

Subject **Gavi's Response to Mpox**

Agenda item **07**

Category **For Information**

Executive Summary

The purpose of this report is to provide an update on Gavi's response to the ongoing mpox outbreak. It provides highlights of mpox response coordination and activities from across key partners and donors linked to Phase I of the mpox response (which is projected to span September 2024-February 2025). Phase I activities are being driven by complementary and aligned approaches articulated in the WHO Global Strategic Preparedness and Response Plan and the Africa Centers for Disease Control (CDC)-WHO African Continental Preparedness and Response Plan.

Recognising both the outbreak and coordinated response efforts continue to evolve, the report provides a summary of engagements across key partners and the Gavi Secretariat as of early November. The Programme and Policy Committee discussed this update in October 2024 and Alliance partners were consulted on the paper.

Action Requested of the Board

This report is for information only.

Next steps/timeline

The Gavi Secretariat will consider Board perspectives in the evolving response to the mpox outbreak.

Previous PPC or Board deliberations related to this topic

In October 2024 Programme and Policy Committee Meeting: Doc 05 - Gavi's response to mpox

Gavi Board Technical Briefing on mpox – September 2024

In June 2024 Board meeting book: Doc 11a - Day Zero Financing Facility – First Response Fund & Doc 11b African Vaccine Manufacturing Accelerator & Doc 10 Vaccine Investment Strategy 2024 – Investment cases

In December 2023 Board meeting: Doc 10a - Pandemic Prevention, Preparedness and Response Approach – UPDATED

In October 2023 Programme and Policy Committee Meeting: Doc 5a - Pandemic Prevention, Preparedness and Response Approach

Report

1. Update and context

Epidemiology and burden

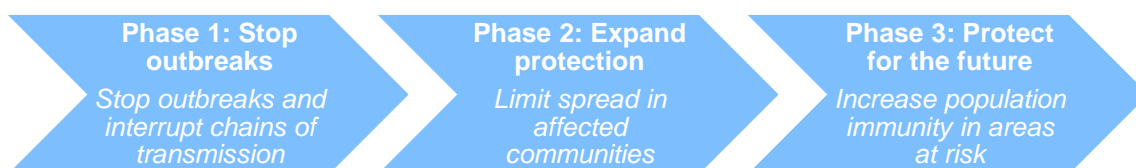
- 1.1 Gavi has been closely monitoring mpox since a multi-country outbreak of mpox was first declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO) in July 2022. In June 2024, the Gavi Board approved, in principle, contingent on replenishment, a global stockpile of mpox vaccines beginning in 2026, as well as critical investments in a learning agenda to fill identified evidence gaps and to help inform future vaccination efforts. At the same meeting, the Board also approved a role for Gavi to facilitate dose donations in view of increasing cases and deaths since early 2024.
- 1.2 Africa Centres for Disease Control and Prevention (Africa CDC) declared mpox as a Public Health Emergency of Continental Security (PHECS) for Africa on 13 August 2024 and WHO declared mpox a Public Health Emergency of International Concern (PHEIC) on 14 August 2024. Gavi activated emergency funding flexibilities for mpox per its Fragility, Emergencies and Displaced Populations (FED) Policy¹ on 15 August 2024.
- 1.3 As of 10 November 2024, there have been 50,549 suspected cases reported (including 12,178 confirmed) and 1,140 deaths (including 53 confirmed) reported across 19 countries in Africa, according to the WHO since the beginning of 2024. The Democratic Republic of Congo (DRC) remains the epicentre of the outbreak, representing 85% of all suspected cases and 99% of suspected deaths reported to date. Outside of Africa, 62 countries have reported a total of 8,409 confirmed mpox cases and 21 deaths in 2024. Among these, exported cases of Clade Ib have been confirmed in Germany, India, Sweden, Thailand, and the United Kingdom.

The role of vaccines as part of a comprehensive response

- 1.4 Vaccines are one part of a broader comprehensive response to the mpox outbreak, and an effective response is contingent on other interventions alongside vaccination. Phase I activities are being driven by complementary and aligned approaches articulated in the WHO Global Strategic Preparedness and Response Plan (SPRP) and the Africa Centers for Disease Control (CDC)-WHO African Continental Preparedness and Response Plan – with the goal of phase I to stop human-to-human transmission.

