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The US Bilateral Specimen Sharing Agreement in the Proposed PEPFAR MOUs Would Leave African Countries More Vulnerable in the Next Pandemic

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ABSTRACT

This Policy Brief examines the implications of the United States' (US) PEPFAR Memorandum of Understanding (PEPFAR MOU) proposed to African countries on the negotiations for a multilateral system for access to pathogens and benefit sharing (PABS) as part of the World Health Organization's (WHO) Pandemic Agreement. It recommends that African countries do not accept the MOU provisions on specimen sharing and data access that undermine national sovereignty and calls for a coordinated regional response.

KEYWORDS: United States' (US) PEPFAR Memorandum of Understanding (PEPFAR MOU), Africa, Pathogen Access and Benefit-Sharing (PABS), World Health Organization's (WHO) Pandemic Agreement

Ce rapport sur les politiques examine les implications du protocole d'accord PEPFAR (PEPFAR Memorandum of Understanding) proposé par les États-Unis aux pays africains dans le cadre des négociations sur un système multilatéral d'accès aux agents pathogènes et de partage des avantages (PABS) dans le cadre de l'accord sur les pandémies adopté par l'Organisation mondiale de la santé (OMS). Il recommande aux pays africains de ne pas accepter les dispositions du protocole d'accord relatives au partage despécimens et à l'accès aux données qui comrpomettent la souveraineté nationale et appelle à une réponse régionale coordonnée.

KEY MESSAGES

- The Specimen Sharing Agreement is outside the scope of the PEPFAR activities; it may undermine the regional and multilateral approach for access to pathogens and benefit sharing.
- By giving priority to a bilateral arrangement with a non-Party to the Pandemic Agreement, African countries may weaken multilateral mechanisms to advance equity in sharing of pathogen materials and data and rapid access to vaccines, diagnostics and treatments in the next pandemic.

MOTS-CLÉS: *Le protocole d'accord PEPFAR (PEPFAR Memorandum of Understanding) proposé par les États-Unis, Afrique, L'accès aux agents pathogènes et de partage des avantages (PABS), L'accord sur les pandémies adopté par l'Organisation mondiale de la santé (OMS)*

Este informe sobre políticas analiza las implicaciones del Memorando de Entendimiento del PEPFAR (PEPFAR MOU) de los Estados Unidos propuesto a los países africanos en las negociaciones para un sistema multilateral de acceso a los patógenos y distribución de beneficios (PABS) como parte del Acuerdo sobre Pandemias adoptado por la Organización Mundial de la Salud (OMS). Recomienda a los paises Africanos no aceptar las disposiciones del memorando de entendimiento sobre el intercambio de muestras y el acceso a los datos que socavan la soberanía nacional y hace un llamado a una respuesta regional coordinada.

PALABRAS CLAVES: *El Memorando de Entendimiento del PEPFAR (PEPFAR MOU) de los Estados Unidos, África, El acceso a los patógenos y distribución de beneficios (PABS), El Acuerdo sobre Pandemias adoptado por la Organización Mundial de la Salud (OMS)*

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I. Context

The Appendix A of the United States' (US) proposed PEPFAR Memorandum of Understanding (PEPFAR MOU) requires African partner countries to share pathogen specimens and genetic sequence data with US-approved laboratories within five days of detection and for a period of 25-years, effectively granting the United States priority access over regional and WHO)-coordinated systems, and without commitments by the US for delivering medical countermeasures in the case of outbreaks, epidemics or pandemics. In addition, The US MOU requires African partner countries to agree to one-way data sharing from their national health information systems. The US proposal may undermine the adoption of a multilateral system for access to pathogens and benefit sharing currently under negotiations on the Annex of the adopted WHO Pandemic Agreement.

Currently, there are no international obligations that bind States to provide physical specimens and/or related data, including genetic sequence data (GSD), for pathogens with pandemic or epidemic potential to third countries.

African countries are working together to improve how they share pathogen samples and data across the region. They have created the Africa Pathogen Data Sharing and Archive Platform (AGARI) as part of this effort. However, significant challenges remain.

