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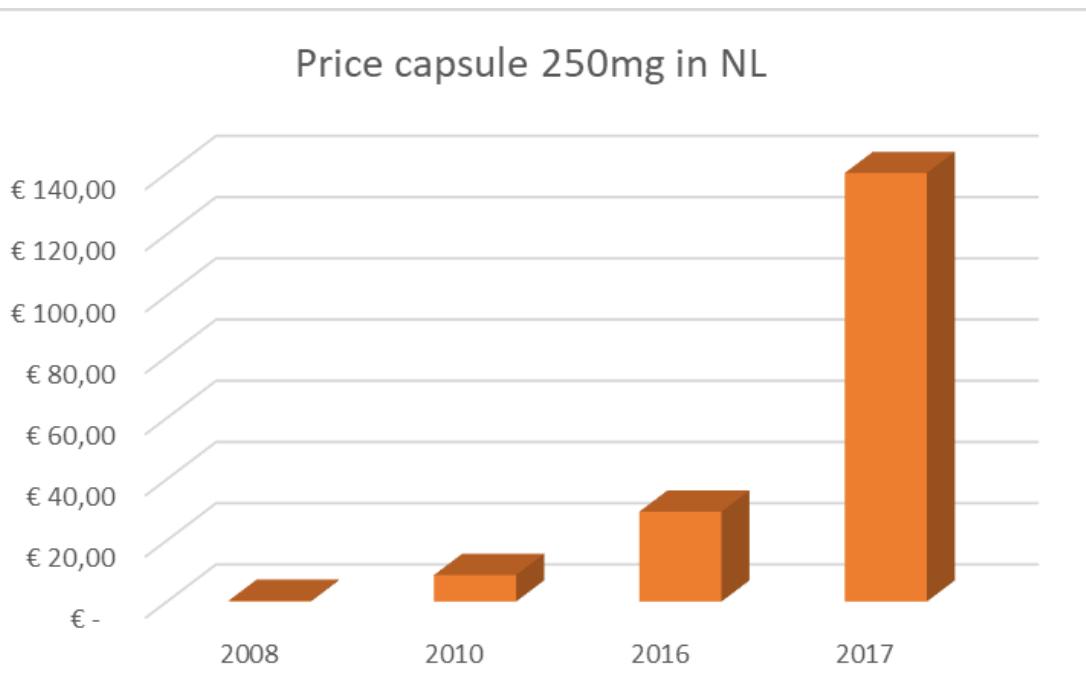
Pharmaceutical  
Accountability  
Foundation

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Gaming the system to  
maintain excessive  
medicines prices, and the  
need for legal remedies -  
some case studies from the  
Netherlands

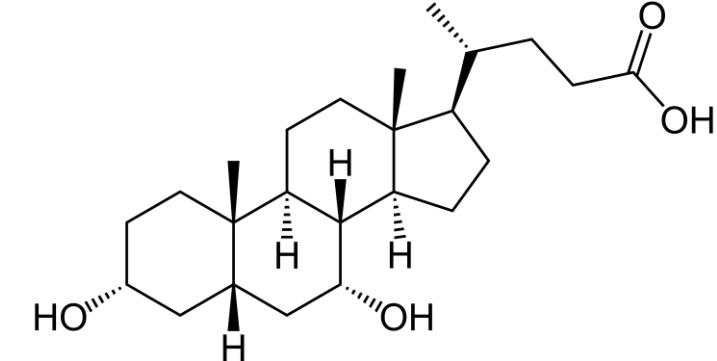
# Excessive medicines pricing – a different epidemic

How can a simple medicine become 500x more expensive in 10 years?



Year	Brand name	Manufacturer	Price capsule 250mg in NL	Price Index
2008	Chenofalk	Dr Falk	€ 0,28	1
2010	Xenbilox	Sigma-Tau	€ 8,67	31
2016	Xenbilox	Sigma-Tau	€ 29,38	105
2017	CDCA Leadiant	Leadiant	€ 140,00	500

# Case study: CDCA Leadiant



- Chenodeoxycholic acid (CDCA) = human bile acid
  - marketed > 1976 for dissolving gallstones by Dr Falk, Germany.
  - Chenofalk® cost 28 eurocents/capsule
- Only known effective therapy for Cerebrotendinous Xanthomatosis (CTX)
  - Affects 1:50,000. 65 known cases in NL, 10 in Belgium
  - CDCA was affordably prescribed (off-label) until 2009 for €308/patient/year
- Sigma-Tau (now Leadiant) bought (and killed) all existing generic products in 2008/9
  - Launched its own brand Xenbilox® first at 30x, later 100x price in Germany
- CDCA Leadiant received EU orphan status in 2014, and EMA registration in 2017
  - EU price increased 500x to €140/capsule; €153,300/CTX patient/year
  - CDCA in USA costs \$560,000 / patient / year (Retrophin)



# How industry games the system

1. Identify an “old” drug that is used off-label for an orphan disease
2. Buy all existing products, and control sources of raw material (API)
3. Do an observational study with existing patients, and a literature review
4. Apply for orphan designation/registration with EU/EMA
5. Remove all potentially competitive products from the market
6. Launch your own version as an exclusive orphan drug
7. After obtaining 10 years market exclusivity, raise the price as you like, and lobby for reimbursement
8. Challenge all efforts to provide affordable alternatives

