



POLICY BRIEF

Time to Legislate

Realising access to medicines through States' obligation to protect the human right to health

The Pharmaceutical Accountability Foundation¹

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Summary

According to the human right to the highest attainable standard of health, governments have obligations to ensure access to essential medicines for their population. Pharmaceutical companies do not have obligations under international human rights law, but they do have responsibilities, which lay out a set of important norms for industry to follow. However, though the pharmaceutical industry contributes to the enjoyment of the right to health by

¹ The Pharmaceutical Accountability Foundation (PAF) is a non-profit foundation based in the Netherlands and striving for equal access to medicines and medical technologies. www.pharmaceuticalaccountability.org
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producing lifesaving medicines, it has a skewed incentive which makes it liable to prioritising profit over public health.

Stronger norms are needed to hold pharmaceutical companies accountable under the right to health. Governments have a legal mandate to protect the right to health from interference by private actors, and to ensure that these actors respect their own human rights responsibilities. States thus have binding obligations to create a legal and policy environment that will serve the public interest, rather than industry interests. In the Netherlands, the term ‘duty of care’ is well-established in case law and legislation in relation to private actors. It is used in this brief to refer to the responsibilities of private actors under international human rights law.

This policy brief explores how governments can create an enabling environment around access to medicines through stronger regulation of the pharmaceutical sector. It starts by outlining the human rights framework surrounding access to medicines, before mapping some of the issues in policy and legislation. To solve some of these issues, governments can: (1) mandate due diligence in the pharmaceutical sector; (2) implement the World Health Organisation’s 2019 transparency resolution; (3) use tort law to hold pharmaceutical companies accountable through the courts; (4) use competition law to fight anti-competitive practices; (5) safeguard against unethical lobbying practices.

Description of the problem

Barriers in access to medicines have been a persistent human rights issue for several decades.¹ Affordability is key to access and determines whether individuals will get hold of the treatments they need. The high prices of pharmaceuticals limit and/or hinder the ability of governments, especially in low- and middle-income countries (LMICs), to purchase these products and hence obstruct individual access, which in turn increases health inequities.²

There are many reasons for the unequal worldwide distribution of medicines, such as weaknesses in health systems, supply chain disruptions and capped health budgets.³ The Pharmaceutical Accountability Foundation finds that the commercial decisions of the pharmaceutical companies developing and marketing medicines are major obstacles to achieving an equitable global distribution of medicines.

According to the human right to the highest attainable standard of health, governments have legal obligations to ensure access to essential medicines for their population, and to prevent third parties from interfering with this right – known as the State obligation to protect.⁴ Pharmaceutical companies do not have obligations under international human rights law, but they do have responsibilities. While these responsibilities are non-binding, they do lay out a set of important norms for industry and have led to processes at the UN for monitoring and dialogue. Furthermore, neglect of human rights responsibilities by industry should not remain



without consequences. However, many pharmaceutical companies failed to live up to these responsibilities during the Covid-19 pandemic.⁵ Though the pharmaceutical industry plays a major role in contributing to the enjoyment of the right to health by producing lifesaving medicines, it has a skewed incentive which makes it liable to prioritising profit over public health. The People's Vaccine Alliance estimated that major Covid-19 vaccine producers Pfizer/BioNTech and Moderna charged governments 'as much as \$41 billion dollars above the estimated cost of production'.⁶ This is despite substantial public funding of pharmaceutical innovation.⁷

Stronger norms are needed to hold pharmaceutical companies accountable under the right to health. Governments have a legal mandate to protect the right to health from interference by private actors, and to ensure that these actors respect their own human rights responsibilities. States thus have binding obligations to create a legal and policy environment that will serve the public interest, rather than industry interests. Our actionable definition of the State's obligations with regards to regulating pharma is:

A legal obligation imposed on the State and in line with its obligation to protect the human right to health, to adopt a standard of protection which ensures that pharmaceutical companies respect their human rights responsibilities and are held accountable for infringements of the right to health in the production, distribution, and pricing of medicines, in all aspects of the value chain (upstream and downstream). The State should adopt such legal measures that are necessary to create a regulatory framework in which pharmaceutical companies respect their right-to-health responsibilities.

