



Lessons learned and recommendations to ensure access to vaccines, medicines and diagnostics in the COVID-19 pandemic response and beyond

Executive Summary

Almost two years into the COVID-19 global pandemic, Médecins Sans Frontières (MSF) continues to witness severe inequity in access to COVID-19 vaccines, medicines, diagnostics and other treatment and prevention measures in many low- and middle-income countries (LMICs) where we work.

Structural and systemic flaws in the global COVID-19 response have impeded access to these medical tools. Despite early promises by world leaders, a lack of global solidarity and insufficient governance of temporary global mechanisms, combined with ineffective mechanisms for global allocation, have enabled nationalistic hoarding of supplies from major pharmaceutical corporations. At the same time, an overreliance on market dynamics and corporate goodwill has stymied opportunities to increase and diversify global production and supply of many COVID-19 medical tools from other manufacturers. COVID-19 medical tools have benefitted from billions of Euros in public funding, yet manufacturers lack the transparency and accountability that could help promote access to these publicly supported tools. Insufficient support for local production has further undermined LMICs' abilities to promote regional self-reliance. For COVID-19 vaccines in particular, manufacturers' efforts to pass on their legal liabilities to purchasers like governments and non-governmental organisations (NGOs) providing vaccines in humanitarian settings harm access and set a worrying precedent for future pandemics.

Many of these lessons learned from COVID-19 represent unfortunately familiar global health challenges and suggest the need to break from the status quo to address the structural and systemic flaws in this pandemic response and to shape future pandemic preparedness and response efforts.

Inequity of access to COVID-19 vaccines, medicines and diagnostics

Inequity of access to vaccines

A number of high-income countries (HICs), including the US, UK, Switzerland, and many EU countries, have accumulated excessive portions of the global supply of vaccine doses. MSF analysis shows that 10 HICs will have 870 million excess vaccine doses in total by the end of 2021 while many healthcare workers and vulnerable people in LMICs have not received their first dose.¹ As of October 2021, 6.39 billion doses of COVID-19 vaccines have been administered worldwide, but just 2.3% of people in LICs have received at least one dose.² The overwhelming majority of people remain at risk of becoming ill with COVID-19, especially with the emergence of new variants.

In addition to supply constraints, vaccine rollout in LMICs has also been impacted by complexities within countries. These challenges include logistical concerns (e.g., maintaining cold chain requirements, accessing hard-to-reach areas, ensuring distribution before vaccines' expiry) limitations in absorption capacity by countries to roll out implementation, need for community sensitisation and information sharing to promote better vaccine uptake, and country preferences for certain vaccine types.

Inequity of access to medicines

In many LMICs there are significant access challenges for the most recently WHO-recommended biological drugs (monoclonal antibodies), tocilizumab, sarilumab and casirivimab/imdevimab. Access challenges also impact liposomal amphotericin B treatments and are expected for the promising oral antiviral drug, molnupiravir, which has shown preliminary positive clinical trial results.

These access challenges are largely because the pharmaceutical corporations that supply these medicines hold key patents and other intellectual property (IP) that could block generic and biosimilar production. For example, Merck, the company supplying molnupiravir, signed voluntary licenses bilaterally with a few Indian generic companies and later signed a license with the Medicines Patent Pool (MPP). These agreements limit the countries where licensees can supply molnupiravir. The license with MPP also contains a harmful clause that can undermine licensees' legal rights to challenge molnupiravir patents.³ These limited licenses may create uncertainties that could hinder other manufacturers in LMICs' ability to independently produce and supply generic molnupiravir.

Major suppliers of monoclonal antibodies maintain exclusive control over master cell lines and regulatory and manufacturing data. Roche, the primary manufacturer of tocilizumab, has not responded to MSF's demand for supply information for several months and has not transferred tocilizumab manufacturing technology to LMICs despite calls from WHO. Regeneron has filed or been granted a large number of patents on sarilumab in more than 50 LMICs. Meanwhile, Gilead's high prices and insufficient production and supply have hindered access to liposomal amphotericin B for COVID-19-related mucormycosis in India and Nepal.⁴

At the same time, many LMICs have not added the widely available, affordable, WHO-recommended treatment, dexamethasone to their guidelines,⁵ but have included alternative, dubious treatments. Additionally, insufficient access to other key components of care, including medical oxygen and intensive care resources, continues to undermine many LMICs' ability to provide treatment for people who are severely ill while infection rates continue to surge.

