



What are the obligations of pharmaceutical companies in a global health emergency?

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Introduction

During a global health emergency, everyone is morally required to help to combat the disease. With approximately 8000–10 000 people dying every day from COVID-19, as of writing, only rapid and globally distributed vaccinations will end the pandemic. With the support of national governments, pharmaceutical companies have produced more than 250 vaccine candidates to date.

WHO, the Coalition for Epidemic Preparedness Innovations, and Gavi, the Vaccine Alliance have established COVID-19 Vaccines Global Access (COVAX) to procure and fairly distribute vaccines.¹ But much vaccine development, production, procurement, and distribution is ad hoc, generating controversy and inconsistency. Pharmaceutical companies have been criticised for knowledge hoarding, secret pricing, unreasonable profits, unfair bilateral deals, and extortionate demands for indemnification against liability.^{2,3} COVAX has been criticised for an absence of transparency and accountability and for ignoring need in COVID-19 vaccine distribution.^{4,7} All parties involved in researching, developing, manufacturing, and distributing COVID-19 vaccines need guidance on their ethical obligations. We focus on pharmaceutical companies' obligations because their capacities to research, develop, manufacture, and distribute vaccines make them uniquely placed for stemming the pandemic.

Principles governing the response to COVID-19

An ethical approach to COVID-19 vaccine production and distribution should satisfy four uncontroversial principles: optimising vaccine production, including development, testing, and manufacturing; fair distribution; sustainability; and accountability (table 1).

These four principles should be taken as a coherent whole, for all companies and applied globally. For instance, ensuring accountability should not undermine optimising production. There are multiple ways to balance these principles. Any decision to give greater weight to some principles rather than others is inherently controversial. Optimising production is obviously necessary to end vaccine scarcity. Fair distribution requires that no segment of the world's population should be unvaccinated because of inability to afford vaccination.⁵ Importantly, any practical approach should ensure sustainability and companies' continued engagement in addressing COVID-19 and their focus on future infectious diseases and health emergencies.

Additionally, all parties' obligations should be coordinated and mutually consistent. For instance, companies should not be obligated to provide host countries with additional booster shots at the expense of fulfilling bilateral contracts with countries in which there are surges.

Finally, any satisfactory approach should include mechanisms for assurance that all parties are honouring their obligations. This assurance enables countries, pharmaceutical companies, global organisations, and others to verify compliance with the chosen approach and protect ethically compliant stakeholders from being unfairly exploited by unethical behaviour of others.⁸

Potential approaches to pharmaceutical companies' ethical obligations

Pharmaceutical companies have special obligations in this emergency, which follow from their indispensable capacity to help to end the pandemic by developing, manufacturing, and distributing COVID-19 vaccines. However, the capacity to help alone does not fully specify companies' obligations. Additionally, market-based arrangements, with patents, marketing exclusivity, and confidentiality clauses, give pharmaceutical companies the freedom to choose what treatments to research and develop, how to price and distribute their products, and whom to furnish with products through bilateral agreements.⁹ Indeed, companies need not produce vaccines or infectious disease therapies at all. Patents and exclusivity, alongside the absence of price controls or requirements for technology transfer, also permit companies to charge higher prices than they otherwise could. Governments adopt intellectual property rights, limited pricing regulations (ie, each country has its own pricing, with no one country controlling the pricing, at most being able to set limits on the prices that can be charged), trade agreements, and other limited interventions (eg, manufacturing, inspections of facilities, etc) in the hope of incentivising the development, manufacturing, and distribution of socially valuable products.⁹

Everyone—including pharmaceutical companies—agrees that business as usual is unacceptable in a pandemic. Glaringly, the largely market-based approach unfairly distributes vaccines on the basis of wealth and not COVID-19 burden.¹⁰ Absent international coordination or subsidised purchasing, standard pricing practices, and market-driven distribution will incentivise vaccine production that can be effectively distributed in wealthy countries and underproduction of vaccine to address the pandemic elsewhere. Poor countries will be pushed to the end of the queue.^{10,11} Recognising such

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problems, many pharmaceutical companies, COVAX, and governments have already deviated from the market approach, as shown by agreements to donate vaccines to COVAX and low-income countries, pledges to sell vaccines at marginal cost during the pandemic, and, by some firms, non-enforcement of vaccine patents.^{12,13} Yet, such responses have been uncoordinated and have not achieved fair distribution.

