

Obligations in a global health emergency

Ezekiel Emanuel and colleagues note in their Viewpoint¹ that everyone agrees that business as usual is unacceptable in a pandemic. Yet their focus on sustainability for industry implicitly supports the status quo.

The status quo allows patents and other intellectual property (IP) barriers to impede access to medical tools.² IP-backed monopolies have left countries such as Brazil paying double their total 2021 routine immunisation programmes budget to Pfizer for COVID-19 vaccines, jeopardising the sustainability of the public health system by perpetuating reliance on corporate goodwill for access to lifesaving vaccines and therapeutics.³

Some voluntary measures could improve access to medicines. For example, the new WHO COVID-19 mRNA Vaccine Technology Transfer Hub is an opportunity for companies to share IP and know-how to help scale up and diversify production, not in years but in months.⁴ However, no mRNA vaccine developers have joined this initiative yet.

Contrary to the Ezekiel Emanuel and colleagues' scepticism, more than 100 countries, many of which are low-income or middle-income countries, endorse waiving certain COVID-19 IP protections to enable additional legal tools to overcome IP monopolies.² This strategy could help change the status quo and would not undermine innovation. Patents are not the driving force for medical innovation,⁵ and public funding contributed considerably to the development of COVID-19 vaccines.

With a world locked down and millions of excess deaths, what will it take for us to improve the IP system? How can we build a more equitable, sustainable, and accountable medical innovation system that serves everyone's health needs, starting today with the COVID-19 pandemic? We cannot wait for the next emergency.

We declare no competing interests.

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- 1 Emanuel EJ, Buchanan A, Chan SY, et al. What are the obligations of pharmaceutical companies in a global health emergency? *Lancet* 2021; **398**: 1015–20.
- 2 Médecins Sans Frontières. WTO COVID-19 TRIPS waiver proposal: myths, realities and an opportunity for governments to protect access to medical tools in a pandemic. Dec 3, 2020. https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf (accessed Aug 24, 2021).
- 3 Hallal M. Em nova oferta ao Ministério da Saúde, Pfizer cobra R\$ 1 bilhão a mais pelo mesmo nº de vacinas. May 7, 2021. <https://saude.estadao.com.br/noticias/geraldo,nova-oferta-da-pfizer-para-o-brasil-preve-mesmo-numero-de-vacinas-mas-preco-r-1-bilhao-maior,70003706502> (accessed Aug 25, 2021).
- 4 Médecins Sans Frontières. Following full FDA approval, Pfizer and BioNTech must urgently share COVID-19 vaccine know-how to increase global production and supply. Aug 23, 2021. <https://msfaccess.org/following-full-fda-approval-pfizer-and-biontech-must-urgently-share-covid-19-vaccine-know-how> (accessed Aug 24, 2021).
- 5 Fontana R, Nuvolari A, Shimizu H, Vezzulli A. Reassessing patent propensity: evidence from a data-set of R&D awards, 1977–2004. *Res Policy* 2013; **42**: 1780–92.

Ezekiel Emanuel and colleagues¹ emphasise the ethical obligations of pharmaceutical companies to combat the COVID-19 pandemic on the basis of four ethical principles: optimising vaccine production; fair distribution; sustainability; and accountability.

We here add a fifth principle that arises from ethical considerations enshrined in the Helsinki Declaration, which requires that vulnerable groups participating in medical research benefit from resulting interventions.² Populations in low-income and middle-income countries (LMICs) can be considered particularly vulnerable during the COVID-19 pandemic due to weak health systems, few possibilities to self-isolate in manual and informal

labour markets, and insufficient social protection mechanisms.

LMICs have nonetheless contributed substantially to the research on COVID-19 vaccines: of 199 country locations for 145 registered trials for the seven vaccines currently recommended by WHO, 2% were in low-income, 9% in lower-middle-income, 28% in upper-middle-income, and 62% in high-income countries (appendix). The considerable share of country locations in LMICs (39%) stands in stark contrast to the fragile access to vaccines in these regions. As of July, 2021, the share of the population that had received at least one dose of a COVID-19 vaccine was 1% in low-income, 8% in lower-middle-income, and 19% in upper-middle-income countries.³

By September, 2021, the share had increased in lower-middle-income and upper-middle-income countries, but the pace has been painstakingly slow, and low-income countries have barely made any progress.⁴ It is unacceptable that COVID-19 vaccine access in LMICs is based on voluntary international initiatives (eg, COVAX) or donations alone. Instead, the aforementioned ethical principle should be translated into binding legal mechanisms obliging pharmaceutical companies to guarantee access to the fruits of medical research for vulnerable populations who participated in human experiments.

We declare no competing interests.

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- 1 Emanuel EJ, Buchanan A, Chan SY, et al. What are the obligations of pharmaceutical companies in a global health emergency? *Lancet* 2021; **398**: 1015–20.
- 2 World Medical Association. WMA Declaration of Helsinki—ethical principles for medical research involving human subjects. July 9, 2018. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (accessed Sept 22, 2021).



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For more on COVID-19 vaccine candidates see <https://covid19.trackvaccines.org/>

See Online for appendix



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