

## DOCUMENT ADMINISTRATION

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## Introduction

Every organisation needs to take risk to achieve its objectives and sometimes the greatest risk is inaction. Clarity on risk appetite – the amount of risk an organisation is willing to take, accept, or tolerate to achieve its goals – is needed to limit excessive and unrewarded risk-taking as well as undue risk aversion which can impede progress and success. Effective risk management seeks to optimise potential outcomes by balancing risk versus reward and weighing the costs and potential benefits of risk mitigation. Gavi's Risk Appetite Statement defines on a broad level the criteria and trade-off considerations that guide the Alliance's appetite for risk at the mission, strategy and organisational level.

Having a high appetite for a risk represents a willingness to be exposed to the possibility of an uncertain event occurring in the future, e.g. because the downside of the risk, if it were to materialise, is manageable or acceptable in light of the rewards being pursued; because exposure to the risk is required to achieve Gavi's mission; or because the costs of mitigation or trade-offs with other risks are deemed too high. A high risk appetite does not mean that actual occurrence of the risk is desirable or the event should be tolerated should it occur. It also does not mean that managing and monitoring of a risk is no longer needed. The Alliance is in general accepting to face risks that are required to achieve its goals, and it is able to do so by relying on robust risk management to ensure these risks stay within the Board-approved risk appetite.

The purpose of this Board-approved statement is to align stakeholders across the Alliance and guide decision-makers in taking the right amount of the right type of risks to deliver on Gavi's mission. It aims to encourage staff and stakeholders to be risk-aware and to feel comfortable to take agreed and calculated risks where appropriate, to recognise uncertainty and plan for the possibility of failure, and to learn from both positive and negative results.

## Risk appetite at the mission level

The Gavi Alliance **embraces the need to take risk to achieve its ambitious mission** of leaving no-one behind with immunisation in the world's poorest countries. It acknowledges the risks inherent in its distributed **operating model**, being an Alliance with a lean Secretariat without in-country presence and dependent on many partners. It also acknowledges the risks inherent in its **business model**, which requires working through still developing country systems and providing highly catalytic support to implementing countries to ensure country ownership and sustainability.

The Alliance also acknowledges that it needs to operate in a highly uncertain and volatile external environment, especially against the backdrop of the ongoing **COVID-19 pandemic**. This comes with increased levels of risk, while also hampering risk mitigation and assurance due to COVID-19 related restrictions and affected capacities. The Alliance therefore acknowledges that, during the duration of the crisis, risks may increasingly materialise despite best efforts to mitigate them. The Alliance is also willing to take a high level of risk where it is needed to respond flexibly and quickly to evolving needs, recognising that Gavi's support to maintain, restore and strengthen immunisation services is needed now more than ever due to the impact of the pandemic on routine immunisation programmes.

The Alliance equally acknowledges that its mission of **securing equitable access to COVID-19 vaccines** through the administration of the COVAX Facility requires navigating

uncharted territory at unprecedented speed and scale. It is understood that operating at this magnitude and speed carries risks, and that these risks are worth taking in an effort to end the acute phase of the pandemic, as inaction would leave lower income countries behind and the global economy and Gavi's core mission would continue to be disrupted by the pandemic. The Alliance therefore seeks to find the right balance between successfully delivering on the promise of the Facility and minimising risks to Gavi core resources and programmes.

### Risk appetite at the strategy level

The Alliance acknowledges that the [Gavi 5.0 strategy](#) is inherently more risky as it represents a very aspirational ambition requiring more and novel support to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments. It therefore adopts an **overall high risk appetite** to achieve its strategic goals.

### Strategic goals

#### The vaccine goal: introduce and scale up vaccines

- The Alliance has in general a high appetite for **risks required to introduce and scale up coverage** of immunisation, especially in the most fragile countries where vaccines can have the highest impact on child mortality, or in emergency situations (e.g. disease outbreaks and conflicts). However, **vaccine introduction decisions** should not risk exacerbating inequities by reaching already covered children with new vaccines while continuing to miss zero-dose children. Introduction and scale-up should also not put the sustainability of routine immunisation programmes at risk, particularly as countries come closer to transitioning out of Gavi support.
- The Alliance has in general a low appetite for the risk of preventive **immunisation campaigns** undermining the capacity to manage and deliver long-term sustainable routine health and immunisation services and bring zero-dose children into the routine health system. It also has in general a low appetite for the risk of such supplementary campaigns being of low quality due to sub-optimal planning and implementation. However, the Alliance may need to assume a higher level of risk in the case of fragile settings where routine immunisation coverage is very low and unlikely to improve in the shorter term, and in emergency situations where immunity gaps need to be closed rapidly to prevent imminent disease outbreaks.
- The Alliance aims to reduce the risk of **vaccine-preventable disease outbreaks** through enhanced routine vaccine support for outbreak-prone diseases, funding of global stockpiles for outbreak response and investments in disease surveillance. It however accepts that disease outbreaks will continue to occur since fully addressing the significant gaps in health systems and preparedness and response capacities require engagement beyond its current mission and resources. It furthermore acknowledges that reducing reliance on frequent and disruptive planned campaigns (as described above) may require a higher acceptance of the risk of outbreaks in the short-term.
- The Alliance has in general a high appetite for risks required to pursue **equitable allocation and timely delivery of COVID-19 vaccines** to AMC countries, given the emergency needs during the pandemic. It acknowledges that COVID-19 vaccines have a heightened risk profile compared to routine childhood vaccines as these are new products with different target groups, have specific cold chain and shelf-life characteristics, and are subject to competition, high expectations and politicisation due to the supply-constraint environment. It uses best efforts to mitigate country readiness and roll-out risks in-country, but acknowledges that high levels of residual risk will likely remain and may require ad-hoc reactive responses.