During this pandemic, how should pharmaceutical companies contribute to realising the four ethical principles? We delineate four approaches, and determine

which are ethically acceptable and how they can be implemented—and improved—to realise the four principles (table 2). There is not one uniquely optimal approach. Choosing among the ethically acceptable approaches involves establishing which principles should be given most weight and how feasible each approach is to adoption during this pandemic.

Tiered pricing approach

On a tiered pricing approach, vaccines are distributed through bilateral deals between governments and

	Type of principle	Definition
Optimising vaccine production	Substantive	Resources should be mobilised as quickly as possible to reduce the health and economic burdens of the pandemic; this research and development process occurs within the bounds of an increased risk tolerance for authorising interventions, given the pandemic’s enormous burdens; rapidly vaccinating as many people as possible is necessary to end the pandemic
Fair distribution	Substantive	Fairness requires that vaccine allocation should appropriately prioritise countries in great need, not those with great wealth; fairness also requires not leaving people who are in need at the back of the queue, and instead ensuring that they receive the vaccine in a timely manner; no segment of the world’s population should be left behind because of inability to afford vaccines
Sustainability	Substantive	Requires a long-term perspective to ensure that emergency responses that are appealing in the short term do not unacceptably imperil the future development of and access to affordable and socially valuable vaccines and therapies; institutional arrangements made for the current situation should not impair the ability or willingness of any party to optimally respond either to COVID-19 or future health emergencies; this long-term perspective and commitment to sustainability does not commit society to accepting the status quo, since well considered reforms could improve outcomes while fairly balancing the legitimate interests of all parties—i.e, pharmaceutical companies, patients, governments, and others
Accountability	Procedural	Accountability empowers the public to demand justification for decisions made, actively monitor their implementation, and exert pressure on decision makers to fulfil their ethical obligations; there should be established public standards for behaviour, ways to assure that these standards are met, and mechanisms for sanctioning violations of these standards

Table 1: Four principles for ethical obligations of all parties engaged in allocating vaccines during the COVID-19 pandemic

	Description	Principles emphasised	Evaluation	Companies’ obligations
Tiered pricing	Pharmaceutical companies distribute vaccines on the basis of tiered pricing, charging more to wealthy nations and less or even nothing for low-income countries	Sustainability	Insufficient vaccines are produced overall or distributed to poor countries; absence of transparency and effective accountability mechanisms	Tiered pricing among bilateral contractors; publicly disclose details of bilateral contracts
Global public goods	Pharmaceutical companies voluntarily waive their patent rights and engage in technology transfer; vaccines are made available to all	Optimising vaccine production; fair distribution	Might not be sustainable if pharmaceutical companies are insufficiently compensated for knowledge transfer; might target the wrong bottleneck because production know-how and capacity seem to be rate limiting rather than patents; because vaccines are not true public goods and require scarce raw materials, this approach needs complementary approaches to optimise production and achieve fair distribution	Non-enforcement of patent rights; transfer of knowledge and expertise
Partly bilateral	Pharmaceutical companies distribute vaccines through both bilateral contracts and to an international facility (eg, COVAX)	Optimising vaccine production; fair distribution; sustainability	For fair distribution, a principled mechanism to determine how many vaccines are reserved for bilateral agreements and how many for COVAX, a schedule for fulfilling bilateral deals, and an ethical pricing policy are needed	Allocate vaccines between bilateral contracts and the international facilities, such as COVAX, concurrently and in proportion to COVID-19 need; sell to international facilities, such as COVAX, at marginal cost for participating countries; publicly disclose details of bilateral contracts, agreements with international facilities, such as COVAX, and the schedule for fulfilling both agreements
Fully multilateral	Pharmaceutical companies distribute all vaccines through an international facility, such as COVAX	Fair distribution; accountability	Requires levels of international coordination and trust that do not exist; positioning the international facility as the sole distributor exposes it to greater political pressures from wealthy countries; having a single purchaser can conflict with optimising production	Refrain from making bilateral deals; publicly disclose details of the agreement with the international facility

