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VIEWPOINT

Upholding Human Rights in the Wake of COVID-19: Time to Strengthen Pharmaceutical Accountability

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Introduction

Pharmaceutical companies have the power and the responsibility to help governments realize the human right to health for all, yet there are egregious examples—such as the recent COVID-19 pandemic—where companies have violated these responsibilities. The Pharmaceutical Accountability Foundation, a nonprofit organization based in the Netherlands, argues that it is time to hold drug companies accountable for their excessive pricing policies and abuse of the intellectual property framework.[1] As a first step toward accountability, the foundation developed a monitoring and evaluation scorecard to measure pharmaceutical companies' compliance with human rights during the COVID-19 pandemic. The results of this scorecard, published in June 2022, demonstrate that stronger regulation is needed to obtain better adherence to human rights in the pharmaceutical field (see Figure 1). We propose a legal standard in Dutch law—a requirement for a duty of care—as a promising avenue for enforcing the pharmaceutical industry's human rights responsibilities, which has been difficult until now.

Pharmaceutical companies and access to medicines: Key players, limited accountability

Ensuring access to essential medicines is part of the core obligations imposed on governments under the right to the highest attainable standard of health.[2] However, private companies cannot be held directly accountable for failing to uphold the right to health, unless national law allows for this. The United Nations Guiding Principles on Business and Human Rights, endorsed by the Human Rights Council in 2011, clarify that businesses have a secondary set of nonbinding responsibilities to respect human rights.[3] These principles have been largely acknowledged by major pharmaceutical companies around the world.

Pharmaceutical companies play an essential role in countries' health care systems by researching and developing new drugs to treat or prevent new and existing diseases. Governments across Europe outsource the development, production, and sale of medicines to such companies, without imposing conditions on the results.[4] Access to medicines is thus no longer controlled by the state but largely by the private pharmaceutical sector. Although governments are required to regulate private companies when their activities interfere

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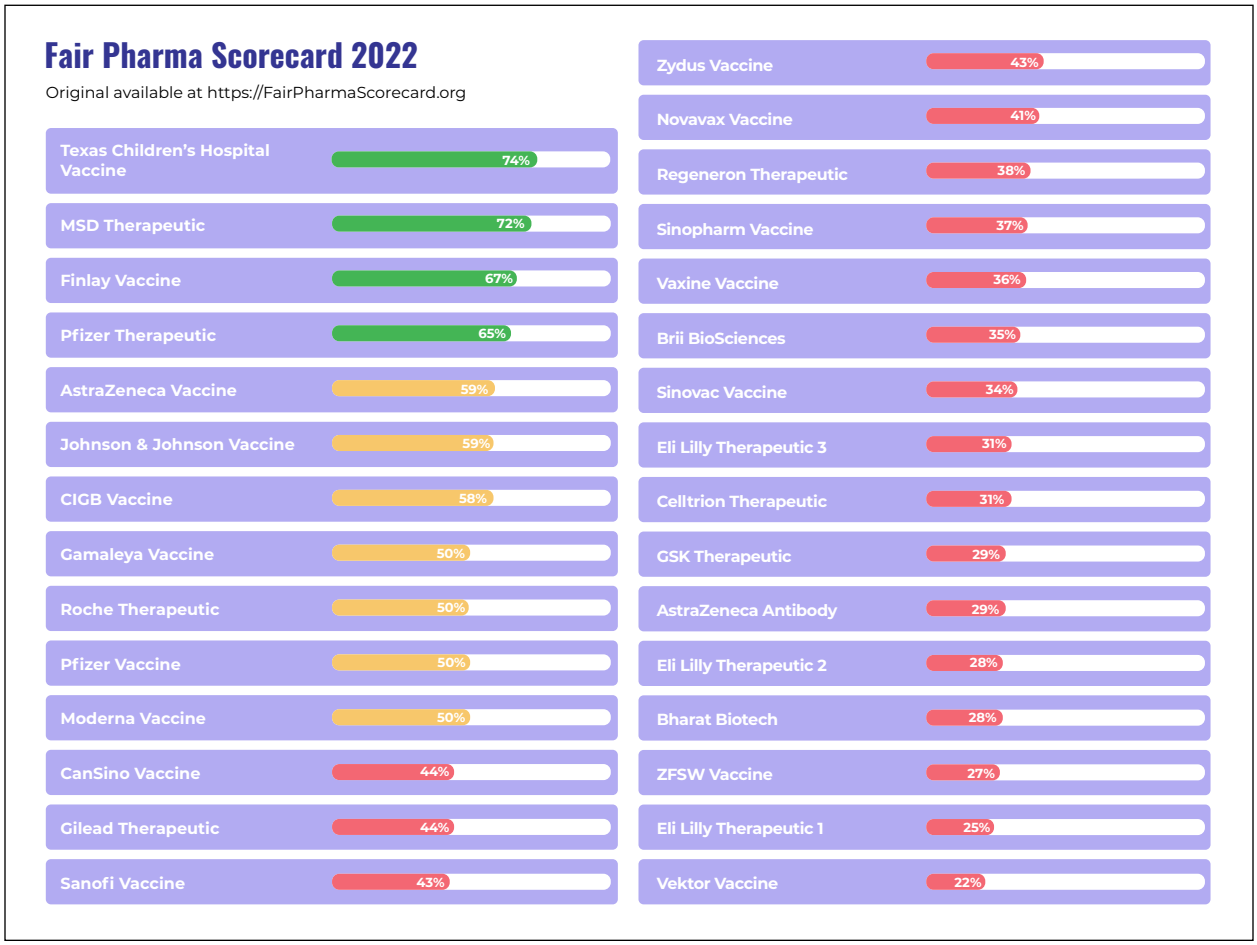
with human rights, in practice this is challenging. International law does not provide mechanisms for enforcing pharmaceutical companies' human rights responsibilities, which has led to their poor implementation.

