Question for written answer P-000730/2019
to the Commission
Rule 130
Richard Corbett (S&D)

Subject: Authorisation of Olaratumab (Lartruvo) in the European Union

On 23 January 2018, the European Medicines Agency (EMA) announced that patients in Europe should no longer be treated with Olaratumab (Lartruvo), an orphan medicine approved by the Commission in 2016, on account of a disappointing phase three clinical trial. Olaratumab, manufactured by US-based pharmaceutical company Eli Lilly, had received a conditional marketing authorisation, subject to further clinical trial results.

What is the Commission doing to ensure that Eli Lilly will conduct and communicate to the EMA, Commission, health professionals and patients a thorough analysis to understand why the phase three clinical trial failed?

According to the EMA, about 1 000 patients in Europe are still being treated with Lartruvo. What is being done to ensure that these patients continue to be monitored in a structured way, to assess the impact of the treatment on their health and shed light on the discrepancy between the phase three trial and the previous assessments, and will the Commission ensure that Eli Lilly continues to fund research into Lartruvo, given the very strong results leading to its conditional authorisation?

What is the Commission doing to ensure European patients suffering from soft-tissue sarcoma are fully informed about all treatment options available in the EU, given its rarity in individual Member States?