

Annex C: COVAX Risk Report

The COVAX Facility's mission of securing equitable access to COVID-19 vaccines continues to require navigating uncharted territory at unprecedented speed and scale, which naturally comes with risk. The COVAX Facility acknowledges that many risks are worth taking, given that inaction would leave many countries behind, and the global economy and Gavi's core mission would continue to be disrupted by the pandemic. Anticipating what might happen and proactive management of these potential risks helps the COVAX Facility to manage expectations, reduce vulnerabilities, and secure success.

Gavi's last Risk & Assurance Report included a high-level assessment of the risks associated with the COVAX Facility¹. Building on this initial assessment, the Office of the COVAX Facility has created and maintains a central COVAX Facility-wide risk register, bringing together all top risks across the COVAX Facility, from deal-making to allocation and delivery. This serves to clarify risk ownership, stay abreast of new risks, track mitigation actions, and inform decisions, prioritisation and management attention. Since the COVAX risk landscape is very dynamic, it is continuously updated and aligned with other risk-related information sources, e.g. in the Country Readiness and Delivery (CRD) workstream of the COVAX Pillar and the COVAX Pillar Strategic Coordination Office.

Now that the Facility has moved towards shipping actual vaccines to countries, risk exposures have also shifted towards supply, allocation and delivery risks in-country. The COVAX Facility continues to operate in a dynamic, competitive and challenging external environment, continues to develop new initiatives such as dose-sharing, cost-sharing and the humanitarian buffer, and awaits a large scale-up of activities and transactions towards the end of the year after the current smaller first wave of vaccine allocations and shipments. The emergence of new virus variants and safety signals for some vaccines has also created further uncertainty both for supply and allocation/uptake, with the potential for refusals due to product preferences and vaccine confidence potentially being affected in country populations due to (perceived) safety concerns. Finally, the development of the 2022 strategy and future country participation model for the COVAX Facility have the potential to reduce some inherent risks, but may also bring new risks.

COVAX Facility-wide top risks

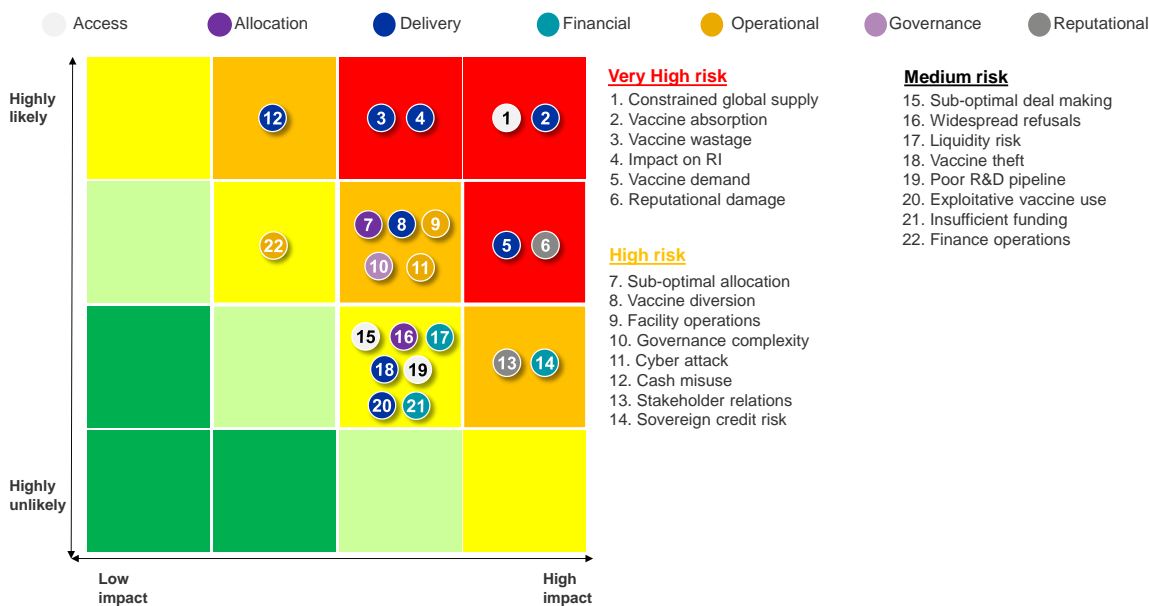
The heatmap below depicts the most critical risks that could potentially have an impact on the ability of the COVAX Facility to achieve its mission and goals.

