



## **MSF Position Paper: Ensuring Timely and Equitable Access to Medical Products in Global Public Health Emergencies**

As the COVID pandemic recedes, governments have started to reflect on the deeply ingrained global health inequities that the pandemic revealed and exacerbated. There are currently multiple global processes and initiatives underway that seek to create and improve global systems to prevent, prepare for and respond to future global health emergencies (PPR). These include a High-Level Meeting during the United Nations General Assembly in September 2023, the negotiation for a new legal instrument under the Intergovernmental Negotiating Body (INB) and amendments to the International Health Regulations (IHR) at the World Health Organization (WHO).<sup>1,2,3</sup> These efforts will reshape not only PPR but also the broader global health architecture itself.

As an international medical humanitarian organisation that provides medical care to people during emergencies, Médecins Sans Frontières/Doctors Without Borders (MSF) has responded to many infectious disease outbreaks, epidemics and pandemics over the last 50 years. These experiences – which include the West African Ebola virus disease (EVD) outbreak between 2014 – 2016, the HIV epidemic in sub-Saharan Africa in the 2000s, and the COVID pandemic, among many others – have shown that access to medical products is crucial for an effective response to health emergencies. In responding to such crises, MSF has repeatedly witnessed the lack of availability, affordability and accessibility of lifesaving medical products in a timely and sufficient manner, particularly for the most marginalised communities and people living in developing countries and other resource-limited settings. Based on this experience, we assert that the inequities on display during the COVID pandemic are cumulative manifestations of long-term systemic injustice and structural flaws in the context of global health.<sup>4</sup> These injustices and flaws include, but are not limited to:

- Unrepresentative and imbalanced global health governance and accountability mechanisms, which marginalise or exclude developing countries, civil society organisations, and affected communities;
- An overreliance on “market dynamics” and voluntary actions by the private sector to resolve access issues, while downplaying state responsibility, including through – where relevant – international assistance and cooperation;
- Deficient utilisation of all available law and policy options to overcome monopolies on lifesaving medical products in order to facilitate more independent production and supply in and for developing countries;
- The absence of binding norms and enforceable conditions to ensure adequate and equitable public investment for research, development and production of, and equitable access to, lifesaving medical products;
- Insufficient transparency and restricted access to information which undermine efforts to ensure governance and accountability of global PPR initiatives; and
- Inadequate global mechanisms to prioritise and ensure equitable allocation of scarce medical products for humanitarian contexts during public health emergencies.

Addressing inequities in how medical products are developed, where they are produced, at what price they are sold, and who gets access to them first, requires that we break from the status quo. In order for PPR mechanisms to be truly equitable, we cannot rely on the goodwill of pharmaceutical corporations and governments of a handful of developed countries. Failing to address the structural determinants of inequity will continue to undermine the global response to pandemics and infectious disease outbreaks. We believe the following considerations and recommendations can help ensure equitable and affordable access to medical tools.

## **1. Inclusive, transparent and accountable governance and decision-making processes and mechanisms**

PPR initiatives and negotiations should be governed by transparent and inclusive decision-making processes, and should include adequate representation and participation from developing countries, civil society organisations, and affected and marginalised communities. Their extensive experience in preparing for and responding to epidemics and infectious disease outbreaks is critical in shaping and establishing successful and effective global PPR mechanisms. In addition, information related to PPR negotiations and processes should be made publicly available in a timely manner to allow sufficient public scrutiny and feedback.

## **2. Achieving equity with common but differentiated responsibilities**

It is critical that global discussions on PPR recognise that while all governments share common responsibilities to prepare for and respond to global health emergencies, there are wide differences in levels of economic development, capabilities and resources among countries. These differences should be appropriately and adequately taken into account in determining the nature and level of responsibility assigned to a given government.<sup>5</sup> The common but differentiated responsibility (CBDR) principle as first established in the context of climate change provides a viable option to address this concern.<sup>6</sup> Differential responsibilities are also established under various instruments of public international law, rules and practices.<sup>7</sup>

In the context of PPR negotiations, while each government has the responsibility to respond to global health emergencies and address inequity within their borders, better-resourced governments, particularly those of developed countries, should have greater responsibilities towards supporting developing countries. The differentiated responsibilities should be operationalised via binding obligations on a number of fronts: financing, transfer of technologies, establishing and improving local and regional capacities in R&D, and production and supply of medical products.

