

---

# The accountability of the private sector towards citizens in times of crisis: vaccines, medicines and equipment

Elena Petelos<sup>1,2,3</sup>, Dimitra Lingri<sup>4,5</sup>, Jinane Ghattas<sup>6,7</sup>, Silvia MAA Evers<sup>2,8</sup>, Dineke Zeegers Paget<sup>9</sup>, Chiara de Waure<sup>1,10</sup>

- 1 Health Technology Assessment Section, European Public Health Association (EUPHA), Utrecht, The Netherlands
- 2 Health Services Research, CAPHRI Care and Public Health Research Institute, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands
- 3 Clinic of Social and Family Medicine, Faculty of Medicine, University of Crete, Iraklion, Greece
- 4 Department of Law, Faculty of Law, Aristotle University of Thessaloniki, Thessaloniki, Greece
- 5 European Healthcare Fraud and Corruption Network, Brussels, Belgium
- 6 EUPHANxt, Utrecht, The Netherlands
- 7 Institute of Health and Society (IRSS), Université catholique de Louvain, Brussels, Belgium
- 8 Trimbos Institute, Utrecht, The Netherlands
- 9 EUPHA, Utrecht, The Netherlands
- 10 Department of Medicine and Surgery, University of Perugia, Perugia, Italy

**Correspondence:** Elena Petelos, Health Technology Assessment Section, European Public Health Association, Utrecht, The Netherlands, Tel: + 31 68 22 354 33, e-mail: [elena.petelos@med.uoc.gr](mailto:elena.petelos@med.uoc.gr)

In this article, we examine what the role of the private sector in times of crises is and whether the private sector is, and can be held to be, accountable. COVID-19 has amplified the difficulties with public–private partnerships and this article addresses several aspects concerning business enterprises, in particular transnational corporations, human rights and health sector activities, highlighting the key aspects to understand and address accountability issues. The article also explores accountability for the private sector, the processes to ensure accountability, and the relevance of regulation and self-regulation.

---

## Introduction

Globalization has allowed enterprise activity to span the entire globe. The rapid technological advancements, the emergence of new markets and cross-border economic integration, particularly over the past three decades, necessitates a closer examination of the complex interplay between business activities and human rights. What are our priorities in a globalized world? Can consensus be reached, particularly given the highly divergent positioning of governments, corporations and civil society, when it comes to regulation? The COVID-19 pandemic, the defining global health crisis of our time, has brought these questions to the fore given the need for fast deployment of different health technologies worldwide to effectively control the disease and combat the COVID-19 pandemic. What is the role of the private sector in times of crisis, such as the one we are currently encountering? Are there mechanisms for robust, transparent and efficient public–private partnerships? Is the private sector accountable, and can transnational corporations (TNCs) and other business enterprises be held accountable? This article explores the accountability of the private sector, the processes to ensure accountability, the relevance of regulation and self-regulation, and the role of corporate social responsibility (CSR), to determine how to best address the COVID-19 challenges in Europe and, given the global nature of this public health crisis, across the whole world.

## The private sector and global public health

We recently witnessed the opioid crisis, with the substantial challenges on effectively assessing and addressing the causal relationship

between the industry's business practices and the irreparable harm caused.<sup>1</sup> There are, however, examples indicating that public and private interests often are incompatible. Big Tobacco has certainly taught us that exact lesson, whereas the perils of ignoring history have been highlighted by public health researchers and practitioners across the world time and time again.<sup>2</sup> The consequences of the deception of the tobacco industry—it failed to honour the promises made to consumers in the 'Frank Statement' (1954)—not only resulted in the loss of millions of lives but also in citizens of many countries across the world that, even today, remain misinformed about the health risks of smoking.<sup>3</sup> An honest approach by the industry might have saved more lives than any public health measure taken during the past 50 years. Furthermore, if the industry had made good faith efforts globally, rather than exploit the developing world, the benefits could have been stunning. Arguably, the products and operations of some companies, as for example, tobacco companies, weapons manufacturers or oil companies, seem to be incongruent with CSR and sustainability.<sup>4</sup>

Are Big Pharma and Big MedTech any different given they deal in goods intended to protect the health of people? Indeed, statements indicating such TNCs are heavily invested in contributing towards safeguarding the right to health, saving lives, providing access and improving the lives of everyone across the world, are found on every corporate mission statement and across their branding. Are their goods and activities regulated differently? Are there, for example, special provisions for accountability for these companies? Most critically, are there incentives, motives, grounds or controlling mechanisms for Big Pharma and Big MedTech to operate differently? Do rules and practices really change at a time of crisis?

