



Pharmaceutical Accountability Foundation

Using Law to Promote Pharmaceutical Accountability and Access to Medicines

Guidelines for legal actions by NGOs

Version 24 January 2022 - This is a living document on FtV/PAF website that will be regularly updated

If you have comments/suggestions: please send to PAF through email: guidelines@farmaterverantwoording.nl

Disclaimer:

These guidelines have been developed by Farma ter Verantwoording (Pharmaceutical Accountability Foundation (FtV/PAF)) as a service to other NGOs that want to campaign for access to medicines. They are based on FtV's and other NGOs' experiences, and have been enriched by discussions and examples mentioned in FtV webinars and literature reviews. Examples have been added where possible. FtV brings these guidelines as possibly helpful suggestions; NGOs should establish proper cases and consult local lawyers before applying any of the recommendations. FtV cannot be held responsible for any omissions or advice in this document. FtV will consider all reasonable comments or requests for changes.

Introduction

- The [human right to health](#), which includes [access to essential medicines](#), imposes legally binding obligations on States, signifying that they have to put in place laws and policies to enable the realisation of these rights.
- Pharmaceutical companies have a responsibility to respect the right to health through the [Business and Human Rights Principles](#) ('Ruggie Principles').
- Pharmaceutical companies often state on their websites that they adhere to the UN Business and Human Rights *principles*. These have been converted by former UN Special Rapporteur on the right to health Paul Hunt into 47 [Guidelines on the human rights responsibilities of pharmaceutical companies towards access to medicines](#). ([alternative link to a word file](#))
- The PAF [Good Covid-19 Company Practices](#) (GCCP) are based on these human rights principles and responsibilities for pharmaceutical companies, and have resulted in a set of recommended good practices 'Guidelines for responsible pharmaceutical behaviour' that pharmaceutical companies should adhere to.

- The [GCCP Scorecard](#) of March 2021 (2nd edition) scores 9 vaccine and 3 therapeutics manufacturers with a traffic light system. The scorecard is being updated to score 25 products in March 2022.
- The GCCP Scorecard shows that, although the scores vary, in general pharmaceutical companies do not substantially adhere to the GCCP criteria, despite the fact that nearly all agree on their websites to adhere to the UN Business & Human Rights principles.
- Pharmaceutical companies cannot currently be held accountable under international human rights mechanisms. This means that no one (e.g., neither a state, non-governmental organisation (NGO), nor an individual) can raise a formal complaint against a pharmaceutical company at the international level under human rights law.
- NGOs can, however, lobby national law and policy makers (e.g., parliament, government) to introduce national binding norms that are enforceable against pharmaceutical companies. For example, PAF has advocated for a ‘duty of care’ norm for pharmaceutical companies in the Netherlands. There are other types of legal actions that NGOs can take.
- These guidelines are intended to inform NGOs considering legal action against pharmaceutical companies that prevent, endanger or restrict access to (their) medicines and/or access to health care in general.
- These guidelines are based on PAF’s experience and examples from other NGOs who have inter alia taken legal actions against pharmaceutical companies in order to improve access to their products.
- These guidelines, although developed initially for Covid-19 products in the GCCP project, can also apply to all other essential medicines that people need access to.

Definitions

- [\(Legal\) procedure](#): the methods by which legal rights are enforced; the specific machinery for carrying on a lawsuit, including process, the pleadings, rules of evidence, and rules of Civil Procedure or Criminal Procedure.
- [Legal action](#): any lawsuit, petition or prosecution.

Before you consider legal action

Taking legal action is a process that can take a long time and demand substantial human and financial resources. NGOs should therefore investigate whether they can stimulate pharmaceutical companies to do the right things before considering legal action. NGOs can lobby parliament or government to change laws, or they can organize campaigns to make the general public aware of the problem, and thus exert pressure on pharmaceutical companies. The GCCP project has taught PAF that there is value in pointing pharmaceutical companies to the human rights principles to which they have publicly committed. The debate on the human rights responsibilities of pharmaceutical companies can also be used to change the legal system in countries. However, the GCCP project also showed that pharmaceutical companies are not willing to change on certain aspects that might undermine their long-term profits or business model. There is also increasing attention paid to ‘fair’ medicine pricing, and its logical consequence: that unfair medicines pricing might lead to unfair, excessive profits, and thus to damage to patients and health care systems that can only spend each health care dollar once.