In the Netherlands, the term 'duty of care' is well-established in case law and legislation in relation to private actors. It is used in this brief to refer to the responsibilities of private actors under international human rights law.

This policy brief explores how governments can create an enabling environment around access to medicines through stronger regulation of the pharmaceutical sector, and in that way comply with their human rights obligations. It starts by outlining the human rights framework surrounding access to medicines, before mapping some of the issues in policy and legislation and outlining solutions.

Unpacking the human rights framework

Under international human rights law, States have committed to *respect* (not interfere with), *protect* (shield from abuses by third parties) and *fulfil* (take active steps to realise) human rights.⁸ Formally, pharmaceutical companies do not have obligations under international



human rights law; however, it is increasingly recognised by the international community that they do have (formally non-binding) responsibilities to respect human rights.

The human right to health is found in the Constitution of the World Health Organization (WHO)⁹ as well as the International Covenant on Economic, Social and Cultural Rights (ICESCR) in article 12, which has been ratified by 171 State Parties.¹⁰ Under the right to health, States have a 'core obligation' to ensure non-discriminatory access to essential medicines, which includes an obligation to protect the right to health from interference by private actors.¹¹ In practice, it is difficult for States to implement their obligation to protect access to medicines because, while pharmaceutical companies play a crucial role in global medicine distribution, they lack formal obligations under international human rights law.

The interplay between the State obligation to protect and pharmaceutical companies' responsibility to respect the right to health is particularly important with regards to ensuring access to medicines. The commercial decisions of pharmaceutical companies regarding pricing and distribution of medicines greatly impact the availability, accessibility, and affordability of such products. During the Covid-19 pandemic, human rights bodies called on States to regulate pharmaceutical companies more effectively to ensure the equitable distribution of vaccines.¹² It is therefore not only legally required, but also urgently needed, for States to take measures to ensure that pharmaceutical companies respect their human rights responsibilities. Governments must have the means of legal recourse to hold pharmaceutical companies accountable and restore some public control over downstream human rights issues such as drug pricing and distribution.

Mapping the issues: poor enabling environments

The legal and policy environments in which pharmaceutical companies operate can have a profound influence on their behaviour, but are all too often designed in ways that serve industry rather than the public interest. In many countries, laws are poorly designed and applied. These issues can create an environment that does not optimally enable innovation and access to medicines.

Legal procedures to create strong and equitable enabling environments for access to medicines either do not exist, or there is a lack of awareness around them which means that they are rarely used. The Pharmaceutical Accountability Foundation strives to raise awareness of the existing procedures and proposes legislative initiatives to optimise innovation while also ensuring equitable access. We focus on four areas: displacement of care, misuse of competition law, lack of corporate accountability under human rights law, and lack of political will.



Displacement of care

National health plans and hospitals have limited financing. Health authorities therefore set priorities about which medicines the health system can afford. This section relies heavily on illustrative examples from the Netherlands, but the issues have global applicability.

In the Netherlands health insurers cannot automatically add new medicines to the roster of what they cover; a medicine can be put on hold¹³ by the Healthcare Institute of the Netherlands if it would cost more than €40 million per year across the country or more than €50,000 per patient per year and more than €10 million across the Netherlands.

When medicines prices are high, there are four paths health authorities might take: Negotiate for lower prices, increase health spending, ration care, or set priorities on which care to give. They are detailed below.

When medicines costs are *unjustifiably* high, this can act to 'displace' care: that is, replace other useful services or limit access to needed services.

1. Negotiate lower prices:

- In the Netherlands, the health ministry began negotiations with pharmaceutical companies on behalf of the whole country in 2012. This saved the country's health systems overall €272 million Euro between 2012 and 2018.¹⁴
- But negotiations are not always cost-effective, the Netherlands Court of Audit found,¹⁵ especially in cases of medicines that have no viable alternatives (such as Spinraza (Nusinersen), which treats a genetic illness called spinal muscular atrophy, or Orkambi (lumacaftor/ivacaftor), which treats cystic fibrosis) that the Health Ministry was unable to successfully negotiate to prices as low as those recommended by the Dutch National Health Care Institute.

