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Pharmaceutical
Accountability
Foundation

2nd Global Fair
Pricing Forum,
Johannesburg

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Unfair prices, human rights – legal options?

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 2nd Pricing Forum?
- Everyone struggles with disclosure & transparency

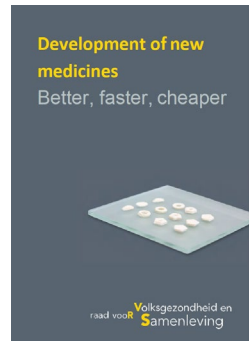
What is the basis for unfair pricing?

- 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 2nd 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



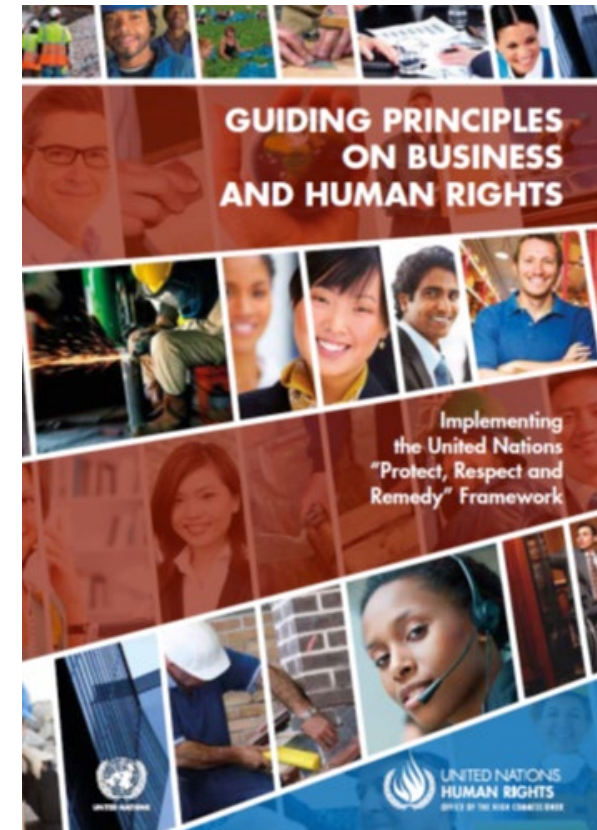
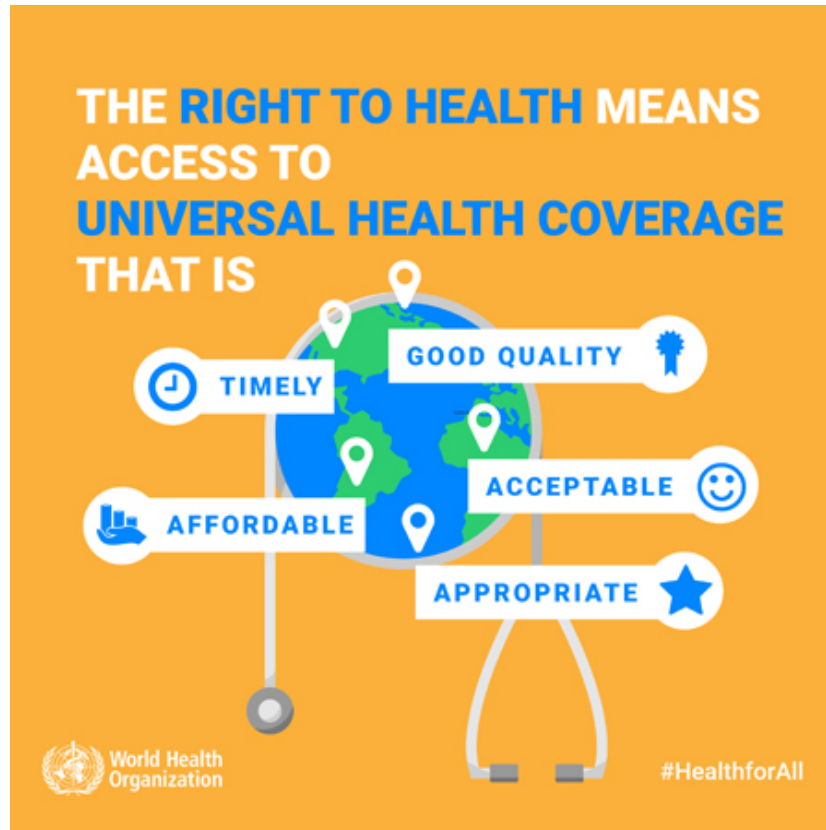
Dutch Council for Public Health and Society (RVS) report 2017 “Development of new medicines - Better, faster, cheaper”, and Report “Big Pharma – not healthy!” by 3 political parties in NL. <https://www.raadrvs.nl/documenten/persberichten/2017/11/09/smarter-development-stronger-negotiation>

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
- 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



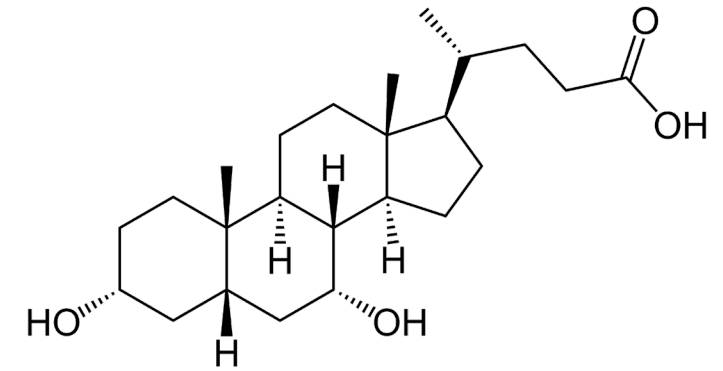
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Objectives

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/>
- 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?
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