PAF has listed on its website all the issues that lead to access problems or excessive pricing and profits. It has also listed solutions on how governments, professionals, patients (organisations) and NGOs can mitigate these issues. Some problems, however, cannot be adequately addressed by the known solutions, as governments have failed to regulate excesses in national legislation. It is in that context that NGOs could explore and consider other solutions such as legal action.

Below PAF describes some possible steps that NGOs can take to advocate for companies to improve their practices, or solve the problem before taking legal action.

1. **Describe**- what is the problem? What is the desired solution/outcome?
2. Check the status of the pharmaceutical company: does this company:
 - Have a valid company license to operate in your country?

- Is it subject to regular inspections on its GMP/GDP status?
 - Have the legal right to manufacture and/or sell the product in your country? (registration)
 - Have a patent, market exclusivity or other monopoly for the product?
 - If not, is it producing the product under license? If so, what are the licensing conditions?
 - Does the company adhere to the UN Business & Human Rights Principles?
 - Is it a member of a Pharmaceutical Manufacturing Association which adheres to a Code of Conduct or other Principles?
3. Does the company directly **cause** the problem, or is the problem due to an **outside factor** or poor enabling environment?
 - Is the problem an **excessive, unfair price** that is
 - not accepted by your country,
 - not reimbursed by your health insurance system or
 - not affordable to you, or
 - displaces access to other health care
 - You have **no access** to a product which is
 - in principle available or registered in your country
 - not available / registered in your country (but available in other countries)
 - not available due to global inequitable distribution
 - Other problems?
 4. Determine your **strategy**: make a plan for how to roll out the campaign, which advocacy or public pressure strategy would work best, and consider which type of legal action would eventually be appropriate.
 5. **Research**: investigate which norms or legal frameworks exist for the problem. Consult professionals and institutions. Document your case meticulously. Apply investigative journalist techniques, and be fair by applying ‘hear and hear’ (Dutch ‘hoor en wederhoor’). Be transparent in your actions, and document them on your website.
 6. **Compare** your findings about the company’s behaviour with established societal norms, laws and good practices (such as the Good Covid-19 Company Practices).
 7. **Document** all your findings and sources in a safe computer with an encrypted backup in the cloud.

Then start approaching the company:

8. **Ask**: send a public, open letter to the company; explain the problem, and ask them to apply the “Good Practices”, and stop any “Bad Practices”.
9. **Explain** in your exchanges with the pharmaceutical company their Human Rights Responsibilities: praise them for having a statement on their company website that they adhere to the “UN Business & Human Rights principles”, and for their good practices. But also clearly explain where they are not adhering to them. Request the company to change their bad practices. Point to the GCCP or other scorecards, and request a public answer.
10. **Compare** companies: for their bad practices, point to other companies with good or better practices. You can find examples of better scoring companies on the PAF GCCP website. Use them as comparisons in their communication with companies.
11. If they **reply**, ensure that all documents can be made public on your website (if needed)
12. If they ignore you, **remind them**, and state that you have published the open letter on your website, or point to a blog that you have written about it.
13. Raise general **awareness** (use your findings to write a scientific paper, work with press, ask questions in Parliament etc)
14. Use **social media** with your demands

15. **Work with other NGOs or networks** that are working on similar issues (CIFA partners, Access-Covid-19 group, dedicated NGOs like Health Action International, Amnesty Intl, Human Rights Watch etc)
16. **Engage public institutions** which can possibly investigate whether regulatory action is possible (pharmaceutical inspectorate, regulatory authority, competition authority, pricing authority etc)

A single case of 'bad' behaviour can also be used in a wider campaign as an example of the need for change. You could use this example to:

17. **Lobby** national or regional lawmakers to provide a stronger legal basis for the Good Practices
18. If the unwanted practices are not violating current laws, **campaign for better laws/regulations** in NL/EU/globally
19. Request institutions that have **leverage** (purchase agreements, political power) over pharma to intervene (Governments, UN Agencies)

When the above methods have failed... Time to consider legal action

When the above steps have failed to bring a solution, and you still want to stop / mitigate the problem or bad practice, it may be time to consider possible legal action.