2. Ask for an increased budget:

- One way to accommodate rising medicines costs is to ask for an increased budget.
- However, without government action, this has led to an increase in the cost of expensive hospital pharmaceuticals by up to 10% every year,¹⁶ which is not sustainable.
- It is even more unsustainable as the Netherlands has decided to cap growth on the cost¹⁷ of specialised care nationally until 2022
- At the hospital level, case studies on the introduction of six expensive treatments¹⁸ found that the introduction of high-priced treatments resulted primarily in increased spending as well as rationing (see next point), and



predicted that with more budget pressure more drastic decisions might be made.

3. Ration care:

- Given limited budgets, health authorities might decide to limit who has access to high-priced care, for example by delaying treatment until a patient has reached an acute phase of disease. This happened across Europe in response to high prices for sofosbuvir,¹⁹ a treatment for hepatitis C that was priced at €55,000 for a 12-week course of treatment.²⁰
- Rationing can take many forms²¹ in addition to delayed care: patients may be selected to receive treatment on basis of their prognosis; patients may be directed to other services; services may be offered in a limited form or ended earlier than previously; or by making a treatment harder to access.
- In the Netherlands, a study found²² that hidden ‘bedside’ rationing is happening in hospitals. In a survey, 64% of physicians reported prescribing a lower-cost course of treatment when a more effective, but more expensive treatment was available. These decisions were not always disclosed to patients.
- Rationing of care can lead to suboptimal health outcomes.

4. Make trade-offs:

- In addition to rationing of high-priced care, health authorities may trade-out other health services.
- This is known as ‘priority setting’, and decisions might be made on the basis of clinical need as well as cost-efficiency.
- A case study²³ in public hospitals in Australia found that priority-setting at the hospital level required difficult moral decisions, between the needs of individual patients with the need to maximise benefit over all patients.

Rationing and priority setting constitute ‘*displacement*’ of care: health authorities at all levels –nationally, at hospitals, and in physician/patient settings – must make tough choices when the cost of treatments puts pressure on budgets. Some medicines are costly to produce and/or costly to administer, and difficult choices will always be part of health financing. But some other medicines are inexpensive to produce but have excessive prices due to abuse of a monopoly position in the market. In these cases, displacement of care undermines individuals’ enjoyment of their right to health in a bid to feed pharmaceutical company profits.

Anti-competitive practices

Competition law can be a powerful tool to rein in poor company behaviour. But when it is unevenly applied or poorly enforced, companies get away with abuse. Most countries and regional areas have laws intended to maintain the ability of companies to compete on the



market. These laws can be leveraged in the pharmaceutical sector when a monopoly is being unfairly maintained or unfairly leveraged to charge high prices. In Europe, for example, between 2009 and 2017 there were 29 antitrust decisions made against pharmaceutical companies, with fines totalling over €1 billion;²⁴ over 100 other cases were investigated and also leading in some cases to the issuing of compulsory licenses allowing competitors to enter the market (particularly in Italy).

Examples of anti-competitive practices that can result in sanction include: trying to prevent launch of generic medicines through abuse of regulatory procedures; mergers between originator companies and generic producers leading to high prices or reduced competition, or reduced pressure to innovate; coordination/collusion between companies over price fixing; limiting others' access to either needed pharmaceutical inputs or to a customer base (for example by providing discounts in order to ensure continued stock of originator medicines) and excessive pricing.²⁵

Lack of corporate accountability under human rights law

Under international human rights law, pharmaceutical companies have clear responsibilities to respect the right to health. However, these responsibilities are not matched by formal international legal obligations. To close this accountability gap, the UN General Assembly endorsed the United Nations Guiding Principles on Business and Human Rights (UNGPs) in 2010.²⁶ By formalising the global debate on private actor accountability for human rights violations, the UNGPs remain today an important milestone in the business and human rights discussion. According to the UNGPs, companies' human rights responsibilities require them to conduct due diligence. Paul Hunt, as UN Special Rapporteur on the Right to Health, clarified the specific responsibilities of pharmaceutical companies in relation to the right to health in the 2008 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines'.²⁷ He made 47 recommendations for pharma to align its practices with human rights, in the areas of patenting and licensing, transparency, pricing, monitoring and accountability, and lobbying.

