

**The Undersigned Civil Society Organizations**

Public Citizen, MSF Access Campaign, Health GAP, NETWORK Lobby for Catholic Social Justice, People's Medicine Alliance, Partners In Health

**16 October 2024**

Dear Colleagues,

Thank you for your recent letter and for your continued efforts to promote transparency in our collective mission to respond to public health emergencies. Ensuring swift and equitable access to vaccines for the most vulnerable populations remains a vital goal for Gavi and UNICEF as we strive to save millions of lives. Regarding mpox, we agree with you that reaching impacted communities with vaccines (and other countermeasures) is critical to halting this public health emergency. Gavi and UNICEF are working closely with governments, industry and global health agencies to ensure equitable access to mpox vaccines.

We are fully committed to the principles of transparency, accountability, and equitable access that you have outlined. As you will have seen, we recently signed agreements for up to 1 million doses of mpox vaccine from Bavarian Nordic, with published prices and building on an inclusive process with key partners. Gavi and UNICEF are leveraging our innovative initiatives, financing tools and partnerships to secure affordable and sustainable solutions. This includes strong support for the Africa Centres for Disease Control and Prevention (CDC) and the World Health Organization-led response to mpox, as well as close coordination with all relevant stakeholders. Our goal is to maximize collective impact and prevent the inequities experienced during the COVID-19 pandemic.

While countries donating vaccines is a welcome first step in the response to get doses to people, in the near-term it will be important to ensure that there is a sustainable supply of vaccine. Your concerns regarding transparency and pricing in the procurement of mpox vaccines, particularly in relation to the Jynneos vaccine, are well noted and have informed our approach. The high-cost per dose, and the need for a two-dose regiment, could impact the amount of vaccines Gavi and UNICEF can purchase and ultimately the number of people reached and potentially even our ability to stop this outbreak. We share your commitment to responsible stewardship of public funds and are making every effort to ensure the mpox vaccine can be made accessible to all, while safeguarding the integrity of the resources entrusted to us.

Our efforts include providing rapid operational support to affected countries, including managing vaccine distribution complexities. UNICEF's comprehensive approach involves deploying technical resources, emergency supplies, and addressing secondary impacts on communities. Gavi is repurposing existing funding and is drawing down from the First Response Fund to support immediate vaccine procurement and distribution, ensuring that resources are utilized efficiently in alignment with country needs and WHO and Africa CDC's strategic guidance.

Through the Africa Vaccine Manufacturing Accelerator (Gavi) and the Partnership for Vaccine Manufacturing (UNICEF) both agencies are committed to strengthening vaccine production capacity in Africa, a crucial step for future public health security. We ask for your support to encourage - in addition to our efforts - governments and industry to seek solutions, including through the transfer of technology and know-how, to help boost vaccine production.

We look forward to continuing our partnership with civil society and other key stakeholders to deliver an equitable and robust response to the mpox crisis. As a next step, we would welcome setting up a discussion to get further inputs from civil society on the mpox response.

Please find attached a detailed response, prepared jointly by Gavi and UNICEF, addressing the specific concerns raised in your letter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sania Nishtar".

Sania Nishtar

CEO, Gavi

A handwritten signature in blue ink, appearing to read "Catherine Russell".

Catherine Russell

Executive Director, UNICEF

## **Annex: Joint Gavi and UNICEF Response to CSO Concerns on Mpox Vaccine Access and Pricing**

Gavi and UNICEF remain committed to supporting the Africa CDC and WHO-led response to the mpox emergency and to working together to curb the spread of mpox with the necessary operational, technical and financial resources so that these life-saving vaccines reach those who need them most.

Key learnings from the COVID-19 pandemic have given rise to a range of innovative tools and flexible approaches designed to enable a faster and more efficient response to public health emergencies like mpox. We have activated mechanisms such as the First Response Fund (FRF), which allows us to rapidly deploy seed funding in support of the mpox response. Our approach is grounded in a commitment to constant learning and adaptation. We are using these tools not as reactive measures, but as proactive strategies designed to anticipate and meet the challenges of emerging health threats head-on, while continuing our mission to protect the most vulnerable communities with life-saving vaccines.

### **Short-Term Actions: Immediate Vaccine Access**

In the immediate term, Gavi and UNICEF would like to re-emphasize that dose donations can be one of the quickest ways to get vaccines to the most vulnerable populations in the greatest need. We commend Africa CDC's leadership and the collaborative efforts that are moving toward securing doses for Africa .

Gavi, the Vaccine Alliance and partners are actively working on multiple fronts to support these efforts. We are responding to WHO's stated demand for vaccines and coordinating closely with WHO, Africa CDC, and other stakeholders to ensure that all contributions are allocated and managed. Additionally, we are leveraging our expertise to manage the complexities of vaccine distribution. UNICEF has also provided support to Africa CDC in the distribution of the vaccines that were donated to them.