First you need to do the research to determine the facts of the precise violation that you will allege, who is responsible for the violation, through which actions, which legal rules apply to this case, and, depending on your NGO, which options you have to take legal action.

Analyse the pharmaceutical product

Most problems are caused by [single-source products](#). This means that the product is subject to a monopoly that the company has obtained through:

20. a [patent](#)
 - A product patent on the original compound lasts 20 years. Have a patent expert investigate whether
 - You can oppose the granting of a patent before the Patent Office grants it (pre-grant opposition, e.g., [NGOs in India](#))
 - The patent is weak, futile or can be challenged (Patent challenge, e.g. [Gilead sofosbuvir, EU, by Médecins du Monde, Kymriah, Switzerland, PublicEye](#))
 - The product is important for public health (see [Doha Declaration](#)), and not made available on reasonable grounds, or the company refuses to market the invention (non-working)
 - NGOs can lobby governments who can issue a 'Government Use' license ([Pfizer Paxlovid, Chile, Inovart](#))
 - Anyone (competing companies, NGOs) can apply for a 'Compulsory License' under national patent law. Medicines Law & Policy maintains a [TRIPS Flexibilities database](#) of such examples.
 - Some companies use a 'patent thicket' technique, whereby they apply for many more patents on other aspects of the product
 - This is misuse of the patent system and needs a specific campaign ([AbbVie, adalimumab/Humira, I-MAK](#))
 - Companies try to extend the protection by changing something in the product and obtain a new 20-year patent protection for the product ('evergreening')

- By changing something to the molecule (a new salt, ester, etc)
 - By changing the dosage form (slow release, different dosage form)
 - By using 'easier' injection methods (insulin or EPI pens)
 - Companies may 'forget' that the original research underlying the patent was funded by public sources, as this confers certain duties on the marketing of the product.
 - NGOs petitioned the US Government for non-compliance by Moderna of a contract with BARDA (e.g., covid-19 vaccine [Moderna, USA, KEI/Public Citizen](#))
 - NGOs asked the USA Government to grant a march-in request for the patents on a drug partially invented and developed in clinical trials funded by US Army and NIH, which is sold at > \$156,000 per year, 3 to 5 times higher than any other high-income country? (e.g., prostate drug Enzalutamide/[Xtandi, KEI](#))
 - EU allows companies 'compensation' for
 - shorter than usual patent life due to prolonged regulatory processes (Supplementary Protection Certificates)
 - Developing a paediatric version of an existing drug (6 months patent extension)
21. [Data exclusivity](#): EU allows 8 years protection against the registration of a second version of the drug by blocking referral to the efficacy/safety data of the first registered on the market (usually the originator, but it could also be a generic)
22. [Orphan drug market exclusivity](#) (given to encourage development of products for very rare diseases)
 - EU grants 10 years marketing exclusivity from the time EMA registers the product with a new orphan drug indication.
 - USA 7 years [check]
23. [Being the only one in the market](#) (why are no competing products available?)

Analyse the pharmaceutical company

Is the company responsible for the problematic product showing any specific behaviour that could be legally tackled?

24. Not adhering to national pharmaceutical laws
 - Consider bringing a complaint to the National Health/Pharmaceutical Inspectorate or Medicines Regulatory Authority
25. Not adhering to agreed Principles or ethical norms (e.g., Socially Responsible Licensing, Netherlands)
 - Consider bringing a complaint to the supervisory organisation, or ask Parliamentary questions
26. Not adhering to agreed Codes of Conduct of the National/Regional/Global pharmaceutical industry association, e.g., [VIG Code](#) the Netherlands, [PhRMA](#) USA.
 - Consider a complaint with the pharmaceutical association (e.g., anabolic steroids, Organon, Netherlands, [Wemos vs Nefarma 1983](#))
27. Not adhering to procurement contracts (e.g., Covid-19 vaccine AstraZeneca, EU)
 - Consider a civil case (contract law)
28. Not adhering to the [Business & Human Rights principles](#) (more specifically, [Paul Hunts 47 responsibilities](#) or PAF [GCCP criteria](#))
 - If the company does not (yet) adhere to Business & Human Rights principles (normally in a statement on the website or in the Annual or Corporate Accountability Report), campaign for its inclusion.
 - If companies agree to the principles, but show bad practices:

- Engage with the companies, pointing them to the fact that the above mentioned principles have been converted into responsibilities by the UN, and show them the GCCP criteria (FtV)
- Complain to their Corporate Social Responsibility or Sustainability departments
- Involve [big investors](#) that can put pressure on the company
- Raise a motion at the annual Shareholders' Conference
- Naming and shaming in the media
- Although companies cannot be held accountable in court for international human rights violations, they should have a duty of care to the patients that are dependent on their medicines:
 - Governments (which have a legally binding duty of care under human rights law) enshrine this duty of care in legislation and financing to private sector / companies
 - In some countries (France, Germany) national laws have been passed which force company board members to take care of sustainability and HR issues (OECD Due Diligence)
 - Campaign for a 'duty of care' for pharmaceutical companies (e.g., Netherlands FtV campaign for 'zorgplicht')
- You could use the principles/responsibilities in other legal action (see tort)

29. Anti-competitive behaviour

- If the company is showing signs of
 - cartel forming with other companies (vitamins, Roche, EU, [Adams vs Roche](#))
 - Misuse of a dominant economic power position (orphan drug CDCA, Leadiant, Netherlands, [FtV](#))
 - [Pay for delay](#) (where an originator pays a generic company to delay generic market entry)
 - Increasing prices and/or creating shortages (e.g., oncology medicines, [Aspen EU case](#))
- You could consider bringing your complaint to the National (or European) Competition Authority

30. [Tort law](#) (Dutch: [onrechtmatige daad](#))

- Something might not be expressly legally forbidden, but if most parties in society find some practice unwanted/unreasonable or against [\(un\)written legal norms](#) (including international human rights' norms) then in some jurisdictions (NL, Belgium) you can start a tort procedure
- Successful legal action has been taken by environmental NGOs: [Urgenda vs the Netherlands State](#), [Milieudefensie vs Shell](#)
- Can companies be held responsible for making excessive profits? ([Humira](#), [AbbVie](#), [PAF](#) Netherlands).

Analyse your specific country's legal situation

You should consider national (and in some countries sub-national laws) that apply to companies established in your territory, as well as any supra-national laws, such as regional laws (e.g., EU Directives) or international agreements (e.g., [WTO TRIPS Agreement](#)), that create enforceable rights for individuals and/or binding obligations for states or companies operating in your territory.

Your country:

31. The applicability of international IP standards depends on your country's level of economic development:

- If your country is a Least Developed Country ([LDC](#)), your country will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 2033. In lay terms, you can probably ignore pharmaceutical patent applications unless your country has specifically approved them.
 - Your country is not an LDC but may use higher protection ([TRIPS-plus](#)) than is required under TRIPS
32. The applicable IP standards in your country are established in regional and/or national law:
- Your country's (or regional) Patent Office permits futile patent applications, or grants patents without examination (pre-2018 South African situation)
 - May have inappropriate IP/patent laws (See explanation below in section on TRIPS-plus)
 - May have exclusivities for medicines in other types of laws, such as pharmaceutical regulation
33. Your rights under national law should be protected in the national constitution:
- Does your country have a constitution that recognises an enforceable right to health (or other right that would require the provision of essential medicines)? If so, you can use it to protect citizens against unfair government decisions (e.g., nevirapine, South Africa, [Minister of Health vs Treatment Action Campaign](#))
34. If you have a weak constitution, an unjust, corrupt or poorly operating legal system,
- this might hinder you from enjoying your rights. Consider strengthening your legal system.
35. Can you refer the case to supranational courts, appeal to international agreements, or use international covenants?
- The [Court of Justice of the European Union](#), the [European Court of Human Rights](#), the WTO [dispute settlement body](#) system

Which legal actions could be appropriate for my organisation?

