

# 2021 ANNUAL REPORT

---



**The Pharmaceutical  
Accountability Foundation**

---

# ABOUT US

---

## Farma ter Verantwoording / The Pharmaceutical Accountability Foundation (PAF)

PAF strives to ensure access to medicine by stopping pharmaceutical company abuses of their market position to overcharge for medicines. We attach a value to fair pricing in accordance with European and international legal and human rights standards, and therefore take action through the provision of advice and information to governments, stakeholders, professionals and the general public. If that does not help, we achieve our objectives through the possible legal action around excessively high priced medicines.

# 2021 HIGHLIGHTS

PAF had a busy 2021, with several important steps forward. Highlights include:

## **€19.6 MILLION JUDGEMENT AGAINST LEADIANT BIOSCIENCES**

A decision by the Dutch competition authority (ACM) in July, following a request by PAF to investigate Leadiant's anti-competitive practices. The case has now inspired action in several other countries.

## **GOOD COVID-19 COMPANY PRACTICES (GCCP)**

Launched in January, the GCCP evaluates whether pharmaceutical company behaviour will result in equitable access to Covid countermeasures.

## **SIGNIFICANT EXPANSION IN PAF'S PUBLIC PROFILE**

PAF experts spoke at several high-profile events well-attended by global public health experts, and were interviewed by health journalists in the Netherlands and abroad.

2021 also saw the launch and widespread uptake of a new website, with more than 13,321 page views from 3,687 unique visitors. Significant growth in social media presence, notably on Twitter with almost 100 new followers (a 25% increase) and a reach far greater: PAF's Tweet views totalled 58,978 for the year.

## **LEGAL GUIDELINES FOR NON-GOVERNMENTAL ORGANISATIONS**

Launched in November, the guidelines are a distillation of years of PAF experience into a format intended to aid other organisations seeking to use legal action to increase access to medicines.

## **LETTER OF LIABILITY SENT TO ABBVIE**

Pricing decisions AbbVie has made over its blockbuster medicine Humira have caused displacement of care in the Netherlands. PAF has sent AbbVie notice asking it to remedy this.

## **A GROWING TEAM**

To keep pace with its growing and expanding list of activities, the PAF team has also grown. In 2021, our board added three new members (Hans Smits, Tegan Insoll and Sabina Voogd). Our expert advisory group added Anna Laskai and Richard van Slobbe. And three new staff members: Emily Dowdalls, Rosalind Turkie, and Kaitlin Mara have joined the organisation.

# RESPONSE TO COVID-19

---



*As the world headed into its second year of the Covid-19 Pandemic, PAF in collaboration with several partners stepped up efforts to ensure equitable access to pandemic countermeasures around the world. Key actions included:*

### **THE LAUNCH OF THE GOOD COVID-19 COMPANY PRACTICES (GCCP):**

The GCCP aims to maximise transparent and equitable access to Covid-19 vaccines and therapeutics. We monitor adherence of companies developing and marketing these products to legal principles along four important themes. These themes are: commitments & accountability; transparency; international cooperation; and equality, non-discrimination, & equity.

Companies are ranked in an interactive scorecard that is published on PAF's website. Tiered rankings by indicator measure whether the company is not following good practice, has made some progress, or is well-aligned with best practices. The first GCCP scorecard, launched on 22 January, ranked the 12 leading vaccine and treatment candidates at the time along 18 different good practice parameters.

PAF also made considerable progress on an updated version of the GCCP to take into account the latest in medical advances and company behaviour data, as well as expanding and further detailing the list of parameters upon which companies will be scored. The updated scorecard will be published in early 2022.

PAF has also written a set of guidelines for responsible pharmaceutical company behaviour during a pandemic, with supporting policy recommendations for governments, international institutions, investors and others seeking to hold companies to account. This will also be published on the website in early 2022.

The latest version of the GCCP scorecard can be accessed here: <https://www.farmaterverantwoording.nl/covid-19-practices/gccp-scorecard/>

### **SPEAKING ENGAGEMENTS:**

PAF experts have been called on to speak at and participate in several high-profile events and have used this space in particular to advocate for better update of technology sharing mechanisms, especially the World Health Organization's Covid-19 Technology Access Pool (C-TAP). PAF has been aiming to keep the promise of technology sharing, especially through C-TAP, in the forefront of public consciousness through engagements at speaking events as well as with the media.

### **MEDIA WORK:**

PAF has conducted multiple interviews with journalists for print publication as well as for radio and television, ensuring that the need for equitable access to Covid countermeasures remains a public focus. Nearly 40 articles quote PAF experts in 2021, including in leading Dutch media such as Volkskrant and Trouw as well as international media such as Der Spiegel.

