

**The CNMC fines the pharmaceutical company Leadiant 10.25 million for selling its orphan drug for the treatment of a rare disease at an excessive price.**

- The company has abused its dominant position as the holder of the only medicine available in Spain for the treatment of a rare disease: cerebrotendinous xanthomatosis (**CTX**).
- There are around 200 to 250 patients diagnosed with this disease in Europe, of which around **50 are in Spain**.
- Leadiant secured **exclusive supply of the active ingredient** on which the drug is based, thus preventing the emergence of alternative products.
- It charged the **National Health System** 14 times the price of another (essentially identical) medicine it had marketed in Spain to treat CTX back in 2010.
- Leadiant will now have to **sell** the drug in Spain at a **non-excessive price** negotiated with the Ministry of Health and lift the exclusivity agreement signed with the sole supplier of the active ingredient.

**Madrid, 14 November 2022.-** The CNMC has fined the pharmaceutical company **Leadiant** 10,250,000 euros for abusing its dominant position in the market for the manufacture and supply of medicines using chenodeoxycholic acid (**CDCA**) for the treatment of a rare disease called cerebrotendinous xanthomatosis (CTX). ([S/0028/20: LEADIANT](#))

**Cerebrotendinous xanthomatosis and its treatment**

CTX is an ultra-rare hereditary metabolic disease resulting from a defect in one of the enzymes leading to the synthesis of CDCA, a bile acid, which manifests with both systemic (chronic diarrhoea in children, juvenile cataracts and tendon xanthomas) and neurological (cognitive impairment) symptoms.

There are around 200 to 250 patients diagnosed with this disease in Europe, of which around 50 are in Spain.

For decades, CTX has been treated with medicines that use CDCA as the active ingredient. It has been shown to be effective in preventing the progression of the disease and even partially reversing its symptoms if administered chronically and at an early stage.

Leadiant has been the sole supplier of CDCA-based medicines for the treatment of CTX in Spain since 2010. First with the drug called Xenbilox<sup>®</sup> and, since June 2017, with CDCA-Leadiant<sup>®</sup>.

### **Origin of the disciplinary proceedings and cooperation with the Netherlands and Italy**

The investigation originated in an official communication from the Ministry of Health together with a complaint from the Organisation of Consumers and Users (OCU) for a possible abuse of a dominant position by Leadiant for having significantly increased the price of its CDCA-based drug in June 2017. Both complainants pointed out that the price of CDCA-Leadiant<sup>®</sup> was more than 1000 times higher than that of the CDCA drugs used until 2008 for the treatment of CTX. ([Press releases](#))

The Dutch and Italian competition authorities had already initiated proceedings against Leadiant for overpricing the CDCA-based drug in their respective national markets. The CNMC maintained ongoing cooperation with these authorities, including the sharing of documents collected during inspections of Leadiant group companies located in Italy, Germany, and the United Kingdom.

### **The CDCA-Leadiant project**

Since 2007, Leadiant devised a strategy consisting of obtaining exclusivity for CDCA-based drugs, withdrawing the CDCA-based drug it had been marketing since 2010 (Xenbilox<sup>®</sup>) from the Spanish market, and reformulating it in order to launch it on the market as an orphan drug under a different brand name (CDCA-Leadiant<sup>®</sup>) at a price 14 times higher.

The only drug available in Spain for the treatment of CTX went from costing €984/package in September 2010 to €14,618/package in June 2017.

### **Abusive practices attributed to Leadiant**

The CNMC has sanctioned Leadiant for committing abusive practices prohibited by Article 2 of the LDC and Article 102 of the TFEU consisting of excluding

competitors from the market and imposing excessive prices significantly higher than those that would have existed in the absence of its abuse.

In order to achieve market exclusivity, Leadiant conducted a **series of actions** combining lawful behaviour—such as obtaining orphan drug designation with the corresponding marketing authorisation—and anti-competitive practices.

Among these anti-competitive practices, it maintained an **exclusivity clause** with the only supplier of the active ingredient authorised to supply CDCA in sufficient quantities and quality. This prevented the emergence of alternative medicines, both industrial and in the form of magistral formulations.

With regard to the **selling prices** of the medicine in Spain as of 2017, the CNMC has concluded that they are abusive due to their disproportionate and unfair nature, which are requirements for the price applied by a dominant operator to be considered contrary to competition law.

The CNMC's analysis establishes, firstly, an excessive disproportion between the risks and the costs actually borne by Leadiant for the development and marketing of CDCA-Leadiant<sup>®</sup> and the price actually charged in Spain. Secondly, the CNMC's analysis establishes that said price is not fair in itself in terms of its economic value.

Leadiant has denied throughout the proceedings that the price of CDCA-Leadiant<sup>®</sup> in Spain is excessive and claims that it is justified by the significant advantages this drug offers over its previous CDCA-based drug, Xenbilox<sup>®</sup>. Specifically, Leadiant claims that not only has the quality of the active ingredient been improved, but the new drug has also obtained a specific indication for the treatment of CTX, which implies benefits for CTX patients in terms of quality, effectiveness, and safety compared to the use of Xenbilox<sup>®</sup>.

The reality, however, is that from a clinical point of view the two drugs are equivalent and CDCA-Leadiant<sup>®</sup> **has no substantial added value** over the former drug. In addition, CDCA had been used off-label for the treatment of CTX since the mid-1970s. Therefore, the effectiveness and safety of CDCA had already been supported by established clinical practice and extensive scientific literature. As a result, LEADIANT was able to obtain the specific indication for its new drug, reformulated on the basis of its previous drug, **with virtually no investment in R&D and clinical research.**

Therefore, there is no justification for Leadiant taking advantage of its dominant position to multiply by 14 the price of its CDCA-based treatment for CTX and unduly increasing the cost borne by the National Health System.

### Penalties and obligations imposed

As a result, the CNMC has imposed a fine of 10,250,000 euros on Leadiant for a very serious infringement which constitutes an abuse of a dominant position and is punishable under Article 2 of the Spanish Competition Act (LDC in Spanish) and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

In addition, Leadiant has been required by the CNMC to comply with a series of obligations in order to eliminate the exclusive control of the active ingredient in Spain and to market CDCA in Spain at the price negotiated with the Ministry of Health.

The CNMC would like to point out that an administrative appeal may be lodged directly with the National High Court against this decision within two months from the day following its notification.

### Evolution of the price of CDCA-based CTX treatment paid in Spain

EVOLUTION OF THE PRICE OF CDCA-BASED CTX TREATMENT PAID IN SPAIN				
Pharmaceutical company	Multiple	LEADIANT*		
Medication with CDCA	Multiple	Xenbilox®		CDCA-Leadiant®
Time period	until September 2010	September 2010 to August 2014	August 2014 to May 2017	Since 23 June 2017
Selling price in Spain (euros/package of 100 units)	€50 (approx.)	€984	€3.903	€14.618

\* Until 2016 the LEADIANT laboratory was known as SIGMA TAU

