EuropaBio meets EMA to exchange views on topics of common interest

NEWS RELEASE

On 5 May 2021, a virtual bilateral meeting took place between the European Medicines Agency (EMA) and EuropaBio. The purpose of the meeting was to exchange views and promote dialogue on topics of common interest, such as the biotechnology pipeline and future key trends, international regulatory convergence, and preparing the EU regulatory environment for the next wave of innovative products.

EMA Executive Director Emer Cooke emphasized that the ongoing evaluation and upcoming revisions of the basic EU pharmaceutical legislation in the context of the EU Pharmaceutical Strategy is a unique opportunity to improve regulatory processes.

In view of the need for the EMA and the EU Network of Medicines Agencies to build expertise and guidance in accordance with the future pipeline, EMA showed a lot of interest to receive more information on the new technologies and innovation, particularly concerning the pipeline of advanced therapies, which are expected to come to scientific assessment and to the market in the next 5-10 years.
EMA is a strong believer in the biotechnology sector as a powerful source of human medicine innovation.

"We are absolutely convinced that biotech is going to bring in wonderful innovation to market. The timing is really interesting and EMA has invested in the development of its Regulatory Science Strategy to 2025 which put innovation at its heart and has been later reinforced by the Regulatory Strategy of the European Network of Medicine Agencies. We are in the middle of a very ambitious new EU Pharmaceutical Strategy. It is a once-in-a-generation opportunity to make a stereo change in the EU innovation ecosystem.", commented an EMA representative at the meeting.

To further support innovation and speed up patient access, EuropaBio encouraged the adoption of fit-for-purpose real world evidence in clinical trials as well as of

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innovative approaches to clinical trials, reinforced by the use of digital tools, such as decentralised and single-arm trials. EuropaBio has also called upon the Agency to build upon the learnings from the COVID-19 regulatory response and streamline the regulatory process, e.g. through the admission and staged assessment of incoming scientific evidence and remote source data verification in clinical trials. EMA showed willingness to discuss and meet with EuropaBio on a yearly basis.

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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 2500 biotech SMEs. Read more about our work at www.europabio.org.