

Dutch watchdog fines Italian drug company for surcharge

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Italian pharmaceutical Leadiant has been fined almost 20 million euros for allegedly overcharging for medicine used to treat a rare cholesterol disease, the Dutch consumer watchdog said on Monday.

The Authority for Consumers and Markets "established that <u>drug</u> manufacturer Leadiant charged far too high a price for its prescription drug CDCA-Leadiant," it said in a statement.

"As such, Leadiant abused its <u>dominant position</u>," the Hague-based regulator said.

In just over a decade, the medicine's name changed and its price leapt from 46 euros (\$54) for a box of 100 capsules in 2008 to 14,000 euros in 2019, the ACM said.

This represented 153,000 euros per year for a patient, an amount the authority deemed "excessive" and "unfair".

"After a small, low-risk investment, Leadiant implemented a huge price increase for a drug that had already existed for years," ACM board chairman Martijn Snoep said.

"We consider this to be a very serious violation," he said.

The ACM handed Leadiant a 19,569,500-euro fine.



The Italian pharmaceutical said it "fundamentally disagreed" with the fine, telling the Dutch ANP news agency it planned to challenge the decision.

"We are convinced that we have always acted correctly and in accordance with all applicable regulations," Leadiant managing director Antonio Gama da Silva said.

The drug chenodeoxycholic acid (CDCA)-Leadiant is used for the treatment of patients with a rare hereditary metabolic disorder called cerebrotendinous xanthomatosis (CTX).

The rare condition affects the body's ability to break down cholesterol fats and symptoms include brittle bones in children and dementia and seizures in adults.

In the Netherlands, approximately sixty patients suffer from this disease.

These individuals need to use the drug for the rest of their lives, the ACM said.

Leadiant maintained the price of 14,000 euros in the Netherlands until a hospital in Amsterdam managed to manufacture the same drug in its own laboratory in January 2020, the ACM noted.

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