Most countries in the region lack strong genomic surveillance capabilities, and these systems are not well integrated into national public health programmes. Building this capacity will require major investments. Additionally, there is no unified regional framework governing how pathogen data and materials are shared between countries. Most countries require agreements (legal contracts) for sharing subject to compliance with national law, while efforts are underway to regionally standardize the terms.

A regional coordination has become more urgent as African countries engage in negotiations on the Annex to the WHO Pandemic Agreement[1] for the implementation of a multilateral Pathogen Benefit Sharing and Access System (PABS).[2]

In these negotiations, they have been working closely to maintain a common African position for the negotiations. A core element of the African Group position is that all users, notably manufacturers, of the PABS should have benefit sharing obligations defined in standardized legally binding contracts (i.e., access agreements, material transfer, data transfer) with the WHO.[3]

1 World Health Organization, WHO Pandemic Agreement, document WHA78.1. Available from https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
2 Viviana Munoz Tellez and German Velasquez, "The negotiations on the Pathogen Access and Benefit Sharing System under the WHO Pandemic Agreement: State of Play as of September 2025", *SouthViews* No. 297, 3 October 2025. Available from https://www.southcentre.int/wp-content/uploads/2025/10/SV297_251003.pdf.
3 See "Africa Region + Egypt, Libya, Somalia, Sudan and Group for Equity Lead 80-Country Push for Fair Pathogen Access and Benefit Sharing System", *SouthNews* No. 544, 1 December 2025. Available from https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=62bd0eca0a.

The proposal by the United States for a bilateral Memorandum of Understanding (MOU) with countries for a new framework to provide health aid for HIV/AIDS and Malaria through the President's Emergency Plan for AIDS Relief (hereinafter PEPFAR MOU).

The US froze the PEPFAR programmes in January 2025, and later issued an emergency waiver. However, many activities remain suspended. Under the America First Global Health Strategy announced in September 2025, the US will negotiate bilateral, multi-year agreements with countries receiving PEPFAR assistance. The US PEPFAR MOU has been leaked.[4] **Appendix 4 would contain a "specimen sharing agreement"** which has not been made public.[5] Kenya has recently signed a framework cooperation agreement with the US based on the PEPFAR MOU.[6]

- The United States and [INSERT COUNTRY NAME] plan to enter into a specimen sharing agreement substantially in the form of Appendix 4 for the purpose of providing physical specimens and related data, including genetic sequence data, of detected pathogens with epidemic potential to the United States within five (5) days of detection. Both parties intend this specimen sharing agreement will continue for [twenty-five (25)] years.

II. Implications of the PEPFAR MOU Appendix

Priority Access for the US

The PEPFAR MOU does not explicitly prohibit African countries from sharing pathogen samples or data with WHO or its designated reference laboratories. However, the MOU effectively gives the United States priority access –at the time a pathogen is identified as a potential epidemic threat– much before a pandemic threat.

The MOU commits the partner country to agree to a separate specimen-sharing agreement, requiring the partner country to send physical specimens and related data, including GSD, to the US within 5 days of detection. The agreement would remain in force for 25 years. This obligation is time-bound, operational, and framed without any reference to WHO systems or multilateral platforms.

In practice, this means that samples, data, and sequencing capacity generated by the country's surveillance systems would be shared first with the US to fulfil the obligations under the agreement, rather than at the regional level as is the focus of the current efforts and priority in the African region. This would also take precedence over the WHO-coordinated mechanisms envisaged under the PABS as part of the WHO Pandemic Agreement, which is meant to operate during interpandemic periods as well as during public health emergencies of interna-

4 Priti Patnaik, "American Barter: Aid In Exchange for Information on Pathogens", Geneva Health Watch, 7 November 2025. Available from https://genevahealthfiles.substack.com/p/american-barter-aid-in-exchange-for-pathogen-information-united-states-pabs-negotiations-world-health-organization.
5 Kerry Cullinan, "US Ties Global Health Aid to Data Sharing on Pathogens – Undermining WHO Talks", Health Policy Watch, 7 November 2025. Available from https://healthpolicy-watch.news/exclusive-us-ties-new-health-funding-to-pathogen-sharing-disrupting-who-talks/.
6 Kerry Cullinan, "Africa is Stuck Between Global Pathogen-Sharing Talks and Conflicting US Bilateral Agreements", Health Policy Watch, 2 December 2025. Available from https://healthpolicy-watch.news/africa-stuck-between-global-pathogen-sharing-talks-and-conflicting-us-bilateral-agreements/.

tional concern (PHEICs) including pandemic emergencies.