The 6 top risks rated **very high** are:

1) Constrained global supply (access) – The risk of significantly reduced supply following signature of Advance Purchase Agreements (APAs) has already materialised and remains a very high risk going forward. While the current supply constraints are mainly caused by manufacturer production issues and export controls,

¹ See Section 3 of the report: <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2020>

Risk mapping: COVAX risks ranked by likelihood and impact



they could also happen due to lack of ingredients (e.g. adjuvants, glass vials, filters), overwhelmed validation/testing labs, logistical bottlenecks, contract defaults, regulatory delays, or newly discovered safety or efficacy issues post approval. This risk is being mitigated by entering into agreements with options for volumes in excess of the targeted demand, geographical and manufacturer portfolio diversification, advocacy against export controls, early engagement of suppliers (with CEPI) on supply chain challenges, and dose-sharing by countries with excess supply to compensate for shortfalls.

2) Vaccine absorption (delivery) – The risk that AMC countries cannot absorb supply leading to idle doses is very high and may become more prominent during the expected supply surge towards the end of the year (with countries facing an estimated five times the normal throughput of vaccine volumes per month). Idle doses represent an opportunity cost globally and could lead to wastage if these doses expire. Insufficient absorption can happen due to poor planning or weak (management, service delivery or cold chain) capacity, including insufficiently adapted delivery strategies to vaccinate COVID-19 specific target groups. Implementation or strengthening of these critical delivery systems risks being held back by delayed access to operational funding, delivery funding gaps, or inadequate coordination of different sources of delivery funding support. It may also be caused by a lack of coordination across bilateral and COVAX deals, and a lack of established relationships in countries that don't receive traditional Gavi support. This risk is being mitigated by country-readiness reviews (“NDVPs”) led by WHO Regional review committees to ensure countries have articulated plans on delivery strategy, vaccine monitoring, supply chain management, and budgeting. As vaccines continue to be shipped and rolled-out, country preparedness and implementation are now being monitored through a cross-Alliance implementation monitoring review under the Country Readiness and Delivery workstream. This rolling review on a weekly basis brings together real-time quantitative and qualitative data to identify and mitigate delivery issues across core areas such as absorption rates and uptake, cold chain, safety and operational funding. WHO also provides technical guidance to countries on vaccine

distribution and supports national planning and preparation. Standard timelines to install and expand cold chain equipment are being accelerated, including upfront delivery/cold chain investments at risk (due to unknown vaccine characteristics). Gavi has also mobilised US\$ 775 million to take a more proactive role in COVID-19 vaccine delivery funding while ensuring strong collaboration with multilateral banks and other funders to ensure a complementary funding landscape. It is proposed to allow for an accelerated at-risk disbursement process without requiring independent review given the emergency context and urgent country needs.

3) Vaccine wastage (delivery) – The risk that doses are being wasted in AMC countries due to expiry, poor handling, temperature excursions or force majeure events is very high and may become more prominent during the expected supply surge towards the end of the year. Large amounts will be flowing through the system with a short shelf life and there are ultra cold chain requirements for some vaccines. There are already increased signs of wastage from expiry management in several countries. This risk is being mitigated by having integrated COVID-19 vaccines into regular stock management and monitoring systems (eLMIS), technical assistance through Alliance Partners to support vaccine management, and a COVAX CCE platform to strengthen supply chains with 57 countries having applied for COVAX CCE. There are also enhanced monitoring solutions in development, through contracting Monitoring Agents in-country and funding CSOs to monitor COVAX implementation. It is also being explored whether insurance can cover some aspects of wastage.