## Multilateral bodies, international law and human rights

Admittedly, the history of the relationship between TNCs and nations-states is one with a tortuous evolution.<sup>5</sup> It took a key United Nations (UN) resolution to appoint a Special Rapporteur with a mandate to examine the responsibilities of TNCs and other business enterprises regarding human rights<sup>6</sup> and, notably, another global health crisis, that of HIV/AIDS, for access to life-saving medicines to gain the world's attention; the price of AIDS medication being at the crux of establishing a potential conflict between World Trade Organization (WTO) law with international human rights law.<sup>7,8</sup> These efforts led to the first-ever decision to amend a core WTO agreement (2005), allowing for human rights' provisions as part of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>9</sup> The first institution-building effort resulted in the proposal of the 'Protect, Respect and Remedy' framework<sup>10</sup> for business involvement in human rights abuse.<sup>11</sup> This framework has three pillars, i.e.,

- a. the duty of States to protect their citizens against human rights violations, including those by business, through appropriate policies, regulation and adjudication;
- b. the corporate responsibility of business to respect human rights, essentially meaning to act with due diligence to avoid infringing upon the rights of others and to address any adverse impacts potentially occurring; and
- c. to facilitate overall access to effective remedies, both judicial and non-judicial, for victims of human rights violations committed by business.<sup>11</sup>

The responsibility to respect human rights mainly rests on the 'basic expectation society has of business' forming a part of a company's 'social license to operate', with explicit focus on not violating human rights, but, also, on exercising 'due diligence' to anticipate, avoid and/or mitigate any adverse impact on human rights arising from their activities.<sup>12</sup> The human rights responsibilities of pharmaceutical companies had been debated for years by non-governmental organizations, but it was the UN's Special Rapporteur report on the right to health that sharply defined them, submitting the 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines' to the UN General Assembly (UNGA) (2008). These guidelines outline responsibilities for transparency, management, monitoring and accountability, pricing, and ethical marketing; there are also explicit provisions against lobbying for more protection in intellectual property (IP) laws, applying for patents for trivial modifications of existing medicines, inappropriate drug promotion, and excessive pricing. A lot of debate has ensued regarding the extent to which TNCs fulfil their responsibilities and on governance structures to monitor and evaluate their activities, and on what mechanisms are appropriate to hold them accountable.<sup>13</sup> An implementation framework of 'Protect, Respect and Remedy' on the role of the UN system on advancing the business and human rights agenda, and the dissemination and implementation of the 'Guiding Principles on Business and Human Rights' (2012) (UNGPs) followed.<sup>11,14</sup> By 2014, all Member States of the UN Human Rights Council, including the US, called upon 'all business enterprises to meet their responsibility to respect human rights in accordance with the [UN] Guiding Principles (UNGPs) [on Business and Human Rights]'.<sup>12,14,15</sup> Notably, this was adopted by Member-States of the Council of Europe (2016).<sup>16</sup>

## Implementing rules and regulations: the role transparency and reporting

With human rights responsibilities clearly defined, how could activities of TNCs and related businesses be assessed? Transparency is a

key concept to inform discourse, whereas implementation should include monitoring for various aspects, e.g. in terms of human rights, in relation to Research and Development (R&D) state funding, the pricing of medicines, vaccines, and equipment, and in terms environmental impact. Excluding regulatory mechanisms for a product's safety and effectiveness assessment in the context of entering the market, there is little systematic work on the evaluation of corporate activities in response to the call of 2014. Monitoring of corporate practices in terms of how they affect European and global public health, and regarding their contribution to the Sustainable Development Goals (SDGs) is limited, confined to work largely funded or conducted by the TNCs themselves. Beyond the lack of scientifically robust evidence, there are serious issues of conflict of interest and, oftentimes, of transparency. With the body of research and analysis emerging from the retrospective examination of best practices, more prospective work is urgently needed based on sound frames of accountability capturing the distinct dimensions of transparency, liability, controllability, responsibility and responsiveness.<sup>17,18</sup>