The PEPFAR MOU stipulates obligations requiring providing physical specimens and related data of detected pathogens with epidemic potential to a US approved laboratory through specific reporting systems. Accordingly, it will create for countries that sign the MOU a structural dependency that can make it difficult for the partner country to share data independently with regional and WHO-coordinated networks. If the systems used to store and transmit information are US funded or hosted, or if the bilateral Appendix impose confidentiality or data-handling conditions that restrict onward sharing, then WHO coordinated laboratories under PABS could be effectively excluded from timely access. Even if not formally prevented, regional and WHO collaboration would be slowed down or complicated by the need to navigate overlapping reporting requirements and separate data-governance rules. Over time, this operational asymmetry would turn the proposed cooperative arrangement into a parallel system of surveillance and information control centred on US institutions, outside the regional and the multilateral coordination framework of the WHO.

This will effectively nullify the obligations under Article 12 of the Pandemic Agreement which require that multilateral pathogen **access** and **benefit-sharing** take place **on an equal footing** through WHO-coordinated systems, in a transparent and equitable manner.

By giving priority to a bilateral arrangement with a non-Party to the Pandemic Agreement, African countries risk fragmenting their legal and practical commitments and weaken mechanisms to ensure equitable and ethical sharing of pathogen materials and data, as well as rapid access to vaccines, diagnostics and treatments that are developed from the materials and data shared (the heart of the PABS Annex negotiations).

In summary, while the PEPFAR MOU does not legally bar African countries from cooperating regionally and with the WHO, it effectively reorders their priorities and obligations, giving the US a privileged and long-term channel of access to pathogen samples and GSD without any corresponding obligation regarding benefit sharing, for instance, in terms of access to vaccines produced using the accessed samples or information.

Loss of Leverage on PABS Negotiations

If several African countries enter into bilateral specimen sharing agreements with the US under the PEPFAR MOU, the position of the African continent on the WHO PABS negotiations is likely to be weakened. The leverage for demanding equal footing on benefit sharing regarding pathogen materials and data through standardized contracts, including the provision of medical countermeasures, may be lost.

Regulatory Dependency and Local Production

Under the Pandemic Agreement all parties have committed to promote equitable access to health products and to support local manufacturing, technology transfer and regulatory capacity (articles 8-11). These provisions aim to reduce dependency on external suppliers and ensure that every region can produce and distribute essential countermeasures during pandemics. The PEPFAR MOU takes the opposite approach. It requires the US FDA approval or emergency authorization to serve as the sole basis for using medical countermeasures within the partner country, thereby increasing regulatory dependency on US FDA determinations. The PEPFAR MOU does not facilitate or require manufacturers to register the product in the partner country, and it also does not assure any access to the regulatory dossier information that could contain relevant information that other manufacturers could use to scale up manufacturing and supplies during an epidemic or pandemic. Furthermore, by requiring the use of US approved procurement systems, laboratory standards, and digital tools, the PEPFAR MOU would deepen technological dependence on US systems.

Data Sharing

In addition to the specimen sharing obligations, the PEPFAR MOU includes a separate data access agreement that sharply expands US access into national health information systems. Under this agreement, the US is entitled to access any data systems, platforms, and infrastructure that support the health programmes financed, technically assisted, or otherwise backed by the US Government. These are defined as "covered data systems." The agreement grants the US access not only to the systems themselves but to the full ecosystem around them, including metadata, dashboards, reporting tools, data models, data dictionaries, and analysis code repositories.

While the agreement states that countries are not expected to provide individual-level or personally identifiable data unless no other timely and accurate method exists, the threshold is broad. Even where covered data includes potentially identifiable information, the US is only required to protect confidentiality "to the extent required under US law," which may fall short of the domestic privacy guarantees that several African countries have codified in their constitutions and data protection statutes.