The human rights framework therefore offers opportunities for responding to the problem of access to medicines. Companies have clear-cut responsibilities to respect the right to health, and pharmaceutical companies have specific responsibilities in relation to access to medicines. However, most companies fail to live up to their human rights responsibilities. In June 2022, the Pharmaceutical Accountability Foundation assessed the compliance of 26 Covid-19 vaccine and therapeutics producers with a set of 19 criteria, based on human rights principles and Hunt's Guidelines.²⁸ 19 out of 26 companies scored poorly. On the other hand, all 26 companies scored full points for publishing their clinical trial results, which is the only criterion that is legally required in most countries. **Human rights principles that are matched by legally binding norms are therefore often more effective than those that rely on soft enforcement.**



As of yet, few legislative initiatives in the field of corporate accountability contain hard enforcement mechanisms. The recent proposal by the European Commission for a mandatory due diligence directive,²⁹ as well as a proposed bill currently being discussed in Dutch parliament for a duty of care for all companies,³⁰ have the potential for becoming effective laws, in line with international standards. Stronger norms for holding pharmaceutical companies accountable are needed to ensure that States have the means of legal recourse to ensure access to medicines for their population and uphold their human rights obligations.

Lack of political will

In many countries, laws are poorly designed and applied. Sub-optimal legislation continues to exist because there is a lack of political will to stand up to the pharmaceutical industry and an overinfluence of lobby groups for pharmaceutical companies in public spaces. A 2019 report³¹ published by the Roosevelt institute identifies four main tactics used by industry to influence policy spaces:

- lobbying and campaign contributions: when industry representatives directly seek to influence legislators or regulators
- the revolving door: when individuals move between government service and the private sector, resulting in legislators becoming lobbyists for the industries they once regulated, and vice versa.
- funding medical research: when pharmaceutical companies fund clinical trials to test new drugs, their financial stakes in the products under evaluation may create bias towards the results. One study³² from the US found that '85 percent of industry research reported positive outcomes for their trials, compared to just a 50 percent rate of positive outcomes in government research'.
- funnelling industry priorities through seemingly independent organisations: when pharmaceutical companies fund think tanks and patient advocacy groups to influence policymakers.

At European level, Corporate Europe Observatory found that 'the top ten biggest-spending pharmaceutical companies currently report spending between €14.75 and €16.5 million per year on lobbying in Brussels'.³³ The report also states that 'the European Federation of Pharmaceutical Industries and Associations (EFPIA) lobbied against a tool designed to facilitate equitable access and pricing for pandemic treatments in Europe'. EFPIA is also lobbying the negotiations for the EU Pharmaceutical Strategy to protect and strengthen intellectual property policies – which are, according to them, 'designed to support innovation'.³⁴ EFPIA director Richard Bergstrom, a former high-ranking lobbyist for Big Pharma, was allowed to negotiate the Covid-19 vaccine deals with pharmaceutical companies on behalf of the EU – a clear conflict of interest.³⁵



Policy recommendations

Governments have the power to adopt better legislation or to better enforce existing legislation in order to optimise innovation and access to meet pressing public health needs. Countries can enforce the affordability, accessibility and availability of medicines through the use of – unfortunately often unused – laws and regulations. We make the following recommendations for governments to better regulate pharma and uphold their human rights obligations regarding access to medicines in the fields of due diligence, competition law, tort law and lobbying.

1) Adopt mandatory due diligence legislation

Due diligence is a core requirement for businesses in fulfilling their responsibility to respect human rights.³⁶ It refers to the process of exercising reasonable care to avoid adverse impacts on human rights linked to a company's activities – by identifying and assessing potential risks to human rights and acting to prevent and mitigate those impacts.

