Annex B: Supporting Considerations for a Future COVAX-Supported Paediatrics Programme and Risks and Trade-offs

Supporting considerations related to Option 2

Paediatric vaccine supply: At present, there is one vaccine product (Pfizer) which has received WHO EUL and SAGE recommendation for administration to children aged 5-11 and which could be readily available through COVAX; currently there are no vaccines with WHO EUL or SAGE recommendation for administration in children under 5. In addition, although the Moderna vaccine has not yet received EUL or SAGE recommendation for use in under 12s, the EMA has approved a 6-11 year paediatric indication that is the same formulation as the booster already available through the COVAX Facility. Subject to national policy, it is possible that countries could decide to use Moderna booster doses they have received through COVAX for a paediatric vaccination programme. The products available and expected over the next months come with programmatic challenges including UCC requirements (Pfizer), the management of paediatric vs. adult formulations, and the availability of syringes. Regarding devices, Pfizer requires a 0.2ml and Moderna a 0.25ml dose – volumes without readily available supply of AD devices - and will require COVAX to provide 1ml RUPs as an alternative (in line with WHO guidance). Several other products across different platforms (mRNA, inactivated, ad-based, protein subunit) are undergoing regulatory review and awaiting SRA, WHO EUL or SAGE recommendation in the short and medium term (i.e. mid 2022 and 2023), broadening the supply options to meet existing and future demand.

Paediatric vaccine demand from COVAX AMC participants: The AMC participants that sought COVAX support for paediatric vaccination in the first few months of 2022 would be covered by the interim policy approach. While there are no specific estimates, additional demand from COVAX participants is expected to materialise in the coming months as participants follow the policies and practices of high-income-countries (HICs), countries in their respective region, and highly absorptive countries, to direct resources to vaccinate children in parallel with their continued efforts to reach their higher priority populations. This trend will accelerate as additional vaccines for 5-11 and as vaccines for younger age groups (under 5-year-olds) receive WHO EUL and are recommended by SAGE. Option 2 would seek to meet demand whilst also putting in place limited guardrails to ensure focus on higher priority population groups is reinforced and avoid displacing routine immunisation.

Public health impact of paediatric vaccination: The WHO SAGE roadmap for prioritising use of COVID-19 vaccines advises the administration of primary series and boosters to higher priority groups, such as older adults, immunocompromised persons or health care workers, before reaching medium and lower priority groups, such as children and adolescents. The rationale for this is that globally, there are fewer symptomatic infections and cases of severe disease and death in children than in older adult age groups; the burden of long COVID also appears lower among children compared to adults. However, benefits of vaccinating children go beyond direct health benefits, such as positive psychosocial benefits and minimising school disruptions and consequently disruptions to parents and society at large.[22] Paediatric vaccine effectiveness data in the context of Omicron indicates that immunity against infection wanes rapidly but, as for adults, protection against severe disease is

maintained. There is limited data on cost-effectiveness of paediatric COVID-19 vaccination but depending on disease transmission and burden it may be lower than other paediatric vaccines supported by Gavi

While the public health impact of paediatric vaccination in AMC participants may be limited in the current context, this could shift if additional vaccines are more effective in this population (against severe disease, infection and/or transmission) and/or additional data on disease burden in this age group becomes available. Other factors to be monitored include evidence on the risk and long-term impact of COVID-19 infection in younger populations, such as multisystem inflammatory syndrome or long COVID; SAGE recommendations for boosters or periodic vaccination in this age group; and evolution of the pandemic, including the emergence of new variants of concern.