The case of Kenya shows how far-reaching these commitments can be. Under the recently concluded Kenya-US framework cooperation agreement, the US has reportedly gained real-time access to Kenya's national health data systems, broad querying abilities, and long-term extraction and monitoring rights. This includes direct access into dashboards, metadata, and analytics tools, giving the US deep insight into Kenya's health ecosystem. Such access risks undermining privacy protections and weakening national control over health information, according to an advisory opinion filed in a court in Kenya relating to the constitutionality of the data sharing agreement.[7]

For other African countries, the Kenyan example highlights what long-term digital dependency can look like. Once a country's core health-data infrastructure is tied to donor-controlled

7 Mugambi Laibuta, "Advisory on the Data Sharing Agreement (DSA) between the Government of the United States of America and the Government of Kenya", 2025. Available from https://www.studocu.com/row/document/mount-kenya-university/database-systems/data-compliance-advisory-on-us-kenya-health-compact-2025/147480599.

systems and 25 years of data-access obligations, domestic governance becomes harder to assert, regional data-sovereignty efforts are diluted, and national health information begins to operate through a parallel channel shaped by a foreign government.

While the details of the Kenya-US framework cooperation agreement are not publicly available, it has been reported that the agreement does not include the Annex for a Specimen Agreement.[8]

No Binding and Reciprocal Obligations on the US

The PEPFAR MOU explicitly states that it is not legally binding to the US. Nevertheless, it imposes a series of binding operational, financial, and reporting obligations on the partner country. The US retains unilateral audit rights and the authority to suspend or terminate funding at its discretion. This asymmetry means that the African country assumes obligations without enforceable reciprocal commitments from the US.

Under the PEPFAR MOU Annex, in particular, there is no reciprocal obligation for the US to provide access to specimen materials and data, nor to provide funding and other support for laboratory capacity strengthening, genomic sequencing or other benefits including access to technology or to products derived from the pathogen materials or sequences shared.

III. Recommendations

Based on the analysis above, the South Centre advances the following recommendations:

• **African countries that are approached with the US PEPFAR MOU should seek deletion of Appendix A (a specimen sharing agreement).** The Specimen Sharing Agreement is outside the scope of the PEPFAR activities; it may undermine the regional and multilateral approach for access to pathogens and benefit sharing, including the ongoing Pandemic Agreement Annex negotiations where the African countries are prioritizing a multilateral approach.

• **The United States should withdraw Appendix A requirements from PEPFAR MOUs:** In line with the US America First Global Health Strategy and its recent funding commitment to the Global Fund to Fight AIDS, Tuberculosis and Malaria, removing the Appendix A for a bilateral specimen sharing obligation on African countries would demonstrate consistent support for multilateral approaches. Moreover, the US is a party to the International Health Regulations (2005) although it has not adopted the recent amendments to the IHR,[9] and therefore it should not require from bilateral partners obligations beyond the IHR requirements.

• **African countries should request the removal of the Data Access Agreement from the PEPFAR MOU.** As noted, this agreement would grant the United States broad and long-term access to national health data systems, metadata, and analytical tools in ways that compromise digital sovereignty and may fall short of domestic constitutional and statutory privacy protections. Eliminating this provision would allow countries to maintain control over their health information systems, uphold their own privacy frameworks, and safeguard regional efforts to build coherent, African-led data governance.

• **An urgent regional response to the bilateral US PEPFAR MOUs.** Such a response would support the negotiation position of African countries with the US in order to delete the Appendix A from the scope of the PEPFAR MOU and preserve African regional data sovereignty.

• **Support from the international community for a multilateral approach for access to pathogens and benefit sharing as part of pandemic prevention, preparedness and response.** The international community, including global health institutions, should be vocal in supporting the current multilateral negotiations under the Pandemic Agreement for pathogen access and benefit sharing, and the regional framework for enhanced cooperation that African countries are pursuing, which the bilateral agreements proposed by the US may undermine.

8 Sara Jerving, "Kenya limits US access to disease outbreak data in new bilateral deal", Devex, 8 December 2025. Available from https://www.devex.com/news/kenya-limits-us-access-to-disease-outbreak-data-in-new-bilateral-deal-111519.
9 Viviana Munoz Tellez, "New Amendments to the International Health Regulations: Strengthening Access to Health Products in Emergencies and Pandemics", *SouthViews* No. 295, 24 September 2025. Available from https://www.southcentre.int/southviews-no-295-24-september-2025/#more-24955.

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