**The equity goal: strengthen health systems to increase equity in immunisation**

- The Alliance has in general a high appetite for **risks required to strengthen health systems and increase equity** in immunisation by extending immunisation services to regularly reach under-immunised and zero-dose children, since this is essential for achieving the mission of leaving no-one behind with immunisation. It recognises that improving equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations. The Alliance therefore has a high appetite for risks associated with **working with new partners**, including local organisations and CSOs, which have critical context-specific expertise and the ability to reach zero-dose children in humanitarian and conflict areas outside government reach. To achieve its zero-dose aspirations, the Alliance has to be ambitious and explore **innovative strategies** to strengthen health systems and immunisation programmes. It therefore acknowledges that health systems and immunisation investments may not always improve outcomes as long as there is robust design, implementation and oversight of grants.
- The Alliance is willing to face risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries). It acknowledges that building **management capacity in-country** takes a long time to take effect and sustainable mitigation depends on many factors outside of Gavi's control, such as government ownership, broader efforts across the health sector, turnover of staff, and external disruption such as conflict, natural disasters and disease outbreaks. It however has a lower appetite for risks to aspects of country management capacity that are critical to maintain, restore and strengthen immunisation programmes and reach zero-dose communities, and where the Alliance has a comparative advantage over other actors to make a real difference with targeted, scalable and sustainable interventions.
- The Alliance is willing to face risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries). It acknowledges that improving **data availability, quality and use** in-country is not fully within Gavi's control and would likely remain a challenge for a long time. It however has a lower appetite for risks to critical types of data that if poor or lacking will affect the ability to find and target zero-dose children, implement effective interventions, understand progress and demonstrate impact; and which are addressable within Gavi's sphere of influence.
- The Alliance has in general a low appetite for the risk of **deliberate fraudulent misuse** occurring, or for any form of misuse occurring at scale. However, inherent risks are heightened in the current pandemic context and the ability to mitigate and obtain assurance is constrained. The Alliance therefore acknowledges that, during the duration of the crisis, risks may increasingly materialise despite best efforts to mitigate them. The Alliance is also willing to take risk where this is needed to respond flexibly and quickly to evolving needs, recognising that Gavi support to maintain, restore and strengthen immunisation services is needed more than ever due to the impact of the pandemic on routine immunisation programmes. Risks furthermore need to be balanced when reaching zero-dose children requires working more subnationally and in challenging operating environments with very weak financial management capacity; and when building sustainable country capacity and ownership requires channelling support through government systems. Accepting to be exposed to fiduciary risk does not mean actual occurrence is desirable or it should be tolerated should it occur. In case of actual misuse, Gavi will always require reimbursement as a condition of continued support.
- The Alliance has a low appetite for the risk of a significant drop or insufficient increase in **demand and public confidence** in vaccines in implementing countries, including

due to vaccine hesitancy and gender-related barriers, as this is critical for achieving the equity agenda and reaching missed communities. The Alliance also has a low appetite for health systems posing risks to **vaccine and immunisation safety**.

- The Alliance aims to reduce the risk that **COVID-19 vaccine roll-out adversely affects routine immunisation** programmes and capacities, as well as for risks of **missed opportunities to exploit synergies** and leverage momentum from the COVID-19 vaccine rollout for routine immunisation programmes and Gavi 5.0 objectives (e.g. establishing life course platforms, demand generation, zero-dose identification). It however recognises the dual burden on countries and systems and the need to balance this with an urgent roll-out of COVID-19 vaccine in a global pandemic.