¹ <https://www.gavi.org/news/media-room/gavi-statement-mpox-emergency-africa>

Excerpt of WHO SPRP for mpox phased vaccination strategy



- 1.5 There are three vaccines currently available and approved for preventing mpox (see Appendix A for further details). Currently, there are no approved treatments specifically for mpox. Antivirals are considered options only for severe cases and their availability in low- and middle-income countries (LMICs) is very limited.

2. Highlights of response from partners and donors

- 2.1 This section summarises highlights of mpox response activities and commitments from across key partners and donors linked to Phase I of the mpox response (which is projected to span September 2024-February 2025). Phase I activities are being driven by complementary and aligned approaches articulated in the WHO SPRP and the Africa CDC-WHO CPRP.
- 2.2 To operationalise and oversee the implementation of these strategies and plans, partners are regularly convening as part of the **interim Medical Countermeasures (iMCM) Coordination** group for mpox (refer to Figure 1). As per the visual, the vaccination Senior Leaders across Africa CDC, the Coalition for Epidemic and Pandemic Innovations (CEPI), Gavi, WHO and UNICEF oversee strategy and provide critical decision-making and accountability at the highest level. These same institutions are further collaborating as a Vaccination Operational Group (Table 1) to accelerate, oversee and coordinate across three priority operational workstreams: 1) Research, Regulatory and Policy; 2) Access and Allocation; and 3) Delivery.

Figure 1: i-MCM Vaccination Coordination

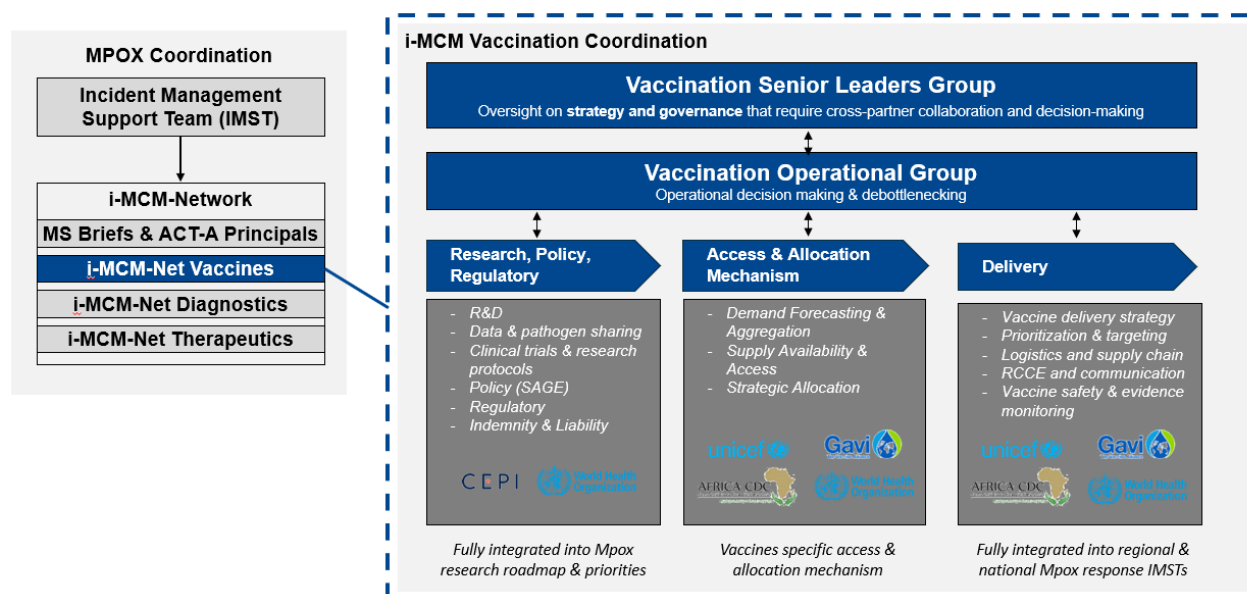


Table 1: Overview of Alliance and other select partner activities in mpox response