4) Impact on RI (delivery) – The risk that the roll-out of COVID-19 vaccines may have an adverse impact on routine immunisation programmes or that opportunities for synergies are being missed is very high and may become more prominent during the expected supply surge towards the end of the year. COVID-19 vaccine delivery may divert focus and capacity (across countries, partners and Secretariat) from routine immunisation, use RI resources such as syringes, and potential COVID-19 vaccine safety events may have a broader impact on routine vaccine confidence. If deployed carefully and deliberately, the timely provision of dedicated COVID-19 delivery support can help in mitigating this risk and at the same time be used to exploit synergies and leverage momentum of COVID-19 vaccine delivery to contribute to Gavi 5.0 goals and routine immunisation (e.g. establishing life course platforms, demand generation, zero-dose identification).

5) Vaccine demand (delivery) – The risk that vaccine demand in AMC countries drops or remains low due to vaccine hesitancy and safety or efficacy concerns is very high and may become more prominent during the expected supply surge towards the end of the year. Vaccine hesitancy can increase or persist due to misinformation, a perception of rushed vaccine development, substandard other COVID-19 vaccines, counterfeit vaccines, or a lack of product choice. Uptake can also be affected by an increased incidence of serious adverse events (SAEs) or evolving evidence on safety and efficacy (e.g. in light of variants) restricting appropriate use. This risk is being mitigated by demand generation and building community trust. Alliance partners and CSOs provide information and advice to challenge misinformation, advocate for vaccine benefits, and engage communities. There is a global assessment of safety of COVID-19 vaccines by WHO PQ and the Global Advisory Committee on Vaccine safety, as well as active surveillance for adverse events following immunisation.

Moreover, the No Fault Compensation (NFC) scheme makes compensation available to eligible individuals in AMC countries for rare but serious adverse events associated with COVAX-distributed vaccines without the need to resort to law courts. Furthermore, a COVID-19 Vaccine Verification SteerCo (UNICEF, WB, USAID, Gavi, BMGF, GF) is launching a vaccine traceability solution to mitigate the risk of counterfeit vaccines infiltrating the supply chain.

6) Reputational damage (*reputational*) – The risk of reputational damage for the COVAX Facility is very high. Its high-profile nature, the high expectations and the global participation make the Facility and Gavi vulnerable to reputational backlashes, e.g. in case of failures in execution or crystallisation of some of the risks described in this report, serious adverse events following immunisation, (geo)political tensions around IP and perceived vaccine diplomacy regarding dose sharing, and anti-vaccine sentiment. This risk is being mitigated by a proactive media and communications strategy that does not downplay the challenge of ending the pandemic or overstate the role of vaccines, but supports the achievements of COVAX. New champions are recruited to tell the COVAX story, and country stories are developed for digital media to capture the progress COVAX is making away from the public eye.

The 8 top risks rated **high** are:

7) Sub-optimal allocation (*allocation*) – The risk that allocation of vaccines is (perceived as) sub-optimal is high as the allocation framework may become unaligned with the evolution of the pandemic and in-country realities, while the allocation mechanism is optimised to achieve increases in vaccine coverage levels equally across all participants, and not to target specific emergency situations. Lack of country readiness and poor absorption as well as earmarked dose-sharing or the perception of dose-dumping of lesser vaccines by HICs may result in (the perception of) an uneven roll-out across countries. This risk is being mitigated using redistribution and reallocation to ensure optimal use of vaccines, and by exploring adjustments to the allocation framework design to take into account criteria that could include total population coverage data, absorptive capacity and epidemiological considerations. Regarding dose-sharing, there are guardrails on earmarking of shared doses with only broad earmarking being encouraged and a scorecard to evaluate incoming offers including political risks and transaction costs. To combat the perception of dose-dumping, real-time sharing of doses that donors already use and donations of a variety of vaccines are being encouraged.

8) Vaccine diversion (*delivery*) – The risk of failing to reach target populations in AMC countries and diversion to other populations in-country is high, given COVID-19 vaccines are scarce commodities in high demand. This risk is being mitigated by having SAGE guidelines on vaccine target populations and countries having committed to target groups through their vaccine request forms. The terms and conditions in participant contracts frame parameters of Gavi support and include the requirement of reimbursement for any misuse determined. Suspicions can be shared through the whistle-blower hotline, and enhanced monitoring solutions are in development, through contracting Monitoring Agents in-country and funding CSOs to monitor COVAX implementation.

