

Annex B – Risk analysis

1. Risk of inaction - Gavi not administering the COVAX Facility

Complexity/delays of setting up other mechanisms or inaction will cause missed opportunities, with a massive negative impact on global health such as:

- The Facility is at risk of not being established at all, or at a time where it would have missed numerous opportunities to build a successful portfolio of candidate vaccines. As explained in this paper, it would be difficult to find an alternative to Gavi, with the possibility that no third party picks up the COVAX Facility.
- Vaccine provision to developing economies would become fragmented or delayed: should a Facility go ahead without Gavi's involvement, the challenges resulting from the cooperation between the two entities could result in inefficiencies, while still being labour intensive
- Suboptimal investment strategy in vaccine candidates,
- Lack of sufficient incentives for manufacturers to scale up develop vaccines,
- GHS/pandemic continues,
- Routine immunisation disruption in Gavi supported economies continues

2. Risk of Gavi administering the COVAX Facility

Gavi administering the COVAX Facility is not exempt from risks including:

- Impact on core business (ringfencing, resourcing)
- Challenges of multi stakeholder coordination/governance
- Challenges of engaging with HICs/UMICs on their own behalf as opposed to with respect to ODA
- Reputational/liability/geopolitical/security risks that come with the raised profile of working with SARS-Cov-2 vaccines at a time of unprecedented rumours/antivaccine sentiment/heightened political concerns/nationalism
- Impact on core business (ringfencing, resourcing)
- Risks associated with the allocation methodology
- Risks associated with Gavi being engaged in an innovative finance mechanism in relation with COVID-19 vaccines (supply shortages, regulatory issues, oversupply and liability guarantees, default by Participants on commitments etc).

However, should Gavi administer the COVAX Facility these risks can be managed by framing Gavi's engagement in the COVAX Facility within the principles defined in this Paper, through legal contracts and bank guarantees for certain financial risk and through the establishment of a dedicated risk management framework.

3. Risks of Gavi administering the COVAX AMC and the COVAX Facility

The main reputational risks identified as a result of Gavi administering the COVAX AMC and COVAX Facility include the following:

- As a result of administering the COVAX AMC, Gavi is engaging significant donor resources on a programme that has not gone through standard assessment processes. Recognising that Gavi is currently acting in the context of an ongoing pandemic and acts in a space where vaccine nationalism can jeopardise the access to COVID-19 vaccines by lower income economies, it is acknowledged that time is of the essence and that the standard due diligence process cannot be completed in parallel to the current effort to design the COVAX Facility and COVAX AMC. At the May Board Teleconference, this was discussed, and the initial set-up of the ACT-Accelerator vaccine pillar was delegated to the Chair of the Board and Gavi CEO given the need for speed. In its most recent Vaccine Investment Strategy (VIS) process, the Gavi Board approved a new assessment framework specifically for investments in epidemic preparedness and response, noting that investment decisions could be taken outside of the standard VIS process given the unique nature of epidemic diseases and the development process for related vaccines.
- The framework sets out four high level criteria against which investments should be assessed: disease risk and burden; vaccine impact and feasibility; fit for Gavi and partners; and financial implications. While a formal assessment against this epidemic's assessment framework has not been conducted, COVID-19 vaccines are agreed to address significant disease risk and burden and as noted above, there is a strong fit for Gavi and partners to administer the Facility. Vaccine impact and feasibility would be a condition for future procurement as part of the contingent volume guarantees. The Secretariat is also mitigating this risk by ensuring regular engagement with key stakeholders including nearly daily touchpoints with ACT Accelerator stakeholders convened through the vaccine pillar, and close consultation with technical partners, potential participants to the Facility, industry, CSOs and other stakeholders in the design and implementation of the COVAX Facility. The Gavi Board Chair is also co-chairing the pillar coordination mechanism.

Additional risks include the following:

- Risk that a successful vaccine does not materialise through the Facility or one that is ineffective in certain populations. This is mitigated by active portfolio management, recognising that this can not be mitigated to zero.
- The risks of over contracting; this can be mitigated with careful portfolio planning and insuring against
- Risks that manufacturers refuse to ship to economies that have not adopted immunity schemes due to liability issues; there is a working group, comprising representatives of Gavi, WHO, CEPI, UNICEF looking at this issue; and