Partner	Summary
WHO	<ul style="list-style-type: none"> The WHO's SPRP provides a framework for the three phases of the outbreak response, and the strategy for Phase I (Stop the outbreak and aiming to interrupt human-to-human transmission) which is estimated to last the six-month period of September 2024-February 2025. The SPRP for mpox has an estimated budget of US\$ 290 million for international support to affected countries and regions (excluding the cost of vaccines) for implementation over the Phase I period. WHO published a smallpox and mpox vaccine position paper in August 2024 providing policy recommendation for use of mpox vaccines. WHO engagement extends beyond vaccine activities to the provision of essential non-vaccine supplies, including personal protective equipment and health kits, and in the areas of infection prevention and control and continuity of essential services.
Africa CDC-WHO mpox Continental Plan	<ul style="list-style-type: none"> Consistent with the SPRP, Africa CDC-WHO and other key partners have developed the mpox continental preparedness and response plan. This plan is structured around ten pillars which stretch across coordination and leadership, surveillance, infection prevention and control, vaccination, operations and logistics. Africa CDC and WHO have set up a joint Continental Incident Management Support Team (IMST) to facilitate coordination across partners engaged in mpox response efforts. On 5-7 November 2024, WHO and Africa CDC organised a workshop with 17 countries to guide and support the development of mpox vaccination plans based on targeted vaccination strategies. The Gavi Secretariat and partners are actively participating in this Continental IMST. Africa CDC and WHO have estimated a funding need of approximately US\$ 600 million (excluding the cost of vaccines) associated with the Continental Plan for both readiness and response related activities over the Phase I period.
UNICEF	<ul style="list-style-type: none"> Like WHO, UNICEF's engagement extends beyond vaccines, including support for essential non-vaccine supplies such as personal protective equipment and health kits, infection prevention and control, risk communications and community engagement and continuity of essential services. On vaccines, UNICEF is engaging across the supply and access and delivery workstreams. UNICEF launched an emergency tender on 29 August 2024 to secure access to mpox vaccines. The award letter was issued on 19 September 2024 against which purchase orders for MVA-BN can be placed.
CEPI	<ul style="list-style-type: none"> CEPI is engaged in the Research, Policy and Regulatory workstream and is a member of the Senior Leaders Group.

	<ul style="list-style-type: none"> CEPI is supporting several clinical trials for the MVA-BN vaccine to assess the safety and efficacy of mpox vaccination in post-exposure scenarios² and in paediatric populations.³ CEPI is also supporting BioNTech to advance mRNA-based vaccine candidates for mpox.
Civil Society Organisation (CSOs)	<ul style="list-style-type: none"> CSOs, such as Médecins Sans Frontières (MSF) and the International Federation of the Red Cross and Red Crescent Societies (IFRC), are critical and active participants as part of iMCM Coordination groups and global and regional IMST launched for mpox. CSOs are also engaging in vaccination planning and delivery in countries (e.g.: MSF engagement in the DRC). Insights from civil society organisations – and the communities they work with – are informing outbreak response and vaccination design strategies. In August 2024, a joint civil society letter was sent to Gavi and UNICEF advocating for the negotiation of fair pricing of Mpox vaccines to which Gavi's CEO responded with an offer to continue communication with Civil Society partners throughout the response. As part of Gavi's commitment to civil society engagement, the Secretariat is engaging with CSOs platforms like Resilience Action Network Africa (RANA), AMREF Health Africa, Pandemic Action Network (PAN) and others via a CSO working group on mpox that interfaces directly with Africa CDC in order to reinforce the importance of equitable access. In addition, the Gavi Secretariat, in partnership with the Gavi CSO Constituency, plans to discuss Mpox and the role of civil society in a future joint webinar as part of the 'Gavi Talks with Civil Society' series.
Donors	<ul style="list-style-type: none"> The donor support of the response is grounded in the context of the importance of protecting routine immunisation and other outbreak response Some have pledged or provided support direct to DRC and other affected countries. Bilateral donations and donations facilitated by Gavi – from national stockpiles and new purchases - have formed a significant part of available supply up until now. See Annex A for an overview of supply (as of early November 2024).

3. Update on Gavi response

- 3.1 The Gavi Secretariat was rapid in communicating its commitment to support a coordinated response⁴. Grounded in Gavi's Pandemic Prevention Preparedness and Response (PPPR) framework (countries, vaccine, and coalition ready), certain preparedness activities started before the PHEIC declaration – including capacity investments via the vaccine coalition. As noted above, the Gavi Board provided an in-principle approval of an mpox stockpile for Gavi 6.0 (subject to replenishment), with a learning agenda recently launched to inform the sizing and design of this stockpile.
- 3.2 In terms of response activities, the Gavi Secretariat is engaging predominantly across the Access and Allocation and Delivery workstreams (and in a targeted manner in the Research, Policy and Regulatory workstream).