Analyse:

- Do we know enough about the problem?
- NGO legal status: can we take a company to Court? Admissibility of case/parties?
- Budget: small/medium/big? Can we do it pro bono? (or: let others do the work e.g. Competition law)
- Legal expertise: do we have access to a team of competent lawyers? Do they have access to legal experts in national / regional law (whichever law is applicable to the case)
- Time frame: how urgent is our case? Are preliminary measures required? (Dutch law: kort geding)
- Territory: is this a national/EU-wide/global case?
- National/international legal enabling environment: which laws are in place at country, regional or international level which help/hinder my case?

Set clear goals:

- What do we want to achieve? (financial compensation, public 'shaming', general price reduction, Court ruling (jurisprudence), change in the laws/EU regulations)
- Who is our target? (global company, national company, brand/generic, parliament/health ministries)
- What kind of support do we have? (media, communications, civil society, political, institutional)
- Which steps do we want to take, in which order? based on the support/ resources that we have or organise?

More explanations about the underlying laws

1. Problematic Laws/Practices

TRIPS/TRIPS + :

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides the minimum standards for the protection of intellectual property rights (IPRs) WTO Members need to implement. Currently, IPRs in knowhow are a barrier to increasing covid-19 vaccine access by scaling up production.

TRIPS+ or TRIPS-plus: higher levels of protection (often demanded by developed countries) that are not prescribed by the WTO's TRIPs regime. Rather, the term is used to indicate that these requirements go beyond the minimum standards imposed by TRIPs (TRIPS- or TRIPS-minus). See [our website](#) for further explanation.

Legal recourses:

- *If you are a Least-Developed country, use the LDC exemption:* under [Article 66.1](#) of the TRIPS agreement, LDCs are given a transition period that exempts them from the obligation to fully implement TRIPS. This was extended until July 2034. This exemption should be promoted and encouraged to avoid unnecessary barriers to drug access due to IPRs.
 - ❓ Pharmaceutical companies in LDCs can possibly ignore patents and produce generic versions, if the country makes use of the LDC transition. Exception: if the country implements a patent law that allows for medicines patenting, AND starts granting them, then you cannot 'ignore' them. You may be willing to take the risk because an infringement suit is less likely... Example: [Uganda](#)
 - ❓ If your LDC country is a member of a regional economic community (REC) with a majority of LDCs, then certain restrictions (like exporting max 50% of domestic production) do not apply. Most African LDCs are member of RECs where locally produced goods can circulate freely
- *Promote use of TRIPS flexibilities/TRIPS minus in national laws:* these [enable 'developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies'](#) and include:
 - ❓ Make sure that your country only applies TRIPS minus, and removes TRIPS-plus aspects of national laws. Examples: [SARPAM TTATM report Southern Africa](#)

Apply TRIPS flexibilities

- ❓ Government Use or Compulsory licenses: countries can grant this to override a medicine patent ❓ [Russian Government Use License on Remdesivir](#)
- ❓ Pre-grant patent opposition systems offers the opportunity to oppose a patent before it is granted
- ❓ Minimum patenting criteria : TRIPS establishes a minimum standard of protection of rights – Members may choose to follow this minimum (TRIPS minus) or raise the level of protection of rights (TRIPS plus). States should be encouraged to opt for TRIPS minus measures in patenting ❓ Examples: [UNDP/ WHO Reports](#)
- ❓ Ellen 't Hoen's handbook . [Private patents and public health.](#)

What is the legal strategy?

