These studies also raise the question of the degree to which the fines imposed have a deterrent effect. Over the past five years, such fines have totalled €780 million: a pittance in comparison to the global revenues of pharmaceutical companies, which reached, for example, $1.29 trillion in 2021 alone, with the European market accounting for one-quarter of sales (1,12). This disparity, which may explain why the fines imposed by the Commission and national authorities have had little impact, highlights the urgent need for tougher penalties in order to effectively deter companies from employing tactics designed to hinder the market entry and uptake of generics and biosimilars.

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Biotechnologies: proposed European legislation underpinned by a biased approach

● Prescrire has warned the European Commission about the risks associated with reducing the regulatory requirements on drugs and medical devices derived from biotechnology.

In November 2025, Prescrire responded to a public consultation held by the European Commission to seek input on its future European Biotech Act (1). According to the Commission, the objective of this initiative is to "*improve the size and competitiveness of the biotechnology sector in the European Union while maintaining high safety standards*" in the field of health, as well as those of farming, forestry and industry (2).

Prescrire was critical of the biased nature of some of the questions asked as part of the consultation, which assumed the existence of regulatory obstacles impeding access to biotechnologies and the implicit need to introduce simplification and rationalisation measures. The approach taken by the Commission thus favours the interests of industry, rather than focusing on the protection of public health and the public interest.

Prescrire also called for drugs and medical devices to be covered by specific legislation rather than as part of an overall biotechnology regulation, given the risks that the use of these health products may pose to patients.

Prescrire emphasised that the reform of the 2017 Medical Devices Regulation is not sufficient to ensure patient safety. The examination of medical devices prior to their market introduction is subcontracted to certification organisations called "notified bodies", most of which are privately operated. Prescrire takes the view that medical devices should be evaluated by a centralised public-sector European agency, as is the case with drugs.

Prescrire called for health products to be covered by more stringent regulatory requirements, in relation to the quality of evidence to be provided and good manufacturing practices. Randomised clinical trials with clinical endpoints that are relevant to patients, such as mortality and quality of life, should be the norm.

The European Commission published the first part of its proposed Biotech Act in December 2025 (3). We will discuss this proposal in a future issue.

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Volume 46 N° 511 • Page 387

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