

Annex D: COVAX Country Participation Model: Risk Considerations

Section A: Summary

- In May 2021, the PPC requested the Secretariat perform a high-level analysis on the risk considerations for the three country participation model options. This paper considers the financial, reputational, pandemic response, governance, and operational risks of the three models along with the impact on AMC-92 in terms of pricing structure, supply, and the ability to make deals. The high-level risk analysis and considerations indicate that the AMC+ model tends to mitigate the most risks to Gavi and the COVAX Facility with the greatest advantage seen in the areas of reputational and pandemic response risk.

Section B: Risk Considerations

Financial

- The main financial risk with the Status Quo model is created when Gavi enters into legally binding commitments with manufacturers on behalf of Self-Financing Participants (SFPs) without full payment from them. Currently, the sovereign credit risks are to be mitigated using bespoke insurance products. The Status Quo model maintains the current financial risk to the COVAX Facility and the Secretariat, which the Facility is working to mitigate, while the AMC+ and AMC-92 only models carry less, or no inherent financial risk related to SFPs and therefore would not require the same level of mitigation through insurance solutions.
- The AMC+ model would redefine key principles for future engagement with SFPs. The revised key principles currently envision that SFPs would be required to provide a complete financial backstop (e.g., full payment in escrow, standby letter of credit, guarantee from a multilateral development bank) in advance of Gavi making a firm order commitment to a manufacturer thereby mitigating Gavi's financial exposure. The AMC-92 only model also eliminates the financial risk to Gavi as there would not be any SFPs participating in the Facility.

Reputational

- Both the Status Quo and the AMC+ model options present some risk to Gavi associated with deviating from Gavi's core mission of focusing on the poorest countries. However, the AMC-92-only model carries the highest reputational risk to Gavi as it moves away from an equity-based approach and would exclude SFPs reliant on the COVAX Facility for procurement of COVID-19 vaccines in 2022. Without other secure avenues to procure vaccines, some SFPs may object to being excluded before the end of the acute phase of the pandemic. The AMC+ model puts the onus on SFPs themselves to choose whether they would like to participate in the COVAX Facility in 2022. Therefore, the reputational risk will be lower as the Facility will be open to all participants who need COVAX.

Pandemic Response

- The Status Quo and AMC+ models have the lowest risk to the COVAX Facility vis-a-vis the pandemic response. This is because the models ensure there is at least

one avenue for access to Covid-19 vaccines for non-AMC eligible participants who need support in accessing vaccines to halt the pandemic.

- The AMC-92 Only model risks delaying the end the acute phase of pandemic as without the COVAX Facility, countries will have to rely on a new regional and/or global mechanism that might become available and perhaps last choice bilateral deals. As the epidemiological situation evolves with the possibility of new variants, there is risk that some SFPs that rely on the Facility are left behind, unable to procure vaccines and control the infection rates. An inclusive approach is key to supporting countries that rely on a global, trusted multilateral body to provide the technical, scientific, and operational expertise, as well as purchasing power, to help them navigate the complex evolution of the epidemiological situation, including variants.

Operational

- In 2020 several flexibilities were introduced to encourage SFP participation, such as Optional vs. the Committed Purchase model as well as the option to either procure through UNICEF/PAHO or self-procure. This resulted in significant operational complexity. The current Status Quo model maintains the operational risks and transaction costs of engaging with SFPs that do not need COVAX for the procurement of Covid-19 vaccines. There is minimal impact on administrative or operational costs as SFPs' fees cover the overhead costs. The risk is the timely recruitment of qualified SFP-dedicated resources and knock-on impact in the meantime to some Secretariat functions, along with the operational complexity of managing some SFP functions. This includes the optional and committed purchase models, the 'opt-out' windows and staff time dedicated towards certain functions as well as recruiting and training SFP-dedicated COVAX Facility staff.
- The AMC+ model mitigates the risk by simplifying the operations of the Facility. This will be achieved by consolidating SFP participation into a single model with key principles designed to simplify operations. The participants would be provided with a single decision window to buy a specific vaccine and the Facility would streamline procurement with a requirement to use UNICEF or PAHO as a procurement agency¹, further reducing the operational complexity.
- The AMC-92 only model removes the operational risks to the Secretariat through the exclusion of SFP participation. However, to note that without the administrative fees paid by the SFP, the operational costs of the COVAX Facility would be incrementally higher per unit and would be fully financed by the COVAX AMC.

Implication on Governance

- The Status Quo model has high risk to the Governance functions of the COVAX Facility, which manages both the Shareholders Council, the governance body for the SFPs, and the AMC Engagement Group, the governance body of the AMC-92. These governance bodies are time and resource intensive, and given multiple bodies in this space, can result in conflicting opinions on key issues. With the AMC+ model, there may be an opportunity to simplify the operations of the

¹ Unless specified by manufacturers for self-procurement in certain cases.

governance bodies and facilitate more exchange between SFP and AMC participants, subject to consultations and existing governance arrangements. In turn, this could lead to a medium risk.

- The AMC-92 only model would simplify the governance to focus solely on the AMC-92 participants and donors.