The Fair Pharma Scorecard found that 11 out of 26 pharmaceutical companies assessed had published a commitment to comply with human rights standards which included adherence to the UNGPs. MSD's human rights policy, for example, promises to 'conduct(...) appropriate due diligence and determines the risks – including those related to human rights, prior to entering a business relationship with a supplier'.³⁷ However, in 2018, a UN study found that 'the majority of companies do not demonstrate practices that meet the requirements set by the Guiding Principles',³⁸ and called on governments to establish stronger regulatory frameworks to improve compliance. Today, mandatory due diligence legislation is on the rise, with proposals being discussed at EU-level and within the Dutch Parliament. There is already legislation on this in France, Germany, and Norway, and proposals in Austria and Belgium. In this policy brief, we focus on the EU and Dutch proposals.³⁹

a. The EU proposal

In December 2022, the European Commission adopted a proposal for a directive on corporate due diligence rules. As it stands, the directive would apply to large EU companies and non-EU companies that are active within the EU (calculated according to net turnover and number of employees). The directive could be a promising mechanism for stimulating accountability in the pharmaceutical sector; however, currently, it focuses on labour rights and environmental damage, and does not explicitly mention health. Moreover, the Council's position is that the due diligence should apply to a company's 'chain of activities', which includes a company's upstream supply chain (related to the production process), but only to a limited extent a company's downstream activities.



Accordingly, we make two recommendations to strengthen the directive's promise in terms of strengthening pharmaceutical company accountability:

- **Explicitly mention health in the annex of protected rights.** The EU's commitment to ensuring access to essential medicines, as expressed in the 'Pharmaceutical Strategy for Europe', highlights the legitimacy and importance of including pharmaceutical companies in the proposed due diligence directive.⁴⁰ Mentioning health as a legal principle in the annex of protected rights, in accordance with article 35 of the European Charter of Fundamental Rights and Freedoms,⁴¹ would make it applicable to pharmaceutical companies in national implementation. Fines could then be imposed on these companies for not preventing the adverse impacts of their pricing policies, for example, on access to medicines.
- **Mandate downstream HRDD:** The directive initially proposed by the Commission in February 2022 required companies to conduct HRDD for their entire value chain, but the Council is pushing⁴² to restrict the proposal's scope to the upstream aspects of the supply chain. Downstream operations include those that take place post-manufacturing and connected to the distribution of the product to the consumer. To ensure that the directive will mandate that pharmaceutical companies manage the social and human rights impacts of eg, their pricing and access models, it is crucial that it applies to downstream activities. The High Commissioner for Human Rights (OHCHR) has called for the directive to include downstream HRDD.⁴³ International litigation is also increasingly holding companies accountable for the downstream human rights impacts of their activities – a form of regulation by litigation wherein 'courts are increasingly accepting that companies owe downstream human rights duties of care'.⁴⁴ The EU should now enshrine mandatory downstream HRDD in law by maintaining its original proposal to apply it to a company's entire value chain.

b. The Dutch duty of care bill

In November 2022, six political parties in the Netherlands submitted a bill proposal in Parliament entitled the Responsible and Sustainable International Business Act (*Wet verantwoord en duurzaam internationaal ondernemen*). The bill is based on the OECD Guidelines for Multinational Enterprises and would impose a duty of care on all companies operating in the Netherlands as well as due diligence requirements. As opposed to the EU directive, the bill would apply to 'the entirety of an enterprise's activities, products, production lines, supply chain and business relationships' – therefore, to the entire value chain, and not only the 'chain of activities' as proposed by the European Commission. Although health is not mentioned explicitly, the bill will apply to all companies, which includes pharmaceutical corporations. Moreover, the bill proposes to make due diligence a concern at the director-level (paras 2.2.2 & 2.2.3).



One company has threatened to leave the Netherlands if the bill is passed, stating that ‘the legislation is unclear because the duty of care is not clearly defined’.⁴⁵ The Dutch proposal clearly establishes that by complying with the due diligence requirements mandated in the bill, the duty of care criterion is satisfied. Maria van der Heijden, Director of the MVO-network defended the bill: ‘the time without obligations is over. We had agreed in 2018 that by 2023, 90% of all companies would report on CSR and that has not happened so far.’ She added that ‘companies must take into account the human rights and environmental challenges of our time’, pointing out that ‘even if there is European legislation, you need national legislation to implement it’.⁴⁶

Update: The bill was discussed in the Parliament on 18th January 2023. One of the government parties changed its position, meaning the bill’s implementation is delayed until the adoption of the European directive, to ensure a level playing field. Parties and NGOs should continue advocating for the Dutch bill to pass, independently of the European Commission’s directive. If one Member State has already adopted stricter due diligence legislation than the EU, it could avoid the European directive being further watered down.

