



Input from civil society stakeholders on Solidarity, equity and the global response to COVID-19

Submission by: Médecins Sans Frontières (MSF) Access Campaign

1. Background

The Global Preparedness Monitoring Board (GPMB) is an independent monitoring and accountability body to ensure preparedness for global health crises. Comprised of political leaders, agency principals and world-class experts, the Board provides an independent and comprehensive appraisal for policy makers and the world about progress towards increased preparedness and response capacity for disease outbreaks and other emergencies with health consequences. Created in response to recommendations by the UN Secretary General's Global Health Crises Task Force in 2017, the GPMB was co-convened by the World Health Organization and the World Bank Group and formally launched in May 2018.

Each year the GPMB issues a report on the state of global preparedness. Last year the report focused on five dimensions of preparedness: responsible leadership, engaged citizenship, strong and agile national and global systems, sustainable financing and robust governance. This year, the GPMB report will examine, among other themes, the urgent need to address fragmentation, incoherence and inequalities that have undermined the global collective response to COVID-19 and other health emergencies and to find a path to a more equitable, more effective health emergency ecosystem. The report will be launched in October 2021.

2. Civil society stakeholder input

As an input to the report, the GPMB is organizing a roundtable on Solidarity, equity and the global response to COVID-19. To support this process, the Board is seeking written input from civil society stakeholders on this issue. This input will be used as part of background documentation for the roundtable.

The GPMB would be grateful if you could submit your written responses to the following questions by email to gpmbscretariat@who.int no later than **25 August 2021**.

3. Questions

1. *Solidarity and the global COVID-19 response*

In many ways, the collective response to COVID-19 has been defined by failed leadership, nationalism, inequalities and obstacles to cooperation and global solidarity.

a) **How have these issues impacted low- and middle-income countries' response to the pandemic?**

While high-income countries (HICs) are on the way of introducing booster vaccines, many low- and middle-income countries (L/MICs) are struggling to keep up with another deadly wave of the virus. With a small number of HIC countries stockpiling vaccines and other medical tools, many L/MICs have not yet been able to vaccinate their healthcare workers and other vulnerable groups and do not have equal access to quality COVID-19 diagnostics. Ensuring timely, appropriate and sufficient access to lifesaving drugs, diagnostics and vaccines in L/MICs continues to be challenging in countries where Médecins Sans Frontières (MSF) works.

Inequity of access to vaccines

A number of HIC countries that host some of the major pharmaceutical corporations, including the US, UK, Switzerland, and many EU countries such as Germany, are hoarding large portions of the global supply of vaccine doses and have been reluctant to demand that these corporations grant immediately transparent, non-exclusive, globally covered licensing and transfer of vaccine technologies and regulatory data to enable production and supply in different countries and regions. The consequences of these supply limitations and inaction have been drastic for L/MICs, facing a frightening rise in infections and deaths from COVID-19, with healthcare systems reaching their breaking points.

Further, some HIC countries are due to offer booster shots this year before people around the world have a chance to be protected with their first and second vaccine dose.

So far 3.6 billion doses of COVID-19 vaccines have been administered worldwide, but just 1% of people in low-income countries have received at least one dose. The overwhelming majority of people remain at risk of becoming ill with COVID-19 with life threatening consequences, especially with the emergence of new variants. MSF has witnessed these sharp and ever-deepening inequities of access in countries where we work. MSF considers it [unconscionable](#) to offer people in high-income countries (HICs) who have already been fully vaccinated another dose before protecting more people globally with their first.

MSF and the World Health Organization (WHO) have called on governments that have secured more doses than required to urgently redistribute these excess doses and prioritise countries that urgently need to protect their healthcare workers and vulnerable groups. Leaving LMICs behind leaves everyone at risk worldwide.