# Why is this possible?

- Monopolies
  - Patents
  - Special Protection Certificates
  - Data exclusivity
  - Marketing exclusivity (EU orphan drug)
  - Being the only product registered in a market
- Profit motives, greed
- Because it is possible, and not (yet?) illegal
- “We cannot achieve any real progress without acknowledging that the current **patent-based business model** and the way we apply international patent rules need to change. **The system is broken.**” (Dutch Health Minister Edith Schippers)
- Lancet: [http://dx.doi.org/10.1016/S0140-6736\(16\)31905-5](http://dx.doi.org/10.1016/S0140-6736(16)31905-5)



# Methods to fight expensive medicines pricing

- Different R&D system
  - Govt R&D fund, Public-Private Devt
  - Fair pricing / delinkage
  - Responsible licensing
- Fix barriers like orphan drug law, SPC, data exclusivity
- Patent opposition
- Use of TRIPS flexibilities
  - No 2<sup>nd</sup> use patents / evergreening
  - Compulsory / Govt use license
  - LDC transition
- Competition law
- Generic competition / policies
- Stricter regulation, price control
- External reference pricing
- Price/volume agreements
- Bulk purchasing (BeNeLuxAI)
- Negotiations
- Pharmacy Compounding
- Buyer's club
- Individual patient import
- **Missing: legal action in the court**



Dutch Council for Public Health and Society (RVS) report 2017 “Development of new medicines - Better, faster, cheaper”, and Report “Big Pharma – not healthy!” by 3 political parties in NL. <https://www.raadrvs.nl/documenten/persberichten/2017/11/09/smarter-development-stronger-negotiation>

# Pharmaceutical Accountability Foundation

- Set up to challenge unfair pricing in court
- NL: Stichting Farma ter Verantwoording
  - 'public good' foundation under NL law (ANBI)
  - Physicians, lawyers, pharmaceutical experts
  - Board, Advisory Council, Volunteers
  - [www.farmaterverantwoording.nl](http://www.farmaterverantwoording.nl)
- Legal methods against unfair pricing:
  - Competition law
  - IP law
  - Unlawful Act (Dutch civil law clause)
  - Human Rights / Right to Health / Essential medicines



# CDCA 500x case – what happened?



- Health insurance companies refused to pay 500x at €153,000/ CTX patient
- Minister, Parliament, Drug Industry Association: this is misuse! But not illegal?
- Amsterdam University Hospital started compounding it at 15% of the cost
- Leadiant complained in May 2018 about this with Dutch Health Inspectorate
- Oct 2018 Health Inspectorate rejected Leadiant's complaint, warned the Hospital about API quality, but confirmed that compounding of CDCA is OK
  - Leadiant appealed – case being heard
- FtV/PAF filed a complaint to Dutch Competition Authority (ACM) on 7 Sept 2018
  - Ground: misuse of economic power position by Leadiant
  - <https://www.farmaterverantwoording.nl/information-in-english/>
- TestAankoop (Belgium) also filed a competition law complaint. More to follow!

# IP evergreening

- Menzis vs Astra Zeneca (2018)
  - Seroquel® (quetiapine, anti-psychotic, top-10 global, \$3.6bn), patent expired 2012
  - Astra Zeneca tried to patent an extended release version (Seroquel XR), but courts in UK and Germany declared this patent invalid in 2012
  - NL insurer Menzis claimed 4m from Astra Zeneca in Sept 2018 as compensation for overpaying in NL until 2014
  - Parties could not agree; court now to decide
- Pfizer vs NHS
  - Lyrica® (pregabalin, anti-epileptic, \$5.1bn sales), patent expired 2013
  - Pfizer claimed 2<sup>nd</sup> use patent for use in neuropathic pain (until 2018)
  - Pfizer tried to stop doctors prescribing generics in UK, and sued Actavis, Mylan for infringing with generics
  - Pfizer won 1<sup>st</sup> case, but lost 2<sup>nd</sup>, on appeal and in Supreme Court (2018)
    - Reason: Pfizer had no convincing data when it asked for the 2<sup>nd</sup> use patent
  - BMJ Open article 2018 estimated damages for NHS at €580m



# Competition law cases



- NL: Competition Authority also investigating **rheumatoid arthritis** market (Humira® €600/vial dropped to €100 after patent expiry)
- UK: case against Pfizer & Flynn for inflating prices, causing NHS to spend £50m instead of £2m/year for simple **phenytoin**.
- Italy fined Aspen Pharma for €5 million for abusing of its dominant position and fixing unfair prices (500-1500% increases) in **cancer medicines** which it had bought from GSK
- Italy also fined Roche € 92m and Novartis respectively € 90.5m for **collusion** to exclude the drug Avastin® (bevacizumab) towards the much more expensive drug Lucentis® (ranibizumab).

# What next?

- FtV/PAF received 68 proposed targets
  - “old” repurposed products
  - Cancer medicines
  - Products with unexpected price increases
- Volunteers and professionals are assessing the evidence
- Document & publish the cases
- Lawyers are preparing pilot legal cases in NL courts
- European collaboration with other groups



# Discussion / contact

- Questions on our legal approaches?
- Interested in collaboration?
- Contact?
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