# LEGAL ACTION: SUCCESSES AND NEW CASES

---



*Outside the pandemic, PAF continues to fight for fair pricing by researching cases where high medicines prices may be the result of unjust abuse of a monopoly position. In 2021, there were several important milestones in this work, which are detailed on the following pages.*

## **DUTCH COMPETITION AUTHORITY FINES LEADIANT BIOSCIENCES €19.6 MILLION:**

On 7 September 2018, PAF submitted an enforcement request<sup>1</sup> to the Netherlands Authority for Consumers and Markets (ACM), responsible for enforcing competition laws in the Netherlands. The request was made in response to Leadiant's abuse of its market position to hike prices of a medicine 500 times.

The medicine was Chenodeoxycholic acid (CDCA), which treats the rare genetic disease Cerebrotendinous xanthomatosis (CTX), characterised by an inability to metabolise cholesterol. CTX is exceedingly rare, with some estimates placing its prevalence as less than 5 in 100,000.

CDCA was marketed from 1976 to 2008 in the Netherlands as a treatment for gallstones, at a price of €0,28 per capsule.<sup>2</sup> In 2015, Leadiant withdrew CDCA from the market, sought and received orphan drug status from the European Medicines Agency<sup>3</sup>, and then brought the medicine back to the market in 2017. The orphan designation gave Leadiant 10 additional years of monopoly protection for the use of CDCA specifically to treat CTX. Orphan designations are generally meant to incentivise the creation of new medicines for rare diseases, not old molecules with new indications. Leadiant promptly raised its price to €140 per capsule and €153,300 per patient per year.

On 19 July 2021, the ACM decided that Leadiant had indeed abused its market position to raise prices, and issued a €19.5 million judgement against the company.

"We welcome the ACM's ruling that Leadiant has abused its dominant economic position," says Wilbert Bannenberg, PAF's chairman, in a press release<sup>4</sup>. "Pharma-pirate Leadiant was rightly fined by the ACM for the excessively high price of CDCA. Because of this ruling, hijacking old and affordable medicines no longer pays".

Leadiant has managed to be able to (likely temporarily) put off paying the fine<sup>5</sup>, which was originally due in December, but PAF expects this will be resolved in early 2022.

In the meantime, PAF's case has inspired others. NGOs in Belgium, Italy and Spain have now complained to their respective competition authorities about CDCA Leadiant. And in November 2021, the Israeli Competition Authority announced<sup>6</sup> it is considering a financial sanction of €2.2 million against MBI Pharma, and 2 fines of €172,000 to its directors, for abuse of its monopoly position to charge unjust prices for CDCA. MBI Pharma markets CDCA Leadiant in Israel. In 2017, the medicine sold for the already costly Israeli New Shekel (ILS) 8,000 (€2,200) a pack. But in 2018, when MBI Pharma took over supply, they hiked the price to ILS 50,000 (€14,000) a pack<sup>7</sup>.

## PROGRESS IN OTHER ORPHAN DRUG CASES:

Interesting developments have also happened on two other medicines that PAF considers of interest: mexiletine and tiratricol. Mexiletine treats irregular heartbeat and some chronic pain; it is also effective against rare muscular illnesses, Tiratricol is a common supplement for those suffering from thyroid problems, but was recently found to be effective against a hereditary thyroid condition known as Allan-Herndon-Dudley syndrome (AHDS).

On 7 July, Dutch Health Minister Tamara van Ark decided not to include the brand name of mexiletine, Namuscla by pharmaceutical company Lupin, in the basic package of medicines reimbursed by the Dutch healthcare system. In a letter explaining her reasoning<sup>8</sup>, van Ark explained that mexiletine had been registered in the Netherlands for several decades, that a pharmacy preparation of the medicine was available and that generic versions of it could be imported. On achieving orphan medicine status in 2018, Lupin tried to raise the price of the newly named Namuscla by 100 times. This is “much more expensive, but not more effective” than alternatives available, van Ark said, adding that the Dutch health care authority “disapproves of ... unsubstantiated price increases.”

While not involved directly in legal action on mexiletine, PAF staff have been published regularly on the abuse of orphan legislation to hike the price of this medicine<sup>9</sup> and the danger it poses to patients.

Tiratricol was also an old medicine that in 2014 began to be investigated as a promising treatment for AHDS, a rare disease that causes movement and communication difficulties and premature death. In 2017, the European Medicines Agency granted it an orphan designation for AHDS treatment<sup>10</sup>. Shortly thereafter, Swedish pharmaceutical company Egetis announced its intention to manufacture and market the medicine, raising the price from €0,35 to €14 for a capsule and prompting concerns about hijacking<sup>11</sup>. The cost of the raw material to make this medicine costs only €22 per patient per year, and PAF is keeping an eye on this case for potential abuse of orphan legislation<sup>12</sup>.

