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Answer given by Mr Várhelyi
on behalf of the European Commission
(23.6.2025)

1. The Commission is in the preparatory phase of the Biotech Act¹. The Commission will conduct extensive consultations with stakeholders to determine the most appropriate measures to translate innovation in the field of biotechnology into products which can be brought to the market and benefit citizens. The Act will cover different sectors of biotechnology, in particular health. Its actions on the health sector will indirectly also benefit patients suffering from autoimmune diseases.
2. The reform of the EU's general pharmaceutical legislation², currently being discussed by the co-legislators, includes many measures to streamline and modernise the regulatory framework to foster and facilitate innovation especially for breakthrough therapies. The Biotech Act could complement the pharmaceutical reform for example in facilitating the authorisation of clinical trials in the EU.
3. The pharmaceutical reform proposes incentives for research in areas of unmet medical needs through additional regulatory protection and pre-authorisation regulatory support. In particular, early advice in the framework of PRIME programme will facilitate timely access to medicines that bring significant innovation. It also introduces incentives in the field of repurposing existing medicines to new indications especially in case of unmet medical needs.

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act_en.

² COM/2023/193 final and COM/2023/192 final.