharmaceutical legislative revision should be to transform the EU’s strong research base into breakthrough innovation to better address the health needs of Europeans and to regain EU’s global leadership as a home for R&D and cutting-edge industry.”, says Bernard J. Grimm, Healthcare Biotechnology Director.

To truly capitalise on the potential biotechnology offers, the EU needs a streamlined, flexible and coherent regulatory system. A focus on increasing the attractiveness of the EU as a region to conduct first-launches of new treatments is key. Our members spoke to the need for competitive assessment timelines and iterative scientific advice, in particular for SMEs. To support this, adequate resourcing and funding of EMA is necessary to keep pace with evolving regulatory approaches globally, such as the increased use of RWE.

EuropaBio members seek to make their medicines available to as many patients, and in as many countries, as early as possible. However, a plethora of issues relating to the accessibility of medicines lie outside industry and EU control, such as national pricing and reimbursement policies that depend on Member State health systems’ organisation and administration. We believe improving coordination between EMA and Member States can accelerate patient access to new advances in health innovation at EU level. More effective pricing and reimbursement systems in Member States, that avoid duplication of HTA and payer requirements, would lower administrative burden for SMEs.

For EU life sciences and biotechnology companies to prosper a competitive environment conducive to furthering clinical research needs to be in place. **Proper incentivisation of R&D, in addition to upholding**



necessary intellectual property protections, allows the development of biotechnology and encourages investment and risk-taking for innovation.

The last comprehensive review of the pharmaceutical legislation was tabled almost 20 years ago, since then, healthcare has rapidly advanced thanks to advances in biotechnological R&D. The future of medicine is evolving from traditional one-size-fits-all medical care to personalised medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients. **A future-driven review of the pharmaceutical legislation is needed to bring the next generation of biotechnology medicines to patients across Europe.**

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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, plus national biotechnology associations and bioregions.

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