Impact on AMC-92

Supply

- The risk of supply availability due to ongoing global supply constraints will remain the same across the three options. Thus, the risk of supply and its impact on AMC does not change between the models from a production standpoint, as Gavi contracts the volumes based on the participant's demand.
- In the Status Quo model, the volume is higher along with a greater number of participants, while in the AMC+ model, the volume of demand would likely be lower with a smaller number of SFPs. The changes in volume will likely not result in a changed manufacturer preference to engage with the COVAX Facility; as the predicted volumes in the AMC+ model, noted in the Appendix 1 scenarios, are approximately 147M – 245M, equating to 30-50% of SFP demand in the Status Quo model. The Facility offers the manufacturers a level of predictable revenue and demand along with reputational benefit to participate in global solidarity.
- In the AMC-92 only scenario, there is a possibility to see more competition for supply as HICs and UMICs would be pressured to engage in bilateral deals as they can no longer rely on the COVAX Facility.
- Thus, the country participation model of the Facility would likely not be a primary driver of the willingness of manufacturers to engage and supply doses to the COVAX Facility.

Complexity in the Deal Making Process:

- The ability to finalize deals in the Status Quo model will be medium as there is complexity in the deal making process leading to a longer timeline to negotiate and finalize the deals. If the Facility were to move to an AMC+ model, it would simplify the deal making process as potentially higher income, high purchasing power economies might not be under consideration, thereby shortening the negotiation process. The AMC-92 only model will lead to a further simplified model for deal making, as terms such as indemnity and liability are already defined, and benefit of the COVAX AMC being fully financed. Thus, in theory, the process will be least complex with manufacturers in an AMC-92 only scenario.

Price:

- There is medium risk and impact on pricing structures in the AMC+ and the AMC-92 only models.
- With the AMC+ model, the risk could be reduced as some manufacturers would prefer the inclusion of HICs and UMICs in the pricing structure, allowing for tiered pricing between the AMC and SFPs with an overall revenue that is a blend of

different price points. This would mean the AMC-92 economies pay the lowest price possible, while SFPs pay a price that is higher. On the other hand, there are other manufacturers that prefer to only offer the lowest price, tailored only for the AMC-92 group, and to manage higher price points outside of COVAX through bilateral deals as Gavi imposes the ‘most favoured nation’ clause. For manufacturers with a single price point, country scope is not relevant.

- In the AMC-92 Only model, there is risk that might make it more difficult to secure deals with smaller biotechnology companies, who are looking for the volume from HICs and UMICs in the Facility and offer tiered pricing. These manufacturers may not have the resources to engage in multiple bilateral conversations with SFPs.

Risk Considerations	Status Quo	AMC+	AMC-92
1. Financial	Higher Risk: Continued financial risks	Lower Risk: reduced financial risk to Gavi with an updated model of participation	Lower Risk: No financial risk to Gavi
2. Reputational	Lower Risk: Continues the multilateral solution to end the pandemic with greatest impact on equity. Some risk with Gavi deviating from its core mission supporting the poorest countries.	Lower Risk: By giving countries the option to self-select into COVAX for 2022	Higher Risk: Reputational risk to Gavi, moving away from a global equity-based objective
3. Pandemic Response	Lower Risk: Greatest impact providing SFPs options to secure vaccines to end the pandemic	Lower Risk: Inclusion of countries that rely on COVAX as a primary secure for vaccines	Higher Risk: Participants that need COVAX will be excluded, potentially prolonging the acute phase of the pandemic with impact on future global health security efforts
4. Operational	Higher Risk: Complexity in operations and transaction costs for the Facility in engaging with countries that do not rely on COVAX	Medium Risk: Simplified Facility operations lowering the risk compared to status quo. Does not deviate from Gavi resources, although may impact	Lower Risk: Simplified Facility operations with focus on only the AMC-92

		some support functions from Gavi.	
5. Governance	Higher Risk: Time and resource intensive to manage both the Shareholders Council and the AMC Engagement Group	Medium Risk: There is potential to streamline governance structures	Lower Risk: Governance body solely focused on the AMC-92
6. Impact on AMCs <i>Supply</i>	Risk: Global supply constraints remain No impact on manufacturers' willingness to engage with COVAX from a production standpoint as Gavi contracts the volumes based on the participants' demand	Risk: Global supply constraints remain No impact on manufacturers' willingness to engage with COVAX from a production standpoint as Gavi contracts the volumes based on the participants' demand	Risk: Global supply constraints remain No impact on manufacturer's willingness to engage with COVAX from a production standpoint as Gavi contracts the volumes based on the participants' demand
7. Impact on AMCs <i>Complexity in the deal making process</i>	Medium Risk: Complexity in negotiating deals, thus the timeline for negotiation is longer.	Medium Risk: The negotiation period is less complex than current but reflecting SFP terms still required.	Lower Risk: Least complex as the financing for AMC is available and terms already defined.
8. Impact on AMCs <i>Pricing Structure</i>	Medium Risk: Some manufacturers prefer the higher volume deals and tiered pricing allowing for lower prices for AMC-92. While other manufacturers prefer to just offer the lowest price possible for the COVAX AMC group.	Medium Risk: Some manufacturers prefer the higher volume deals and tiered pricing allowing for lower prices for AMC-92. While other manufacturers prefer to just offer the lowest price possible for the COVAX AMC group.	Medium Risk: Without HICs and UMICs in COVAX, it would be difficult to secure deals with some manufacturers, who prefer tiered pricing. While other manufacturers prefer one price for the COVAX AMC group.