Subject	**Update on Mpox**
Agenda item	**07**
Category	**For Decision**

Executive Summary

The purpose of this paper is to provide an update on the ongoing mpox response, with a focus on the Gavi Secretariat's actions, and on the potential establishment of a global mpox vaccine stockpile for outbreak response. This update and the investment case have been informed by guidance from Alliance partners and builds on the consultative process of the Vaccine Investment Strategy leading to the June 2024 in-principle approval of a global mpox stockpile.

Action Requested of the Board

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that, contingent on financial resources being made available for the Gavi 6.0 strategic period, it:

a) **Approve** the opening of a funding window for the establishment of an mpox programme through an emergency stockpile for i) reactive vaccination in an outbreak setting and ii) potential repurposing of stockpile doses at risk of expiring for preventive vaccination in at-risk groups contingent on SAGE recommendations;

b) **Note** ongoing efforts to address data gaps, including the stockpile sizing learning agenda and the collaborative design of the global stockpile, shaping the final programme and financial estimates.

Next steps/timeline

If approved, taking into consideration any potential recalibration of Gavi 6.0 priorities by the Board and contingent on financial resources being made available, the Gavi Secretariat will initiate the programme planning and design phase in consultation with the ICG and Alliance partners. This phase is expected to last approximately 9- 12 months with an expected earliest availability of vaccines through a stockpile in H2 2026.

Previous Board Committee or Board deliberations related to this topic

In May 2025 Programme and Policy Committee folder: Doc 15 - *Update on mpox*

In December 2024 Board meeting book: Doc 07 - *Gavi's response to mpox*

In June 2024 Board meeting book: Doc 11 - *Vaccine Investment Strategy 2024 - Proposed shortlist*

Report

1. Context

1.1 Mpox, a disease endemic in Central and West Africa, remains a public health emergency of international concern (PHEIC) and continental security (PHECS) with both the World Health Organization (WHO) and Africa Centres for Disease Control and Prevention (Africa CDC) reaffirming its emergency status in June 2025[1]. Further details on mpox epidemiology are provided in Annex B.

1.2 Vaccines are an effective tool for outbreak response, as part of a holistic mpox response[2]. For mpox, WHO granted Prequalification (PQ) to a vaccine manufactured by Bavarian Nordic (MVA-BN) and granted Emergency Use Listing (EUL) to a vaccine from KM Biologics (LC16m8) in late 2024.

1.3 In June 2024, in the context of an upsurge in mpox cases in Africa, the Gavi Board approved, in principle, a global stockpile of mpox vaccines for outbreak response beginning in 2026. It also approved a learning agenda to fill evidence gaps, and a role in facilitating dose donations should they prove necessary and be available as part of a global response to a PHEIC.

2. Gavi Secretariat's response to the mpox emergency

2.1 The Secretariat, guided by the June 2024 Board decision and subsequent WHO and the African Continental mpox response plans[3], worked with partners to establish response approaches and governance to focus on equitable and rapid access to vaccines and funding. Governance is cross-partner in nature, including the Secretariat, and comprises the Vaccination Operational Group (VOG), as part of the Access and Allocation Mechanism (AAM), the Continental mpox Incident Management Support Team (IMST), and the Supply Working Group. The Secretariat is also represented by its CEO on the Senior Leaders Group, which has overall responsibility for the vaccine response.

2.2 Since the December 2024 update to the Board, the Secretariat, with partners, has continued to play a critical role in the mpox response, becoming the largest funder/facilitator of MVA-BN vaccines through the AAM to date. The Secretariat has provided both vaccines and delivery funding, which have been primarily funded via the first ever First Response Fund (FRF) drawdown. Highlights of the Secretariat's efforts include:

2.2.1 Securing and delivering mpox vaccines: Within a month of the emergency declarations in August 2024, Gavi secured access to 500,000 mpox vaccines through an Advance Purchase Agreement

[1] See WHO's announcement
[2] WHO Position Paper on smallpox and mpox vaccines
[3] WHO's Global Strategic Preparedness and Response Plan (Apr 2025) and the Mpox Continental Preparedness and Response Plan 2.0 (Apr 2025)

(APA) with Bavarian Nordic. All these doses have now been shipped to nine affected countries.

