Autoriteit
Consument & Markt

Summary of decision on abuse of dominant position by Leadiant

Chapter 1 of the decision of the Netherlands Authority for Consumers and Markets (ACM) within the meaning of Section 56 of the Dutch Competition Act, addressed to Essetifin S.p.A., Leadiant Biosciences S.p.A., Leadiant Biosciences Ltd. and Leadiant GmbH (jointly: Leadiant)
ACM/UIT/554938

Our reference : ACM/UIT/557164
Case number : ACM/20/041239
Date : 1 July 2021

1. ACM imposes a fine on pharmaceutical company Leadiant. Leadiant used an excessive price for selling its prescription drug CDCA-Leadiant in the Netherlands. This occurred in the period from June 2017 through December 2019. As such, Leadiant abused its dominant position. The fine is 19,569,500 euros.

2. CDCA-Leadiant is a vital drug for patients suffering from cerebrotendinous xanthomatosis (CTX), which is a rare genetic metabolic disorder. Without proper treatment, CTX patients' health will deteriorate severely, and they will eventually die prematurely. Since the 1970s, CTX is treated in the Netherlands with chenodeoxycholic acid (CDCA), which was originally used for the treatment of gallstones. If CTX patients are treated with CDCA-based drugs on time, they can live normal lifespans. For the rest of their lives, they will depend on such drugs.

3. Since 2008, Leadiant offers a CDCA-based drug on the Dutch market, Chenofalk. This drug was not developed by Leadiant itself, but was acquired from another manufacturer. In the Netherlands, this drug's maximum price at the time was 46 euros per pack of 100 capsules. In late 2009, Leadiant changed the name of the drug into Xenbilox, and it raised the price, as a result of which the selling price rose to 885 euros (including distribution fee for wholesalers), which was almost 20 times the original price. In 2014, Leadiant decided to launch a project for applying for orphan designation and marketing authorization for its CDCA-based drug for the treatment of CTX. In connection therewith, Leadiant in July 2014 again raised the price of Xenbilox, as a result of which the selling price became 3,103 euros (including distribution fee). The drug consequently became almost four times as expensive.

4. In late 2014, Leadiant was granted orphan drug designation, and, in April 2017, was granted the marketing authorization. This gave Leadiant market exclusivity for 10 years in the EU for CDCA-based drugs for the treatment of CTX. In June 2017, Leadiant released CDCA onto the Dutch market under the trade name CDCA-Leadiant, and it stopped selling CDCA under the old trade name Xenbilox. CDCA-Leadiant and Xenbilox are molecularly identical: there is no difference in

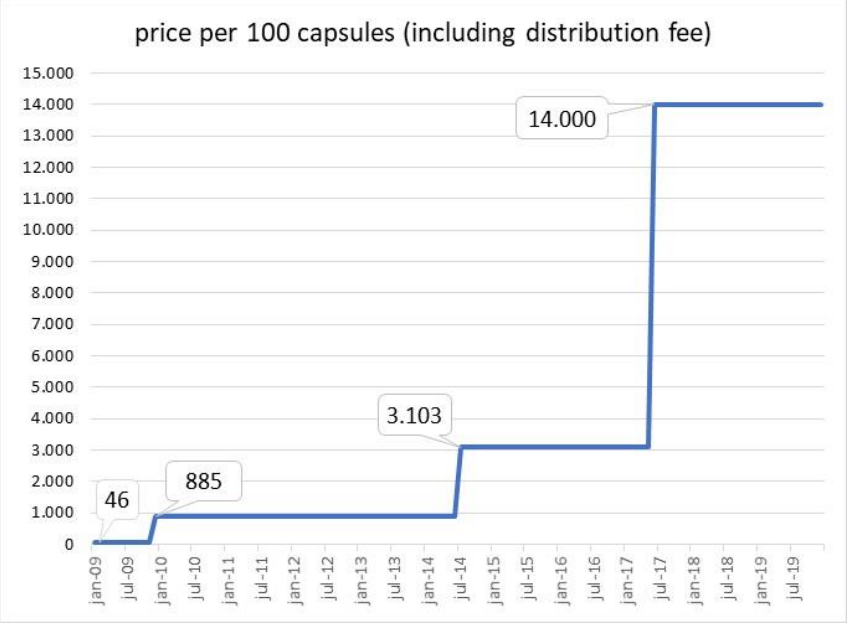
Muzenstraat 41
2511 WB Den Haag
www.acm.nl
070 722 20 00

efficacy and safety. Since then, however, Leadiant has charged and collected the much higher price of 14,000 euros (including distribution fee) for CDCA-Leadiant, more than four times the previous price. This amounts to 153,300 euros per patient per year.

5. This new price is over 15 times as high as the price of Xenbilox before Leadiant launched its project in 2014 to obtain the orphan drug designation. This price increase cannot be explained by the costs associated with the orphan drug designation and marketing authorization, since Leadiant had already recouped those costs when CDCA-Leadiant was released to the market, due to the price increase of Xenbilox in 2014. When Leadiant sold CDCA-Leadiant from 2017, too, the revenues were a multiple of the costs thereof.