2) Implement the WHO transparency resolution

In 2019, Member States of the World Health Organisation adopted a resolution on the transparency of pharmaceutical markets (WHA 72.8),⁴⁷ in which they committed to share information, among others, on net prices of health products and costs of research and development. Transparency is key to determining whether the price of a medicine is fair to both seller and buyer.⁴⁸ Currently, ‘each country negotiates with pharmaceutical companies behind closed doors and has no idea if the proposed price by the industry is higher or lower than the one they proposed in another country. Industry, especially when a company has a monopoly on a life-saving drug, has leverage to push the prices to extremely high levels.’⁴⁹ The resolution’s implementation has been limited out of States’ concern that they will be alone in making the first move and therefore disadvantaged. France and Italy have both adopted laws ‘that aim to disclose biomedical R&D costs and the public contribution towards these costs’ in line with WHA 72.8, but **further steps are needed to implement legislation at both national and regional levels to ensure greater cost and price transparency from medicines manufacturers.**

3) Establish a duty of care for pharmaceutical companies through tort law

In the absence of government legislation, case law has established in the Netherlands that there is a duty of care for private companies. In the landmark judgement *Milieudefensie vs Royal Dutch Shell* (2019), the Dutch District Court ruled that private companies have individual



obligations (in this case, to reduce CO2 emissions), independently of existing State obligations, and that this obligation is enshrined in Dutch tort law in article 6:162.⁵⁰

Article 6:162 relates to a category of torts that violate ‘a rule of unwritten law pertaining to proper social conduct’.⁵¹ In the Shell case, the Court established that it could draw on international legal principles such as the OECD Guidelines, the UNGPs, and the European Convention on Human Rights (ECHR) to define the standard of care mentioned in this provision. **Accordingly, this provision could also be used to hold pharmaceutical companies to account for breaching their duty of care, by e.g. setting high prices that result in displacement of care and loss of life.** This kind of strategic litigation in the Netherlands could then inspire other jurisdictions to instigate similar lawsuits, creating a duty of care precedent for pharma.

- 4) Use competition law to hold pharmaceutical companies accountable
 - a. Abuse of dominant market position

Article 24.1 of the Dutch Competition Act (DCA) holds that ‘undertakings are prohibited from abusing a dominant position’.⁵² More specifically, Article 102 of the Treaty on the Functioning of the European Union (TFEU),⁵³ states: ‘Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.’

Market dominance usually occurs when a private company enjoys a position allowing it to function independently from its competitors, and controls a majority share of the market. In *United Brands v Commission*,⁵⁴ the Court of Justice of the European Union (CJEU) described the dominant position as one ‘of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers



and ultimately of its consumers'. Misusing the regulatory framework by, for example, extending patent protection for drugs in order to delay the market entry of generic products, is considered to be an anti-competitive practice and an abuse of such a dominant market position. Charging excessive prices for a medicine during the patent protection period can also be considered an abuse of dominance.⁵⁵

Competition between different pharmaceutical companies is one of the critical success factors when it comes to making medication affordable, accessible and available. An important example are antiretrovirals (ARVs), where the cost dropped from \$10,000 per person to less than \$300 thanks to the availability of generic ARVs produced in India and the uptake of TRIPS Flexibilities that enabled import of such generic ARVs in countries where the products were patent protected. In South Africa a competition law case (Hazel Tau vs GSK and Boehringer Ingelheim; see UNCTAD and KEI reports.) was important in breaking the monopoly position of pharma companies. The case led to one of the first voluntary licences for the purpose of providing access to ARVs.⁵⁶ A more recent example is the 2017-2021 Aspen EU case where Aspen had to reduce six off-patent cancer medicines by 73% addressing excessive pricing concerns by the EU Commission.⁵⁷

Competition law enforcement in one country can trigger a domino effect in other countries: in 2021, the Dutch Authority for Consumers and Markets (ACM) imposed a 19.6 million euro fine on Leadiant for abusing its dominant position with respect to drug CDCA. This took place after the Pharmaceutical Accountability Foundation submitted a competition law enforcement request⁵⁸ to the ACM in 2018. After translating the Dutch enforcement request into English, NGOs in Belgium, Italy and Spain complained to their respective Competition Authorities about CDCA Leadiant. The Italian Antitrust Authority (AGCM)⁵⁹ in 2019 opened an investigation⁶⁰ against Leadiant for trying to monopolise the production of raw material for CDCA production in order to prevent hospitals from making their own supply as well as for excessive pricing. The investigation was concluded 31 May 2022. Leadiant was fined €3.5m. The Spanish competition authority also opened a case⁶¹ against Leadiant in December 2020, resulting in a 10.25 million euro fine⁶² on the company in 2022. The case in Belgium⁶³ is still pending.