## **3. Binding norms to ensure transparency and access to information**

Ensuring transparency is an essential first step towards achieving accountability and equity in access to medical products, including in the context of PPR. While this was exemplified starkly during the COVID pandemic, lack of access to information has been a consistent challenge witnessed by MSF in tackling access barriers to key medical products. As such, it is crucial to establish binding obligations for governments with respect to access to information and transparency in this area. Such obligations should incorporate all relevant international norms related to access to information and transparency, particularly those arising out of international medical ethics guidelines, human rights obligations, pertinent World Health Assembly resolutions (such as WHA 72.8 on transparency) and other authoritative international instruments.

Public interest doctrines, exceptions and limitations should be strengthened in national laws to provide legal support for governments to reject claims of non-disclosure and confidentiality of key information based on commercial interests, including during public health emergencies.

Key information that should be governed by transparency rules and should be publicly available in a timely manner includes:<sup>8</sup>

- Clinical trial data and costs, net prices of medical products, reports on sales revenues, units sold, marketing costs, subsidies and incentives, patent status information and marketing approval information, as outlined in WHA resolution 72.8;
- Full research and development (R&D) costs, including disaggregated clinical trial costs – including but not limited to public funding contributions;
- Full contractual terms of R&D funding, supply and purchase agreements (without confidentiality provisions which limit disclosure of terms and conditions);

- Intellectual property (IP) licensing, sub-licensing and technology transfer agreements;
- All information pertaining to IP relevant to equitable access to medical products;
- Cost of production;
- Information on supply capacities, forecasts and delivery schedules;
- Information on supply, stock management, allocation and coordination; and
- Governance documents of global health institutions and other relevant bodies involved in PPR.

#### **4. Establishing and coordinating global strategic stockpiling and equitable allocation for humanitarian needs**

An essential element of operationalising equity in the ongoing PPR discussions is both establishing, where appropriate, strategic stockpiles of PPR-relevant medical products, and ensuring the equitable allocation of these products specifically for humanitarian contexts during emergencies.

##### ***Establishing and coordinating global stockpiling efforts***

Strategic stockpiling of essential medical products is a common emergency preparedness strategy, and can be established at national, regional or global levels. Well-established and managed stockpiles can ensure rapid deployment and allocation of lifesaving medical products when emergencies occur. However, when stockpiling decisions and practices at national, regional or global levels are not coordinated or governed by clear rules and norms, particularly over medical products in scarce supply globally, governments with more resources would have a clear advantage in acquiring a disproportionate amount of supplies, leaving the needs of other governments unfulfilled.

This dynamic was evident in the case of stockpiles for EVD treatments, and could be replicated in the future given the investments being poured into R&D for medical products for pathogens of pandemic potential (see EVD example below) and the absence of clear rules to reserve a portion of supply of the end products of these R&D efforts for global strategic stockpiling. Therefore, it is essential for PPR negotiations and initiatives to develop and agree upon binding mechanisms to coordinate across national and regional stockpiling efforts to both guarantee supply for global strategic stockpiles and, in certain cases like EVD, to ensure current need in specific outbreak areas is also met.

##### **Stockpiling treatments for Ebola virus disease (EVD)**

*MSF's experience with treatments for EVD provides a clear illustration of the difficulty in establishing global humanitarian stockpiles.<sup>9</sup> After nearly 50 years without any effective treatments for EVD, two treatments (monoclonal antibodies) were recently approved following substantial investments into their R&D by the US. However, these treatments remain unavailable in countries most prone to EVD outbreaks. Currently, nearly the entire supply of one of the two treatments is stockpiled in the US as part of its strategic national biosecurity stockpile, while the global availability of the other treatment remains unclear.<sup>9</sup> For countries in which the disease is endemic, which does not include the US, and are otherwise most likely to be affected by future outbreaks, this poses major access challenges. To date, there is no established global humanitarian stockpile of these treatments to prepare for possible new outbreaks, nor any stockpile similar to those under the International Coordinating Group on Vaccine Provision (ICG).<sup>10</sup> This is due in part to market distortions generated by the US government's ability to pay extraordinarily high prices for these goods, and to constraints generated by the reliance on a single supplier.*

### ***Equitable and timely allocation to prioritise and simplify supply for humanitarian needs***

While global strategic stockpiles can be used to supply medical products to meet health needs in resource-limited and humanitarian contexts during global outbreaks, a unified and rapid procedure of deployment is a priority for equitable and timely allocation of the stockpiled products. Often, health needs in humanitarian contexts during global emergencies are considered as the “last mile”. However, for people living in conflicts and other humanitarian situations, accessing lifesaving medical products during a public health outbreak is the first priority.

It is imperative to explicitly reserve stockpiles for humanitarian contexts within global mechanisms and to ensure that such reserves are easily and quickly accessible to humanitarian organisations.