COVAX=COVID-19 Vaccines Global Access.

Table 2: Approaches for vaccine distribution and pharmaceutical companies’ obligations

pharmaceutical companies. Companies are ethically obligated to set prices according to each country's financial capacity and donate or subsidise vaccines for the lowest income countries. Profits in rich countries are used to cross-subsidise the poorest countries rather than maximise profits. By focusing on vaccine prices, the tiered pricing approach prioritises sustainability modified by fairness.

This approach has been partly implemented. For instance, Pfizer has pledged to abide by a three-tiered pricing scheme in its bilateral sales of vaccine.¹⁴ But bilateral deals charge higher prices to low-income and middle-income countries (LMICs) than to high-income countries.³

Although ethically superior to an unmodified market approach, tiered pricing alone does not ensure fair distribution of vaccine. Even with tiered pricing, wealthier countries can secure many doses before LMICs.¹⁰ Moreover, companies might not have the expertise or willingness to adopt ethically appropriate pricing.

Global public goods approach

Some representatives of non-governmental organisations, civil society, international organisations, and other institutions have proposed a global public goods approach with the aim of securing universal, free access to COVID-19 vaccines.¹⁵ Although the goal is undoubtedly right, the global public goods approach for vaccines is problematic. Following traditional definitions, Gavi notes that global public goods “must be non-rivalrous, meaning that using it doesn't reduce the amount for anyone else” and “non-excludable, meaning that it should be impossible to prevent anyone else from getting the benefits”.¹⁶ Pandemic control and disease eradication are global public goods. However, as Gavi emphasises, vaccines themselves cannot be global public goods.¹⁶ Even if the immunity of any vaccinated party protects others from infection in ways that count as a non-rival and non-excludable benefit, the supply of actual vaccine doses is both rivalrous and excludable.¹⁶

Can a global public goods framework guide pharmaceutical companies' obligations? Unlike vaccines themselves, vaccine-related knowledge is non-rivalrous. Thus, vaccine manufacturers have a duty to share knowledge with potential vaccine producers. Effectively accelerating and expanding COVID-19 vaccine production requires not only patent non-enforcement but also sharing know-how and trade secrets.¹⁷ However, expecting companies to share vaccine-related knowledge without adequate compensation would jeopardise sustainability. Companies and investors are likely to shift investment into areas with stronger intellectual property protections.¹⁸ Determining appropriate compensation for sharing knowledge is necessary but challenging, with prize funds or other types of public investment as potential mechanisms for compensation.

Beyond supporting duties to share knowledge, a global public goods framework alone is unlikely to realise the fair

distribution of vaccines. Even if pharmaceutical companies waive patents and share know-how, universal access to vaccines will occur only if other companies, governments, non-governmental organisations, and others commit to developing robust manufacturing capability, ensuring raw material supplies, and distributing produced vaccines equitably. Transferring technology and scaling up production will take months, maybe years. Until scarcity abates, pharmaceutical companies are obligated to ensure their vaccine production is both optimised and fairly distributed.

A partly bilateral approach

Another approach combines caps on bilateral agreements with commitments to devote a portion of vaccine production to an international organisation, such as COVAX, which can acquire and distribute vaccine to LMICs. This approach caps the total amount of vaccine that can be distributed through bilateral deals and reserves a proportion of the manufactured vaccine for purchase and distribution by a multilateral organisation from the start.