## NEW MEDICINE OF INTEREST: ADALIMUMAB (HUMIRA):

Adalimumab (brand name: Humira) is a prescription drug for rheumatoid arthritis that was first brought to the market in 2003 by the company Abbott (now, AbbVie). It is an early example of what is biologic medicine, a medicine derived from biological sources (in this case, white blood cells). Humira was the most profitable medicine in the world from 2012 to 2020, netting AbbVie about \$170 billion in sales<sup>13</sup>.

PAF became interested in Humira as it is priced in the Netherlands at €460 per injection; generally, patients need an injection every two weeks, bringing annual costs per patient year to over €12,000. It was sold at these prices in the Netherlands between 2004-2010, during which time AbbVie netted €2.37 billion. When biosimilars entered the market in 2018, the price of Humira dropped by 80% in the Netherlands, indicating that these high prices were based on an abuse of monopoly rather than high cost of production.

While Dutch patients do not bear these costs privately, PAF believes that they imposed an unfair cost on the Dutch health system generally and may have resulted in displacement of care.

Displacement of care happens when limited health budgets encounter rising prices, necessitating rationing of care (for example, delaying care or limiting care to the sickest patients) or trade-off decisions. For a more thorough exploration of displacement of care, see PAF's website here: <https://www.farmaterverantwoording.nl/issues/poor-enabling-environment/#displacement>

In PAF's estimation, AbbVie may have charged the Dutch healthcare system an excess of €1 billion.

On 21 December 2021, the Pharmaceutical Accountability Foundation (PAF) sent a Letter of Liability to AbbVie. In accordance with the value that PAF attaches to fair pricing, we have called AbbVie to account for the excessive pricing it charged for Humira between 2004-2018 while the drug was still protected by patent. We have asked AbbVie to respond to our view that it acted unfairly by charging these excessive prices, and that this resulted in a displacement of care within the Dutch healthcare system, creating access barriers to healthcare products and services for Dutch citizens, and resulting in a severe loss of Quality Adjusted Life Years (QALYs).

The Foundation has requested a meeting with AbbVie in an effort to settle this matter out of court, and has asked the company to respond substantially by 28 February, 2022.

## LEGAL MENTORSHIP: GUIDING NGOS, PHARMACISTS AND OTHER EXPERTS:

PAF believes that better understanding of the legislation and legal procedures governing healthcare can provide non-governmental organisations and others seeking to expand access to health products with avenues for action. In particular, the human right to health imposes binding legal obligations on governments; but companies, too, have a responsibility to protect the right to health.

In PAF's work to hold specific companies accountable for high prices (see section above), we have gathered several important lessons that can aid others in their own struggles. Just as the Leadiant case in the Netherlands was able to inspire action in several other countries, PAF expects that the dissemination of critical legal information can help guide and encourage accountability measures taken by others. To that end, the organisation has stepped up in 2021 its mentoring work, including through:

The launch of guidelines for legal actions by NGOs: Based on PAF's experience as well as on the experience of other NGOs that have used legal action to increase access to medicines, PAF has pulled together a set of legal guidelines.

This document is intended to aid NGOs considering legal action by detailing all necessary steps, from prior research – i.e., knowing the patent status of the medicine at issue, and whether high prices are caused by the company or by an outside factor (such as poor insurance coverage) – to key preparatory phases such as contacting the company about their human rights responsibilities or engaging with public institutions; and finally through what is needed to take legal action if other means to bring down prices fail.



When legal action is required, the guidelines also lay out where problematic legislation can cause access problems and provide links to resources and ideas for combatting those problems. Explored legislation includes the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement; strategies for increasing market monopolies such as orphan drug legislation or ever-greening of patents (a process whereby companies obtain additional patents on the same product under the claim that it is a 'new invention', whereas it is actually just a slight modification of the drug); abuses of competition law; and abuses in contract law.

The guidelines were first introduced in a webinar attended by more than 60 global public health experts held on 22 November 2021<sup>14</sup>.

PAF's plan is to continuously refine and develop these guidelines as more lessons are learned and information is compiled; the aim is that they will be a living resource for all seeking to use legal action to improve access to medicines.