#### **COVAX Humanitarian Buffer: A flawed experiment in equitable allocation**

*While attempts at setting aside specific quantities of COVID vaccines for humanitarian contexts were made through the establishment of the COVAX Humanitarian Buffer, MSF’s experience with this instrument made clear that it was fundamentally flawed and not fit for the purpose of providing rapid supply in an emergency situation.<sup>11</sup> In November 2021, MSF applied to use the COVID vaccine reserve after receiving authorisation to launch an immunisation campaign with its local partner Al Ameen in the area of Tell Abyad and Ras Al-Ain in northern Syria that is currently under Turkish control. After the application was initially approved, months of negotiations ensued to clarify various contractual and legal requirements with different entities involved in the management of the humanitarian buffer, including unreasonable requests for MSF to take over part of the product’s liabilities from pharmaceutical companies.<sup>12</sup> Due to the excessive delay, MSF withdrew its application to the buffer, and the Turkish government eventually made an alternative plan to provide vaccinations in the area.<sup>12</sup>*

While global strategic stockpiles and equitable allocation are included in the ongoing PPR discussions, the effectiveness of the outcomes will be determined by the following:<sup>13</sup>

- An effective mechanism to prevent and reject hoarding of essential goods when emergencies occur;
- Upfront commitments and agreements between governments and WHO to reserve portions of domestic supplies for global stockpiling and allocation, using the experience of the Smallpox Vaccine Emergency Stockpile (SVES) as a reference;<sup>14</sup>
- Securing dedicated production and supply for global stockpiling and allocation through a mandatory benefit-sharing condition under global access and benefit-sharing mechanisms and as a mandatory condition attached in public R&D investment agreements;
- Governments coordinating with each other and with WHO to plan stockpiling at national and regional levels, to ensure proportionality and to prioritise sufficient global stockpiles dedicated to supplying resource-limited settings, countries most affected, vulnerable and at-risk people and communities, and humanitarian contexts;
- Including regional organisations, governments of developing countries, particularly those most affected, and humanitarian and civil society organisations, in the design and governance of strategic stockpiles at the global level; and
- Prioritising humanitarian needs in equitable allocation schemes, with a simplified, transparent, fair and unified process to facilitate rapid supply and access.

## **5. Reducing intellectual property (IP) barriers to access lifesaving medical products and facilitate technology transfer**

MSF's experience in addressing HIV, TB, EVD, COVID, and many other infectious diseases has made it clear that IP rules present obstacles to equitable access to key medical products. They do so by creating monopolies which delay, limit or altogether prohibit additional suppliers to make available medical products, restrict the geographic scope of production, and enable high prices that further obstruct access.

As such, during pandemics:

- At the global level, time-bound waivers should be instituted in order to provide expeditious legal options for governments to restrict the use of relevant forms of IP on all medical products needed to tackle the pandemic; and
- At the national level, all legal and policy options, public health safeguards and flexibilities should be used by governments to address all barriers to access created by IP protections and facilitate rapid production, supply, export and import of lifesaving medical products.

Outside of pandemic situations, but as an integral part of preparedness strategies and for the purpose of ensuring equity at all times:

- Governments should review and revise national laws, policies and regulations to ensure full incorporation of all relevant IP flexibilities protecting access to medical products; and
- Governments should refrain from introducing IP provisions beyond existing TRIPS requirements in unilateral actions and bilateral/regional trade and investment negotiations and agreements or any other provisions that could undermine states' ability to use TRIPS flexibilities.

Meanwhile, affirmative steps should be taken by governments to ensure technology transfer, especially to entities in developing countries, both during and outside of pandemic times. Multiple measures and incentives should be considered to ensure that transfer of technologies is not solely based on voluntary actions, but is backed by mandatory requirements and obligations which contribute towards growing geographically diverse independent capacity for production and supply of essential medical products.

## **6. Attaching conditions to research and development (R&D) agreements to ensure equitable access at the global level**

MSF's recent work on access to therapeutics for EVD demonstrates that without conditions being built into R&D agreements from the outset there is a high likelihood that, once developed, medical products will not reach people in need or do so far too late.<sup>9</sup>

Ensuring equitable access should be considered from the very beginning of the R&D process. This requires governments to attach concrete and enforceable conditions when they support or fund R&D, including clinical trials. Governments should also require other R&D funders, such as private philanthropies, to include these provisions in their funding agreements, particularly if they host these entities in their territories, have a representative sitting in their governing body or provide funding to them.