Inequity of access to diagnostics

While HICs have numerous options for quality-assured COVID-19 testing, the GeneXpert molecular platform from the US-based corporation Cepheid quickly emerged as a critical option for many LMICs given the placement of Cepheid's instruments in these countries for testing of tuberculosis, HIV and other diseases. Cepheid launched its COVID-19 test in March 2020 and charged LMICs US\$19.80 per test until September 2021 when the corporation reduced the price to \$14.90 after civil society repeatedly expressed concerns.⁶ The current price per test is still at least three times the estimated manufacturing cost based on MSF's analysis, developed in response to Cepheid's refusal to disclose the test's cost of production.⁷ A March 2021 investigation of Cepheid's business conduct has revealed the detrimental health impact of Cepheid undersupplying and overcharging LMICs as the company

prioritised sales profits in HICs, while limiting supplies to LMICs.⁸ Cepheid received over \$250 million in public investments to develop the GeneXpert technology but has not offered the public affordable tests in return and has not shared its technologies with any diagnostics producers in LMICs to facilitate local production and diversity of supply.

In addition, the WHO Access to COVID-19 Tools Accelerator's (ACT-A) diagnostics work is disconnected from its therapeutics work. WHO now recommends the neutralising monoclonal antibodies casirivimab and imdevimab to treat people with severe COVID-19 disease who are seronegative.⁹ However, to test for serostatus, the WHO Emergency Use List includes only one antibody test, which must be used in settings with significant lab infrastructure and cannot be used at the point of care (the Elecsys Anti-SARS-CoV-2 test, which requires the Roche Cobas immunoanalyzer).¹⁰ Many countries will thus remain without quality-assured serological tests to guide decisions to treat people with casirivimab and imdevimab.

Structural and systemic flaws undermining access to medical tools during the COVID-19 response

Insufficient global governance and solidarity in mechanisms for COVID-19 medical tools access

The establishment and operation of a central global mechanism intended to address access issues in the pandemic, ACT-A, has failed to deliver true multilateral collaboration. Instead of ensuring equal representation and decision-making of all countries, ACT-A was designed and established by a few institutions and donors, backed by a small group of HICs, without the opportunity for meaningful participation of LMICs and civil society organisations in its governance. As a result, ACT-A could not embrace national and regional differences when access challenges needed to be addressed. Some regional institutions and LMICs countries with experience managing and responding to epidemics were not consulted when ACT-A was established, which is a missed opportunity to develop a more inclusive multilateral collaboration from the beginning. Similarly, inherent flaws in the design of ACT-A's vaccines pillar, the COVAX Facility (COVAX), has led to insufficient mitigation of inevitable supply and procurement risks and challenges, compounding inequitable access to COVID-19 vaccines, especially for LMICs.

Delays in the negotiation process for measures to help address production and supply of COVID-19 medical tools also demonstrate a lack of true solidarity in the global community, particularly among HICs. Governments have negotiated for over a year for a temporary waiver from certain IP provisions concerning COVID-19 medical tools under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of World Trade Organization (WTO). If adopted, the waiver would provide an expedited option for governments to remove legal barriers on COVID-19 medical tools to facilitate increased and diversified production and supply, moving away from the overall dependence on corporate voluntary actions. Despite the overwhelming support by a majority of LMICs, a small group of HICs (particularly the European Union, Norway, Switzerland and the UK) has been delaying and derailing the negotiation.

Ineffective global allocation mechanism to ensure equity in access

It was clear a pandemic of this proportion due to a novel disease would initially result in an acute scarcity of safe and effective medical tools to control COVID-19. To address these challenges, WHO

proposed guidance for an equitable allocation and fair access framework,¹¹ but this was unfortunately not an enforceable framework that held member states to account for ensuring equitable access to COVID-19 vaccines for all countries. Instead, some member states competed for scarce medical tools to the detriment of global cooperation and assurances of equitable access to COVID-19 medical tools for all countries.

In terms of COVID-19 vaccines, actions taken by some member states have undermined the global mechanism created to ensure global equitable access (COVAX). HICs often present their financial support to COVAX as a demonstration of cooperation and international solidarity. Yet their prioritisation of nationalistic interests leading to excessive accumulation of COVID-19 vaccines undermines the very nature of a global coordinated commitment to tackle the pandemic. Unfortunately, COVAX is primarily reliant on vaccine donations as a result.

Overreliance on market dynamics and voluntary actions for production and supply

The vertical control of global production and supply of lifesaving medical tools by major multinational pharmaceutical corporations, based on the ownership of IP, technologies and data, has caused multiple obstacles to ensuring reliable and equitable access during the pandemic.¹² Additionally, confidential and limited bilateral licensing and technology transfer agreements signed between companies lack adequate public oversight and regulations.^{13,14}

Access to COVID-19 medical products is based on the same flawed biomedical R&D system, which relies on a market-driven and monopoly-based model that perpetuates the private control of publicly supported medical science and research outputs. This system fails to ensure access and affordability for all, sustains the concentration of power and capabilities in HICs, and prevents many LMICs from improving their self-reliance by growing local capacity in innovation and production.