Implementation feasibility and impact on Gavi's core mission: While supply of the Pfizer paediatric formulation for 5–11-year-olds is readily available, some challenges remain, including its ultra-cold chain characteristics and syringe availability in 2022. Other products expected to become available in 2022 may be programmatically easier to implement. Many AMC participants have experience with delivery of vaccines to both the 5-11 and the under 5 age group through campaign mode and can achieve high coverage. Successfully reaching these age groups is nonetheless resource intensive and presents many programmatic and financial challenges. Impact of campaigns on routine immunisation tends to vary depending on context; stronger EPI programmes can leverage these activities to strengthen their RI system with strong linkages to the zero-dose agenda, but for weaker programmes this risks diversion of resources away from RI. Enhanced engagement with countries would be envisaged to maintain RI programmes for non-COVID-19 vaccines and to not preclude the extension of RI to zero-dose children and missed communities in line with Gavi 5.0 objectives. The proposed use of the IRC review post allocation provides a mechanism through which to identify and advise on risks and potential solutions for how to efficiently and effectively role out the vaccines.

COVAX comparative advantage: Facilitating access to a supply of paediatric doses through COVAX would meet country demand, limit diversion of resources away from other programmes, leverage donor appetite to dose-share, capitalise on existing supply, and align with COVAX's equity agenda by improving access between HICs and LMICs.

Financial implications: For COVAX itself, a paediatric vaccine programme based on the existing dose-sharing programme would not increase overall costs. For participants, in the short and medium term, access to paediatric doses through COVAX could avoid the cost of buying directly from manufacturers. Option 2 proposes that donors cover ancillary costs, including syringes, and that CDS funding would not be provided to avoid diverting resources away from higher priority use groups. Nonetheless, in the absence of CDS funding, delivery of COVID-19 doses to this age group could increase financial pressure on participants to invest limited delivery resources on vaccinating lower priority use groups. The extent of the opportunity costs of pursuing COVID-19 vaccination of children instead of RI will vary by context and reinforces the importance of the proposed guardrails.

Assessment of different options

High rating · Medium rating · Low rating · Unclear

	Option 1: Expand eligibility for paediatric doses to all AMC participants, regardless of coverage levels.	Option 2: Limited provision of paediatric doses with guardrails (higher priority coverage; RI maintenance)	Option 3: No further support of paediatric doses provided beyond the interim, time-bound, approach.
Public health impact of paediatric vaccination	(+) Addresses higher burden in children with comorbidities; mitigates risk of long COVID-19, Multisystem Inflammatory Syndrome in Children (MIS-C) (+) Positive psychosocial benefits; minimizing school disruptions (-) Limited public health impact due to low severe disease and deaths in healthy children (-) Limited impact on transmission/ indirect benefits; uncertain cost effectiveness	(+) Addresses higher burden in children with comorbidities; mitigates risk of long COVID-19, MIS-C, etc. (+) Positive psychosocial benefits; minimizing school disruptions (-) Limited public health impact due to low severe disease and deaths; (-) Limited impact on transmission/indirect benefits; uncertain cost effectiveness (-) Volumes are (donated) supply driven, not necessarily perfectly meeting demand/ need	(+) Allows for allocation of limited resources elsewhere in medium/ long term (e.g., improved vaccine) (-) Does not address burden in medium risk groups (children with comorbidities)
Implementation feasibility and impact on Gavi's core mission	(+) AMC participants experienced in delivering vaccines to both 5-11/ under 5; can achieve high coverage (+) Initial dominance of mRNA with some programmatic challenges but longer-term access to diverse product platforms (-) No paediatric AD syringe available in 2022, even 1ml RUP access may be challenging for H1 2022, and not usable in all places (-) If countries would not otherwise introduce, may divert resources from other health programmes (-) Resource intensive and may divert resources away from RI	(+) AMC participants experienced in delivering vaccines to both 5-11/ under 5; can achieve high coverage. (+) Enhanced engagement and guardrails manage risks to RI (+) Early donor volumes likely to be taken up in high absorbers (+) Initial dominance of mRNA with some programmatic challenges but longer term access to diverse product platforms (-) Limited use of platform in children hence less safety data (-) No paediatric AD syringe available in 2022, even 1ml RUP access may be challenging for H1 2022, and not usable in all places	(+) Signals that participants should optimize resources on higher-risk priority groups (+) Reduces GAVI-specific efforts associated with converting production and supplying 1ml RUP syringes (-) In practice, COVAX/Gavi in country efforts will still need to account for paediatrics as countries self-procure
COVAX comparative advantage	(+) Meets country demand (+) Leverages donor's willingness to share doses (+) Helps utilize existing supply, esp. short-term (+) Align with equity agenda between HICs and LMICs (+) Avoids wasting avail. supply (+) Signal for future market shaping, including access to different platforms (-) Countries that wish to pursue this can self-fund through bilateral deals (at high cost) (-) Could lead to delivery funds being used for lower-priority use groups	(+) Meets country demand (+) Leverages donor's willingness to share doses (+) Helps utilize existing supply, esp. short-term (+) Align with equity agenda between HICs and LMICs (+) Avoids wasting avail. supply; country funds (+) Signal for future market shaping, including access to different platforms (-) Countries that wish to pursue this can self-fund through bilateral deals (at high cost)	(+) Avoids Gavi supplying doses that could displace RI-related efforts (-) Does not respond to country demand; country funding spent on bilateral deals could be better used elsewhere. (-) 2022 supply/demand outlook unchanged; COVAX likely forced to refuse up large % (up to 400M) of USG + EU Pfizer doses w/o demand
Financial implications	(+) Dose-sharing means no increase in overall COVAX costs (+) COVAX may avoid bilateral procurement costs (-) Participants face pressure to invest limited delivery resources on vaccinating lower priority groups	(+) Dose-sharing means no increase in overall COVAX costs (+) COVAX may avoid bilateral procurement costs	(+) No additional financial liabilities taken on by COVAX (-) Bilateral deals may divert participants' resources