Although many have asserted the critical role of TNCs in catalysing innovation, supporting technological and scientific progress, and ensuring sustainable growth, the emerging paradigm<sup>19</sup> in development thinking has yet to materialize. Indeed, the counterargument has been made on whether profit-motivated business can contribute meaningfully towards the SDGs and whether there is sufficient incentivization for commercial success to be combined with more sustainable approaches in terms of development outcomes.<sup>19,20</sup> In the absence of regulatory mechanisms to enable the private sector to incorporate appropriate business models and set goals to transform business practices, it is apparent that implementation remains challenging at best. Furthermore, in a very competitive global environment, where business practices often must factor geopolitical dynamics, there is evidence that the rhetoric of the private sector on transforming development may represent a further impediment to the transformative progress required across sectors to ensure progress.<sup>20</sup> To what extent is it possible to effectively monitor business practices and hold TNCs accountable at a time of crisis? Is it feasible to implement remedies? And even if it is feasible, is it necessary or simply desirable?

## Accountability and the private sector

Accountability generally refers to the responsibility for one's actions (or inactions) towards another.<sup>21</sup> This implies a relation between at least two actors: the 'principal' or accountability holder and the 'agent' or accountability holdee. From the principal's perspective, accountability guarantees that the agent acts in the interest of the principal and does not abuse his/her power. From the perspective of the agent, accountability refers to being responsible for one's actions, delivering accurate information and acting according to certain standards. According to the UN resolution on Universal Health Coverage (UHC), a transparent, inclusive, and equitable decision-making process that emphasizes accountability and fairness is essential to achieve UHC.<sup>22</sup> What are the incentives, if any, for the private sector to contribute to the SDGs/UHC? Can CSR and shareholder activism play a part in accountability processes?

Corporations compete for customers<sup>23</sup> and accountability initiatives could allow developing a positive ethical identity<sup>24,25</sup> gaining employees' and stakeholders' trust,<sup>26</sup> incorporating CSR across activities.<sup>27</sup> The importance of stakeholders' trust is highlighted in corporate marketing and identity literature, suggesting stakeholders' perceptions and attitudes about a business's ethics play an important role in shaping how they perceive management and the general trust in it.<sup>25</sup>

Transparency is a milestone of accountability and often refers to access to information. In fact, the availability of information is a requisite in order to make stakeholders able to ask for justifications

and responsive actions. It is a key element qualifying CSR in terms of normativity and legitimacy in the context of a framework to regulate it.<sup>28–30</sup> A recent review<sup>31</sup> captured mechanisms to increase transparency, including the World Health Organizations (WHO) Medicines Transparency Alliance (MeTA) for low-income countries and the WHO Good Governance in Medicines (GGM) Programme.<sup>31–33</sup> The latter leading to the development of the WHO Pharmaceutical System Transparency and Accountability Assessment Tool.<sup>33</sup>

A major challenge in understanding the pharmaceutical R&D system is represented in the shortage of reliable data on key aspects of its functioning. The lack of reliable, sufficiently detailed, timely information also undermines the objective of a well-informed public debate on medicines prices and makes it far more difficult to agree on policies that can yield better results for the public interest. The lack of transparency regarding R&D costs, inputs and outcomes is of concern to patients and payers, as it can contribute to higher prices, less medical knowledge being made publicly available when all research results are not published in a timely manner, and difficulties regulating the R&D system appropriately. Increasingly rising prices are also disconcerting, particularly when combined with low evidence level.<sup>34–36</sup> These challenges were acknowledged during the 2019 World Health Assembly (WHA), with Resolution 72.817 calling for increased transparency in pharmaceutical markets.<sup>37</sup> The Pharmaceutical Strategy released by the European Union in 2020 also highlighted the lack of transparency, particularly in R&D costs, and of consensus on costing principles, emphasizing the need for better understanding and greater clarity as a basis for policy debates on the pricing of niche medicines and ‘fair return’ on research contributions.<sup>38</sup> Furthermore, responsiveness and compliance necessitate civil society participation,<sup>39</sup> ideally through deliberation for evidence-informed decision-making. Therefore, we often speak about social accountability, namely the civil society engagement to improve accountability.<sup>40</sup> Indeed, mechanisms aimed at promoting transparency and fostering participation are the lifeblood of accountability.

