Question for written answer E-002616/2024
to the Commission
Rule 144
Maria Grapini (S&D)

Subject: Withdrawal of Ataluren for patients with Duchenne muscular dystrophy

Romanians and other Europeans suffering from Duchenne muscular dystrophy and being treated with Ataluren are in a desperate situation. Many EU citizens with Duchenne muscular dystrophy have written to me saying that Ataluren should not be withdrawn from the European medicines market. Despite the fact that the Commission rejected the recommendation by the European Medicines Agency (EMA) to withdraw the medicine from the market and explicitly requested that all measures and evaluations undertaken so far by the EMA/CHMP be cancelled, on 17 October 2024 the EMA/CHMP decided to renew the recommendation to withdraw the medicine from the market.

It should be stressed that Ataluren is the ONLY possible effective and risk-free treatment for such patients with a nonsense genetic mutation, who number over 800 in the European Community. Without this treatment, all those patients are condemned to die!

What will the Commission do to ensure that all the clearly positive aspects of this treatment, along with the Commission’s requests, are taken into due consideration by the EMA/CHMP?

Submitted: 21.11.2024