Furthermore, the increasing privatisation of state responsibility to ensure access and the reliance on market dynamics to deliver access, particularly in the time of a pandemic, threatens the realisation of universal and equitable access to medicines, vaccines and diagnostics for all as a fundamental human right. This dilutes states' obligations to ensure such rights through international cooperation. It also fails to recognise the need for concrete and enforceable mechanisms to ensure all lifesaving medical technologies are developed, produced and provided as global public goods.

Regrettably, the current design and operation of the main global pandemic response mechanism, particularly ACT-A (including COVAX), has largely subscribed to the above-mentioned systemic flaws. This has been another missed opportunity to embed concrete strategies and actions to address monopolies on COVID-19 tools and support many LMICs' efforts to use and develop capacities for local production to strengthen self-reliance and help meet global production needs.

Pharmaceutical companies have resisted the two initiatives launched by WHO that aim to encourage voluntary sharing of IP and technologies, the COVID-19 Technology Access Pool (C-TAP) and the COVID-19 mRNA Vaccine Technology Transfer Hub.^{15,16} HICs that host these corporations have not been willing to exert influence on the corporations to share their medical technologies that were largely developed with public funding and support. There is an overall absence of government regulations on voluntary licensing to ensure transparency and to prevent detrimental terms and conditions that could hinder access and broader global production and supply.¹⁴

Governments in LMICs have for a long time been discouraged by a small number of HICs from making the full use of TRIPS ‘flexibilities’ – public health safeguards in IP laws to facilitate local production and importation of more affordable generic medicines.¹⁷ Yet the existing flexibilities do not address all IP barriers, come with legal risks, and still require countries to go for a piecemeal approach to remove IP barriers on lifesaving medical tools. As described above, the proposed introduction of a temporary waiver to overcome these limitations (TRIPS waiver) has been blocked by a small group HICs for over a year.

Lack of transparency and accountability in public funding

COVID-19 medical tools have benefitted from an unprecedented amount of public funding for research, development and manufacturing. Governments have already spent over €93 billion on vaccines and medicines, with additional funding committed.¹⁸ Despite these public investments, there is very little transparency or accountability regarding how these funds are used. The critical issues of where production should happen, who gets the products and at what prices remain largely controlled by pharmaceutical corporations. Without transparency on public funding and costs of research, development and manufacturing, it is difficult to independently assess the affordability of these products, negotiate lower prices based on true costs, or design or recommend policies to ensure equitable access.

Similarly, ACT-A, including COVAX, has so far failed to be transparent in its operation and governance. Critical information, including prices, manufacturing capacity, delivery schedules and agreements with pharmaceutical corporations is not made public, limiting public accountability and analysis on ACT-A’s (and COVAX’s) role in ensuring equitable access.

Insufficient mechanism to facilitate local production

Many necessary measures and actions are not available at global, regional and national levels to sufficiently support the local production and supply of essential medical tools by LMICs.

Contrary to suggestions that LMICs cannot produce vaccines, some LMICs have been developing and producing different types of quality-assured vaccines for decades.¹⁹ Additionally, MSF’s recent analysis shows that, given sufficient and timely support, producers in a number of African countries could start producing mRNA vaccines for COVID-19 within 10 months.²⁰ However, more support is needed as mechanisms to rapidly remove legal, policy and technological barriers remain insufficient

For COVID-19 medicines, IP barriers can hinder local production, even if LMICs have existing manufacturing capacities. MSF also identified IP barriers as an impediment to sustainable local production of diagnostics in LMICs.²¹ Other barriers to local production of diagnostics included: (i) lack of funding or supportive procurement environment to promote local production; (ii) restricted or unavailable technology transfer, and R&D of products that are not well suited for local manufacturers; (iii) unsustainable local production that does not meet local health needs; and (iv) insufficient regulatory mechanisms and lack of public trust in locally manufactured products.

Unsustainable vaccine liability burdens on purchasers

When vaccines are available to LMICs, manufacturers require purchasers (e.g., governments and NGOs) to accept the legal (and financial) liability that would typically fall to manufacturers themselves in the unlikely event that an individual experiences a severe adverse event (SAE) following

vaccination. These requirements risk impeding equitable access and are no longer justifiable given the tremendous amount of safety and efficacy data available for COVID-19 vaccines. Yet instead of preparing to take their liability back, manufacturers are seeking ways to normalise and expand this strategy of passing on liability to purchasers in public health emergencies.