## Regulation, self-regulation and IP in the health sector

The acknowledgement of the gravity of public health issues afflicting many developing and the least-developed countries, especially those resulting from HIV/AIDS, tuberculosis and malaria, came two decades ago in the Doha Declaration on the TRIPS Agreement and Public Health. Unambiguously, the WTO Ministerial/Doha Declaration (2001) stated ‘[...] the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, [...] we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and to promote access to medicines for all’.<sup>41</sup>

Questions remain on what mechanisms are in place, and where, to ensure access to medicines, vaccines and key equipment. Do the same rules apply in the developed countries too? What were the responsibilities of the TNCs in terms of promoting said access, if any? And if this responsibility is solely a public sector one and for the states to mandate mechanisms to safeguard it, does CSR represent a tool pointing to the right direction to improve access?

CSR in healthcare applies to all healthcare industries, healthcare organizations first of all, but also pharmaceutical (pharma), biotechnology (biotech) and medical technology (medtech) industries. The European Commission calls for CSR not to have any negative impact on human rights.<sup>42,43</sup> There is, however, no general legal framework in national or regional level with specific criteria that define the categories of legal persons subject to social accountability. International Law has traditionally focused on state responsibility, the State being considered the sole institution able to bear such

responsibility. Technological progress and the use of exponential technologies (Internet, AI, blockchain) accelerated the institutionalization of legal responsibility for corporate entities or at least the need to establish a frame for it,<sup>44</sup> particularly given the extent of deploying public-private partnerships (PPPs) for the scale and magnitude of cross-sectoral and cross-border efforts. Elements necessary for social responsibility can be established through contractual clauses. Social responsibility has also become a part of the legal framework in environmental law, with the famous principal ‘the polluter pays’. According to TFEU (art.168), public health is the responsibility of Member States.<sup>45,46</sup> Corporate responsibility in public health is regulated, rather exceptionally, on the basis of the solidarity clause (art. 122 of the TFEU ex. art 100 with a focus on supply chains: ‘[...] may decide, in a spirit of solidarity between Member States, upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products, notably in the area of energy’), and on the Directive 85/374/EEC [25 July 1985] on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. Despite the broad definition for ‘producer’ in terms of liability, i.e., any person who imports into the Community a product for sale, hire, leasing or any form of distribution, the next article (4) in the Directive potentially narrows the field of producer’s liability substantially by stipulating that the citizen bears the burden of proof: ‘The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage’. The burden of proof is tremendously inordinate, whereas in the case of mass interventions, including of potentially mandatory character as currently discussed for vaccines, in the interest of public health or in the context of an emergency, the ramifications in terms of said burden of proof are extremely complex.

Corporate responsibility is often analysed under an ethical approach focused on defining the social responsibilities of business executives as ‘the obligations of businessmen/corporations to pursue those policies, to make those decisions, or to follow those lines of action which are desirable in terms of the objectives and values of our society’.<sup>47</sup> In our contemporary era though, the structure of global enterprises and the capital flows in them, makes it very difficult to identify who may be really morally responsible and to what extent. For this reason, moral responsibility mostly is reduced to a general concept benefactor behaviour. Given this vague context, the only solution is to link CSR with specific contractual responsibility. If not, this aspect of fairness can only have a voluntary basis and cannot be linked to the concept of distributive justice and of the notion of justice as fairness, developed by John Rawls.<sup>48</sup>

In the field of public health, the criteria that define the elements of corporate responsibility are still to be developed. The same stands for the beneficiaries of this responsibility, who cannot be clearly divided from the beneficiaries of commercial promotion. This can be reflected even in the concept of fair pricing. Fair pricing encompasses not only medicines but also vaccines and devices. It has been used to underline the ethical obligation of providing universal access to medicinal products; the term seems rather to define an obligation of the developed countries to guarantee the payment of effective pharmaceuticals and the subsequent access for population of low- and middle-income countries (LMICs), or, to be more precise, to make the relative quantities available for distribution to the relevant public health authorities, rather than to have said obligations associated to any specific aspect of social responsibility and to a relevant scheme of dialogue between the stakeholders involved.

