

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

Key risks and challenges	Proposed mitigations
Delivery support: Lack of clarity on delivery supporting funding, scope / scale and timeliness of this going countries	Comprehensive mpox response financing tracker launched by the G20 Health Financing Taskforce to track funding commitments, pledges and disbursements. Ongoing discussions to share intelligence across partners (e.g.: Continental IMST)
Mpox vaccination in children under 12: Use of with MVA-BN for under 12s would be off-label, with clinical effectiveness data for use in infants not expected in the near term; LC16 presents programmatic challenges	Countries can follow WHO policy position and opt to use MVA-BN off-label for under 12 year olds (noting this generates indemnification & liability challenges). WHO has offered to implement a protocol for expanded access using WHO's insurance, in the short term, if no alternative is available. WHO PQ granted for MVA-BN in 12-17 year olds (noting countries' national regulatory authorities have yet to apply this recommendation to facilitate the inclusion of this population). Technical assistance can be provided to countries to assist in LC16 specific training and programmatic needs
Partner coordination: Broad and inclusive with many partners, where roles and decision making need to be clear - for timely and coordinated response	Coordination structures are in place across key partners, with several critical mechanisms and high-level roles and responsibilities being refined
Supply & Demand forecasts: Need for timely supply and clear demand from across affected countries	Supply and Demand are dedicated cross-partner workstreams to support alignment
Uncertainties: Uncertainties linked to financing landscape, epidemiological evolution of mpox outbreak, country demand and timelines associated with the integrated response strategy all generate challenges in planning and implementation	Cross-partner structures in place offer appropriate avenues to share critical intelligence, to strategize together and to mitigate key risks and challenges as they arise