As a departure from the existing market-based approach, the partly bilateral approach aims to achieve both fair distribution and sustainability. Pharmaceutical companies can profit by selling a small number of doses directly to high-income countries during or after the emergency and, concurrently, distribute vaccine to LMICs at substantially lower cost than to high-income countries. The level of international cooperation and accountability that is needed for this approach is not unprecedented (eg, previously for HIV drugs and other drugs that now have tiered pricing).

Limiting bilateral deals to a predefined threshold and ensuring concurrent delivery to an international organisation does not eliminate bilateral deals. The partly bilateral approach therefore leaves LMICs to share what is likely to be an insufficient quantity of COVAX-procured vaccines, while allowing wealthy countries to obtain higher quantities earlier.^{10,11} Furthermore, bilateral deals are not transparent. The partly bilateral approach also does not guarantee that the international organisation procuring vaccines for LMICs, such as COVAX, will be accountable or fairly distribute procured vaccines.^{5,6}

A fully multilateral approach

A final approach has one international organisation overseeing procurement and distribution of all vaccine doses, with no bilateral deals. By centralising procurement and distribution, this approach could better ensure that vaccine is distributed on the basis of need, not wealth. Eliminating bilateral deals also increases the incentives to hold the procurement organisation accountable. Similar to the market power of large purchasers, such as the UK's National Health Service, the procurement organisation's market power can also counter the power imbalance between poor countries and pharmaceutical companies.

A major challenge for such an approach is that exclusive distribution through an international organisation requires substantially more international cooperation than currently exists. Additionally, if a centralised international body were the only channel through which high-income countries could secure vaccines, then high-income countries might use their donations to press for distribution rules that unfairly advantage them. If high-income countries do not receive priority, they might exit the deal or arrangement, seeking to secure agreements outside the international organisation.¹⁹ Additionally, some vaccine companies are either owned by or have close financial ties to governments. As is now occurring, governments can pressure or induce companies to prioritise their own country's population, withholding vaccines from the centralised international body.^{20–22} Last, permitting sales only to a single purchaser might not optimise production, particularly if the single buyer uses its market power to demand excessively low prices.²³

From theory to practice

In moving from these approaches to practice, we draw four conclusions. First, some multilateralism is ethically necessary. Neither the tiered pricing nor the global public goods approach alone will ensure fair distribution. Second, these approaches are not mutually exclusive. With the exception of partly bilateral and fully multilateral approaches, the approaches can be combined. Third, to ensure fair distribution, optimal production, and sustainability, the partly bilateral or fully multilateral approaches would have to adopt a more ethically defensible distribution framework than COVAX's population-based approach, which ignores differences in need in various countries, and enable accountability through improved transparency.^{5,6}

Fourth, in the current pandemic, path dependence (ie, the way that past decisions and institutional arrangements constrain current options) favours the partly bilateral approach combined with tiered pricing and knowledge transfer. Companies have already executed and are fulfilling bilateral deals while simultaneously selling vaccine to COVAX. Although the fully multilateral approach—perhaps paired with elements of other approaches—might be more satisfactory than bilateral deals, pivoting to a new institutional approach in a crisis presents daunting challenges, as COVAX has shown.²⁴ However, existing bilateral deals are morally flawed, with most initial doses being reserved for high-income countries. How could the partly bilateral approach be improved?^{3,10,11}

Obligations under the partly bilateral approach

Companies need a principled mechanism to establish three points: the proportion of vaccine that can be sold through bilateral agreements; a timing schedule of fulfilling purchases that is sensitive to need and not just wealth; and a pricing policy towards bilateral and

COVAX purchasers. Deciding the proportion of vaccine that can be sold through bilateral agreements ensures that every purchaser receives a fair quantity of vaccines, whereas the timing schedule and pricing policy ensure that every purchaser receives timely and affordable access. Importantly, both proportion and timing are not completely under the control of pharmaceutical companies individually or the industry collectively. Regarding pricing, the extent to which governments, non-governmental organisations, and others should be obligated to contribute to the cost of buying and distributing vaccines will have to be established through international negotiations, where the financial obligations of all parties are delineated.