## COVID-19, the TRIPS waiver and negotiating a pandemic treaty

The current COVID-19 crisis has already given rise to intense debates on corporate accountability, not least in terms of how



corporate practices shape access to vaccines, devices and medicines to combat the pandemic. At the time of COVID-19, we have seen superb mobilization of the private sector to find solutions, unprecedented collaboration within the public and private sector, as well as excellent partnerships. Discovery and development were accelerated, data, ideas and, even, proprietary data, were shared to find rapid, effective and efficient solutions. Yet, the agreements of TNCs with countries, including with the European Commission for the EU were not transparent, contracts not being available to citizens, but also to Members of the European Parliament. Even in the cases where state funding was unprecedented, there appear to be no special provisions in terms of access, pricing or, indeed, knowledge transfer mechanisms to ensure access for the most disadvantaged and vulnerable across the world or, indeed, for citizens of LMICs.

On 2 October 2020, South Africa and India proposed a waiver to the WTO TRIPS Agreement, to allow for suspension of the protection of certain kinds of IP related to the prevention, containment and treatment of COVID-19. This request was put forth solely for the duration of the pandemic. Arguments on it not sufficing to facilitate access and, indeed, on potentially impeding it, polarized debate and led to geopolitical friction within Europe and across the world. Questions—largely remaining unanswered in terms of official position and sound communication strategy to the public, public health practitioners and other healthcare professionals—also arose on who was to make such decisions. Was pricing a matter of a corporate decision at a time of a global health pandemic? Why did companies start to increase prices and/or why where they allowed to increase prices when the better part of the world remained unvaccinated? Was some of the excessive profit to be redirected to efforts to combat the crisis? Or was corporate decision-making and business practice driven by shareholders, often covered by anonymity provided by investment funds, aiming to maximize the return on their investment? Did predatory capital flows have a role to play given previous lessons on greed and profit-maximization practices? Or where the proxy agents in the form of boards and management the real decision-makers? Was there a role for governments and multinational bodies to ensure accountability in terms of business practices? Critically, if all the preventive, therapeutic and diagnostic solutions are to come from the private sector, could an effort to curb excessive profit jeopardize investment flows? Or had state funding sufficiently de-risked investment at a time of crisis?

Vian *et al.*<sup>31</sup> describe several sound mechanisms to promote transparency and accountability of public procurement, such as open contracting, implementing ‘pacts’—i.e., agreement between the government and all bidders, e-procurement, monitoring activities, with many of these being relevant for PPPs. The difference between a well-defined accountability framework, legally binding, with remedy provisions vs. the *ad hoc* creation of agreements lacking these key elements has already backfired; the Astra-Zeneca and EU case is one such example, with legal action brought against a company, and the lack of transparency in the contractual obligations of both sides resulting in not only ineffective actions in terms of public health but most critically in erosion of the public trust both towards the EU, governments, the state and institutions across Member-States, and, of course, the industry. The clause in the CureVac contract, prohibiting European countries from reselling, exporting or donating vaccine doses—including to COVAX, the COVID-19 Vaccines Global Access initiative, an alliance of more than 190 countries aiming to ensure fair and equitable access to vaccines by making the vaccine available to LMICs at no cost or at reduced cost—without prior consent from the company echoes the clauses found in contracts across the Atlantic.<sup>49</sup>

In Spring 2020, early in the global health crisis, the World Health Organization (WHO) established the COVID-19 Technology Access Pool (C-TAP). C-TAP is platform to IP, including cell lines, know-how, data, and all the key elements needed to accelerate the production, availability and, ultimately, ensure access, to all the tools

available to combat the COVID-19. A year later, an empty C-TAP and nationalistic policies on vaccines, prompted the proposal for the TRIPS Waiver. The TRIPS proposal for a temporary waiver was met with opposition from the industry and certain high-income countries. In an unprecedented move, hailed by key multilateral bodies like the WHO and WTO, President Biden in the US announced he was supporting this proposal.<sup>50</sup> Europe’s positioning to propose a focus on mechanisms like C-TAP or the WHO’s COVID-19 mRNA technology transfer hub to facilitate establishment of technology transfer hubs in LMICs raises questions on what the main drivers for this decision are and, indeed, to what extent they are evidence-informed by science, global public health priorities, and foresight on economic and social ramifications for the future.

