Biosimilar drugs: consultation on streamlining their development and evaluation

● In September 2025, Prescrire responded to a consultation by the European Medicines Agency (EMA) on its requirements in relation to the development and evaluation of biosimilars.

Healthcare policy

The draft reflection paper released for public consultation by the European Medicines Agency (EMA) set out a series of proposals for improving the development and evaluation of biosimilar drugs (copies of originator biologic drugs), while maintaining safety standards (1). The objective of this initiative is to reduce the amount of clinical data that companies are required to provide.

In the early 2000s, European legislation introduced strict regulatory requirements for the marketing authorisation application process for biosimilars. A company seeking to market a biosimilar drug is not allowed to refer to the marketing authorisation application for the originator drug, and is instead required to provide new clinical data, in particular to demonstrate equivalence with the originator product. In its response to the consultation, Prescrire cited numerous examples and reports to show how these requirements have held back the development of cheaper biosimilars, especially those with orphan drug status. This may also jeopardise the long-term future of European Union member states' national health insurance systems.

Prescrire welcomed the EMA's initiative to streamline biosimilar development (2). It urged the EMA to require biosimilar companies to produce high-quality packaging. In addition, it called on the EMA to make available all of the data on each originator drug and its biosimilars, in order to facilitate decisions at the national level about pricing, reimbursement, prescribing and substitution by pharmacists.

In its response, Prescrire also condemned the strategies employed by originator companies to block competition and biosimilar substitution. The EMA has a key role to play in anticipating and facilitating national decision-making to promote the use of biosimilars.

In summary, in Prescrire's view, anything that can be done to ensure patient safety, while also reducing unnecessary costs linked to the development and evaluation of biosimilar drugs, will help to accelerate the market introduction of such drugs, and reduce costs for member states.

► Translated from *Rev Prescrire* May 2026 Volume 46 N° 511 • Page 381

References 1- EMA "Draft reflection paper on a tailored clinical approach in biosimilar development" 17 March 2025: 17 pages. **2-** "Prescrire's response to a public consultation of the EMA on a draft reflection paper on a tailored clinical approach in biosimilar development" 17 September 2025: 50 pages.