The following are some examples of conditions that would support equitable access to the final products:

- Affordable and transparent pricing requirements for end products (such as the "cost of goods plus reasonable margin" or "no profit-no loss" models);
- Non-exclusive licensing/technology transfer requirement to ensure diversity of manufacturing and supply;

- Retention of rights by funders linked to the research, in the event that the manufacturers' supply does not meet demand in a timely manner or is not reasonably priced (so-called "march-in rights");
- Transparency requirements, as outlined above;
- Access plans and specific, transparent and disaggregated indicators which encompass registering and making available the drugs, vaccines or diagnostics, particularly where clinical trials were hosted; and
- Timely access to comparator drugs, tests, assays or vaccines needed for comparison studies, regulatory approvals and/or R&D.

While it is important to strengthen collaboration and data sharing in clinical trials involving multiple countries, sufficient ethical and legal obligations are needed to ensure adequate sharing of benefits of R&D outcomes, particularly with developing countries and communities participating in clinical trials.

At the international level, the Council for International Organizations of Medical Sciences' (CIOMS) "International Ethical Guidelines for Health-related Research Involving Humans" has long stated the importance of ensuring post-clinical trial availability of any intervention or product developed for the population or community in which the research is carried out, and for fair distribution of the benefits of research, including investment towards building local research capacity.<sup>15</sup> These non-binding guidelines should be incorporated as binding obligations to strengthen R&D provisions in the current PPR negotiations.

## **7. Ensuring fair and equitable sharing of benefits in exchange for access to pathogens and genetic resources for R&D**

Biomedical R&D, including for PPR-related products, has always involved contributions from multiple entities besides the private sector, including affected countries and communities, individuals and survivors. However, the mainstream model does not sufficiently recognise their contributions, and instead allows pharmaceutical corporations to solely claim the achievement of R&D through IP protections. This places corporations in a position where they can exclude crucial contributors to the R&D process from accessing its end products. This model is entirely extractive, and the examples of patents on turmeric and the neem tree illustrate how multinational enterprises appropriate genetic resources and traditional knowledge from developing countries and indigenous communities to obtain patents on medicinal and other commercial products without legally binding obligations to share the benefits back with the communities.<sup>16,17</sup>

Among many other policy measures, the mechanism of access and benefit sharing (ABS) provides an additional lever for governments and communities to redress this unfairness and imbalance.

The principle of ABS originates from the idea that such extractive systems are unjust, inequitable, and must be remedied. ABS as a legal mechanism was initially developed to tackle the issue of biopiracy under the Convention on Biological Diversity (CBD) in 1992 and specified in its Nagoya Protocol in 2014.<sup>18</sup> This supported governments in establishing national legal and policy frameworks to implement ABS, particularly to regulate R&D practices involving the use of local genetic resources and traditional knowledge.

Application of the ABS principle in the context of global health has its origins in the 2007 H5N1 influenza (bird flu) epidemic. At the time, while the Indonesian government initially complied with the regulations of the WHO Global Influenza Surveillance Network by sharing H5N1 pathogen samples, it became unwilling to do so when faced with difficulties in getting access to the vaccines developed by pharmaceutical corporations using the samples it had shared.<sup>19</sup> In light of these developments, a process was initiated by WHO to regulate the sharing and use of influenza viruses with human pandemic potential and to improve access to the end products by developing countries.



This culminated in the establishment of the Pandemic Influenza Preparedness (PIP) Framework in 2011.<sup>20</sup> In contrast to the Nagoya Protocol, which is an international legal framework to be implemented through national laws, the PIP Framework is a centralised global mechanism based on the ABS principle and administrated by WHO directly.

The ongoing PPR processes provide an important opportunity to enhance the utilisation of ABS as a principle and a legal mechanism to support global access to medical products needed for PPR. The benefit-sharing options under the PIP framework and the Nagoya Protocol are optional.<sup>21,22</sup> Yet they provide valuable references and precedents that can be developed further into binding obligations in PPR negotiations to support equitable access.

Anticipating the continued salience of ABS in the ongoing PPR negotiations, it is imperative that any ABS mechanism negotiated and implemented include essential benefit-sharing requirements to ensure, at a minimum:

- Dedicated production and supply reserved and used for addressing medical needs of people living in resource-limited settings, in humanitarian contexts and other vulnerable situations that can benefit from globally coordinated allocation;
- Transfer of technology and know-how to address growing needs to establish, improve and maintain geographically diverse and independent capacities of developing, producing and supplying lifesaving medical products, both during emergencies and beyond;
- Incorporation of key elements of ethics in health research from the “International Ethical Guidelines for Health-related Research Involving Humans”, such as obtaining informed consent, benefit sharing and post-trial access and registration of medical products, as mandatory provisions.<sup>15</sup>

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