## Conclusion

The COVID-19 pandemic has brought to the fore all the issues plaguing our systems. Lack of adequate access, limited accessibility, the North-South divide, the absence of robust mechanisms for evidence-informed decision-making, and the ambiguity surrounding accountability mechanisms in general, as well as in times of crisis, have not only affected how the pandemic evolved but have played a key role in eroding the citizen’s trust to governments and institutions. Excessive profit-making and business-as-usual practices have been combined with a negotiation that is more political rather than evidence-informed, including by sound evidence and argumentation on economic and legal grounds. All this has marred the superb collaborative effort of scientists in the public and private sector to find solutions to combat the pandemic.

It is also apparent that although tools like the TRIPS waiver, a unilateral legal tool linked to state sovereignty, could be used in case of failure to provide the vaccines of quantities required, States are reluctant to use it, because it requires knowledge transfer of private sector know-how to work, that States are unable to guarantee. The lack of well-established multilateral mechanisms mandated, adequately resourced, and widely accepted to support knowledge transfer, regional autonomy, access and health coverage for the most vulnerable especially during pandemics is demands prompt attention. What, however, should be worrying the European public health community, and every citizen in Europe and beyond, is the decision-making processes. A time of crisis, also, represents an opportunity to examine institutional adequacy and to revisit how to best safeguard institutional integrity and state sovereignty. In these, rather unprecedented times, where an end to the pandemic can be conceived, we urgently require both pan-European alignment and global solutions rather than local thinking and nationalistic policies.

*Conflicts of interest:* None declared.

## Additional Content

A video to accompany this paper is available at <https://youtube.com/playlist?list=PLv5eq4ZCoNWubJurAJ-7Ht33cjNshLw7R>.

## References

- Haffajee R, Mello MM. Drug companies’ liability for the opioid epidemic. *N Engl J Med* 2017;377:2301–5.
- Brownell KD, Warner KE. The perils of ignoring history: big tobacco played dirty and millions died. how similar is big food? *Milbank Q* 2009;87:259–94.
- Cummings KM, Morley CP, Hyland A. Failed promises of the cigarette industry and its effect on consumer misperceptions about the health risks of smoking. *Tob Control* 2002;11(Suppl 1):i110–7.
- Kibert CJ, Thiele L, Peterson A, Monroe M. *The Ethics of Sustainability*. Washington, D.C.: Island Press, 2012.
- Perlmutter H. V. The tortuous evolution of the multinational corporation. In: Buckley PJ, editor. *International Business*. London: Routledge, 2018: 117–26.

