Ensuring Collective Efforts Deliver Equitable Access Through the WHO PABS System

Introduction

For more than 50 years, Médecins Sans Frontières (MSF) has responded to numerous infectious disease outbreaks, epidemics and pandemics across resource-limited and humanitarian settings. On many occasions, MSF's medical teams, patients under MSF's care, and their communities have contributed samples and data that enabled critical biomedical research and development (R&D) and led to lifesaving innovations. Despite these indispensable contributions, the lack of binding and enforceable mechanisms to ensure fair and equitable benefit-sharing—including timely, affordable and sufficient access to resulting medical products—means that access for people most affected is often not guaranteed. This gap becomes even more pronounced during emergencies, as seen during COVID-19 pandemic, when people living in humanitarian settings were pushed to the back of the global response queue.

Drawing on its frontline experience, MSF has consistently advocated for the WHO Pandemic Agreement to establish a multilateral mechanism that ensures fair and equitable sharing of benefits in exchange for access to pathogens and genetic resources for R&D.[1] Following the adoption of the WHO Pandemic Agreement's main text in May 2025—which established the new Pathogen Access and Benefit Sharing System (PABS)—concluding negotiations on the Annex to operationalize this system has become critical. MSF considers a WHO-led multilateral PABS system essential for ensuring reliable, equitable and accountable access and benefit-sharing that reflects collective contributions and global solidarity. By linking pathogen access to clear benefit-sharing obligations in pandemics and interpandemic times, PABS can help ensure that vaccines, therapeutics, and diagnostics (VTDs) developed using the system are made available to WHO for allocation according to health needs rather than discretionary arrangements influenced by reciprocity or geopolitical dynamics. This approach is vital for securing timely and equitable access to medical products for populations that are routinely left at the margins of outbreak response, particularly in humanitarian settings.

In contrast, bilateral arrangements risk creating a parallel and opaque process to the ongoing PABS negotiations. In November 2025, the United States [2] negotiations of bilateral health compacts[3] with several African countries. Although official documentation remains limited, the reported Memoranda of Understanding (MoU) [4] agreements frame 25-years obligations for prompt pathogen and data sharing in exchange for five years of decreasing U.S. global health

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[1] Médecins Sans Frontières (MSF) Access Campaign. *MSF Position Paper: Ensuring timely and equitable access to medical products in global public health emergencies.* 2023 Jul 17. Available from: https://www.msfaccess.org/msf-position-paper-ensuring-timely-and-equitable-access-medical-products-global-public-health

[2] Health Policy Watch. *US Signs Bilateral Health Agreements With 14 African Countries.* 2025 Dec. Available from: https://healthpolicy-watch.news/december-deals-us-signs-bilateral-health-agreements-with-14-african-countries/

[3] Health Policy Watch. December Deals: US Signs Bilateral Health Agreements With 14 African Countries – with some key exceptions. 2026 Jan. Available from: https://healthpolicy-watch.news/december-deals-us-signs-bilateral-health-agreements-with-14-african-countries/

[4] Health Policy Watch. Model Specimen Sharing Agreement (MoU). 2025 Dec. Available from: https://healthpolicy-watch.news/wp-content/uploads/2025/12/Model-Specimen-Sharing-Agreement.pdf

funding.[5] These funds would primarily support health-system strengthening and donated or subsidized health commodities. The requirements for pathogen and data sharing come without concrete benefit-sharing commitments to ensure access to medical products developed using the shared pathogens and data. These imbalanced arrangements risk creating political sidelines, pressuring international negotiations towards weak benefit-sharing requirements, and potentially undermining the PABS process (any outcomes generated through these negotiations), reinforcing power imbalance and jeopardising the rights and health needs of vulnerable local populations and communities.

A strong and effective PABS mechanism is therefore indispensable for the Pandemic Agreement to ensure equitable access. This paper outlines MSF's key considerations to achieve this objective.

1. Access to pathogens, materials and data should be linked with enforceable benefit-sharing obligations upfront to ensure end products are accessible based on health needs

Access to pathogens, clinical samples, and related data cannot be treated separately from clear and enforceable benefit-sharing obligations that ensure access to the medical products developed through their use. Without such linkage, the system risks reproducing extractive research practices that fail to deliver public health benefits to the people most affected.

Access to Ebola treatments

Treatments currently approved for use in patients with Ebola (mAb 114, licensed to Ridgeback Biotherapeutics and Regeneron's Inmazeb), were developed in the United States with support from the U.S. administration, primarily to protect U.S. citizens. R&D programmes relied on samples isolated from Ebola virus disease (EVD) survivors in the Democratic Republic of Congo (DRC), and clinical samples that formed the basis for further research across the globe were collected from survivors of the 2014-2016 West Africa outbreak.[6] Furthermore, the PALM clinical trial—supported by MSF and the first to demonstrate the efficacy of these treatments—was conducted with the participation of EVD-affected communities in the DRC in MSF-run clinics and ultimately led to both drugs' approval.

