Unfair prices, human rights — legal options?

Wilbert Bannenberg
Pharmaceutical Accountability Foundation
2nd Global Fair Pricing Forum, Johannesburg
12 April 2019
Fair pricing?

- Affordable = “allows the purchase of a necessary quantity of a product without suffering undue financial hardship” (Lancet Commission EM)
- ‘Fair’ price (WHO fair pricing report 2016):
  - Assures that new medicines are affordable to all patients and health systems
  - Allows for a reasonable profit margin + investment in innovation
  - Assures a stable supply of generic medicines
- No agreement on benchmark for “fair” pricing @ 1st Pricing Forum
- Impossible to assess “fairness” without disclosure & transparency
Unfair pricing?

• Unaffordable = prevents the purchase of a necessary quantity of a product, or results in suffering due to financial hardship

• “Unfair price”
  • New medicines are not affordable to patients or health systems
  • Results in unreasonable and socially unacceptable profit margins, far beyond costs of R&D, production and marketing
  • Prevents a stable supply of generic medicines, and thus UHC

• Challenge: get agreement on “unfair” pricing at 2\textsuperscript{nd} Pricing Forum?

• Everyone struggles with disclosure & transparency
What is the basis for unfair pricing?

• Monopolies
  • Patents
  • Special Protection Certificates
  • Marketing exclusivity (EU orphan directive)
  • Being the only product registered in a market
• Profit motives, greed
• Because it is possible?
• Because it is not (yet) illegal (?)
How to control unfair 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\textsuperscript{nd} 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

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

• Legal methods against unfair pricing:
  • Competition law
  • IP law
  • Unlawful Act (Dutch civil law clause)
  • Human Rights / Right to Health / Essential medicines
Human right to health, essential medicines: also for pharmaceutical industry!

Ruggie principles: https://www.ohchr.org/documents/publications/GuidingprinciplesBusinesshr_eN.pdf
Pharmaceutical Accountability Foundation

Objectives

Ensure that medicines and other medical technologies are available on the market in a sustainable and socially acceptable manner...

the foundation attaches value to fair pricing and distribution that is in accordance with written and unwritten national, European and international legal norms
Case study: CDCA by Leadiant

- Chenodeoxycholic acid (CDCA) = human bile acid
  - marketed > 1976 for dissolving gallstones by Dr Falk, Germany.
  - Chenofalk® costed 28 eurocents/capsule

- Only known effective therapy for Cerebrotendinous Xanthomathosis (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 15x, later 100x price in Germany

- CDCA Leadiant received EU orphan drug 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)
CDCA 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 for €20,000 /pp / year
• Leadiant complained in May 2018 about this with Dutch Health Inspectorate
• FtV 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/](https://www.farmaterverantwoording.nl/information-in-english/)
• Oct 2018 Health Inspectorate rejected Leadiant’s complaint, warned the Hospital about API quality, but confirmed that compounding of CDCA is OK
• TestAankoop (Belgium Consumer Org) also filed a competition law complaint
More 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 cheap drug Avastin® (bevacizumab) towards the much more expensive drug Lucentis ® (ranibizumab).
What next?

• Foundation received 67 proposed targets
• Volunteers are assessing the evidence
• Making a shortlist for legal action against unfair pricing
• Summarize the cases on our website
• Expanding network, and seeking support
• Start pilot legal cases in NL courts
• Consider European, USA and global expansion once NL firmly established, and legal cases started
Discussion / contact

• Questions on our legal approaches?
• Interested in collaboration?
• Contact?
  • Wilbert Bannenberg
  • Mobile/Facetime/WhatsApp +31-6-20873123
  • info@farmaterverantwoording.nl
  • Skype: wilbertb1
  • www.farmaterverantwoording.nl/information-in-english/