A first step toward accountability: Global monitoring and evaluation

In June 2022, the Pharmaceutical Accountability Foundation assessed the roots of global COVID-19 vaccine and therapeutics inequality through its publication of the *Fair Pharma Scorecard*, which evaluates how producers of COVID-19 vaccines and therapeutics performed according to international human rights principles during the pandemic.[5] The scorecard assessment is based on the *Human Rights Guidelines for Pharmaceutical Companies*, developed by Paul Hunt, the 2002–2008 United Nations Special Rapporteur on the right to health.[6] The foundation adapted these guidelines into a framework for monitoring and evaluating pharmaceutical companies' behavior and then used this framework to score companies on four categories—accountability, equity, international cooperation, and transparency—divided into 19 criteria of equal weight (see Table 1). We used a three-point scale to score information on company behavior. All companies with a COVID-19 vaccine or therapeutic marketed in any country were selected for scoring, resulting in 26 companies being scored on 30 products. Data collection took place through structured internet searches, crowdsourcing information from civil society and professional organizations, and direct consultation with the companies. Each company was informed of its score and invited to

FIGURE 1. Fair Pharma Scorecard 2022



comment and provide additional information prior to publication of the scorecard.

The *Fair Pharma Scorecard*: An indicator of good and bad practices

The scorecard results show that several pharmaceutical companies acknowledge some form of responsibility for human rights: 9 out of 26 companies publicly accept the United Nations Guiding Principles on Business and Human Rights on their websites or publish their own human rights policy documents. Despite this, 19 companies scored poorly overall, showing that pharmaceutical companies largely failed to comply with human rights principles during the pandemic. The scorecard is a useful tool for pointing out the areas in which companies perform well and those where they are failing. For example, while 20 companies publish their production capacity, only 6 score full points for fair or differential pricing practices and for distributing their product equitably. Only two companies have committed to the COVID-19 Technology Access Pool or the Medicines Patent Pool—pooling mechanisms for the sharing of technology and medical products—showing a generalized lack of willingness to share intellectual property, knowledge, and data in global solidarity. Our World in Data estimates that today, for every 100 people in high-income countries, 214 vaccines have been administered, but in low-income countries, this figure drops to 31 doses—meaning that seven times more vaccines have been administered in high-income countries.[7] Although many variables were involved in the global allocation of COVID-19 vaccines, the scorecard suggests that increased compliance with human rights norms by drug companies during the pandemic could have contributed to a more equitable global vaccine coverage.

The need for legal accountability mechanisms

Notably, all 26 companies scored full points for publishing their clinical trial results—a legal requirement in most countries, and the only crite-

TABLE 1. Fair pharma criteria

Fair pharma practices	
A: commitments and accountability	A1 – The company publishes a global access plan for its product.
	A2 – The company commits to complying with human rights standards in relation to product development and marketing.
C: international cooperation	C1 – The company commits to the COVID-19 Technology Access Pool or the Medicines Patent Pool.
	C2 – The company commits to not enforcing the rights of COVID-19-related patents.
	C3 – The company supplies to, or signs agreements with, the vaccines or therapeutics pillar of the ACT-Accelerator (COVAX).
	C4 – The company agrees to license its COVID-19 products to other companies.
E: equality, nondiscrimination, and equity	E1 – The company makes the active ingredient available on reasonable grounds. [only for therapeutics]
	E2 – The company commits to full technology transfer to other manufacturers.
	E3 – The company commits to nonprofit, "fair," or differential pricing.
	E4 – The company equitably distributes supplies globally. [applies only to vaccines]
	E5 – The company does not seek protection beyond the minimum criteria in TRIPS, or enforces TRIPS+ measures. [where applicable]
	E6 – The company agrees to waive exclusive rights in regulatory test data. [where applicable]
T: transparency	T1 – The company publishes its research and development costs.
	T2 – The company publishes its profit margin.
	T3 – The company publishes the average or marginal costs of production.
	T4 – The company publishes its production capacity.
	T5 – The company publishes the public subsidies it received during product development or testing.
	T6 – The company publishes the texts of licensing agreements.
	T7 – The company registers its clinical trials in public repositories.