Regarding proportion, companies should limit the number of doses that are available for bilateral purchases to each country's COVID-19 needs. This means that fair allocation should seek to mitigate future adverse effects of COVID-19 (in each country, focused in phases). Phase 1 aims to reduce premature deaths and other irreversible direct and indirect health effects. Phase 2 aims to reduce serious economic and social deprivations. Phase 3 aims to reduce community transmission.⁷

Until people in all countries are adequately vaccinated to reduce community transmission, vaccine distribution will occur in phases. For instance, if the poorest countries would need 30% of available doses to reduce deaths during surges, the total cap on bilateral deals for all other countries should be 70%. Regarding timing, to secure enough vaccines from the start of the roll-out, the poorest countries should receive 30% of all available doses in any phase of vaccine distribution.

To ensure accountability within the partly bilateral approach, companies would have to make their vaccine contracts transparent. Bilateral deals are secured with public funds, creating a public right to accountability. Bilateral deals also indirectly affect all of the other countries participating in COVAX. Therefore, both bilateral and COVAX agreements should be made public. To enable public assessment of fair distribution, companies should also disclose their plans for delivering vaccines. This commitment, if agreed to, could be implemented through a code of conduct by all companies.

Both vaccine price and availability also depend on liability. Who should bear the cost of any harms that vaccines produce? Liability should be collectively shared at least until postmarket surveillance establishes the full risks of the product. Pharmaceutical companies should not bear strict liability: that is, liability for harms that occur despite reasonable precautions. Companies are accelerating vaccine availability at society's behest. Hence, the strict liability standard is inappropriate. To offset risks, companies would also increase vaccine prices or reduce availability. If the price of COVID-19 vaccines is restricted by regulators in response, then sustainability could be undermined. Furthermore, imposing strict liability would incentivise companies to

sell the vaccine primarily to countries that can provide greater insulation from liability, such as the USA through the National Vaccine Injury Compensation Program.²⁵

By contrast, companies should be liable for harms due to negligence in manufacturing or postmarketing surveillance or due to data concealment. Complete impunity from liability creates perverse incentives that substantially increase public health risks.²⁶

WHO has created a fund for no-fault “global vaccine injury compensation” that is “funded by a small levy on each dose supported” by COVAX.²⁷ This fund covers the 92 LMICs participating in COVAX. This approach ensures compensation for injury but unfortunately eliminates the negligence liability incentives and increases vaccine costs. It also fails to address the problem of pharmaceutical companies asking middle-income countries to provide onerous indemnification against liability for negligence.²

Conclusion

Realising the four ethical principles requires urgent attention to further refine global institutional arrangements.⁵ There is no authoritative and widely accepted institutional arrangement for ensuring a fair distribution of burdens in response to pandemics or other global health emergencies. The need for such an arrangement obligates pharmaceutical companies, along with governments, non-governmental organisations, international organisations, and others, to develop collaboratively the requisite institutional innovations in anticipation of the next emergency.

Fairly responding to global health emergencies requires addressing the broad problem of justice in the global diffusion of valuable innovations.²⁸ When the current crisis abates, improving the system requires a critical evaluation of how well the existing uncoordinated conglomeration of public and private institutions is able to generate and fairly distribute the benefits of innovation, and what is needed for a more sustainable institutional solution that avoids unnecessary death and suffering, while ensuring sufficient incentives to respond to a future crisis. A future institutional solution to the persistent problem of justice in the diffusion of medical innovations should specify obligations for state and corporate stakeholders in facilitating technology and knowledge transfers.

Contributors

All authors contributed equally to the drafting and editing of this Viewpoint.

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