Question for written answer E-006147/2018
to the Commission
Rule 130
Anneleen Van Bossuyt (ECR)

Subject: The sharp price increase of the drug CDCA (chenodeoxycholic acid)

I recently heard that the Italian pharmaceutical company Leadiant Biosciences – formerly: Sigma-Tau Pharmaceuticals – had multiplied the price of CDCA by five hundred times\(^1\). The drug was developed in the 1970s to treat gallstones, but it eventually appeared that it had an excellent effect on patients with the hereditary metabolic disease CTX (cerebrotendinous xanthomatosis)\(^2\).

Through cunning acquisitions in recent years, Leadiant Biosciences managed to obtain a monopoly position in all the production centres of this drug. As the drug was originally developed for gallstones, the company was allowed to remove the drug from the market with the authorisation of the European Medicines Agency, seeing that there were sufficient alternative medicines available for gallstones\(^3\).

Using a loophole in the European legislation of 16 December 1999 on orphan drugs, the company was able to reintroduce the medicine on the market, and has now, for the past ten years, been benefiting from exclusivity\(^4\). Previously, this drug cost less than 30 euro cents per pill. Today, the price is EUR 140 per pill\(^5\).

Is the Commission aware of the perverse market practices of Leadiant Biosciences?

Will the Commission take any initiative to close loopholes in the European legislation on orphan drugs?

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1. https://www.ft.com/content/e394d54e-ae16-11e8-8d14-6f049d06439c
3. Ibid.