6. The below figure shows the abovementioned price trend.

Figure 1: Price trend of CDCA-based drugs of Leadiant, 2009-2019



7. ACM has established that, during the violation period, Leadiant enjoyed a dominant position on the Dutch market for CDCA-based drugs for the treatment of CTX. During the entire violation period of over 2.5 years, Leadiant had a market share of 100%. CTX patients are highly dependent on CDCA, given the serious course of the disease. Other drugs such as Kolbam were no alternatives. Even though Kolbam was registered for the treatment of CTX, Kolbam was not prescribed for CTX in Netherlands. Furthermore, the pharmacy of the Amsterdam University Medical Center (UMC) in 2018 manufactured CDCA (compounding) for a few months for the treatment of CTX. Following a complaint from Leadiant however, Amsterdam UMC had to stop this production, because the raw material contained impurities. Not until January 2020 did Amsterdam UMC manage to relaunch the manufacturing of CDCA. Leadiant denies having a dominant position.

8. Leadiant also denies abusing any alleged dominant position. Leadiant has said that it had always been its intention, after negotiations, to agree on a much lower price than the price of 14,000 euros it charged. According to Leadiant, health insurers and the Ministry of Health, Welfare and Sport (VWS) deliberately thwarted the negotiations. ACM does not follow Leadiant's line of reasoning. Leadiant merely issued a few general calls for negotiations and left it at that. For over 2.5 years, it hardly tried to contact health insurers in order to launch negotiations. In addition, Leadiant did not do enough in its discussions with the Ministry of VWS. All of this does not show a supplier wishing to negotiate effectively and seriously in order to agree on a price that is not excessive. During all that time, Leadiant charged its buyers the price of 14,000 euros and collected this price.

9. As an undertaking with a dominant position, Leadiant had a special responsibility to negotiate effectively and seriously, and not to charge and collect an excessive price. That required active engagement on the part of Leadiant in order to agree a lower price than its list price. It is due to Leadiant that it continued to charge and collect a price of 14,000 euros during a considerable period, from June 2017 through December 2019, until compounding started.

10. ACM has assessed whether the price of 14,000 euros charged by Leadiant is excessive (minus the distribution fee for wholesalers). A price is considered to be excessive, and, as such, an abuse of a dominant position, if that price is exorbitantly high and unfair. This is also the case if that price is charged for an orphan drug in a situation of market exclusivity, such as in this case. It is not this market exclusivity that is under discussion, but rather the way in which Leadiant uses this exclusivity. A higher price can be justified if the manufacturer must recoup high costs or if the product offers many benefits or is innovative. ACM's investigation reveals that neither is the case with CDCA-Leadiant.

11. In order to determine whether the price was exorbitantly high, ACM assessed what costs and revenues can be attributed to Leadiant's project to obtain orphan drug designation and marketing authorization for CDCA-Leadiant. ACM has taken into account the investments Leadiant has made since the start of this project in 2014, and has also taken into account all costs that Leadiant incurred in order to manufacture and distribute the drug. In addition, ACM has taken into consideration the risk that the project could fail. With regard to the revenues, ACM has used the revenues of Xenbilox's price increase in 2014, since that price increase was part of this project, as well as all revenues from sales of CDCA-Leadiant from the moment Leadiant brought this drug to market.

12. Leadiant's CDCA project was characterized by low costs in comparison with the revenues, low risks, and a very high return. ACM comes to the conclusion that the price it charged was exorbitantly high. Leadiant would already have achieved a significant profit if it had charged less than one third of the price it actually collected. Leadiant's internal rate of return on the project was extremely high, even on the basis of conservative assumptions. In its assessment, ACM took account of a required rate of return of 15% (reasonable return for investors).

13. ACM finds that the price is not only exorbitantly high, but also unfair. In this assessment, ACM has also taken into account the context of the orphan drug designation and marketing authorization that Leadiant obtained. Leadiant has obtained the orphan drug designation because of the very limited number of CTX patients. Leadiant did not introduce any innovation, and CDCA-Leadiant does not have any therapeutic added value compared with the previous CDCA-based drugs. In general, the requirements for registered drugs help ensure the safety and efficacy of the drugs. In the case of CDCA-Leadiant, however, this benefit is very limited, considering the fact that, for decades already, CDCA had been prescribed to CTX patients safely and effectively. The unfairness of CDCA-Leadiant's price is also apparent from the fact that this price is far higher than the prices of Chenofalk and Xenbilox a few years earlier, even though they are molecularly identical. CDCA-Leadiant's price is also considerably higher than the price of CDCA that has been compunded by Amsterdam UMC.

14. That is why, taking into consideration the context in which CDCA-Leadiant was introduced as well as the orphan designation that was granted to this drug, ACM comes to the conclusion that the price of 14,000 euros that Leadiant charged and collected from June 2017 through December 2019 is excessive. Furthermore, ACM did not find any indications that Leadiant was willing to agree on a non-excessive price, given that Leadiant did not negotiate effectively or seriously with health insurers and the ministry, and given that even the lower price that, according to its own financial records, Leadiant considered as a possibility is exorbitantly high and unfair, and, as such, excessive.

15. ACM comes to the conclusion that Leadiant has violated competition rules by charging an excessive price. This is a very serious violation. During the violation period, health insurers continued to fund CDCA-Leadiant for patients, for whom this drug is of vital importance. Ultimately, the excessive price that Leadiant collected is paid for by Dutch society as a whole, not just by health insurers but also by all insured, in their capacities of premium-payers and taxpayers. In the calculation of the fine, ACM, with an eye to the general and specific deterrent effect that a fine should have, takes into account the additional profits that Leadiant generated from this violation. ACM therefore sets a fine of 19,569,500 euros.