When governments are forced to assume manufacturer liability, it is assumed that no-fault compensation schemes might offer anyone affected by an SAE a lump sum payment as a faster and easier alternative financial settlement, helping to avoid long, costly lawsuits. Such schemes have been established by the US government and COVAX for certain countries and have been proposed as a solution to purchaser liability concerns. However, no-fault compensation schemes are not a sufficient solution to liability concerns because people affected by SAEs may still pursue a lawsuit, the schemes can be time bound (COVAX's scheme ends June 2022), and not all governments have the means or the will to establish such schemes. Furthermore, for many people living in conflict areas and outside of formal health care systems, without dedicated support and legal representation, their rights to seek compensation could be compromised. To date, there are no data available on how no-fault compensation schemes have been used in COVID-19.

In reality, some companies have reportedly been pursuing excessive liability indemnity requirements for LMICs governments, causing disruptions in procurement negotiations and delaying vaccine supplies.²² There is no effective mechanism in place to limit this conduct by companies.

More concerningly, manufacturers also expect NGOs using COVID-19 vaccines in humanitarian settings to help protect high-risk and vulnerable populations to assume these liabilities. NGOs do not have the legal resources, governance or means to take on this risk and are therefore disincentivised from accessing COVID-19 vaccines for humanitarian uses. Some of the world's most vulnerable people may be left unvaccinated as a result.²³

Recommendations

Governments and international institutions should refuse to accept the failures of the current market-driven models of pandemic response and instead take concrete actions to enhance cooperation and ensure vaccines, medicines and diagnostics are developed, produced and provided as global public goods, free from private monopolies. This should include investing in local innovation and production of health tools in LMICs and using mandatory and enforceable mechanisms to ensure equitable allocation of lifesaving medical tools.

The following recommendations can help turn the corner in this pandemic and inform future global mechanisms for pandemic preparedness and response.

- **Improve LMICs' access to vaccines.** HIC governments should immediately redistribute vaccine doses (via COVAX and regional bodies) to LMICs, and demand that the main vaccine developers they host participate in and share IP and technologies through WHO's COVID-19 mRNA Vaccine Technology Transfer Hub.
- **Adopt the WTO TRIPS waiver.** The EU, Norway, Switzerland and the UK should immediately stop blocking the TRIPS waiver negotiations, and all WTO members should pursue a speedy adoption of the waiver at the WTO Ministerial Conference in November 2021. The waiver should cover patents, trade secrets and other IP on COVID-19 vaccines, medicines and diagnostics and related

technologies, materials, components, with sufficient duration to enable local production and diversified global supplies.

- **Request companies share information and transfer technologies.** Governments that host major pharmaceutical companies should use all possible means to request companies widely share and transfer their technologies with LMIC producers to facilitate diversification of production and supplies of COVID-19 tools. For monoclonal antibody treatments, this should include sharing master cell lines and manufacturing information to facilitate quicker introduction of biosimilar products.
- **Expediently use all legal options to remove IP barriers.** Governments should make full use of all legal and policy options, including through national legislative reforms and judicial proceedings, to provide expeditious options to remove IP monopolies and other market exclusivities on COVID-19 medical tools, and to facilitate national and regional production and supply.
- **Ensure transparency.** Mechanisms financing or supporting R&D, production, procurement and allocation in the pandemic should ensure full transparency of terms and conditions included in R&D funding agreements, purchase agreements and prices, manufacturing and delivery schedules, licensing and technology transfer agreements, IP status, preclinical and clinical trial data, and costs of R&D and manufacturing.
- **Add enforceable access conditions to R&D funding.** Public and philanthropic funders should ensure enforceable conditions are attached to all R&D funding schemes. These conditions should ensure benefit-sharing and access to resulting medical technologies for LMICs. Funders should also require full disclosure of R&D costs, preclinical and clinical trial data, all relevant IP, licensing and technology transfer agreements from the grantees, with consequences for non-compliance to ensure robust public scrutiny and accountability. Additionally, funders should require globally covered, non-exclusive licensing and sustainable technology transfer by grantees to LMICs.
- **Restore vaccine manufacturer liability.** Manufacturers of COVID-19 vaccines emergency-approved by WHO or other regulatory authorities should bear liability for their products, including the costs that derive from this liability, in all circumstances. They should immediately waive any liability requirements, including coverage by others, for vaccines used in humanitarian setting. Governments need to establish clear rules to limit the extent to which sharing liability in an emergency can be considered.

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