Risks and Trade-offs of a Future COVAX-Supported Paediatrics Programme

Providing paediatric doses through COVAX (either Options 1 or 2) presents risks that require consideration and mitigation.

Firstly, making paediatric vaccines available could generate demand for doses from participants with low coverage in higher priority groups, diverting their focus and resources. In Option 2, this risk is mitigated by the proposed coverage threshold and review process.

Secondly, an approach relying exclusively on dose donations could be less sustainable, particularly in the case of a spiked increase in demand due to disease shifts (where the health threat for children increases) and/or supply shocks that slow the willingness of donors to share doses. In the medium term, a shortfall could be met by the procurement of doses, subject to the availability of funding and MSDC and Board approval. Depending on the circumstances, the Pandemic Vaccine Pool might be a vehicle through which finance to purchase is mobilised. Longer term dose sharing agreements can help mitigate in the short term. To mitigate the risk that doses needed for adults have been converted into paediatrics, doses are safeguarded for lower coverage countries to reach higher priority populations.

Thirdly, a paediatric vaccination programme risks impacting with Gavi's core objectives, particularly around maintaining, restoring and extending the reach of routine immunisation in a pandemic context and therefore a paediatric vaccination programme may represent opportunity cost for national health systems.

Furthermore, delivery to the 5-11 and under 5 groups can be challenging, and often rely on resource-intensive vaccination campaigns to achieve high coverage.

Finally, there is a reputational risk for Gavi in supporting an immunisation programme which may bring marginal benefits in terms of public health – though not being responsive to countries' demand when there is supply readily available also brings reputational risks.

Whilst acknowledging these challenges, the approach put forward as option 2 is intended to provide flexibility to enable countries to pursue their public health goals whilst providing reasonable safeguards to maintain protection of the highest priority.

There are also significant risks to pursuing both Options 1 and 3. Option 1 poses the risk of significant distraction from high-priority COVID-19 vaccination and RI programmes. Option 3, on the other hand, could be seen as driving greater inequity in terms of vaccine access between HIC and LMICs, as participants with the lowest GNI per capita would be the least likely to be able to procure doses outside of COVAX. This would also forego the possibility of maximising public health benefit from the supply available to COVAX given the risk that these doses may otherwise go to waste if not converted. In the absence of paediatric supply from COVAX, participants who really want doses will acquire them, with the same risks of diversion and resource use, although leaving COVAX with less visibility into the programmes and connection to the prioritisation decisions. Having a formal programme, including the proposed guardrails and post-allocation IRC review of the programmes, will help ensure Gavi retains a direct line of conversation with the participant regarding their programmes.