Question for written answer P-000817/2019
to the Commission
Rule 130
Kathleen Van Brempt (S&D)

Subject: Orphan medicinal products

The Belgian press has recently reported a shocking case in which the pharmaceutical industry has manipulated the market and abused European legislation governing orphan medicinal products. In particular, this case concerns the Italian pharmaceutical company Leadiant Biosciences, which in recent years has bought up all the producers of the essential medicine CDCA and then closed them down one by one. This has given the Italian company a monopoly. The company has subsequently had CDCA registered as a treatment for the rare disease CTX, and the product has acquired the status of an 'orphan medicinal product for the treatment of CTX'. The price of the medicine has already been increased 335 times over ten years. More specifically, whereas ten years ago patients paid EUR 38 for a month of medication, today they have to pay EUR 12 750 for the same amount.

In my opinion, this is a blatant abuse of the European Regulation of 16 December 1999 on orphan medicinal products, exploiting a loophole in the legislation.

1. What is the Commission's response to this specific abuse of the above-mentioned Regulation?

2. Is the Commission planning to plug this loophole in the legislation and therefore to prevent this abuse in the future?