Inequity of access to diagnostics

While HIC nations have numerous options for quality-assured COVID-19 testing, Cepheid's GeneXpert (molecular) platform quickly emerged as a critical access options for many LMICs given the existing placement of Cepheid's instruments for tuberculosis (TB) testing. Cepheid launched its COVID-19 test in March 2020 and charges LMICs US\$19.80 through the WHO diagnostics consortium for one test. This is twice the price they charge LMICs for their similar TB test (\$9.80) and at least four times its manufacturing cost, based on MSF's [analysis](#). In addition, it chose to prioritise supply high income countries limiting supplies to LMICs. On 25 February 2021, 108 civil society [organizations, including MSF](#), sent an [open letter](#) to Cepheid requesting that the company take the necessary steps to increase access to the COVID-19 GeneXpert test in LMICs by lowering the price of these tests to US\$5 per test. On 1 March, [Reuters](#) published an extensive microsite [article](#) about the impact of Cepheid undersupplying and overcharging countries that have invested for a decade in Cepheid's instruments for the diagnosis of TB and other

diseases but now cannot access COVID-19 test cartridges. [MSF finding](#) also shows that although Cepheid has received over \$250 million public investment to develop its diagnostics system, the company has not shared its technologies with any diagnostics producers in LMICS to facilitate local production and diversity of supply.

Inequity of access to treatment

In most of the LMICS there are significant access challenges for the most recent WHO-recommended biological drugs, tocilizumab and sarilumab. These access challenges are largely caused by monopolies. Besides patents, corporations maintain exclusive control over master cell lines, regulatory and manufacturing data. In countries like India and Nepal, shortage of [access to liposomal amphotericin B](#) for mucormycosis are also witnessed due to high prices and company's holding of manufacturing know-how to restrict alternative production and supply.

At the same time, many LMICS have not added the affordable, WHO-recommended treatment, dexamethasone to their [guidelines](#), but have included other dubious treatments. Insufficient access to lifesaving, other older 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.

These access challenges and inequities reflect the failure to establish a truly coordinated global response and solidarity among countries.

b) How have the global community and the international system dealt with these issues? What have been successful elements of the global response? What have been the biggest failures?

Lack of transparency and accountability in public funding

There has been unprecedented public funding for research, development and manufacturing of COVID-19 medical tools. One [analysis](#) finds that governments spent over €93 billion on vaccines and therapeutics, and there are additional pledges committed. Despite these public investments, there is very little transparency or accountability regarding how these funds are being 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, it is difficult to independently assess the fair pricing of products resulting from publicly funded R&D investments, negotiate lower prices based on true costs, or design or recommend policies to ensure equitable access.

Limited and non-transparent voluntary actions

While some pharmaceutical corporations have signed voluntary licenses for manufacture and supply of vaccines and other medicines, these licenses are confidential and restrictive, and they lack adequate [public oversight and regulation](#). For example, MSF [joined a letter](#) with other civil society organizations addressing to the Director General of World Trade Organization (WTO), and pointed out that the company AstraZeneca almost entirely relies on one manufacturer in India [Serum Institute India-SII], which it has licensed, for the supply of its vaccine to LMICS including the COVAX Facility. The domestic surge of cases and need in India since March has disrupted and delayed the delivery of SII-produced vaccines to COVAX for many LMICS who depend on this supply. The license of AstraZeneca excluded other manufacturers in

India who could have contributed to the production and supply. [Any voluntary mechanism must have enforceable measures](#) to ensure worldwide coverage for supply, full transparency, clear accountability and non-exclusive terms.

WHO launched two initiatives designed to offer opportunities for technology- and intellectual-property-holding companies to voluntarily share their technologies to facilitate scale-up and diversification of production and supply of COVID-19 medical tools, especially in LMICs. However, both initiatives, the COVID-19 Technology Access Pool (C-TAP) and the COVID-19 mRNA Vaccine Technology Transfer Hub, have been resisted by major pharmaceutical corporations. No mRNA vaccine developers have joined COVID-19 mRNA Vaccine Technology Transfer Hub yet, despite its potential to hasten scale-up of mRNA vaccine production. HIC governments that are hosting these corporations continue to take no actions to demand participation from the industry.