- 6 UN High Commissioner for Human Rights. Report of the United Nations High Commissioner on Human Rights on the responsibilities of transnational corporations and related business enterprises with regard to human rights. UN, 2005. Available at: <https://digitallibrary.un.org/record/542041> (23 May 2021, date last accessed).
- 7 Hestermeyer H. *Human Rights and the WTO: The Case of Patents and Access to Medicines*. Oxford: Oxford University Press, 2007, ISBN: 01-9921520-0.
- 8 Ho C. *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*. Oxford: Oxford University Press, 2011. Doi:10.1093/acprof:oso/9780195390124.001.0001.
- 9 Clapham A. *Human Rights Obligations of Non-State Actors*. Oxford: Oxford University Press, 2010, Doi:10.1093/acprof:oso/9780199288465.001.0001.
- 10 UN Human Rights Council. Institution-building of the United Nations Human Rights Council, 18 June 2007, A/HRC/RES/5/1. Available at: <https://www.refworld.org/docid/4ae9acbbd.html>. <https://www.refworld.org/docid/4ae9acbbd.html> (23 May 2021, date last accessed).
- 11 The UN “Protect, Respect and Remedy” Framework for Business and Human Rights Background. 2010. Available at: <http://www.srsconsultation.org> (23 May 2021, date last accessed).
- 12 Cassell D, Ramasastry A. White Paper: Options For a Treaty on Business and Human Rights. 2016. Available at: <http://scholarship.law.nd.edu/ndjicl/vol6/iss1/4> (22 May 2021, date last accessed).
- 13 Gruskin S, Raad Z. Are drug companies living up to their human rights responsibilities? Moving toward assessment. *PLoS Med* 2010;7:e1000310.
- 14 Guiding principles on business and human rights: implementing the United Nations. ‘Protect, Respect and Remedy’ framework (Guiding Principles), UN Doc. HR/PUB/11/04. 2011. Available at [http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR\\_EN.pdf](http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf) (23 May 2021, date last accessed).
- 15 Fasciglione M. Implementing responsible business conduct approaches under the UN guiding principles on business and human rights at the time of COVID-19; Implementing responsible business conduct approaches under the UN guiding principles on business and human rights at the time of COVID-19. *European Papers* 2020;5:1435–50. [www.europeanpapers.eu](http://www.europeanpapers.eu) ISSN.
- 16 Wouters J, Hachez N. Business and human rights in EU external relations. Making the EU a leader at home and internationally, study for the European parliament, Directorate-General for External Policies of the Union, Directorate B - Policy Department, EXPO/B/DROI/2009/2, PE407.014, 2009. Available at: <https://www.europarl.europa.eu/document/activities/cont/200904/20090430ATT54804/20090430ATT54804EN.pdf> (5 August 2021, date last accessed).
- 17 Bovens M. Analysing and assessing accountability: a conceptual framework1. *Eur Law J* 2007;13:447–68.
- 18 Koppell JGS. Pathologies of accountability: ICANN and the challenge of “multiple accountabilities disorder”. *Public Admin Rev* 2005;65:94–108.
- 19 Scheyvens R, Banks G, Hughes E. The private sector and the SDGs: the need to move beyond ‘Business as Usual’. *Sust Dev* 2016;24:371–82.
- 20 Bhutta ZA, Siddiqi S, Aftab W, et al. What will it take to implement health and health-related sustainable development goals? *BMJ Global Health* 2020;5:e002963.
- 21 Steets J. *Accountability in Public Policy Partnerships*. Palgrave Macmillan. <https://www.palgrave.com/gp/book/9780230238978> (5 August 2021, date last accessed).
- 22 Universal Health Coverage. General Assembly of the United Nations. Available at: <https://www.un.org/pga/73/event/universal-health-coverage/> (5 August 2021, date last accessed).
- 23 Matten D, Moon J. “Implicit” and “explicit” CSR: a conceptual framework for a comparative understanding of corporate social responsibility. *Acad Manage Rev* 2008;33:404–24.
- 24 The Nature and Management of Ethical Corporate Identity: A Commentary on Corporate Identity, Corporate Social Responsibility and Ethics on JSTOR. Available at: <https://www.jstor.org/stable/25075491> (5 August 2021, date last accessed).
- 25 Fukukawa K, Balmer JMT, Gray ER. Mapping the interface between corporate identity, ethics and corporate social responsibility. *J Bus Ethics* 2007;76:1–5.
- 26 Dawkins CE, Fraas JW. An exploratory analysis of corporate social responsibility and disclosure. *Bus Soc* 2008;52:245–81. Doi:10.1177/0007650308324047.
- 27 Galbreath J. Building corporate social responsibility into strategy. *Eur Bus Rev* 2009; 21:109–27.
- 28 Tamvada M. Corporate social responsibility and accountability: a new theoretical foundation for regulating CSR. *Int J Corp Soc Responsib* 2020;5:1–14.
- 29 Chauvey J-N, Giordano-Spring S, Cho CH, Patten DM. The normativity and legitimacy of CSR disclosure: evidence from France. *J Bus Ethics* 2015;130:789–803.
