

It takes a global village: advancing equitable access to mpox vaccines

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The monkeypox (mpox) outbreak requires the international community to work in solidarity towards advancing global health security. The public health response requires enhancing disease surveillance, laboratory capacity, risk communication and more. We argue that a major issue that the global community needs to focus on is how to improve vaccine equity given the constraints faced by the African continent.

THE MPOX OUTBREAK AND THE PHEIC DECLARATION

On 14 August 2024, the WHO declared the mpox outbreak a Public Health Emergency of International Concern (PHEIC). This announcement followed the Africa Centres for Disease Control and Prevention (ACDC) declaring mpox a Public Health Emergency of Continental Security on 13 August.¹ The outbreak is worst in Central and East Africa, but cases are being reported around the globe, prompting global disease surveillance.

Fighting this disease could strain African health systems, which have already struggled with the COVID-19 pandemic. International assistance to improve equitable access to mpox vaccines demands a multistakeholder and multipronged approach that includes mobilising funds for procuring vaccines, donating vaccines and strengthening local production capacities.

BARRIERS TO FAIR AND EQUITABLE ACCESS TO MPOX VACCINES

Ensuring fair and equitable access to vaccines has been a persistent global problem. The COVID-19 pandemic showed substantial disparities between low-income and high-income countries, sparking concern about vaccine equity. At the height of the pandemic, high-income countries had administered 69 times more doses per inhabitant than low-income countries, with Africa getting the

brunt of it.² It would be unfortunate if the continent faces similar obstacles again.

Unlike COVID-19, when new vaccines had to be developed, mpox vaccines exist. Bavarian-Nordic, KM Biologics and Emergent BioSolutions are biotechnology companies that have developed vaccines. Still, supplies are scarce. According to ACDC, 10 million dosages are required, but so far only around 4 million doses have been pledged. Also, the price per dose is about US100, making it expensive for low-income countries.

Global initiatives to increase equitable vaccine access to COVID-19 vaccines in low-income countries had been inadequate. For example, Covid-19 Vaccines Global Access (COVAX) struggled to meet its vaccine procurement goals due to competition from high-income countries. Also, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) waiver remained restricted. To address these shortcomings, WHO member states have been negotiating a pandemic agreement that would advance equitable access to vaccines, through a range of mechanisms, but no agreement has been reached so far.

GETTING VACCINES TO THOSE IN NEED: IT TAKES A GLOBAL VILLAGE

To ensure that low-income countries have access to vaccines, the international community should cooperate in solidarity and employ a variety of strategies. This includes major powers like the USA, China, the European Union (EU) and Japan, the WHO, ACDC, and other organisations like GAVI (the Vaccine Alliance),³ UNICEF and Coalition for Epidemic Preparedness Innovation (CEPI), as well as pharmaceutical companies like Bavarian Nordic. In other words, increasing supplies and getting vaccines to those in need 'takes a global village'.

The recently amended International Health Regulations (IHR) require solidarity during a PHEIC. Article 3 (1) determines that



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the IHR ‘shall promote equity and solidarity among State Parties’. While not in legal effect until 2025, the revision reflects member states’ aspirations to act in the spirit of equity and solidarity. The WHO’s Standing Recommendations have also called for global cooperation to increase vaccine access, particularly in low-income and middle-income countries, and stress equity and solidarity in ensuring access to vaccines.

In what follows, we lay out the main pillars that should be tackled for increasing equitable access: mobilising funds, donations from stockpiles, speeding up regulatory approval and expanding local production.

A. Increase vaccine donations

So far, about 4.5 million mpox vaccine doses have been donated or pledged. Japan has pledged 3 million doses of the LC16 vaccine, a handful of European countries have pledged 620 000 Bavarian-Nordic vaccines, and the USA has pledged 1 million doses. Bavarian Nordic and Emergent BioSolutions have donated doses.⁴ Gavi, UNICEF and the WHO are trying to coordinate more donations from countries with stockpiles. To this end, the WHO has established the Access and Allocation Mechanism through which donors can share vaccines. Also, donations are being carried out through purchase agreements. For example, the EU Health Emergency Preparedness and Response Authority has concluded an agreement with Bavarian Nordic and the ACDC. More countries should be encouraged to offer surplus doses from their stockpiles.

