

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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EU legislation requires rigorous assessment and authorisation of new treatments ensuring the quality, safety and efficacy of approved medicines.

Supply of advanced therapy medicinal products (ATMPs) in the EU requires a marketing authorisation, an approved clinical trial, or a nationally-approved hospital exemption.

Patients with severe illnesses may also access unauthorised medicines through compassionate use¹ with Member States required to notify the European Medicines Agency to maintain transparency and coordination, offering controlled early access and mitigating 'therapy tourism' risks.

While it is concerning that experimental therapies are marketed directly to patients through online platforms and social media, it is important to emphasise that the EU and national regulators are vigilant and actively working to ensure patient safety.

The European Medicines Agency and Heads of Medicines Agencies Network have issued joint statements outlining the risks associated with unregulated advanced therapies. The most recent statement, in March 2025², provides practical guidance for patients and caregivers on how to identify unregulated therapies.

The new EU pharmaceutical legislation also clarifies hospital exemption rules for ATMPs, tightening oversight to close loopholes that could be exploited for unproven therapies.

The Commission remains fully committed to the implementation of existing actions under Europe's Beating Cancer Plan³, which support better access to high-quality and safe treatments. For example, last year, the Joint Action EUnetCCC launched the EU Network of Comprehensive Cancer Centres⁴ with the aim of improving eligible patient access across Europe by 2030.

¹ Article 83 of Regulation (EC) No 726/2004.

² https://www.ema.europa.eu/en/documents/public-statement/unregulated-advanced-therapy-medicinal-products-pose-serious-risks-health_en.pdf.

³ https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf.

⁴ <https://eunetccc.eu/>.