2.2.2 Facilitating dose donations: To date, Gavi has facilitated shipment of 246,260 donated MVA-BN doses. This includes 200,000 doses from Canada and 15,460 doses from Bavarian Nordic to the Democratic Republic of the Congo (DRC). Gavi has also facilitated 30,800 doses from the United States of America (USA) to Nigeria and Rwanda and continues to work with USA on additional vaccine shipments.

2.2.3 Providing country support and delivery funding: Via its Fragility, Emergencies and Displaced Populations (FED) policy, Gavi has made available funding flexibilities and five countries have received approval to reprogramme a total of US$ 5.0 million to support mpox vaccine rollout. In addition, as part of the FRF drawdown US$ 1 million of technical assistance was made available to WHO AFRO and eight of ten eligible countries have requested FRF delivery funding for a total of US$ 8.8 million, all of which has been approved. Of this, US$ 1.3 million has been disbursed to seven countries while disbursement of the remaining US$ 7.5 million to DRC is in process.

3. Progress, key learnings to date and looking ahead

3.1 As of 3 July 2025, seven countries (Central African Republic, DRC, Nigeria, Rwanda, Sierra Leone, Liberia, and Uganda)[4] have administered over 780,000 doses. Other countries, including Côte d'Ivoire and Kenya, are expected to start vaccination in the coming weeks. Despite these response efforts, human-to-human transmission continues in several countries and strategic, operational, and other challenges in implementing the vaccine response remain. These include (1) unstable and dangerous security situations in some countries; (2) insufficient resources and difficulties in maintaining timely testing and surveillance data, essential for outbreak control and targeted vaccination; (3) evolving country vaccination strategies; and (4) slow formal acceptances by some countries of allocated vaccines and completing the applications delayed the arrival of doses and the associated FRF delivery funding.

3.2 The Gavi Secretariat has engaged in both internal as well as cross-partner led learning efforts, most notably the Continental mpox IMST Intra-Action Review in December 2024. Several best practices have been highlighted in the first phase of the mpox response, including the establishment of the Continental mpox IMST and complementary structures to coordinate cross-partner activities.

3.3 Looking ahead, guided by the expertise of technical partners, the Gavi Secretariat's engagement will become increasingly more targeted in nature once Gavi delivery funding and facilitated / secured doses are fully disbursed.

[4] Noting that the Secretariat has intensified its engagement with Sierra Leone and partners given the recent increase of mpox cases in the country.

The Secretariat will provide strong stewardship and oversight of the utilisation of these doses and delivery funding and will continue to participate in cross-partner coordination efforts to advance the multisector response in affected countries. This engagement will also provide important intelligence towards finalising the design of the mpox stockpile (subject to approval – see next section). The Secretariat will continue to closely monitor progress and results, with partners, to ensure learning is appropriately integrated into broader outbreak, epidemic and pandemic preparedness and response efforts.

4. Global Mpox Vaccine Stockpile

4.1 Background and decision history: Through the VIS 2024, the Gavi Board approved, in principle, support for a global mpox vaccine stockpile for outbreak response – contingent on regulatory and technical reviews, alignment with the financial assumptions of the mpox investment case, and the availability of funding for 2026-2030 following Gavi's replenishment.

4.2 Key conditions for approval laid out in the Board's 2024 decision have now been met. Two vaccines have now received regulatory approval (MVA-BN and LC16m8) and the WHO Strategic Group of Experts on Immunization (SAGE) has issued recommendations for mpox vaccine use, including in outbreak settings[5]. Final Board approval of the mpox vaccine stockpile is required to make funding available for the next strategic period for vaccine procurement and delivery support, to provide the mandate for the stockpile's operationalisation, and to initiate programme planning and design.