B. Regulatory approval

Before use, vaccines must be approved by regulators and/or WHO prequalification for safety and efficacy. Bavarian Nordic’s vaccine has US Food and Drug Administration (FDA) and European Medical Agency (EMA) approval. And the Democratic Republic of the Congo (DRC) and Nigeria have granted it Emergency Use Authorisation. KM Biologics is only approved in Japan.

The problem is that GAVI, UNICEF and many low-income countries with weaker regulatory capacity, rely on WHO’s prequalification or Emergency Use Listing before procuring vaccines. At the outbreak’s start, WHO approval was lacking, delaying procurement and distribution. Thus, after the PHEIC declaration, the WHO expedited the prequalification process, and on 13 September prequalified the Bavarian Nordic vaccine. Consequently, Bavarian Nordic and GAVI signed a procurement agreement for 500 000 doses. Going forward, to speed up access, GAVI, UNICEF and other low-income countries could consider relying on the approval of strict regulatory agencies (FDA, EMA) rather than waiting for WHO approval, as this causes unnecessary delays.

To further accelerate vaccine access, the WHO, in collaboration with regional regulatory bodies like the African Medicines Agency, can support harmonised and fast-tracked regulatory approval processes across African countries. This would help avoid delays in

vaccine roll-outs caused by lengthy approval processes in multiple jurisdictions. Through training and technical support, this partnership could also strengthen countries’ regulatory capacity.

C. Expanding local production

Since most vaccine development and manufacture happens in high-income countries, the COVID-19 pandemic taught us that local or regional vaccine manufacturing capability is needed to enhance supply and strengthen self-sufficiency. Thus, expanding production capacity is a key feature of the pandemic accord negotiations. However, some say that mpox technology transfer to Africa is unlikely due to the technology used and the absence of suitable third parties. While Bavarian Nordic has reportedly agreed with ACDC to transfer mpox technology to several African manufacturers,⁵ there is little information on the execution status of that agreement.

D. Mobilising financial assistance

The current estimate is that it will cost around US\$245 million to purchase vaccines (though the exact cost is unknown, as it is determined by prices that are not transparent). Financial assistance is, thus, needed.

Several actors have committed funds for the mpox response. The USA pledged US\$500 million to support African countries and the African Union has provided around US\$10 million to ACDC.⁶ The Pandemic Fund, created post-COVID-19 at the World Bank, provided US\$129 million to 10 African Union member states to support surveillance, diagnostics and workforce development, but it is unclear if funds were allocated for vaccine procurement. In June 2024, GAVI established a ‘First Response Fund’⁷ to provide immediate funds during a PHEIC, but it can only be used after the WHO declares a PHEIC, and exclusively for WHO prequalified vaccines. Thus, despite the evolving mpox situation, GAVI’s fund could not be used before the WHO’s PHEIC declaration and prequalification decision. Because it causes delays in vaccine access, this dependency on WHO decision-making should arguably be re-evaluated.

CONCLUSION

Ensuring rapid, fair and equitable access to mpox vaccines in low-income and middle-income countries is a complex challenge. It demands a multipronged approach, where diverse strategies are employed by a global village of stakeholders committed to acting in solidarity. Collaboration should not only stem from goodwill but from a pragmatic understanding that global health security is interconnected, as no one is safe until everyone is safe. Finally, the mpox outbreak and the ad hoc scramble for vaccines which we are witnessing further underscore the necessity of reaching an international pandemic accord that

would establish a more systematic and comprehensive framework for guaranteeing equitable access to vaccines.

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