- Analyse national IP laws to remove TRIPS-plus aspects and maximize TRIPS flexibilities (get help from friendly lawyers, UNDP, or University)
- If you are an LDC, request the Patent Office not to grant any pharmaceutical patents, and invite pharmaceutical manufacturers to produce generic versions of products that might be patented in other countries
- Analyse the National (or Regional) Patent Office policies: Are they critically reviewing pharmaceutical patents? If not, warn the Health Ministry that this will cause problems later (Case: South Africa - the country granted all patents that were requested, without any assessment)
- Promote the use of TRIPS flexibilities (normally the Health Ministry benefits, whereas the Economic Affairs Ministry opposes; example: Netherlands)

Patent extensions

An IP right that extends the duration of certain patent rights. This extends the monopoly for a patent-protected product. In the EU this is called a [Supplementary Protection Certificate](#) and applies to pharmaceutical products under certain conditions and other specific areas.

Legal recourses:

- *Use patent law to prevent the patent extension from being granted:* challenge the granting of the SPC
 - ❓ [CJEU in Truvada case](#): a group of manufacturers of a generic version of an antiretroviral drug marketed under the trademark Truvada commenced invalidity proceedings in the UK against an SPC held by Gilead for the drug. The CJEU ruled in favour of the Generics group, holding that the Truvada SPC did not meet the criteria for legitimacy

What is the strategy or legal recourse?

- Campaign against SPCs in the current EU pharmaceutical strategy
- Campaign at country level not to apply SPCs for essential medicines
- Compare countries: If other EU countries have rejected SPC for a particular drug, convince your government to do the same
- Ask technical support from specialised lawyers and organisations (such as [Medicines Law & Policy](#))
- Civil disobedience (example: UK buyer's club for TDF/FTC (Truvada))

Evergreening

Evergreening is the 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. This creates a barrier to the production of generics and thus to the accessibility of the drug.

Legal recourses:

- *Use patent law to undermine the evergreening* challenge the [legitimacy of the patent](#)
 - ❓ [Novartis v Union of India](#): Swiss pharmaceutical company Novartis was refused a patent for an anti-cancer drug Gleevec by the Indian Supreme Court based on the fact [that the Court did not consider the modification of the original drug to be a patentable 'invention'](#).
 - ❓ [Menzis v AstraZeneca](#): AstraZeneca was in first instance forced to pay damages to health insurance company Menzis after the Dutch court found it had '[unjustly enriched itself](#)', by enforcing a patent on a slightly different version of a known product. The verdict was struck down in the appeal.

What is the legal strategy?

- Analyse the evergreening strategy of your target company: typically they will create a different salt or dosage form and claim this works better for patients, a few years before their original product patent expires.
- Check whether other countries have rejected the patent extension, or whether generic companies have challenged the patent validity
- Document the excessive price as compared to generic versions, and calculate the excess paid
- Request the company to lower the price or to allow generic competitors into the market.
- If they refuse, calculate the excess costs paid and start a civil case

Orphan drug status/Dominant market positions

An orphan drug status is a designation given to pharmaceutical companies to encourage them to develop products for those diseases which are so rare that developing medication for them is not profitable. The status gives them various (monetary) benefits such as marketing exclusivity, tax credit for clinical trial expenditures, etc. The problem is

that this status can lead to excessively high prices for the drugs due to the monopoly market position of the company which holds the rights to the orphan drug.

Legal recourse:

- *Use consumer/competition law to undermine the orphan drug designation:* challenge the legitimacy of the orphan drug designation when companies abuse their dominant position and patients benefit little from the designation
 - ❓ [Hazel Tau & others vs GlaxoSmithKline \(GSK\), Boehringer Ingelheim \(BI\) & others](#): The South African Competition Commission found that two firms (GlaxoSmithKline & Boehringer Ingelheim) had [‘abused their dominant positions by charging excessive prices for their patented antiretroviral medicines’](#). GSK and BI then agreed to license their patented medicines to local generic manufacturers.
 - ❓ [CDCA-Leadiant: the Dutch Authority for Consumers and Markets \(ACM\) fined company Leadiant](#) for abusing its dominant market position and violating competition rules. Leadiant had raised the price of a CDCA-based drug after obtaining orphan drug designation and was granted the exclusive right to supply the drug to the European market.
- Prevention: Mobilise professionals and patient organisations. Convince the Health Technology Agency that the price is excessive, and that the orphan product can be compounded at much lower costs by pharmacists or imported as a generic from abroad
 - Mexiletine (Namuscla, Lupin). The company originally asked for a 430x increased price. Even after dropping the asking price to 100x, [the Netherlands HTA agency ZIN advised against reimbursing the excessive price](#) as good quality generics could be imported and pharmacists could compound the product at lower cost.