4.3 The PPC reviewed these developments and supported the opening of a funding window to establish an mpox programme through a vaccine stockpile, and called for reassessing the stockpile size as funding for Gavi 6.0 becomes clearer, noting concerns that the proposed vaccine stockpile size may be insufficient. The PPC deferred the recommendation related to the projected cost and size for the Board to determine, when there is further visibility on funding availability and outputs of the Gavi-commissioned learning agenda on stockpile sizing are available. The learning agenda evidence is now available, and supports the original proposed procurement of 500,000 doses, with an associated cost of US$ 35.3 million in Gavi 6.0[6], to significantly contribute towards the control of future mpox outbreaks and complement broader mpox outbreak response efforts.

4.4 6.0 Mpox Global Stockpile programme:

4.4.1 The proposed mpox programme builds on the VIS 2024 in-principle decision on a global mpox stockpile for outbreak response and incorporates two key strategies aiming to help countries with rapid containment of outbreaks while ensuring value for money and minimising wastage: i) vaccination for outbreak response, and

[5] Smallpox and mpox (orthopoxviruses): WHO position paper, August 2024
[6] See section 4.6.3 for more details

ii) potential repurposing of stockpile doses at risk of expiring for preventive vaccination in at-risk groups, contingent on SAGE recommendations.

4.4.2 **The envisaged total procurement of doses for this investment case is 500,000 during Gavi 6.0**, in alignment with the Board's initial stockpile size approval in June 2024, which was based on exploratory demand forecasting, health impact modelling[7] and multiple consultations throughout the VIS process. Consultations with partners, recent feedback from the PPC in May 2025, and the report of the learning agenda suggest that the proposed global mpox stockpile could serve as a mechanism to make vaccines available for an initial timely response to an outbreak, complementing and building on the efforts of other organisations and countries. It would provide an important market signal to manufacturers of Gavi's intention to procure mpox vaccines and establish the basis for the Gavi Alliance to engage in market shaping activities in the coming years, with the aim of progressively aligning supply with demand for outbreak response efforts.

4.4.3 **Results from the Gavi-commissioned learning agenda on stockpile sizing** show that the procurement of 500,000 total doses in Gavi 6.0 would be able to successfully respond to 44-52% of mpox outbreaks in Gavi-eligible countries between 2026-2030. It is estimated to avert between ~5.5K to ~10K mpox cases and ~300 to ~600 mpox-associated deaths in the same period. A smaller financial envelope, and hence the procurement of fewer doses, would reduce the expected health impact, limit outbreak response capacity, and weaken market signalling. The outputs of Gavi's learning agenda also include stockpile sizing recommendations for consideration and decision by the International Coordination Group on Vaccine Provision (ICG). Further details on the expected impact of different stockpile sizes can be found in Annex B and Appendix 2.

4.4.4 **As with other Gavi-funded vaccine stockpiles, the mpox vaccine stockpile is proposed to be managed as a global stockpile by the ICG.** This approach would enhance operational efficiency by integrating with existing stockpile governance systems across multiple stockpiles funded by Gavi, leveraging existing expertise, and providing a consistent pathway for countries seeking outbreak response support. In addition, a global stockpile ensures vaccine availability for all countries, including those not eligible for Gavi support (who, as per the existing model, would repay the cost of vaccines), making it a vital asset for global health security. This global mechanism could also collaborate with key additional partners (i.e., Africa CDC), potential regional and national stockpiles to enable a more coordinated and efficient response.

[7] Based on exploratory analysis by the University of Medical Sciences, Ondo, Nigeria.

4.4.5 Access to the mpox vaccine from the stockpile would be provided in line with the 'principles for Gavi support for emergency vaccine stockpiles' approved by the Board in 2016 and ICG's Accountability Framework. Operational support would be tailored to each country's context given the expectation of resource-intensive delivery requirements (e.g. small or targeted vaccination; the use of bifurcated needles if LC16m8 were to be used) and consider complementarity with other funding sources.

4.5 Market shaping and supply considerations:

4.5.1 The global mpox vaccine market is currently driven by demand in high income countries to maintain their national smallpox stockpiles and respond to mpox outbreaks. As mpox manufacturers produce to order and do not currently hold large stocks, a global stockpile is essential to ensure timely access during outbreaks and avoid demand in Gavi eligible countries being crowded out by that of higher-income countries.