Competition law is rarely used as an instrument to lower prices, but better enforcement of this area of law can be an effective tool in a government's arsenal for holding pharmaceutical companies accountable. **Policymakers should attempt to increase knowledge of private competition law and facilitate the pursuit of excessive pricing claims.** The UN Development Programme has published a useful resource on using competition law in Low- and Middle-Income Country (LMIC) settings to promote access to affordable medicines and health technologies.⁶⁴

- b. 'Special responsibility' of dominant providers as a duty of care



When a medicines manufacturer is in a position of dominance, EU law holds that this company has a 'special responsibility' which can be interpreted as a duty of care (article 102 TFEU). By requiring the dominant undertaking *not* to act unfairly, this duty of care includes both negative aspects involving a duty to abstain and positive aspects requiring the company to take steps to avoid a violation from occurring. Whereas the previously mentioned provision that prohibits abuse of dominance is largely a corrective measure, sanctioning companies after the violation has occurred, the 'special responsibility' or duty of care of dominant undertakings makes the standard a preventive one, and the legal environment therefore more predictable. In the Netherlands, the Dutch Authority for Consumers and Markets (ACM) has the power to apply article 102 TFEU 'directly in cases where there is a potential effect on trade between member states.'⁶⁵ **Enhanced awareness of this provision by regulators and by companies would have a positive effect on access to medicines by preventing abuses of dominance resulting in lack of access and/or high prices.**

Note: National and regional competition authorities are still hesitant about enforcing excessive pricing claims. As such, competition law is not yet the most effective solution for lowering the prices of pharmaceuticals, but it may be the best available solution. Since 2017, there have been increasing numbers of excessive pricing claims, so the general trend is positive. However, judicial authorities sometimes lack the expertise to investigate issues relating to pharmaceuticals. Moreover, so far, competition authorities have mostly intervened in cases involving price hikes of generics, but are less willing to address excessive pricing by originators. In the meantime, increasing awareness of the mechanisms available under article 102 TFEU and national competition legislation and, at the same time, encouraging competition authorities to develop robust approaches to address excessive pricing could help increase the number of successful claims invoked under the rules of abuse of dominance.

5) Establish safeguards against unethical lobbying practices

Managing conflicts of interest in health policymaking processes is a crucial step towards ensuring that medicines policies are in the public interest. The Netherlands is one of only three OECD countries that have passed a 'revolving door' law for pre public employment,⁶⁶ stipulating that government officials must wait a certain period before moving to the private sector.⁶⁷ At EU-level, there is a transparency register allowing for public scrutiny of the groups and individuals attempting to influence the policymaking process. However, lobbying remains an important obstacle to the enactment of laws that are far-reaching enough to hold big corporations, including pharmaceutical companies, more accountable for human rights. The 2016 Framework of Engagement with Non-State Actors (FENSA) issued by the WHO tackles conflicts of interest,⁶⁸ singling out the tobacco and arms industries as actors that WHO will not engage with. Governments have the power to institute and/or strengthen safeguards against unethical lobbying practices, by:



- Extending bans on lobbying or ban public servants from becoming lobbyists permanently
- Prohibiting pharmaceutical companies from contributing to political campaigns and funding patient advocacy groups
- Combating sponsorship bias by mandating public registration of clinical trials (in every country) & 'use bias assessment tools⁶⁹ that take funding source into account'

The WHO has also set significant barriers between states and the tobacco-industry in the Framework Convention on Tobacco Control (WHO FCTC).⁷⁰ This list can be further expanded and strengthened by looking at the guidelines for implementation of article 5.3 FCTC.⁷¹

Ends.

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