The latest version of guidelines can be accessed on PAF's website here: <https://www.farmaterverantwoording.nl/legal-guidelines/>

### **STUDENT MENTORSHIP:**

PAF is involved in training the next generation of access to medicines advocates. The Maastricht University Institute for Education Innovation (EDLAB)'s honours programme, 'PREMIUM', aims to bridge the gap between career and study by giving motivated Master's students the chance to complete a group project under the mentorship of experienced professionals. In 2021, PAF partnered with the Universities Allied for Essential Medicines (UAEM) to mentor five students through a project investigating why the medicine Truvada (a treatment for HIV) is so expensive<sup>15</sup>. More on the project can be learned from the team's webpage:

<https://truvadateam.tumblr.com/>.

### **TRAININGS FOR PHARMACISTS:**

In addition to Master's students, PAF is also engaging pharmacists, who are often at the front lines of medicines pricing. On 30 October, several of PAF's staff and advisors gave a workshop at the Dutch Young Pharmacists' Association (VJA) Congress, at which they detailed actions that pharmacists can take to combat medicines piracy. Notably, in the Netherlands pharmacies are able to compound – that is, manufacture – their own versions of medicines and make them available for their patients. Pharmacists can also advocate for and contribute to better transparency on medicines pricing, which is needed to determine what a 'fair price' is.

# PAF'S GROWING TEAM

---



To keep pace with its growing and expanding list of activities, the PAF team has also grown. In 2021, our governance board expanded to include treasurer Hans Smits, a former automotive executive who is volunteering in public health during his retirement; secretary Tegan Insoll, a human rights lawyer with a focus on global health and children's rights; and Sabina Voogd, who owns a business that advises and trains lobbyists working in the public interest. They join chairperson Wilbert Bannenberg, a physician and public health consultant with expertise in improving pharmaceutical systems in developing countries.

Our Expert Advisory Board also added two new members: Anna Laskai, a criminologist and assistant professor at the University of Utrecht; and Richard van Slobbe, a public pharmacist specialist. They join existing members: Brigit Toebes, a professor of health law at the University of Groningen; Ellen 't Hoen, a lawyer and public health advocate who directs Medicines Law & Policy; Tom Buis, a global health advocate at Wemos; Jennifer Sellin, an assistant professor of international and European law at the University of Maastricht; Katrina Perehudoff, a health scientist and legal scholar; and Ella Weggen, a lawyer and senior global health advocate at Wemos.

PAF has also added three new staff members: Emily Dowdalls, a trained pharmacist and community organiser is now PAF's project coordinator. Rosalind Turkie, a human rights lawyer with expertise in using law to promote more sustainable food systems, is coordinating the GCCP work. And Kaitlin Mara, a writer on intellectual property and access to medicines, is providing communications support.

### NEW FACES:



Hans Smits  
*Treasurer*



Tegan Insoll  
*Secretary*



Sabina Voogd  
*Board Member*



Anna Laskai  
*Advisory Board*



Richard van Slobbe  
*Advisory Board*



Emily Dowdalls  
*Project Coordinator*



Rosalind Turkie  
*GCCP Coordinator*



Kaitlin Mara  
*Comms Coordinator*

## **RAISING PAF'S PROFILE: WEBSITE, SOCIAL MEDIA, AND MEDIA WORK:**

In 2021, PAF launched an updated and greatly expanded version of its website, with a new design and expanded information resources. For the first time, it is fully bilingual, with both Dutch and English static and dynamic pages. The site has grown steadily over the year, with new texts added to describe key issues and solutions in access to medicines; with the publication of the legal guidelines (see section above); and with several pages on medicines PAF is investigating.

Uptake of the website has been strong. Between 1 January and 31 December, the website received 13,321 page views from 3,687 unique visitors. Our work in Covid-19 was particularly popular, with 808 views of our page on Covid-19 practices and a further 794 unique views of the GCCP scorecard.

2021 also saw significant growth in PAF's social media presence, notably on Twitter with almost 100 new followers (a 25% increase) and a reach far greater: PAF's Tweet views totalled 58,978 for the year. Our LinkedIn reach also grew, from its launch in February 2021 to 84 followers by the end of the year.

PAF kept a steady press presence, with PAF Founder and Chairperson Wilbert Bannenberg being directly quoted in more than 40 articles and informing many more. Of particular note is the 19 November edition of the Pharmaceutical Weekly Journal (Pharmaceutisch Weekblad, PW), where an interview with Wilbert and expert advisor Richard van Slobbe was featured on the cover as well as in the magazine's weekly editorial cartoon<sup>17</sup>. One of PAF's expert advisors, Ellen t Hoen, was also frequently featured in the press this year: she was quoted in over 100 articles and interviews with her featured in six video and audio media, including three from the Netherlands.