Despite these contributions, it took considerable time for the communities most impacted by EVD to gain meaningful and consistent access to the treatments they helped develop[7] . Owing to their exorbitant price, estimated by MSF at US$6,900 per treatment course (probably an underestimate), the WHO and countries in need couldn't acquire doses of Inmazeb until September 2025, when Regeneron finally agreed to donate 500 treatments to respond to a large outbreak in the DRC[8]. Despite announcements of upcoming donations, Ridgeback has

[5] KFF (Kaiser Family Foundation). KFF Tracker: America First MOU Bilateral Global Health Agreements. 2026 Feb 3. Available from: https://www.kff.org/global-health-policy/kff-tracker-america-first-mou-bilateral-global-health-agreements/
[6] Médecins Sans Frontières (MSF) Access Campaign. *Ensuring access to new treatments for Ebola virus disease.* May 2023. Available from: https://msfaccess.org/sites/default/files/2023-05/MSFAC_EbolaReport_May2023_Final_ENG.pdf
[7] Torreele E., et al. *Breakthrough treatments for Ebola virus disease, but no access—what went wrong, and how can we do better?* Lancet Infect Dis. 2023 Jul;23(7):e253–e258. doi:10.1016/S1473-3099(22)00810-6.
[8] Regeneron Pharmaceuticals, Inc. *Regeneron donates Ebola treatment for use in countries most at risk.* 2025 Sep. Available from: https://newsroom.regeneron.com/news-releases/news-release-details/regeneron-donates-ebola-treatment-use-countries-most-risk/

failed to supply Ebanga, and the few doses still available in the DRC are leftovers from the PALM trial.

The inability of EVD patients to access lifesaving medicines, while effective treatments sit unused in countries with no disease burden, underlines the profound failures of ensuring access and benefit-sharing principles into binding contract obligations from the outset of R&D projects.

Benefit-sharing obligations go beyond access to physical products but also include enabling conditions to foster research and development. As biomedical research on infectious diseases—including on pathogens with outbreak potentials—relies on clinical, laboratory and epidemiological data, accessing and using these data are often fragmented and lack early consideration of equitable benefit-sharing. Establishing clear data-sharing rules under PABS is therefore as important as developing rules for physical pathogens and samples to ensure equity throughout the R&D process.

Ebola Data Platform

To address challenges in data sharing for Ebola virus disease (EVD) research and development, MSF, in collaboration with multiple partners, established the Ebola Data Platform under the Infectious Diseases Data Observatory.[9] The platform pursues a collectively governed data-sharing mechanism that integrates access and benefit-sharing considerations throughout its entire governance structure. To access and use the dataset, prospective users must agree with the Data Sharing Principles and sign a Data Transfer Agreement before any data is released.[10] Several benefit-sharing obligations are specified in the Data Transfer Agreement template,[11] including requesting that users do not enforce their background intellectual property or draft or file any intellectual property applications on the research results without a written consent of the data sharing committee.

We recommend:

- Clear and enforceable benefit-sharing terms and conditions must be agreed upfront before accessing to pathogens, materials and data.

2. Non-exclusive licensing to WHO or WHO-supported initiatives to facilitate transfer of technology and diversified production of medical products must be included as an essential benefit sharing obligation

[9] Infectious Diseases Data Observatory (IDDO). *Ebola Data Platform: About Us.* Available from: https://www.iddo.org/ebola/about-us/ebola-data-platform
[10] Infectious Diseases Data Observatory (IDDO). *Data Access Guidelines.* Available from: https://www.iddo.org/data/data-access-guidelines
[11] Infectious Diseases Data Observatory (IDDO). *Ebola Data Platform – Data Transfer Agreement (English & Français).* 2019 Mar 19. Available from: https://www.iddo.org/sites/default/files/publication/2020-01/EDP%20Data%20Transfer%20Agreement%20English%26Francais%2019MAR19.pdf

Non-exclusive licensing to WHO or WHO-supported initiatives facilitates the transfer of technologies and supports more diversified and geographically distributed production of medical products, reducing reliance on a limited number of originator producers. Licensing on a non-exclusive basis—together with access to relevant technology and know-how—is a necessary mechanism to mitigate monopolies and align production and access with public health needs. Mandatory non-exclusive licensing also addresses the limitations of relying solely on intellectual property (IP) holders' willingness to engage in voluntary licensing agreements.

