European Commission Biotech initiative must spearhead next wave of EU biosimilar advances for patients and stimulate manufacturing

Date of release: 20 March 2024

Biosimilar medicines were invented in Europe over 15 years ago. Since then, they have increased patient access to essential biologic medicines needed to treat the most serious of diseases like cancer, autoimmune conditions and diabetes by well over 50%.

Our sector has already grown to represent over 20% of the volume of the accessible biological medicines market and this is expected to grow significantly up to 2030 with the upcoming loss of exclusivity of important molecules. This home-grown EU innovation has also spurred investment into new biologic manufacturing plants across Europe (Austria, Germany, Poland, Spain, Hungary, Slovenia, among others).

For healthcare, the smart use of biosimilar medicines has generated cumulative savings of more than 50 billion euros since 2006, with 10 billion of that in 2023 alone. European patients have benefitted from a cumulative 5.8 billion treatment days' worth of positive experience with biosimilar medicines.

To better support this key healthcare sector, the European Biotech and Biomanufacturing initiative must:

- **Nurture Europe's skilled workforce, know-how, experience, and global leadership on biosimilar medicines** by ensuring access to any relevant funding instruments.
- **Develop an inclusive industrial policy for all biotech actors including the biosimilar medicines sector,** since all EU biomanufacturing sectors must adhere to the same level of EU quality standards and regulation.
- **Ensure Europe sustains its leadership in the international biotech ecosystem and is equipped to invest in timely evolution, improvement and transformation** of its biotech R&D and manufacturing capabilities towards new technological platforms**.**
- **Consider an integrated policy approach so that European industrial policy considerations are jointly tackled with other pharmaceutical and health policy topics**, and which covers the entire life cycle of a biological medicine (development, authorisation, market entry, competition), including consideration for the specific nature of follow-on multi-source biologic medicines industrial sector.

Resource hub

The details of the European Commission *Communication on Building the future with nature: Boosting biotechnology and biomanufacturing in the EU* can be found at https://ec.europa.eu/commission/presscorner/detail/en/IP_24_1570

Data quoted on biosimilar medicines experience can be accessed at The Impact of Biosimilar Competition in Europe' (2023), https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2023

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The Biosimilar medicines group

The Biosimilar Medicines Group is a sector group of Medicines for Europe representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 15 years of positive patient treatment experience, biosimilar medicines today provide a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients in Europe and around the world, and supporting the sustainability of the European healthcare systems.