Lack of solidarity in WTO TRIPS waiver negotiation

It is regrettable that demands by LMICs to be self-reliant in the production and supply of medical tools needed to tackle the pandemic are continuously ignored and stonewalled by HIC countries. The continued blocking of critical decisions in multilateral fora, particularly the World Trade Organization(WTO) TRIPS waiver proposal to lift corporate monopolies in the pandemic to facilitate global production and diversification of supply has forced LMICs to rely on the charity of HIC countries. The waiver proposal has now been officially sponsored by 64 LMICs and supported by more than 100 countries, endorsed and supported by numerous international and regional organizations, leading academics, medical associations, scientists, religious leaders and civil society organizations and individuals globally. However, the negotiation of its adoption has been delayed and blocked by a small group of HICs, particularly the European Union, UK, Switzerland and Norway. The more than 10 months of delaying and derailing of the TRIPS waiver negotiation process demonstrates the lack of true solidarity in the global community, particularly among HICs.

Insufficient global allocation mechanisms for COVID-19 medical tools

Global mechanisms that have been set up temporarily to increase equitable access to COVID-19 medical products, such as the Access to COVID-19 Tools Accelerator (ACT-A), which comprises the COVAX Facility, have so far failed to ensure that transparency is a core principle and deliverable within their functioning, accountability and governance. Critical information, including prices, manufacturing capacity, delivery schedules and agreements with pharmaceutical corporations are not made public, limiting public accountability and policy analysis on ACT-A (and COVAX)'s functioning in ensuring equitable access, as well as the subsequence impact.

HICs often argue their financial support to the temporary global allocation mechanisms such as COVAX represents cooperation. Yet, our observation shows that from its operational assumption, institutional design and implementation, COVAX has failed to deliver timely and equitable access to vaccines in LMICs. COVAX was designed by a small group of HICs, global health institutions and philanthropy foundations including Gavi, CEPI and the Bill and Melinda Gates Foundation, without the opportunity for meaningful participation of LMICs and civil society organizations in its governance. The small group of HICs are among those who have been hoarding a large portion of existing global supplies, putting the COVAX Facility's

ability to ensure equitable distribution of doses in LMICS in limbo. HICs' failure to support and collaborate with LMICs to scale up and diversify production and supply of vaccines to reduce the dependence on big pharmaceutical corporations has deepened the systemic inequity facing the world in this pandemic.

Insufficient support for local production

In light of the growing recognition of LMICs' needs and accompanying efforts to increase access to medical tools in these countries through improved and sustainable local production, MSF recently published an issue brief [with an analysis of local production of diagnostics in LMICs](#) and recommendations in four key areas: (i) creating an enabling funding and procurement environment to promote local production; (ii) promoting open IP, technology transfer and access-oriented research and development for local manufacturers; (iii) ensuring that local production is sustainable and meets local health needs; and (iv) strengthening regulatory mechanisms and public trust in locally manufactured products. To date, many of these measures and actions are not available at global, regional and national levels to sufficiently support to local production and supply of essential medical tools by LMICs.

Lack of mechanism to ensure access to existing and new treatments

In the treatment area, perhaps the biggest failure has been a lack of access to even more traditional medical forms of therapy. Many LMICs continue to face a shortage of supply of lifesaving medical oxygen, besides the well-known lack of resources for intensive care. More recently, a lack of access to tocilizumab (and other monoclonal antibodies) in LMICs has been a serious concern, caused by high prices, intellectual property (IP) barriers and lack of access to regulatory data, master cell lines and technology transfer. Pharmaceutical [companies continue to hold monopolies](#) on these medicines. Besides the issues with IP, as discussed below, additional actions are needed to facilitate rapid scaling up of production by alternative biosimilar producers in LMICs, including sharing of the master cell lines and transferring of technological know-how. Yet, companies like Roche have [so far rejected to engage these actions](#).

On a positive note, the establishment of international randomized clinical trial (RCT) platforms such as the WHO-coordinated Solidarity [Trial](#) and Drugs for Neglected Diseases *initiative* (DNDi)-coordinated ANTICOV [Trial](#) are positive steps that need to be expanded and improved further. These trials may allow for a bigger sample size and faster enrollment/achievement of results while ensuring the inclusion of partners and people (and therefore data) from LMICs.

