

**Question for written answer E-004465/2025
to the Commission**
Rule 144
Giuseppe Antoci (The Left)

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 Tarlatamab¹ for the treatment of small-cell lung cancer.

According to press reports and a parliamentary inquiry submitted to the Italian Senate², 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 EMA³, 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

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.>