

(English version)

**Question for written answer E-004465/25
to the Commission
Giuseppe Antoci (The Left)
(11 November 2025)**

Subject: Access to innovative cancer drugs and suspension of compassionate use programmes in Italy

The Food and Drug Administration (FDA) recently used an accelerated procedure to approve Tarlatamab ⁽¹⁾ for the treatment of small-cell lung cancer.

According to press reports and a parliamentary inquiry submitted to the Italian Senate ⁽²⁾, the company has suspended its compassionate use/early access programme for the drug in Europe thus making it unavailable to patients and forcing the interruption of treatment plans.

There are already compassionate use programmes for another innovative drug, lurbinectedin, and regulatory procedures for it are under way at the EMA ⁽³⁾, but patient access in the various Member States and in Italy remains fragmented and uneven.

Can the Commission therefore say whether:

1. It is aware of why compassionate use and early administration programmes for Tarlatamab were suspended in Italy or other Member States?
2. How it intends to ensure European patients have fair, timely and non-discriminatory access to innovative cancer treatments, specifically both Tarlatamab and lurbinectedin, in exercise of their rights?

Submitted: 11.11.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(23 January 2026)**

The Commission is not aware of any official information from the concerned company indicating the suspension of the expanded access programme (so called compassionate use) in Italy or other Member States.

It should be noted that *Tarlatamab* is currently undergoing the scientific evaluation for a marketing authorisation in the EU, as shown by the agenda of the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use meeting on 10-13 November 2025 ⁽¹⁾.

The Commission is committed to addressing the issue of access to innovative and affordable medicines for all EU citizens, while respecting the competence and decisions of Member States on pricing and reimbursement of medicines.

The adopted proposal for a reform of the general pharmaceutical legislation ⁽²⁾ will strengthen patients' access to medicines by streamlining administrative requirements and shortening timelines.

Other measures such as simplified procedures, support for small and medium enterprises, and reorganisation of the EMA aim to improve the availability of innovative medicines in all Member States.

In addition, the proposed Critical Medicines Act provides for voluntary collaborative procurement of critical medicines and other medicines of common interest, which could include innovative cancer treatments, subject to certain thresholds and criteria.

The Commission also supports the cooperation among Member States on pricing, payment and procurement policies, for instance through the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR).

¹ <https://healthstories.it/tarlatamab-tumore-polmonare/#:~:text=Tarlatamab%20%C3%A8%20una%20molecola%20definita,una%20proteina%20bersaglio%2C%20la%20DLL3.>

² [https://www.senato.it/show-doc?leg=19&tipodoc=Sindisp&id=1466800&idoggetto=0#:~:text=la%20Food%20and%20drug%20administration%20\(FDA\)%20ha,ha%20mostrato%2C%20nei%20trial%20clinici%2C%20miglioramenti%20significativi.](https://www.senato.it/show-doc?leg=19&tipodoc=Sindisp&id=1466800&idoggetto=0#:~:text=la%20Food%20and%20drug%20administration%20(FDA)%20ha,ha%20mostrato%2C%20nei%20trial%20clinici%2C%20miglioramenti%20significativi.)

³ <https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-23-2876>.

⁽¹⁾ See the Agenda and Annex to Agenda of that 10-13 November 2025 meeting: https://www.ema.europa.eu/en/documents/agenda/agenda-chmp-meeting-10-13-november-2025_en.pdf.

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