Stichting Farma ter Verantwoording

Press release

The Pharmaceutical Accountability Foundation requests the Authority for Consumers and Markets to take action against medicines manufacturer Leadiant for abuse of its dominant market position.

Amsterdam, – On Friday 7th September the Dutch **Pharmaceutical Accountability Foundation** (official Dutch name: Stichting Farma ter Verantwoording) will submit an enforcement request to the **Authority for Consumers and Markets (ACM)** asking it to take action against the medicines manufacturer Leadiant Biosciences on account of the exorbitant price the company is asking for the product chenodeoxycholic acid (CDCA).

Leadiant is currently charging in the Netherlands €140 per capsule. This is equivalent to €153.300 per treatment-year for each person using the medicine to treat the rare metabolic illness cerebrotendinous xanthomatosis (CTX). CDCA is inexpensive to produce and, from 1976 until as recently as 2008, it was available on the market in The Netherlands at the cost of € 0,28 per capsule for the treatment of gallstones. Since 1999 the medicine was prescribed *off label* for the treatment of CTX at a cost of €308 per treatment-year. In 2017 Leadiant was granted exclusive rights to market the product in Europe for the treatment of CTX after the European Medicines Agency (EMA) approved Leadiant's CDCA for marketing and granted the medicine an orphan drug designation.

"By increasing the price by a factor of 500 for a medicine which has required only limited research by Leadiant the company is abusing its dominant position in the market" said Wilbert Bannenberg, Chairperson of the Pharmaceutical Accountability Foundation. "Our research shows that Leadiant has done everything it can to ensure that less expensive versions of the medicine produced by competitors have been taken off the European market. In this way CTX patients have been made dependant on the availability of the over-priced Leadiant product."

In its request for action the Foundation states that Leadiant's actions are in violation of Dutch competition law. The Foundation argues that Leadiant has pursued the strategy of developing a market monopoly position by obtaining the marketing rights to alternative CDCA products and cancelling existing CDCA registrations. By doing this Leadiant has created the opportunity to increase enormously the price of the only effective medicine for the treatment of CTX. As a result of the company's actions and subsequent price-hike anyone purchasing the medicine will be exploited and the Dutch health care system will lose significant amounts of money. The Foundation asks the AMC to take measures and impose a fine on Leadiant citing article 56 of the Competition Law or to take other measures to control the actions of Leadiant.

For more information:
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