

PAF competition case on CDCA Leadiant (2018-202?)

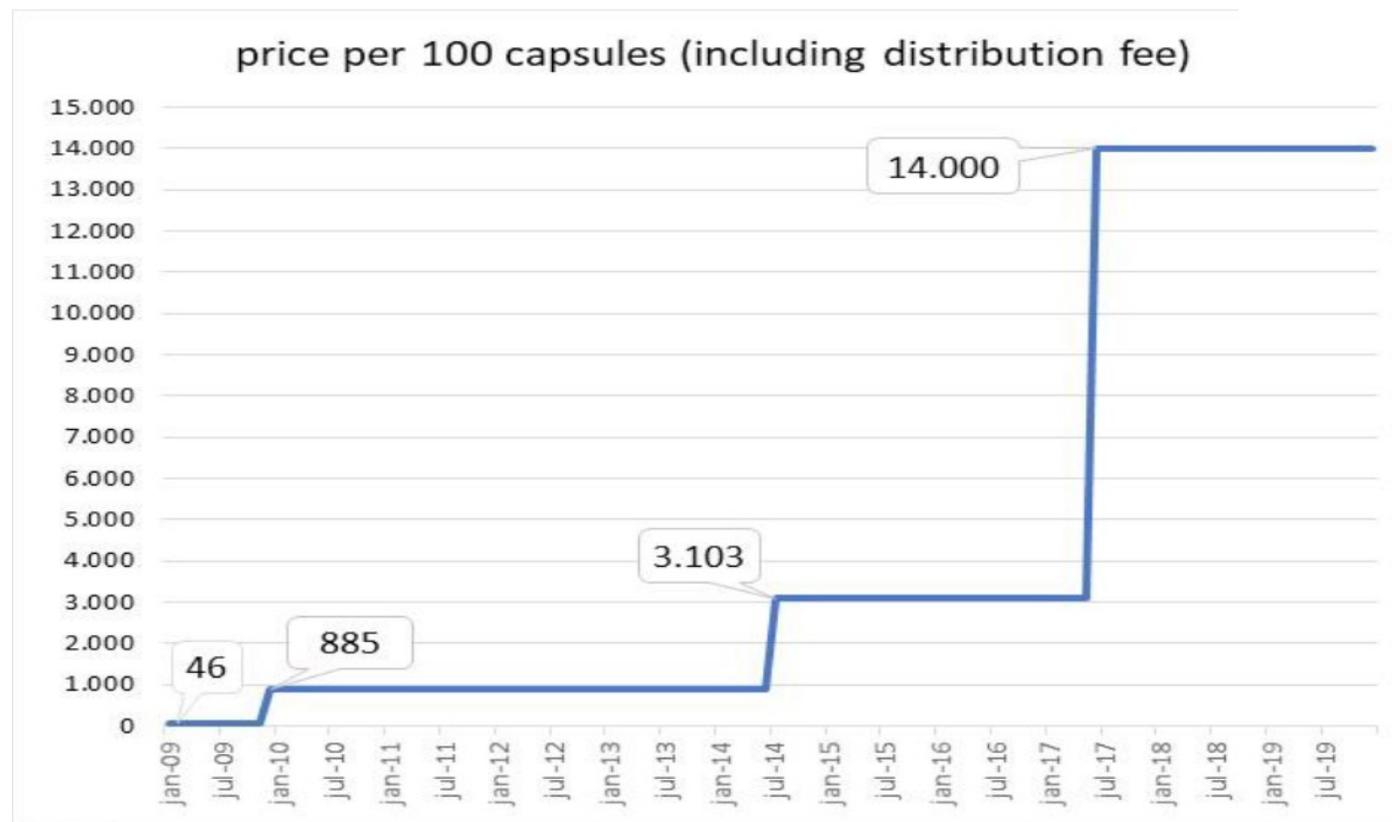
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Leadiant price hike



Chenofalk
used off-label

Xenbilox
used off-label

CDCA-Leadiant
MA + ODD

What to do as an NGO?

- EU Orphan drug regulation is permitting such misuse
 - Campaign needed to change the EU directive (2022-ongoing)
- Dutch legislation does not forbid asking high prices
 - National legislation on fair pricing (and fair profits) needed
 - Competition law forbids misuse of dominant economic position (e.g. excessive prices)
- PAF [complained](#) to Dutch Competition Authority (ACM) Sept 2018
- Health insurers refused to pay the excessive price
 - Patients got access to pharmacy compounded CDCA
 - Leadiant complained about this but lost (appeal pending May 2022)



ACM decision after nearly 3 years...

- 19 July 2021: ACM issues Lediand [a fine of €19.6 million](#)
- So far only a summary report (legal battle Lediand-ACM)
- ACM: Lediand charged ... an **excessive price**... that was **exorbitantly high** because the **price** in combination with the **low costs** and **the low risks** resulted in **exorbitant return**.
- **...unfair** because the drug, under a different trade name, had already been on the market for years at a **much lower price**, while patients **benefitted very little** from the registration as an orphan drug.
- PAF and health care insurers considering **civil case** against Lediand to reclaim excessively paid health care expenditure (€11 million)
- Belgium, Spain & Italian Competition Authorities?

Lessons learned

- Need to do proper **research** and document the case
- Bringing a Competition case is affordable, but **takes long**
- Competition Authorities can confirm and stop **excessive prices**
 - But evidence and procedures are difficult
- The **‘pharma pirate’** business model does no longer pay off
 - A 2nd case was already **prevented**: mexiletine (Namuscla, Lupin)
 - A 3rd case **has been warned** to ask a fair price: tiratricol (Emcitate, Egetis)
- **Pharmacy compounding** is a useful emergency solution
- Better definition of **‘fair pricing’** needed in legislation
- EU orphan legislation needs to be **revised**