4.5.2 As of 28 June 2025, two vaccines have been approved and recommended for use against mpox by WHO and could therefore be considered for the stockpile: MVA-BN (PQ) and LC16m8 (EUL)[8]. Additional vaccines are in clinical development, including mRNA candidates, but are unlikely to achieve licensure until late in Gavi 6.0. Given the relatively small global mpox market, it is unclear how many new vaccine entrants could co-exist and enjoy commercial viability.

4.5.3 Both MVA-BN and LC16m8 have challenges associated with their use in outbreak settings. Gavi, in consultation with Alliance partners, is developing a market shaping roadmap, to be published later in 2025, which will outline priority desired improvements in product characteristics (current characteristics are detailed in Annex B). The Secretariat will continue to monitor the progress of the vaccine pipeline along regulatory and policy pathways to inform which products are included in the stockpile and associated programmatic needs.

4.5.4 **The establishment of a stockpile – and the demand signal it sends – will help to incentivise innovations and development of second-generation vaccines, such as mRNA vaccines.** Any eligible mpox vaccine manufactured in Africa would benefit from AVMA incentives when the vaccine is eligible[9]. However, it should be noted that Gavi's market shaping ability will be very much defined by the size of the mpox investment.

[8] Bavarian Nordic's MVA-BN vaccine was granted WHO PQ in September 2024 and has been used widely in response to recent mpox outbreaks in both high-income countries and across Africa. KM Biologic's LC16m8 vaccine was granted EUL in November 2024, but it has rarely been used outside Japan.
[9] In December, a new set of vaccines will be recommended to the Board for designation as AVMA Priority Vaccines that will benefit from enhanced levels of AVMA subsidy; mpox will be among these.

4.6 Financial implications

4.6.1 The associated costs for the establishment of the 6.0 Global mpox vaccine stockpile are US$ 35.3 million in Gavi 6.0 (US$ 32.8 million for vaccines and ancillary costs and US$ 2.5 million for related cash grants[10]).

4.6.2 Financial assumptions include a target of maintaining the stockpile at 250,000 doses, an annual drawdown of 50,000 doses following utilisation for outbreak response, and a total of 500,000 doses to be procured during the 6.0 period. These assumptions are only intended to inform the expected financial implications of the potential stockpile. As per standard practice with other stockpiles, if and when the programme is approved by the Gavi Board, the ICG and partners will review and finalise the target stockpile level.

4.6.3 The financial estimate is now higher than the initial VIS 2024 in-principle approval associated with the procurement of 500,000 doses. Based on market intelligence at the time, and prior to formal confirmation of vaccine prices secured under UNICEF's tender, the estimated cost for vaccine procurement and delivery was US$ 24.06 million. The updated figure presented in this investment case (US$ 35.3 million) reflects a change in the assumed vaccine composition of the stockpile and incorporates learnings from the ongoing mpox response, resulting in more evidence-informed assumptions while maintaining the same overall stockpile size.

4.6.4 The estimated cash support is based on country budget submissions for Gavi operational cost support for mpox vaccination in 2024/2025. However, operational costs per dose for small, targeted vaccination campaigns for hard-to-reach populations are expected to be higher. As the programme evolves and more data becomes available, this estimate may require reassessment.

4.7 Next steps

4.7.1 If the Gavi 6.0 global mpox stockpile receives Board approval, the Gavi Secretariat will initiate the programme planning and design phase, which includes co-designing programming with ICG and Alliance partners, appropriate resourcing and vaccine procurement. Any adjustments to Gavi's commitment to the stockpile would be presented for Board review and approval.

4.7.2 A timely decision will enable a programme to launch by approximately H2 2026, ensuring a long-term solution to address future outbreaks, and minimising potential supply gap risks.

[10] Vaccine costs are based on a fully loaded vaccine price, costs of freight, safety boxes, and syringes.

Annexes and Appendices

Annex A: Risk and impact

Annex B: Outbreak Overview & Mpox Global Stockpile Investment Case

Additional information available on Board Effect

Appendix 1: Additional Context on Outbreaks and Mpox Stockpile

Appendix 2: Mpox Vaccine Stockpile Sizing Learning Agenda Interim Report – Johns Hopkins University