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Answer given by Mr Várhelyi
on behalf of the European Commission
(24.9.2026)

The President of the Commission announced in her Political Guidelines of July 2024 a Biotech Act by 2025¹. The need to act swiftly was highlighted in the Draghi Report² and echoed by stakeholders given the strong economic, social and public health potential of the health biotech sector. The Commission extensively consulted a broad range of stakeholders and commissioned several supporting studies. This resulted in two well-grounded, evidence-based proposals³ (collectively referred to as the 'Biotech Act') and a Staff Working Document⁴, prepared in line with Better Regulation rules, that brings together all the evidence and assesses the expected impacts of the proposal.

The industrial policy measures included in the proposed Biotech Act foster, with a specific focus on health, food and feed, multi-country cooperation and information sharing, thus building on the capabilities of all Member States. The measures also provide for the establishment of a European Health Biotechnology Steering Group⁵ where all Member States would be represented and, together with the Commission coordinate their implementation.

The proposed Biotech Act includes measures to accelerate and streamline the assessment of clinical trial applications, which support the development of health treatments and medicines and are an opportunity to give patients early access across the EU. Moreover, other initiatives, like the reform of the EU pharmaceutical legislation⁶, the Critical Medicines Act⁷ and the Health Technology Regulation⁸ aim to improve availability of medicines in the EU. In addition, the European Reference Networks⁹ facilitate cross-border exchange of expert knowledge to improve the diagnosis and treatment of rare and complex diseases across the EU.

¹ Political Guidelines 2024-2029, p. 11: https://commission.europa.eu/document/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en.

² https://commission.europa.eu/topics/competitiveness/draghi-report_en.

³ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs COM/2025/1031; and Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) COM/2025/1022.

⁴ Commission Staff Working Document accompanying the proposal for a European Biotech Act (C(2026) 3375 final) - Public Health https://health.ec.europa.eu/publications/commission-staff-working-document-accompanying-proposal-european-biotech-act-c2026-3375-final_en.

⁵ COM/2025/1022, Article 20.

⁶ COM/2023/193 final and COM/2023/192 final.

⁷ COM(2025) 102 final.

⁸ Regulation (EU) 2021/2282.

⁹ Directive 2011/24/EU, Article 12.