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Dutch competition authority ACM imposes EUR 20 million fine on orphan drug manufacturer Leadiant for excessive pricing

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The Netherlands Authority for the Consumer and Markets' ("**ACM**") announced focus on drug price developments has finally come to a tangible enforcement result: a fine of almost EUR 20 million imposed on Leadiant, manufacturer of the orphan drug CDCA-Leadiant. This penalty decision follows the announcement by the ACM in 2018, repeated in2020 and 2021, that it would scrutinize the over-pricing of medicines.

The prices of medicines have long been part of a public debate. In its role of the Dutch competition authority, the ACM got involved in that debate, but so far its participation had been limited to academic-scientific discussions (see for example here and here). This has changed with this hefty fine. See here the summary of the decision and here the press release of the ACM (both in English). The full decision has not yet been published.

The price development of Leadiant's orphan drug

In the summary of the decision, the ACM states the following facts relating to Leadiant's pricing conduct. It starts when Leadiant took over medicine from another manufacturer in 2008 that was vital for the treatment of the rare disease cerebrotendinous xanthomatosis ("**CTX**"). The price at the time was EUR 46 for 100 capsules. In 2009, Leadiant changed the name of the product and increased the price to EUR 885. In 2014, the drug was granted orphan drug status and the price was increased to 3,103 euros. When Leadiant also obtained a marketing authorisation in 2017, which gave Leadiant market exclusivity in the EU for 10 years, the price increased to 14,000 euros. For CTX patients who depend on taking the medicine for the rest of their lives, this means an annual cost of 153,000 euros. The price increase – which resulted in prices being 15 times the price when Leadiant launched its orphan drug strategy – caused a lot of commotion in the media (see among others here and here), questions in Dutch Parliament and an enforcement request to the ACM from the Foundation for Pharmaceutical Accountability, but Leadiant persisted with the allegedly exorbitant price increase. Only when the Amsterdam University Medical Center managed to prepare an alternative medicine in 2020, the price of the product was lowered.

The penalty decision

The ACM bases its fine on Article 24 of the Dutch Competition Act ('**Mw**'): '*it is prohibited for undertakings to abuse a dominant position'*. The ACM allegedly establishes in the decision that Leadiant has a dominant position – after all, without a dominant position, there is no abuse. In the summary, the ACM points to Leadiant's 100% market share, the dependency of patients on the drug and the lack of alternative medicines for CTX patients as reasons for reaching this conclusion.

Excessive prices are also considered abusive, as we know since the *General Motors* and *United Brands*-judgements by the Court of Justice of the EU ("**CJEU**"). The United Brands judgment indicates that a price is excessive if there is no relationship between the price charged and the economic value of the product. This is often the crux of the matter, because how do you determine this? As far as the ACM is concerned, this is the case when the price charged is excessive and unfair. The ACM reasons as follows in the case of Leadiant:

1. The price is considered excessive because it is disproportionate to the low cost of the medicine. The ACM has taken into account the costs incurred to obtain the orphan drug status and the marketing authorisation, the risk that the project would not succeed and a reasonable profit margin of 15%;
2. The price is allegedly unfair because there has been no innovation in relation to the medicine when the price was EUR 46. The price is also significantly higher than the price of the alternative prepared by Amsterdam UMC; and
3. The ACM argues that Leadiant was not actually prepared to negotiate a lower price with the Ministry of Health, Welfare and Sport and the health insurers.

ACM also points to the special responsibility that comes with Leadiant's dominant position as the sole manufacturer of an orphan drug that CTX patients completely depend on. This means that Leadiant should have abstained from charging excessive prices and should have done more to negotiate effectively and seriously to agree on a reasonable price with the Ministry and health insurers.

Conclusion

It is to be encouraged that the ACM also gets involved in the social discussion about (too) high prices for drugs through an enforcement process. The fine will undoubtedly be fought out up to the highest court (Leadiant has already announced that it will appeal the decision), which will bring valuable jurisprudence and thus legal certainty.

Whether the ACM's decision will stand will only become fully clear in a few years' time. The highest court in competition law cases – the Trade and Industry Appeals Tribunal ("**CBb**") – is often critical of the ACM when it comes to establishing a dominant position and also likes to get involved in the economic analyses that are undoubtedly also hidden behind this decision by the ACM.

It is therefore not without reason that the ACM has taken up several anchors when it comes to establishing the excessively high price. The appeal to the relationship between the costs and the price of the product is borrowed from *United Brands*. The reference to the relationship between the price and a comparable product – in this case, the same product but a few years ago – and the price of the product of the Amsterdam UMC was accepted by the CJEU in the cases Corinne Bodson, Lucazeau and Latvijas. The fact that the product does not constitute 'therapeutic added value'

compared to an earlier version of the product seems to refer to a lack of an economic value from Scandlines. As a final element of abuse, the ACM refers to the unwillingness on the part of Leadiant to seriously negotiate about the price. Although this does not seem to us to be behaviour that – viewed in isolation – qualifies as 'abuse', it may contribute to the overall picture of abusive behaviour by Leadiant.

Whereas medicine producer Aspen chose in a – seemingly – similar case to drastically lower its prices for medicines in order to avoid a fine from the European Commission (press release European Commission), Leadiant apparently did not choose to go down this path. In the appeal proceedings, it will become clear why Leadiant believes the fine of the ACM is unjustified and how it defends the price increases. This may show us a different side of the story that is not apparent from the ACM's summary of the case. To be continued!

Also published on https://bio-talk.law/pharmaceuticals/dutch-competition-authority-acm-imposes-eur-20-million-fine-on-orphan-drug-manufacturer-leadiant-for-excessive-pricing

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