Limitations of voluntary licensing during the COVID-19 pandemic

The WHO COVID-19 Technology Access Pool (C-TAP) was designed to combine intellectual property licensing with the sharing of manufacturing know-how and technical data. In practice, participation was extremely limited, and no COVID-19 vaccine technologies were made available through the mechanism. The mRNA vaccines developed by Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) were protected by extensive patent portfolios and trade secrets. Neither company granted non-exclusive licenses for these vaccines through the Medicine Patent Pool (MPP) or C-TAP, nor did they share proprietary manufacturing technologies or know-how with the WHO mRNA Vaccine Technology Transfer Hub .[12]

To address these gaps, the PABS framework for WHO licensing should directly request non-exclusive licensing to WHO or WHO-supported initiatives in order to limit proprietary control of key technologies and facilitate geographically more diversified manufacturing by ensuring timely, non-exclusive access to both intellectual property and essential manufacturing knowledge.

We recommend:

- The PABS System should guarantee non-exclusive licenses from manufacturers of VTDs to WHO or WHO-supported initiatives, including access to relevant technologies, know-how, and associated data to facilitate timely and equitable production.
- Licensing agreements should be made publicly available to ensure transparency and accountability.

3. Enabling WHO-coordinated stockpiling and allocation of health products to meet health needs in humanitarian contexts

The PABS system should facilitate the effective implementation of the Pandemic Agreement by requiring developers to commit to the equitable distribution of health products. This should include commitments to support WHO-coordinated stockpiling and allocation of such products during Public Health Emergencies of International Concern (PHEICs) and pandemics, in order to meet health needs, including in humanitarian settings. WHO should play a leading role in coordinating and implementing decisions on the allocation and distribution of VTDs developed

[12] Médecins Sans Frontières (MSF) Access Campaign. *4 reasons why Pfizer-BioNTech and Moderna must share COVID-19 mRNA vaccine technology now.* Available from: https://msfaccess.org/4-reasons-why-pfizer-biontech-and-moderna-must-share-covid-19-mrna-vaccine-technology-now

through the PABS System, with clear prioritisation of populations in resource-limited settings, humanitarian contexts, and other vulnerable situations.

Humanitarian Buffer

In global health emergencies, humanitarian contexts are often treated as a "last mile," yet for people living in conflict and crisis settings, timely access to lifesaving medical products is the first priority, underscoring the need for global mechanisms to explicitly reserve stockpiles for humanitarian use and ensure their rapid accessibility to humanitarian organisations. This gap was evident during COVID-19, when the COVAX Humanitarian Buffer—intended to reserve vaccines for humanitarian settings—proved unable to deliver rapid access.

MSF's 2021 attempt to use the Buffer for a vaccination campaign in northern Syria was delayed for months by complex legal and liability requirements, ultimately forcing MSF to withdraw its request [13], [14] Although national authorities later authorised vaccination in the area, the experience demonstrated how the absence of a dedicated, operational humanitarian stockpile can prevent timely access even when public health need is clear

Stockpiling treatments for EVD

Similar challenges have arisen in the context of Ebola virus disease, where, despite the approval of effective treatments supplies remain concentrated in national biosecurity stockpiles in the U.S. rather than made available for outbreak response in endemic countries.[15] To date, no global humanitarian stockpile exists for these treatments, unlike mechanisms such as the International Coordinating Group on Vaccine Provision (ICG), in part due to market distortions driven by concentrated purchasing power and supply constraints linked to reliance on a single manufacturer.

These experiences underscore the need for the PABS System to secure dedicated VTDs supplies to the WHO-coordinated Global Supply Chain and Logistic Network, established under Article 13 of the Pandemic Agreement, to facilitate coordinated stockpiling and equitable allocation based on health needs, especially in humanitarian settings and other vulnerable situations.

We recommend:

- PABS implementation should be substantively connected to Article 13 of the Pandemic Agreement to enable coordinated stockpiling and equitable allocation of medical products.
- WHO and partners should prioritise a collectively governed network to distribute and allocate medical products developed through the PABS System.
- Agreements between WHO and manufacturers should guarantee the availability of VTDs whenever WHO identifies a need for stockpiling or allocation

[13] Médecins Sans Frontières (MSF) Access Campaign. *COVAX: A broken promise to the world.* Available from: https://msfaccess.org/covax-broken-promise-world
[14] Médecins Sans Frontières (MSF). *Broken COVAX: COVID-19 vaccination system must be fixed to allow people access.* Available from: https://www.msf.org/broken-covax-covid-19-vaccination-system-must-be-fixed-allow-people-access
[15] Médecins Sans Frontières (MSF) Access Campaign. *Ensuring access to new treatments for Ebola virus disease.* May 2023. Available from: https://msfaccess.org/sites/default/files/2023-05/MSFAC_EbolaReport_May2023_Final_ENG.pdf

- Allocation criteria for VTDs developed through the PABS should clearly define and guarantee access for humanitarian actors and address the needs of populations in humanitarian settings.

