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Short communication

Towards a sustainable biologic medicine's ecosystem: integrating innovation and competition

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Introduction

The biologic medicines ecosystem faces a fundamental policy challenge: sustaining incentives for pharmaceutical innovation while ensuring long-term affordability, access, and capacity to support future therapeutic advances.

As originator biologic medicines lose exclusivity, biosimilar competition can reduce treatment costs and create financial headroom for other health priorities. The instrument of "financial headroom" is budgetary capacity created when biosimilar savings are realized and become available for reinvestment. Innovation incentives and biosimilar competition can shape this cycle, and governance mechanisms could strengthen the contribution of biosimilar savings to access to innovative therapies and responses to unmet and evolving medical needs.

This short communication examines the health policy and regulatory literature across three areas: (i) innovation incentives, including patents and regulatory exclusivities; (ii) competition mechanisms, including biosimilar approval, procurement, and adoption; and (iii) governance mechanisms for capturing, reporting, and potentially reinvesting savings generated through biosimilar competition.

Innovation incentives

Bringing a single innovative medicine to market can cost up to $2.6 billion and take 10 to 15 years from discovery to approval (Guo, 2025) These substantial costs, long development timelines, and scientific uncertainties underscore the importance of maintaining appropriate incentives for innovation. Patent protection, supplementary protection certificates (SPCs), and other regulatory exclusivities provide a period of market exclusivity that enables innovators to recover their investments and supports continued innovation (Grabowski et al., 2011). This is particularly relevant given recent trends in pharmaceutical R&D across Europe. Between 2010 and 2022, pharmaceutical R&D spending grew by 4.4% annually in Europe, compared with 5.5% in the United States and 20.7% in China (EFPIA, 2024). At the same time, population ageing and the increasing prevalence of chronic and complex diseases are expected to increase demand for new and improved therapies. Maintaining incentives for innovative biologic development is therefore important not only to sustain the pipeline but also to address areas of persistent unmet medical need.

Competition mechanisms

Following loss of exclusivity, biosimilar competition can generate substantial savings. By 2025, cumulative list-price savings from biosimilar

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competition in Europe were estimated at €75 billion (IQVIA, 2026). However, only around 10% of the approximately 100 originator biologics expected to lose exclusivity in the EU by 2032 are currently projected to face biosimilar competition (IQVIA, 2026). Biosimilar development remains concentrated in medicines with large patient populations or high treatment costs, where commercial returns are greatest (IQVIA, 2026). Market design also shapes commercial attractiveness: procurement models with few winners and intense price competition may discourage sustained manufacturer participation (Barbier et al., 2021). Expanding biosimilar competition therefore requires a market that remains sufficiently attractive for manufacturers to enter and remain in.

Regulatory efforts may also strengthen incentives for biosimilar manufacturers by reducing regulatory requirements and development costs. In 2026, the European Medicines Agency adopted a reflection paper proposing a tailored clinical approach to biosimilar development. Under this approach, well-characterized biosimilars demonstrating high analytical and functional comparability may, in certain instances, not require comparative efficacy studies. Instead, biosimilarity may be supported by comparative pharmacokinetic data together with appropriate safety and immunogenicity assessments (EMA, 2026). By reducing the need for comparative efficacy studies in selected cases, this approach could lower development costs and encourage broader biosimilar entry. However, generating savings requires not only biosimilar availability and price competition but also clinical adoption by prescribers and patients.

Governance and financial headroom

Biosimilar competition can generate financial headroom for future therapeutic priorities, but the savings realized vary across countries and therapeutic areas (IQVIA, 2026). While the EU has established a common framework for assessing the clinical value of certain new medicines through joint health technology assessments, no equivalent mechanism tracks biosimilar savings (European Parliament & Council of the European Union, 2021). A two-level governance model could address this gap without centralizing national spending decisions: the EU would establish common standards for reporting and monitoring biosimilar savings, while Member States would retain responsibility for reinvestment according to national priorities. Governance should also consider smaller Member States, where limited biosimilar savings may constrain reinvestment despite substantial unmet medical need.

Conclusion

The opportunity to strengthen the sustainability of the biologic medicine's ecosystem lies not simply in generating savings through biosimilar competition, but in governing those savings so that the financial headroom created today can support access to innovative therapies and timely responses to unmet and evolving medical needs.

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