9) Facility operations (operational) – The risk of operational errors, miscoordination and miscommunication in the COVAX Facility is high given that it is a large, unique and structurally complex undertaking requiring new processes, capacities and capabilities, and running at an extremely fast pace. This risk is being mitigated by hiring additional and dedicated resources (with 71 out of up to 106.5 staff and consultant positions recruited), careful onboarding of new staff and consultants, an end-to-end operations plan, workplanning, documentation of priority processes in SOPs and development of IT tools.

10) Governance complexity (governance) – The risk that heavy transaction costs may result from complex governance arrangements and multi-stakeholder demands is high, due to the many new governance bodies and constituencies, potential confusion over roles, accountabilities and where decisions are made, and potentially unclear connections and accountabilities across Pillar institutions. There are also fewer informal opportunities between constituencies in the virtual working environment to align views. This risk is being mitigated by the agreed governance structure with representation of all stakeholders, Board induction and regular engagement to clarify governance arrangements including which meetings are formal (for decisions) and which informal (for communication) with lighter transaction costs. There are conflict resolution processes in place to promote consensus decision-making, and timely provision of Board material is being prioritised to ensure constituencies can align upfront.

11) Cyber attack (operational) – The risk of a cyber-attack on the COVAX Facility is high given the increased profile of COVAX and a general increase in cyber-attacks on COVID-19 vaccine related players. This risk is being mitigated by increasing user awareness (e.g. through training and fake phishing campaigns), increased defense (e.g. through server patching, quarantined e-mails and blocked DNS requests), early detection of malware and account compromise, incident response and recovery playbooks, threat intelligence (including an ongoing security forum with WHO, UNICEF and CEPI) and regular assessments and vulnerability testing.

12) Cash misuse (delivery) – The risk of misuse of financial support intended for rollout of COVID-19 vaccines is high. While Gavi had previously planned to provide additional support for COVID-19 delivery only in exceptional circumstances in recognition of the anticipated significant resources available from multilateral development banks and donors for vaccine delivery, due to country needs, Gavi has now mobilised US\$ 775 million for this purpose. Given the emergency context and urgent country needs, it is proposed that up to 30% of these funds can be disbursed rapidly at-risk without requiring ex-ante review from the Independent Review Committee. While therefore some risk needs to be accepted, this risk is being mitigated by clear guidance on items that can be funded, limited high level review of the budgets from the Secretariat, expanded use of Monitoring Agents, regular audits and support to strengthen financial management and fiduciary risk assurance. The terms and conditions in participant contracts frame the parameters of Gavi support, including reimbursement for misuse.

13) Stakeholder relations (reputational) – The risk of damaged stakeholder relations is high due to varying interests of many stakeholders, a high need for information sharing, and frustration at the current slow pace of shipments. This risk is being

mitigated by the establishment of a country communications team for more effective and timely country communications, and a country communications liaison group with WHO, PAHO, UNICEF, CEPI for better coordination across partners on aligned communications and briefings. Systems are in place to facilitate information sharing and there is active engagement by focal points with governments on concerns, as well as monthly briefings on delivery and supply communications. There is extensive work with CSO focal points to include them in as many new workstreams as possible and establish open communication channels. There is also a tailored governance mechanism with regular, formal participants meetings as well as informal consultations and briefings, and active engagement with Shareholders Council and AMC Engagement Group Co-chairs.

14) Sovereign credit risk (*financial*) – The risk that SFP countries default (being unable to pay) or breach contractual commitments (being unwilling to pay), exposing Gavi's balance sheet to financial risk as it has outstanding commitments with manufacturers, is still high while mitigation is being implemented actively with the help of financial advisors. Mitigation includes a decision-making framework and dashboard to optimise the choice of mitigation solutions (such as insurance policies) vis-à-vis particular participant country exposures, and the actual negotiation of insurance coverage with insurance providers (anticipated to be finalised in July). The new country participation model as part of the 2022 strategy may also further reduce inherent financial risks if it is decided to include less SFPs and to include revised terms and conditions relying more on upfront payments.