Gavi engagement: Access and Allocation

- 3.3 **Dose donations:** Given that no vaccines had yet received WHO Emergency Use Listing (EUL) / Prequalification (PQ) at the time of the Gavi Board meeting in June 2024, the Board approved a role for Gavi to facilitate mpox vaccine donations to ensure immediate vaccine supply for the mpox response. Gavi facilitated a donation of 15,000 doses from Bavarian Nordic to DRC, with complementary UNICEF support to the government, with those doses arriving in the country on 10 September 2024.

² <https://cepi.net/new-clinical-trial-will-assess-if-mpox-vaccination-works-after-virus-exposure>

³ <https://cepi.net/bavarian-nordic-and-cepi-partner-advance-mpox-vaccination-africa>

⁴ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(24\)01706-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01706-9/fulltext)

- 3.4 In early September, the Gavi Secretariat clarified that it would facilitate vaccine donations when formally requested by a donor, underscoring that facilitation will need to be closely aligned with the cross-partner Allocation and Access Mechanism and tied to demand from countries. Gavi is currently facilitating donations from two donors, Canada and the United States of America, following formal requests made directly to Gavi, with the allocations being managed according to the agreed Allocation and Access Mechanism (AAM). To guide our work, the Gavi Secretariat has developed and published key principles of mpox vaccine dose donation⁵.
- 3.5 **Securing further supply:** On 18 September 2024, less than a month after the PHEIC declaration and five days after the MVA-BN vaccine was granted WHO PQ, Gavi signed an Advance Purchase Agreement (APA) with Bavarian Nordic to secure 500,000 MVA-BN doses, all to be made available for delivery in 2024. These doses represent the first utilisation of the First Response Fund. The vaccines will be allocated via the cross-partner AAM and will be delivered, subject to country readiness and demand, via a supply agreement signed between UNICEF and Bavarian Nordic.

Gavi engagement: Delivery

- 3.6 **Financing to support preparation and vaccine delivery:** The Gavi Secretariat rapidly permitted funding flexibilities to mpox affected countries, per its FED policy, including the ability to reprogramme existing grants (up to a threshold) towards mpox vaccine readiness and delivery efforts. Since then, the Gavi Secretariat has approved reprogramming of US\$ 2.7 million to the DRC and US\$ 1.5 million to Rwanda, with several other applications expected. Beyond reprogramming, a drawdown from the First Response Fund also included approximately US\$ 10 million to support mpox vaccination delivery.
- 3.7 **Collaboration with Continental IMST and affected countries:** Gavi and Alliance partners are key partners across several pillars of the Africa-CDC and WHO Continental Plan, to operationalise the Global level Delivery workstream (see Figure 1). To support mpox response activities, including mpox vaccination across all Gavi-eligible affected African countries, Gavi Secretariat is coordinating its efforts and use of delivery funding via the continental IMST. Gavi is also intensively engaging with the Ministry and other colleagues in DRC, as well as with other affected countries.
- 3.8 **Utilising the vaccine coalition:** Gavi has approved flexibilities from its coalition support to Africa CDC towards strengthening mpox coordination and response efforts. In discussion with the Africa CDC, three coalition funded staff have been repurposed to mpox and resources have been provided to support regional mpox training activities – an example of the value of this model in terms of preparedness and the ability to pivot to response when needed.

⁵ <https://www.gavi.org/global-health-security/principles-mpox-dose-donation>

Gavi engagement: Financing

- 3.9 Alongside reprogramming and coalition funds, most Gavi Secretariat response related activities are being funded via the **First Response Fund (FRF)**. Mpox response-related efforts represent the first drawdown of the Fund, with the Gavi Secretariat Steering Committee chaired by the CEO recommending a drawdown just over a month from the declaration of the PHEIC – well ahead of the 50-day target. The funds are intended to support Gavi's contributions to Phase I. The majority are dedicated to vaccine procurement with additional funds to facilitate coordination and delivery. This use is firmly in line with the objectives of the FRF to provide initial funding during the 'first response' phase of a crisis, building on lessons learnt from COVID-19. The drawdown approved was up to US\$ 50 million.
- 3.10 During the PPC meeting in October 2024, the Gavi CEO clarified the intended use of the FRF to be used during the earliest days of a public health emergency and that any further use of the FRF would need Board approval, per the Fund's governance, and to be supported by confirmed country demand. Additional FRF for mpox would reduce funding available to support the first response for other public health emergencies during the rest of 5.1 and 6.0 from the US\$ 500 million Board-approved envelope. Absent a significant change in demand linked to the epidemiologic situation which results in a supply gap that the Board believes Gavi - rather than other available funding sources - should fill, the Secretariat does not foresee a further drawdown from FRF for current mpox-response efforts.