Gavi and partners have also provided rapid operational support to countries affected by mpox outbreaks. UNICEF and WHO are working closely with regional and country offices in the affected areas to deploy technical resources and staff to support national governments' efforts to control the outbreak and Gavi has quickly reallocated funding to operationalise vaccine rollout.

UNICEF's response to the mpox outbreak is comprehensive, with a focus on children, pregnant women and underserved communities, prioritizing the interruption of disease transmission, and monitoring and addressing the secondary impacts on children and communities, such as child protection and school closures. In addition to issuing an emergency tender to secure equitable access to vaccines, UNICEF is deploying personal protection equipment, diagnostic and medical treatment kits, hygiene supplies and tents. These supplies support a host of outbreak countermeasures such as treatment, case isolation, surveillance and infection prevention and control such as hand washing.

As a key funder, Gavi is working to repurpose existing funding to enhance country readiness to deploy vaccines without delay by tapping into the flexibilities offered under its Fragilities, Emergencies and Displaced populations (FED) policy. We are also rapidly assessing a drawdown from Gavi's First Response Fund (FRF), which is designed to provide initial financing during the first 50 days of a public health

emergency, whilst further resources are being mobilised. This initial funding can be used ‘at risk’ to procure vaccines on behalf of lower-income countries, to help prime vaccine delivery in country and, if needed, to protect routine immunisation programmes from disruption. However, financing available from the FRF is finite, underscoring the need to both use it judiciously. At present the cost of the vaccine – especially for a two-dose regimen – is very high and unlikely to be compatible with a large roll out of the mpox vaccines. Gavi and UNICEF are actively discussing with governments and manufacturers how production can be boosted and supply guaranteed for the most affected countries in Africa.

### **Medium-Term Actions: Strategic Procurement and Responsible Use of Funds**

As stewards of public funds, we are fully committed to ensuring that every dollar is used as efficiently as possible to maximize impact. The award recently issued by UNICEF for 1 million doses, builds on GAVI’s APA which supports the first 500,000 doses. To support the remaining doses and any further commitments for 2025, additional financing will be necessary. Potential sources could include bridge funding from UNICEF’s Vaccine Independence Initiative (VII) to frontload financing for contracts or drawing on the \$2 billion in surge capacity available through Gavi’s Day Zero Financing Facility—a suite of instruments negotiated by Gavi with the European Investment Bank and the U.S. Development Finance Corporation—contingent upon new donor agreements and pledges.

Ensuring sustainable immunization systems remains a cornerstone of our mission, and it is within this context that we must consider the broader financial landscape. Any new pledges for the mpox response would need to be additional to the US\$ 9bn required to fully fund Gavi’s Investment Opportunity for 2026-2030 to help protect an additional 500 million children and save 8-9 billion additional lives. This funding is essential for the long-term sustainability of immunization programs globally.

On the issue of pricing, we share your concerns about equity. Our engagement with manufacturers is focused on ensuring equitable access and is done in such a way as to maximise transparency. The Request for Proposal that UNICEF has launched will bring together key external experts in a procurement reference group to provide informed advice.

Vaccine prices are made public by UNICEF, recognizing that the free flow of information and correcting information asymmetry is critical to underpin an efficient market. This has also been done with the recent mpox award. Prices achieved through UNICEF’s tender processes are routinely published, with very rare exceptions.

We are also supportive of the work of our partners including CEPI, WHO, Africa CDC, EDCTP, PAHO and NIH who are investing in evidence generation to identify options that improve the efficiency and effectiveness of the mpox vaccines, including fractional dosing, that will, in the medium term, help us use our scarce resources more efficiently.

### **Medium-Long-Term Vision: Local Manufacturing and Technology Transfer**

We fully support the vision of building a sustainable vaccine manufacturing ecosystem in Africa, recognizing that local production and technology transfer are essential for vaccine sovereignty and long-term public health security. Supply constraints, like with COVID-19 threaten an equitable and effective response, which is why governments, industry and health agencies must identify innovative solutions that can potentially scale-up production, including through technology transfer and the sharing of know-how. While establishing local manufacturing is a longer-term effort, the approval of the mpox vaccine for stockpiling from 2026 under Gavi's 2024 VIS presents a catalytic opportunity.

We also thank you for raising the issue of coordination, which is indeed critical to the success of our response. Gavi and UNICEF are in daily contact with all key stakeholders, including Africa CDC, WHO, and other partners. We fully support Africa CDC's leadership in this response, which began as early as April with the convening of stakeholders to plan and coordinate efforts. We are committed to ensuring that our actions complement those of other organizations and contribute to a cohesive, effective response.

In conclusion, we would like to emphasize that Gavi and UNICEF deeply value the role of civil society organizations. Your voice is crucial in ensuring that our response is transparent, accountable, and inclusive. We are committed to maintaining an ongoing dialogue with you and can organize a meeting to get further insights on how best we can all help drive an equitable and effective mpox response.

Thank you once again for your dedication to this cause.