- 30 Filios VP. Corporate social responsibility and public accountability. *J Bus Ethics* 1984;3:305–14.
- 31 Vian T, Kohler JC, Forte G, Dimancesco D. Promoting transparency, accountability, and access through a multi-stakeholder initiative: lessons from the medicines transparency alliance. *J Pharm Policy Pract* 2017;10:18.
- 32 Kohler JC, Ovtcharenko N. U4 ISSUE Good governance for medicines initiatives: exploring lessons learned. 2013. Available at: [www.u4.no](http://www.u4.no) (5 August 2021, date last accessed).
- 33 Baghdadi-Sabeti G, Serhan F. WHO Good Governance for Medicines programme: an innovative approach to prevent corruption in the pharmaceutical sector World Health Report (2010) Background Paper, 25 Compilation of country case studies and best practices.
- 34 Ross JS, Gross CP, Krumholz HM. Promoting transparency in pharmaceutical industry-sponsored research. *Am J Public Health* 2012;102:72–80.
- 35 Fair pricing forum 2019 meeting report. Available at: <https://www.who.int/publications-detail-redirect/WHO-MVP-EMP-IAU-2019.09> (5 August 2021, date last accessed).
- 36 Strong call for transparency on medicine prices, cost of R&D at WHO Fair Pricing Forum. *Medicines Law & Policy*. Available at: <https://medicineslawandpolicy.org/2019/04/strong-call-for-transparency-on-medicine-prices-cost-of-rd-at-who-fair-pricing-forum/> (5 August 2021, date last accessed).
- 37 World Health Assembly A72/80 Resolution. Seventh report of Committee A. 2019. Available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_80-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_80-en.pdf) (5 August 2021, date last accessed).
- 38 European Commission. Pharmaceutical Strategy for Europe. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&rid=3> (5 August 2021, date last accessed).
- 39 Paschke A, Dimancesco D, Vian T, et al. Increasing transparency and accountability in national pharmaceutical systems. *Bull World Health Organ* 2018;96:782–91.
- 40 Camargo CB, Jacobs E. *Social Accountability and its Conceptual Challenges: An Analytical Framework*. Freiburg i. B., Germany: Max Planck Society for the Advancement of Science c/o Max Planck Institute for Foreign and International Criminal Law, 2013.
- 41 WTO. Ministerial conferences—Doha 4th Ministerial—TRIPS declaration. Available at: [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (12 August 2021, date last accessed).
- 42 Dimancesco D, Paschke A. Transparency and Accountability Assessment Tool. Good Governance for Medicines Progressing access in the SDG era. WHO; 2018. Available at: <https://apps.who.int/iris/bitstream/handle/10665/275370/WHO-EMP-2018.04-eng.pdf?ua=1>—Google Search. <https://www.google.com/search?q=Dimancesco+D%2C+Paschke+A.+Transparency+and+Accountability+Assessment+Tool.+Good+Governance+for+Medicines+Progressing+access+in+the+SDG+era.+WHO%3B+2018.+Available+at%3A+https%3A%2F%2Fapps.who.int%2Firis%2Fbitstream%2Fhandle%2F10665%2F275370%2FWHO-EMP-2018.04-eng.pdf%3Fua%3D1> (5 August 2021, date last accessed).
- 43 Lee M, Kohler J. Benchmarking and transparency: incentives for the pharmaceutical industry’s corporate social responsibility. *J Bus Ethics* 2010;95:641–58.
- 44 European Court of Human Rights. European Convention on Human Rights [as amended by Protocols Nos. 11, 14 and 15] and supplemented by Protocols Nos. 1, 4, 6, 7, 12, 13 and 16. 2021. Available at: [www.conventions.coe.int](http://www.conventions.coe.int) (5 August 2021, date last accessed).
- 45 Treaty on the Functioning of the European Union (TFEU)—The Faculty of Law. Available at: [https://www.jus.uio.no/english/services/library/treaties/09/9-01/tfeu\\_cons.xml](https://www.jus.uio.no/english/services/library/treaties/09/9-01/tfeu_cons.xml) (5 August 2021, date last accessed).
- 46 Public health. Fact Sheets on the European Union. European Parliament. Available at: <https://www.europarl.europa.eu/factsheets/en/sheet/49/public-health> (5 August 2021, date last accessed).
- 47 The Social Responsibilities of the Businessman. University of Iowa Press. Available at: <https://www.uiowa.edu/books/9781609381967/the-social-responsibilities-of-the-businessman> (5 August 2021, date last accessed).
- 48 Rawls J. I. Justice as fairness. *J Philos* 1957;54:653.
- 49 Advance Purchase Agreement between the European Commission and CureVac. Available at: [https://ec.europa.eu/info/sites/default/files/curevac\\_-\\_redacted\\_advance\\_purchase\\_agreement\\_0.pdf](https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf) (17 September 2021, date last accessed).
- 50 COVID shows the world it needs new rules to deal with pandemics. *Medicines Law & Policy*. Available at: <https://medicineslawandpolicy.org/2021/05/covid-shows-the-world-it-needs-new-rules-to-deal-with-pandemics/> (13 August 2021, date last accessed).