

EPSCO Council conclusions: EuropaBio calls for more pragmatic approach addressing access, availability and affordability of medicines

PRESS RELEASE

EuropaBio shares the EPSCO focus on improving the access, availability, and affordability of innovative medicines in the EU, through closer cooperation between Member States and their national medicine agencies, competent authorities, the European Commission and the European Medicines Agency.

‘Whilst we support the Council’s conclusions, we encourage a reality check applied to all key aspects of access, availability and affordability of medicines. Only through better stakeholder involvement in complex processes, and better cooperation between Member States, national agencies, the European Commission and the European Medicines Agency can significant improvements be delivered. Finally, ongoing activities around pharmaceutical legislation revision, in which EuropaBio is actively involved, could facilitate stakeholder inclusion and contribute to a both holistic and pragmatic approach.’, says Dr Claire Skentelbery, Director General of EuropaBio.

Availability

On availability of innovative medicines, we call on the European Commission and national health ministries to take decisive and long-needed steps to achieve better regulatory efficiency, through:

- making EU regulatory processes easy to navigate, swifter and up to date with science and technology to truly support innovation by ground-breaking biotechnology SMEs.
- expediting regulatory pathways in critical areas of unmet needs. For example, this could **partially** be achieved through simplifying and accelerating GMO assessment processes (e.g. via an exemption scheme for clinical trials with investigational advanced therapies), and through a flexible PRIME scheme with clear and accelerated access pathways for eligible products, combined with the capacity to provide rapid scientific advice.



- accepting fit-for-purpose RWE for regulatory benefit-risk assessment to drive clinical development, and decentralised and single-arm clinical trials to speed up access to novel technologies.

EuropaBio welcomes the Council's acknowledgment that incentives for innovation "support the development of new effective and accessible medicines and medical devices." This has proven especially true, as shown by the significant increase in the number of new medicines developed for rare diseases. Following the introduction of incentives for the development of rare diseases in the year 2000, over 2200 treatments in development were granted "orphan" status¹.

Accessibility

On access, EuropaBio welcomes the Council's encouragement to further stimulate R&D in areas of unmet medical need (UNM). However, the definition of unmet medical need should remain broad, as UNM does not only exist in conditions with no currently approved treatment. Many conditions, for which treatments exist, continue to suffer from UNM and can be significantly improved (e.g. reducing disease severity, treatment burden, or increasing life expectancy etc.) Any additional incentives aimed at encouraging R&D in these conditions should complement, not replace, existing incentives in order to build upon prior successes. Finally, we believe it is of utmost importance that principles, criteria, or guidelines on UNM must be developed in a multi-stakeholder forum, where the patient's voice is at the forefront.

We would like to note that cell and gene therapies require highly specialised physicians and hospitals working in networks of reference centres. For rare diseases with limited patient numbers, it is impractical for each Member State to have a dedicated treatment centre, which needs to treat a certain number of patients per year to ensure that trained and certified medics deliver high-quality treatment. It is through better-functioning EU cross-border healthcare legislation that we can ensure patients have access to specialised treatments and novel therapies when these are not available in their home country.

Affordability

On affordability, we stress the emergence of highly targeted and effective biotechnology-derived advanced therapies opening new treatment horizons in the area of complex genetic and rare diseases which necessitate the employment of new pricing models. Through the structured dialogue of the Industrial Strategy we support the further enhancement of manufacturing agility and flexibility by adopting modern continuous and modular manufacturing approaches, modernisation of key advanced manufacturing technologies, and the innovative manufacturing and supply needed to deliver both existing and new therapeutic modalities.

Digital technologies including Artificial Intelligence, Machine Learning, Robotics will help to streamline manufacturing and supply processes and increase process management along the supply chain to mitigate shortages, and enhance quality

¹ https://www.ema.europa.eu/en/documents/report/annual-report-use-special-contribution-orphan-medicinal-products-2020_en.pdf



decision making. Measures for sustainable manufacturing & supply in response to climate change, and innovation in energy efficiency contributing to a circular economy should be in the forefront. However, they should be managed in such a way that they support a competitive and efficient European life sciences and biotechnology industry. EuropaBio recommends that priority areas in advanced manufacturing be identified for investment to enable a competitive and continuous transformation of the sector.

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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 2600 biotech companies, 2300 out of them are SMEs.

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