What is the legal strategy?

Consider a competition law complaint (misuse of economic power position)

Campaign for a changed EU Orphan drug Directive (ongoing debate in EU 2022-2023)

Cartels

Cartels are companies that compete in the same industry and act together to reduce competition by restricting trade.

Legal recourse: *Use competition law to curb malpractices (Article 101 of the Treaty on the Functioning of the European Union prohibits [‘anti-competitive agreements between two or more independent market operators.’](#))*

- ❓ [Roche vs Adams](#): a group of giant drug companies, including Swiss company Roche, were fined 523 million pounds by the European Commission in 2001 after Stanley Adams blew the whistle on Roche, revealing the groups’ collusion to fix prices.

What is the legal strategy?

- If you suspect a cartel, report it to the competition authority.

Human Rights Law: Primary responsibility lies with the State

The system of international human rights law is legally binding on governments, which have obligations to respect, protect, and fulfil the human rights of their populations. The [WHO Constitution of 1946](#) views the “...the highest attainable standard of health as a fundamental right of every human being.”

Legally enforceable accountability therefore rests primarily with States.

Legal recourse

- *Use and promote the notion of private actor responsibilities to respect human rights:* The [United Nations Guiding Principles on Business and Human Rights](#) make clear that private companies also have a responsibility to respect human rights. In 2008, the first UN Special Rapporteur on the right to the highest attainable standard of health, wrote the [Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines](#). Specific responsibilities therefore apply to pharmaceutical companies in relation to access to medicines. These guidelines should be promoted and reinforced in order to increase the accountability of private actors under human rights law.
- *Tort law:* no examples for A2M but in other areas of human rights, tort litigation has been successful in holding private actors accountable for human rights violations, e.g. <https://earthrights.org/case/wiwa-v-royal-dutch-shell/>; <https://www.urgenda.nl/en/themas/climate-case/>

What is the legal recourse?

Convince the court in a tort or civil case that the company has failed to honour its human rights responsibilities.

Campaign in the national parliament for more binding legislation for pharmaceuticals, including duty of care.

Abusive Clauses in Contracts

Pharmaceutical companies often insert unfair clauses in their supply contracts. These can range from liability waivers for any side effects of the medical product, confidentiality agreements which prevent the publishing of the contracts (these are not only detrimental to transparency, but also protect the company from any liability in case of delays in delivery, etc), and stipulating that dispute are resolved by private arbitrators instead of in a public court hearing.

Legal recourses:

- *Before signing the contract:* lobby governments to adopt socially responsible licensing clauses in advance purchase agreement contracts for products in development (e.g. [NL NFU Principles](#))
- Lobby for transparency in purchase agreements (ref [WHO pharmaceutical transparency resolution of 2019](#))
- *After the contract is signed:* use contract/consumer law to sue the company for **breach or claim abusive contract (illegal/unfair to one of the parties)**
 - ❓ [EU suing AstraZeneca for insufficient delivery of Covid-19 vaccines](#)
 - ❓ [Could COVAX sue the pharmaceutical companies that have not delivered on their supply contracts?](#)

Questions to ask in considering legal action

Patent law

- How to analyse and fix the national patent law?
- How to get your country TRIPS-minus?
- How to get rid of/avoid TRIPS-plus?
- How to influence decisions by the national/regional patent office?
- How to prevent a patent from being granted? (pre-grant opposition)
- How to challenge/neutralise a patent in the interest of public health? (CL)
- How to prevent evergreening possibilities?
- How to challenge an evergreening case?
- How to prevent an SPC from being granted?
- How to challenge an SPC?
- Are there restrictive data exclusivity laws? How to challenge them?

Orphan drug regulation (EU)

- What are the other incentives for companies to produce these drugs?