2. Systemic inequity in the global health emergency ecosystem¹

- a) The COVID-19 pandemic has exposed longstanding systemic inequities in the global health emergency ecosystem and the broader international system.**
- b) What are some key structural elements of the ecosystem that contributes to these inequities ?**

¹ Here we define the ecosystem as the institutions, leadership and governance structures, mechanisms, frameworks, policies, actors and stakeholders that contribute to global health emergency preparedness and response.

During the pandemic, we've repeatedly seen how control of global production and supply of lifesaving medical tools based on IP and technology ownership by a handful of multinational pharmaceutical corporations has created multiple obstacles for countries to secure reliable access. HIC countries have so far not shown any willingness to break from the status quo and exert influence on pharmaceutical corporations to share medical technology that was largely developed with public funding.

The situation in the pandemic reflects the historical and systemic flaws of the mainstream biomedical research and development (R&D) system, which has failed to ensure equal and timely access to knowledge and scientific advancements for all, especially in LMICs. The current system perpetuates the private control of publicly supported medical science and research outputs. It provides an insufficient mechanism to ensure accountability of the private sector to ensure global access and affordability of lifesaving medicines for all. It also 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.

We have seen the structural inequity between countries when ACT-A and particularly COVAX were set in place. Richest countries get prioritised in accessing in both designing the platforms that would ultimately deliver COVID-19 tools (such as ACT-A and COVAX) but also through direct contracts with manufacturers. The global mechanisms set in place were unable to prevent the hoarding of doses by wealthier countries or to ensure transparency on purchase agreements signed with companies, prices, production plans and allocation schemes. These factors have reduced the capacity of these mechanisms to support an effective response to the pandemic, particularly for LMICs.

In addition, the standardised approach used in the ACT-A mechanism is questionable. Not all countries have been affected in the same way and ACT-A has not been able to adapt its strategies based on countries' specific profiles and contexts.

In many international policy forums, HICs dominate the discussions, leading to a perpetuation of the charity model. LMICs, particularly those with the capacity to play a greater role in production of COVID-19 tools, do not have opportunities and participation in decision-making, although they can efficiently contribute to the global efforts.

a) What impact do these structural elements have on effective and equitable health emergency preparedness and response?

From past experiences and current actions, we have seen that the IP and monopoly-based model is the key structural barrier contributing to inequity. IP poses a major challenge in ensuring global equitable access to the medical tools needed in response to COVID-19. In the last few months, treatment providers and governments have faced IP and other types of monopoly [barriers](#) over medicines, masks, ventilator valves and reagents for testing kits.

The available global allocation mechanism, i.e. ACT-A including COVAX, is ineffective because of its flawed design and other environmental factors, particularly HICs' hoarding of existing supplies and undermining of LMICs' self-reliance in production and supply. The global community shows no concrete solidarity or

cooperation in many international policy processes and forums, hindering the global efforts to address access inequities that continue to deepen following the resurgence of COVID-19 cases in LMICs.

At a global level, one important negative public health consequence of all these structural and systemic barriers to equitable access is the lack of a truly global approach for effective pandemic control. The unequal response, especially in terms of vaccination, neglects many LMICs with high levels of transmission, which may bring negative consequences for all, including those in HIC countries as the variants of concern can emerge and spread. Any outbreak response activity must target all of the areas experiencing high transmission. Lack of proper actions and all needed tools to tackle all of these areas in LMICs puts everybody at risk and perpetuates the epidemic.

IP challenges to key medical tools:

Treatments

WHO recently recommended tocilizumab and sarilumab for the treatment of critically and severely ill COVID-19 patients. However, [access to these drugs remains limited](#) due to patent monopolies, limited supply and high prices.