PAF experts continue to be invited to speak from their expertise to inspire university students. Two notable examples were a 22 November appearance at the University of Amsterdam detailing the policies and practice of access to medicines, and a 3 November talk at the Erasmus Law School in Rotterdam on the subject of pharmaceuticals, expensive medicines, human rights and duty of care. Press Conference to call for international vaccine access.

# LOOKING TOWARDS 2022

---

Highlights from the last year have poised PAF for even more success in 2022. Expected highlights from the upcoming year include:

- The progress of PAF's research into potential displacement of care by AbbVie over its Humira prices, as well as the impact of the letter of liability sent to AbbVie in December 2021.
- The launch of the second iteration of the GCCP, with both an expanded list of evaluated companies and products as well as new legal parameters.
- The launch of a companion document to the GCCP, on guidelines for responsible company behaviour in pandemic situations.
- Continuing evolution of PAF's legal guidelines to expand access to medicines.
- The expected conclusion of the ongoing AMC case against Leadiant.

## ENDNOTES:

1. See here for its full text in Dutch: [https://www.farmaterverantwoording.nl/wp-content/uploads/2021/04/2018.09.07\\_Handhavingsverzoek-FtV-inzake-Leadiant.pdf](https://www.farmaterverantwoording.nl/wp-content/uploads/2021/04/2018.09.07_Handhavingsverzoek-FtV-inzake-Leadiant.pdf) and in English: [https://www.farmaterverantwoording.nl/wp-content/uploads/2021/04/2018.09.07-Handhavingsverzoek-CDCA\\_English-unofficial-translation.pdf](https://www.farmaterverantwoording.nl/wp-content/uploads/2021/04/2018.09.07-Handhavingsverzoek-CDCA_English-unofficial-translation.pdf)
2. <https://www.acm.nl/en/publications/acm-imposes-fine-drug-manufacturer-leadiant-cdcas-excessive-price>
3. <https://www.ema.europa.eu/en/medicines/human/EPAR/chenodeoxycholic-acid-leadiant>
4. <https://www.farmaterverantwoording.nl/2021/07/19/acm-has-honored-the-enforcement-request-of-farma-for-accountability-foundation-and-fined-pharmaceutical-company-leadiant-with-e19-5-million/>
5. <https://mlexmarketinsight.com/news/insight/leadiant-wins-suspension-of-dutch-excessive-pricing-fine-as-regulator-probes-insurers>
6. [https://www.gov.il/BlobFolder/news/mbi/he/pressreleases2021\\_%D7%9C%D7%99%D7%93%D7%99%D7%90%D7%A0%D7%98.pdf](https://www.gov.il/BlobFolder/news/mbi/he/pressreleases2021_%D7%9C%D7%99%D7%93%D7%99%D7%90%D7%A0%D7%98.pdf)
7. <https://barlaw.co.il/client-updates/for-the-first-time-israel-competition-authority-enforces-prohibition-on-excessive-pricing>
8. <https://open.overheid.nl/repository/ronl-336e4b07-7772-42c7-bde6-f205325f5e93/1/pdf/kamerbrief-over-geen-opname-namuscla-in-basispakket.pdf>
9. See, for example: <https://pubmed.ncbi.nlm.nih.gov/32006435/>
10. <https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3171945>
11. <https://www.volkskrant.nl/wetenschap/hoe-duur-wordt-diego-s-medicijn-de-prijs-van-een-oud-middel-gaat-bij-een-nieuwe-eigenaar-hard-omhoog~be503130/>
12. <https://www.volkskrant.nl/wetenschap/hoe-duur-wordt-diego-s-medicijn-de-prijs-van-een-oud-middel-gaat-bij-een-nieuwe-eigenaar-hard-omhoog~be503130/>
13. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>
14. <https://www.farmaterverantwoording.nl/2021/11/08/event-power-of-law/> . A recording of the webinar is available on PAF's YouTube channel here: <https://www.youtube.com/watch?v=eY7GnbNVOaw>
15. <https://edlab.nl/excellence/premium/current-premium-students/premium-finishers-2021/#farma>
16. <https://www.farmaterverantwoording.nl/nl/2021/11/11/workshop-at-dutch-young-pharmacists-association-vja-congress/>
17. <https://www.farmaterverantwoording.nl/2021/12/06/interview-in-pharmaceutical-journal/>

# FINANCIAL REPORT

Cash 1-1-2021	21,388.28 €
Subsidies	144,312.18 €
Donations	6,053.79 €
Total income cash	150,365.97 €
Staff costs	50,444.48 €
Organisational costs	947.37 €
Project costs	56,378.86 €
Interest and other costs	-
Total expenditure cash	107,770.71 €
Cash 31.12.2021	63,983.54 €