- Is the orphan drug regulation abused?
- Can we influence the EU pharmaceutical policy? (orphan drug regulations in the process of being changed)
- How to undermine the business model of pharma-piracy?
- What are the reimbursement policies/capacities in your EU country?
- Is there a national definition of fair pricing? Are the cost-benefit calculations appropriate?
- How many expensive orphan drugs have already entered your country's market?
- Can an excessively priced orphan medicine be compounded by a pharmacist, and can the pharmacist get good quality raw materials at a reasonable price?
- Can the orphan drug candidate be imported from outside the EU at a lower price?
- Can you start a naming and shaming campaign against the potential pharma-pirate?
- Can you convince the national reimbursement authority to refuse the high price and recommend the more affordable compounding/importation?
- If the product is already excessively priced, can you start a competition law case?

Competition law (EU cartel and abuse of dominant economic market position)

- What are legal grounds for a competition challenge?
- How to assess and fix the national competition laws?
- How to assess the quality of the policy of the competition authority?
- How to bring a case?
- What to ask for? (a fine/statement of the competition authority/negotiated settlement? (e.g. lower price/generic entry))
- After the fine, how to sue for damages?

Human rights (using State responsibility to increase private actor accountability)

- Has the government enabled laws that pass on the State duty of care to the private sector/pharma company?
- Is there a national/international human rights commission to which you can complain? (Ombudsman etc) (has the government respected its duty to prevent private actors from violating HR?)
- Does the company adhere to the UN Business and HR principles? / Paul Hunt criteria?
- Can you distil other criteria from these? (e.g. on the basis of the [Good Covid-19 Company practices \(GCCP\)](#) developed by PAF)
- Does the company have a corporate social responsibility or HR statement/department?
- Is there jurisprudence on socially responsible pharma practices/behaviour? (not really – but yes on climate and environment e.g. Shell)
- Can [the OECD guidelines](#) be used to make a formal complaint against corporate management?
- Can you use HR arguments in other legal forums as additional evidence? (e.g. tort law – [Urgenda](#))

Tort law

- Analyse the tort law possibilities in your country/economic region
- Analyse previous cases using tort law to promote private actor accountability
- Has tort already been used to promote access to medicines?
- How responsive are the Courts to human rights-sensitive interpretation of tort laws?

Pharmaceutical laws

- Does your country allow pharmacists to compound drugs and protect them from infringement cases? (e.g., Netherlands)
- Are the quality guidelines for compounding restrictive or enabling? Is there a government policy on it? (NL pharmacists have their own professional rules)
- Can your country import a more affordable, but unregistered medicine (a cheaper generic)?
- If not systematically, are individuals enabled/empowered to import these unregistered medicines for personal use?
- Can you organise a buyers' club? (Cystic fibrosis UK, PREP-UK, Dallas Buyers Club HIV ARVs)

Contract law

- Are there national/regional laws on contracts that protect the buyer?
- How transparent are the clauses in standard pharmaceutical contracts?
- Are there clauses on abuse of contract that can be used to the benefit of the patient?

Top websites to refer to when considering legal action against pharma

- [Medicines Law & Policy](#)
- [Health Action International](#)
- [Knowledge Ecology International](#)
- [South Centre](#)
- [Farmatoverantwoording/Pharmaceutical Accountability Foundation](#)
- [Good Covid-19 Company Practises](#)
- [Office of the High Commissioner of Human Rights](#)
- [United Nations Business and Human Rights Principles](#)
- [Paul Hunt Guidelines for Pharmaceutical Companies in relation to Access to Medicines + 2010 article](#)
- [United Nations Development Programme](#)
- [International Commission of Jurists](#)
- [International Law Association](#)
- [OECD Guidelines](#)
- [Patent Opposition Database](#)

Acknowledgements

The following NGOs and/or professionals contributed to these guidelines:

- Dr Ellen 't Hoen
- Prof Dr Brigit Toebes
- Dr Katrina Perehudoff
- Rosalind Turkie
- Wemos Foundation
- Medicines Law & Policy
- Knowledge Ecology International
- Health Action International
- Panellists from PAF webinar on the Power of Law
- Wilbert Bannenberg