Gavi engagement: Mitigating any potential negative implications to ongoing programmes

- 3.11 The PPC paper⁶ included an overview of Gavi's work with partners to monitor potential implications of the mpox outbreak and particularly any negative impacts on existing immunisation programmes (noting there is no empirical evidence to suggest this to date). Notably, Gavi has included activities linked to the protection of routine immunisation (e.g. ability to recruit time-limited surge workforce, funds to augment vaccine trust and demand activities) as eligible expenditures under reprogramming. Gavi is not advocating reprogramming of funds away from other key priorities, such as the Big Catch-Up.

4. Update on response: Demand, supply, allocation and vaccination uptake

- 4.1 The Gavi Alliance, Africa CDC and other partners continue to support the development and refinement of national mpox vaccination plans, including identification of target populations, delivery strategies and demand. As of early November, 380,000 doses of mpox vaccines have been shipped, with an additional ~800,000 allocated doses, approved by the Vaccine Senior Leaders Group in late October following the recommendation of the Technical Review

⁶ PPC paper, Doc 05, Gavi's response to Mpox, October 2024

Committee⁷, awaiting country acceptance, country readiness, and shipment (see Annex A for an overview of available supply). At least one additional allocation round is expected before the end of 2024. As of early November, targeted vaccination has begun in DRC and Rwanda, with approximately 50,000 persons vaccinated with first dose.

5. Scenario planning and looking beyond Phase I of the response

- 5.1 The evolution of the mpox PHEIC remains unclear. While the timeline for Phase I mpox response is estimated to be approximately six months, these timelines may extend with the outbreak and response still dynamic (see Annex B for key risks and mitigations).
- 5.2 Gavi is progressing supply scenario planning in parallel to its targeted and rapid contributions to phase I. There are three key scenarios associated with supply and demand for phase I⁸:
 - i. Supply and demand are sufficiently matched: This currently appears to be the case – noting however that demand estimate work is ongoing and evidence on absorptive capacity forthcoming.
 - ii. Demand increases beyond current secured supply: This scenario could be linked to factors relating to vaccine supply including timing of LC16 availability, implementation feasibility and potential strategies to support SAGE recommended paediatric vaccination strategies, including off-label use. In this scenario, there could be a need to revert back to the Gavi Board to seek their guidance on procuring additional vaccine doses. Given the FRF is only intended for initial funding, and there are no other Board Approved funds, new and additional donor pledges would be required in this scenario. These could be frontloaded by the tools in the Day Zero Financing Facility designed to be the ‘second layer’ in Gavi’s PPPR emergency financing.
 - iii. Supply exceeds demand for phase I: Should the comprehensive response and objectives of phase I be met with some of the secured supply remaining, the AAM will consider rephasing of these doses into phase II / III efforts.
- 5.3 Looking beyond Phase I, the Gavi Secretariat is in the initial phases of exploring the feasibility to move the Gavi mpox stockpile (subject to replenishment and a Gavi Board decision) up from 2026 to 2025. Feasibility analyses considering stockpile sizing, cost implications and design options to be elaborated in

⁷ The Technical Review Committee is a group of independent experts, convened by the Continental IMST, to review national mpox vaccination plans and recommend vaccine allocations. These vaccine allocation recommendations are then endorsed by the Vaccine Senior Leaders Group.

⁸ These scenarios are driven by the successful identification and targeting of vaccination and other outbreak control interventions to localities with sustained human to human transmission in the previous four weeks, the ability to identify and vaccinate people at risk of infection and the efficacy of the vaccine/s.

consultation with key partners will be critical (noting the desire to have some learning agenda insights inform these).

- 5.4 The Secretariat is also reviewing the potential designation of vaccines recently adopted through the Vaccine Investment Strategy, including mpox vaccine, as "Priority Vaccine" under the African Vaccine Manufacturing Accelerator (AVMA). Criteria include contribution of an African source to the global supply base, predicted commercial viability and sustainability, and relevance of the pathogen in the African context. The Secretariat will report findings and recommendations of this exercise to the PPC in the second quarter of 2025.

Annexes

Annex A: Summary of available mpox vaccine supply

Annex B: Key risks and mitigations associated with mpox and Gavi's response

Additional information available on BoardEffect

Appendix 1: Mpox vaccine overview