The pharmaceutical corporation Roche supplies tocilizumab and continues to charge high prices for the medicine, and recently announced [a half-hearted decision](#) to not enforce its secondary patents on the medicine in LMICs. The basic patent on tocilizumab held by Roche has expired but the Swiss corporation has continued to pursue a patent extending or “evergreening” strategy to seek additional patents, refuse to engage transfer of technology and continues to be the sole registered supplier in the global market.

Sarilumab is under wide patent protection globally by Regeneron, which has been granted patents for the medicine and its formulation in at least 50 LMICs. The medicine is exorbitantly priced at US\$1,830 per dose in the US. Two new potential COVID-19 therapeutics, casirivimab and imdevimab, are also patented by Regeneron and are being sold as a cocktail at a price of \$820 per dose in India, \$2,000 in Germany and \$2,100 in the US. These high medicine prices and monopolistic actions are barriers to global access.

Gilead continues to hold trade secrets on producing liposomal amphotericin B (L-AmB) treatment. The medicine has been [priced out of reach](#) for treating fungi infections of people with COVID-19 in India and Nepal.

While there is no doubt that manufacturers in countries like India, China, South Korea and other will produce biological medicines like tocilizumab in the coming years, but delays will cost lives as patients wait for these lifesaving medicines.

Vaccines

When alternative vaccine producers independently developed 13-valent pneumococcal conjugate vaccines (PCV-13), Pfizer’s aggressive patenting strategy compelled a South Korean company to stop development, [delaying the availability](#) of more affordable versions of the pneumonia vaccine for children.

Patents have also been [applied for or granted](#) across the entire vaccine development, production and delivery process. These patents increase uncertainty and costs for alternative developers, delaying competition and keeping prices high for LMICs. This in turn hinders people's access to important vaccines. IP issues, including patents, can be a barrier to cheaper vaccines entering the market. One [study](#) demonstrated how the complex network of patents on COVID-19 mRNA vaccine technologies brings legal uncertainty to alternative producers.

Since there are many different types of IP attached to different vaccine candidates at different stages of vaccine development, production and use, it becomes a legal minefield for any independent developers to be sure that they will not run into legal risks when using a technology route to develop their products that is similar to one of a major pharmaceutical company. IP disputes over COVID-19 vaccine technologies and materials have been happening since the beginning of the pandemic.

Diagnostics

South Africa faced challenges accessing key chemical reagents for COVID-19 diagnostic tests due to [proprietary protection on the machines and the reagents](#). The Swiss pharmaceutical corporation [Roche initially rejected](#) a request from the Netherlands to release the recipe of key chemical reagents needed to increase production of diagnostic kits and only released it after facing pressure from the European Commission.

Although few blocking patents have been identified for infectious disease diagnostics, IP on diagnostic tests can include patents and patent thickets on reagents, instruments, methods and software. Diagnostic companies typically file many patents.

The pandemic presents an unprecedented and complex context to use the traditional approaches in addressing these IP challenges. Evolving landscapes of IP and the need to access proprietary technologies across the entire supply chain and on all components of the final medical products means that multiple types of IP, not just patents, need to be tackled at once. It also requires private monopolies to be removed in multiple countries to enable uninterrupted collaboration and sharing of production resources.

Use of existing legal tools to address those challenges [is insufficient](#), and additional legal options are urgently needed. The TRIPS waiver proposal pending at the World Trade Organization provides additional legal options that overcome the limitations in the existing legal mechanisms to address IP challenges in a pandemic.

3. Addressing these inequities and improving the global health emergency ecosystem

a) How should the global health emergency ecosystem be reformed to improve equity?

Some HICs have started proposing the current COVID-19 response mechanisms, especially ACT-A (including COVAX), to be replicated and expanded to address the next global pandemics, perpetuating a model that relies on HIC charity. As mentioned above, this is a deeply concerning development given the multiple levels of failure to ensure global equitable access and effective pandemic control.

It is a serious concern to see states ceding power to the private and philanthropic sectors and letting them primarily run the outbreak response. This has proven to be a flawed approach, particularly for accessing lifesaving health technologies needed for all and more generally for preserving public health systems' sustainability and access to healthcare in LMICs.