4. Transparency and access to the PABS information

Transparency is a prerequisite for equitable access, as decisions on allocation and stockpiling of scarce medical products can only be guided by public health needs when reliable information on regulatory status, production capacity, stockpiles, and supply commitments are available at global, national and regional levels. Where such information is opaque or withheld, global mechanisms struggle to ensure fair distribution, accountability is weakened, and access inequities are reinforced. Transparent PABS agreements enable early verification that benefit-sharing obligations are clearly specified and enforceable. This reduces the risk that such commitments are deprioritised once products developed from shared samples and data reach the market. It also ensures that access and benefit-sharing remain concretely interconnected.

Access failures during Ebola and COVID-19 outbreaks

MSF's experience during the 2014–2016 West Africa Ebola outbreak and the COVID-19 pandemic showed that, in the absence of transparency across the systems, allocation decisions were largely driven by purchasing power rather than public health need. During COVID-19, initiatives such as the ACT-Accelerator sought to pool procurement and enable needs-based allocation of health tools, but these efforts were undermined by confidential purchase and supply agreements that allowed high-income countries to secure priority access. Limited transparency on manufacturing capacity, delivery timelines, and stockpiling further weakened global planning and delayed access for countries facing acute outbreaks.[16]

During Ebola outbreaks, there was little transparency about the development and management of global stockpiles, the costs of manufacturing and the prices of the rVSV-ZEBOV vaccine,[17] which severely constrained timely access for countries and humanitarian responders. Decisions on who received doses, when, and at what price were made without clear public information, undermining needs-based allocation and preparedness planning. Furthermore, agreements governing the export and use of Ebola clinical samples were often not publicly disclosed, and there is no indication that they contained provisions to ensure access, availability, or affordability of the products subsequently developed.[18]

Similar risks are emerging for the M72 TB vaccine, where uncertainty and lacking transparency around supply and pricing of the proprietary AS01E adjuvant raises concerns that production constraints could delay or limit access in high-burden countries.[19]

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[16] Médecins Sans Frontières (MSF) Access Campaign. *Secrets cost lives: Transparency and access to medical products*. Available from: https://msfaccess.org/secrets-cost-lives-transparency-and-access-medical-products

[17] Médecins Sans Frontières (MSF) Access Campaign. *MSF response to Gavi announcement on financing a global emergency stockpile of Ebola vaccine.* Available from: https://msfaccess.org/msf-response-gavi-announcement-financing-global-emergency-stockpile-ebola-vaccine

[18] Médecins Sans Frontières (MSF) Access Campaign. *Ensuring access to new treatments for Ebola virus disease.* May 2023. Available from: https://msfaccess.org/sites/default/files/2023-05/MSFAC_EbolaReport_May2023_Final_ENG.pdf

[19] Treatment Action Group (TAG). *From forest to factory: Tracing the supply chains for two modern adjuvants of global health importance — QS-21 and MPL.* New York: Treatment Action Group; 2025. Available from:

We recommend:

- Member States should provide public access to information on regulatory approvals for VTDs developed through participation in the PABS.
- The PABS system should establish norms that requires public disclosure of information regarding recipients of PABS materials and sequence information, as well as agreements with manufacturers, other PABS participants and the decisions governing allocation.

Explanatory Note:

Access and Benefit-Sharing (ABS) emerged in the early 1990s under the Convention on Biological Diversity[20] and was later specified in the Nagoya Protocol,[21] marking the first global framework to link access to fair and equitable benefit-sharing. ABS principles have since been applied across a range of sectoral systems[22, 23, 24] including global health under the WHO Pandemic Influenza Preparedness (PIP) Framework.[25]

https://www.treatmentactiongroup.org/publication/from-forest-to-factory-tracing-the-supply-chains-for-two-modern-adjuvants-of-global-health-importance-qs-21-and-mpl/

[20] Convention on Biological Diversity (CBD). *Convention on Biological Diversity – Official Website*. Available from: https://www.cbd.int/

[21] Convention on Biological Diversity (CBD). *The Nagoya Protocol on Access and Benefit -Sharing.* Available from: https://www.cbd.int/abs/default.shtml

[22] Food and Agriculture Organization of the United Nations (FAO). *International Treaty on Plant Genetic Resources for Food and Agriculture – The Multilateral System.* Available from: https://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/en

[23] Convention on Biological Diversity (CBD). *Decision adopted by the Conference of the Parties to the Convention on Biological Diversity on 1 November 2024: Decision 16/2 – Digital sequence information on genetic resources.* Cali (Colombia): Conference of the Parties, sixteenth meeting; 2024 Nov 1. Available from: https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf

[24] United Nations. *Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement)*. Available from: https://www.un.org/bbnjagreement/en

[25] World Health Organization (WHO). *Pandemic Influenza Preparedness (PIP) Framework.* Available from: https://www.who.int/initiatives/pandemic-influenza-preparedness-framework