rion matched by binding norms. This suggests that translating human rights principles into "hard" law may achieve higher compliance rates than relying on "soft" enforcement mechanisms. Reinforcing this is the fact that companies often refuse to release raw data after publication of the initial trial results, as access to these data—not assessed in the scorecard—is not effectively covered by existing legislation. Full transparency is therefore probably achievable only when required by law.

Overall, the scorecard shows that drug companies need to improve their adherence to human rights principles in order to respect the right to health. It also suggests that this will require going beyond moral and ethical responsibilities through the establishment of binding accountability mechanisms. Legal avenues to hold pharmaceutical companies directly accountable for infringements on the right to health are required at both the international and the domestic level. National law has the advantage of being directly enforceable within the concerned state and can address the problem at its source. Moreover, successful domestic policies can then become the source of "legal transplants" from one state to another. Recent developments in Dutch case law suggest that domestic litigation in the Netherlands could be successful in establishing strong norms for holding the pharmaceutical industry accountable.

Next steps for pharmaceutical accountability: The Dutch example

The Dutch civil courts are a promising avenue for enforcing pharmaceutical human rights responsibilities at the national level. In 2021, the District Court of the Hague held a private company liable for violating its duty of care in the unprecedented *Milieudefensie v. Shell* judgment.[8] Relying on article 6:162 of the Dutch Civil Code, containing an "unwritten" standard of care, the court held that private companies have individual obligations to act in accordance with generally accepted norms of social conduct—including human rights.[9] A new Dutch precedent could be created for pharmaceutical companies, using the same provision to create accountability for noncompliance with human rights. A company could then be held liable under Dutch law, for example, for the excessive pricing of medicines resulting in the displacement of health care budgets. Displaced budgets refers to the opportunity costs in health systems with finite health care budgets, meaning that public funds spent in one area (for example, expensive medicines) prevents financing for treating patients in another area and hinders the realization of their right to health. Generating a legal precedent that flouting human rights is not socially acceptable is one way of realizing the judicial enforcement of the right to health at the national level and could inspire other civil law systems to similarly strengthen pharmaceutical accountability in their jurisdictions.

Conclusion

The *Fair Pharma Scorecard* quantifies pharmaceutical companies' compliance with human rights principles during the COVID-19 pandemic. The overall picture is that pharmaceutical companies are not sufficiently adhering to certain human rights norms that are essential to the realization of the right to health. The results clearly indicate the need for robust accountability mechanisms in this field: failure to establish these will entrench health inequalities among the world's most vulnerable populations. Accountability through national law may be easier to implement than international approaches and, if successful, can inspire other states to adopt similar approaches to the problem. Strategic litigation in the Netherlands is one way to bring accountability in this sector and ensure that pharmaceutical companies' influence on public health systems facilitates equitable access to medicines worldwide, as the Dutch courts have shown that they are willing to hold private companies accountable for not complying with their social duty of care. It is now time to test this principle on the pharmaceutical industry.

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2. Committee on Economic, Social and Cultural Rights, General Comment No. 14, UN Doc. E/C.12/2000/4 (2000).

3. Office of the United Nations High Commissioner for Human Rights, Guiding Principles on Business and Human Rights, UN Doc. HR/PUB/11/04 (2011).

4. See, for example, O. Dyer, "COVID-19: Moderna Seeks to Exclude US Government Scientists from Vaccine Patents, Despite Public Investment," *BMJ* (Novemer 12, 2021).

5. See Pharmaceutical Accountability Foundation (see note 1).

6. United Nations General Assembly, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, UN Doc. A/63/263 (2008).

7. See Our World in Data, "Cumulative COVID-19 Vaccinations per 100 People," https://ourworldindata.org/grapher/covid-vaccination-doses-per-capita?tab=table. Last accessed on 03 November 2022.

8. *Milieudefensie et al v. Royal Dutch Shell* (May 26, 2021) ECLI:NL:RBDHA:2021:5337.

9. Burgerlijk Wetboek (Civil Code) (1992), art. 6:162.