The increasing privatisation of state responsibility regarding healthcare access and the reliance on market dynamics to deliver healthcare, particularly in the time of a pandemic, threatens the realisation of universal and equitable access to healthcare and 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 good.

Concrete actions need to happen now to address the multiple failures. We are still in the middle of a pandemic with severe inequity in access to lifesaving medical tools and services. HICs who hoard excessive vaccine doses need to take immediate actions to redistribute and refrain from introducing booster vaccines. At the same time, healthcare workers and vulnerable populations in many LMICs have not received their first dose. HICs should stop blocking critical international processes, especially the TRIPS waiver negotiation requested by LMICs to have additional legal options to facilitate the scaling up of production and supply of COVID-19 medical tools. MSF has called for urgent full technology transfer to the newly established WHO COVID-19 mRNA Vaccine Technology Transfer Hub to support independent and sustainable vaccine production and supply of mRNA vaccines in countries in Africa, a region that has been particularly neglected when it comes to vaccine production capacity and is one of the factors exacerbating COVID-19 vaccine inequity.

b) What are key measures that should be implemented to ensure future global responses to health emergencies are fairer, more equitable and more effective?

COVID-19 has highlighted the inequality and inequity between HICs and the rest of the world in access to vaccines, medicines, diagnostic tests, ventilators, and other COVID-19-related medical supplies. Millions of people are still waiting to benefit from the important medical innovations of the past year and half.

For the future reform of the global health emergency responses, the global community needs start with critically review and recognize the failures as above mentioned and refrain from perpetuating the charity model utilised by ACT-A and COVAX.

The fundamental and systemic flaw of letting private sectors and market forces determine access to health care needs to be addressed with a new mechanism that gives responsibilities back to governments to ensure medicines, vaccines, diagnostics and other medical tools are developed, produced and distributed equitably and sufficiently for all. A truly coordinated global health emergency response mechanism requires measures to prevent countries from hoarding limited global resources and requires them to fulfil their obligation to cooperate in global efforts.

Breaking the status quo will be a courageous step to an effective and inclusive response to present and future health emergencies.

Particularly, to reduce the geographic concentration of technology ownership and production capacity and increase access to technologies as promised at the time of the TRIPS agreement, LMICs should be treated not as just receivers of donations of medical products but encouraged and supported to develop and improve rigorous local innovation and manufacturing capacity to reduce the overall dependency to HICs' and big pharmaceutical companies' mercy. This will require governments to engage multiple changes, including the timely adoption and use of the temporary TRIPs waiver in COVID-19, and overall reform of IP systems to enable maximum policy spaces to facilitate local production. Governments should also take concrete actions to ensure enforceable mechanisms and regulations that enable transparent, unconditional sharing of data and technologies of COVID-19 medical tools. Concrete policy measures are needed to support local production of vaccines and diagnostics that meet local health needs in more LMICs, as mentioned above.

High prices and lack of transparency in the cost of production and license agreements limit access to medical tools and the ability of the global public to hold manufacturers accountable for affordable pricing, and fair terms and conditions in licenses. COVID-19 has again demonstrated that solely relying on pharmaceutical companies to voluntarily disclose prices and R&D, manufacturing costs, and licensing of their drugs, vaccines or diagnostic tools is ineffective. Pro-access conditions in public funding agreements with manufacturers, collective and bundled price negotiations across diseases, and a normative framework for transparent and affordable pricing of medical tools are important strategies to advance access in the short- and long-term.

Ultimately, all mechanism mentioned (e.g. IP waivers, tech transfer, manufacturing hubs in LMICs, financing mechanisms, RCT platforms, proper surveillance, vaccine and antiviral development amenable to fast adaptation to new pathogens, support for regulatory systems strengthening initiatives) are essential for equity and affordability, availability and accessibility. Pragmatically, when it comes to pandemics and outbreaks, these [mechanisms] are also essential for establishing access to tools and other medical and public health interventions needed for an effective response and control, be it global or local.