### The sustainability goal: improve sustainability of immunisation programmes

- The Alliance has a low appetite for the risk that national and subnational **political will and social commitment** of communities for immunisation will drop or insufficiently increase. It seeks to ensure that the value of vaccines is well recognised in Gavi recipient countries and that immunisation remains a priority at all levels, while balancing reputational risks in politically sensitive settings.
- The Alliance has a low appetite for the risk of countries **defaulting on their co-financing obligations**, unless this is justified by exceptional circumstances as determined by the Alliance Board.
- The Alliance has in general a low appetite for the risk of many countries reaching the point of **transitioning out of Gavi support** without having built sufficient financial and programmatic capacity to sustain their programmes. Short-term efforts to increase coverage and equity (e.g. without bringing missed communities into the routine health system or without establishing lasting contact points for life-course vaccines), to complement lacking country capacity and to mitigate fiduciary risk need to be undertaken mindful of the longer-term need to build sustainable country capacity, particularly as countries come closer to transitioning out of Gavi support. The Alliance however recognises that it cannot completely guarantee that every country is ready to transition, despite its best efforts, and to avoid the risk of moral hazard. It is therefore willing to consider tailored approaches to support countries who are at high risk of not being ready for transition and have strong political commitment to immunisation, but it is also willing to consider a few countries failing where this is not the case (and therefore accepts that a limited number of countries may not transition successfully).
- The Alliance aims to reduce the risk of a significant reduction in immunisation programme **performance post-transition**. The Alliance actively prepares countries to be ready for transition and continues to engage after transition, but recognises that it will have less ability to fully mitigate performance stagnating or declining once it stops financing a country's programme.

### The healthy markets goal: ensure healthy markets for vaccines and related products

- The Alliance has a high appetite for **risks required to transform markets** for vaccines and other immunisation products in order to create and sustain healthy markets. It is willing to undertake bold steps to fundamentally and sustainably change market dynamics.
- The Alliance takes a balanced approach to the risk of **supply shortages** and aims to ensure sufficient and uninterrupted supply of vaccines, especially if this may impact existing programmes. It however also acknowledges that demand and supply are inherently volatile and future supply security is dependent on assumptions of supplier production capacity scale-ups and new market entrants that introduce sufficient buffer capacity and supplier diversity into the markets. Furthermore, mitigation is constrained



by limitations in the degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges.

- The Alliance takes a balanced approach to risks required to incentivise **innovation** for the development of suitable vaccines and scaling up innovative immunisation-related products. It accepts that being successful in innovation requires an amount of risk commensurate with the potential impact being sought under conditions of uncertainty and allowing for failure. It aims to spread risk across a balanced portfolio with a higher focus on scaling proven innovations. It seeks to reduce risks related to the inability to scale up and sustain innovations in country, as well as risks related to private sector partnerships, e.g. conflicts of interest and reputational risks.
- The Alliance takes a balanced approach to risks required for **securing access to and sufficient supply of safe and efficacious COVID-19 vaccines**. It aims to reduce the risk that deal-making delays put the Facility at the back of the queue with manufacturers, but acknowledges that it has no control over competition from bilateral deals and that it needs to minimise financial risk to Gavi's balance sheet. It understands that an actively managed portfolio of vaccine candidates based upon diverse technologies and geographies will maximise the chance of successful outcomes and accepts that some candidates in the portfolio may fail or represent less value for money than others.

### Risk appetite at the organisational level

The Alliance has **overall a lower appetite for operational risks** that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners. It seeks to maintain a low level of risk related to the quality and robustness of Secretariat **processes, facilities and business continuity**, as well as related to critical information **systems or data** being compromised, since these are critical to coordinate the Alliance. It furthermore has a low appetite for risks related to **staff health and safety, engagement and capacity**, including zero tolerance for sexual exploitation and abuse or other forms of harassment and exclusion in the workplace, e.g. based on race, gender or sexual orientation.

The Alliance seeks to reduce risks related to the **capacity and performance of Alliance partners**. As such, it is aiming to engage with a wider set of partners, including local organisations and CSOs, and to collaborate with other health actors to strengthen primary health care and multisectoral approaches. This broader engagement requires a constant trade-off with the **increased complexity of managing many partners** at country level. The Alliance also aims to reduce risks related to **grant performance in-country** through differentiated grant monitoring and oversight. It however recognises the challenges of weak capacity and systems in many countries, as well as the need to ensure that the reporting burden on countries is manageable and harmonised with other donor requirements where possible. The Alliance has a low appetite for risks which could undermine **accountability and transparency** within and between the Secretariat, Alliance partners and implementing countries.

Since Gavi's **reputation** is critical to its ability to deliver on the mission, the Alliance has in general a low appetite for risks affecting its image and confidence of its stakeholders, including its governance bodies, but is also accepting that in administering the COVAX Facility it needs to assume new levels of reputational risk. The Alliance has a low appetite for the risk that immunisation becomes a lower priority on the global policy agendas. The Alliance equally has a low appetite for risks affecting the sustainability of **donor funding** in order to safeguard predictable financing of vaccines, as this is crucial to sustaining Gavi's existing programmes and the Alliance's ability to fund new vaccines. It is willing to take risk where this is required for attracting new donors to broaden its donor base. The

Alliance in general has a low appetite for **risks affecting its finances** and seeks to maintain low levels of accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk. The Alliance has a higher appetite for the risk of financial forecasts being on the higher edge of the plausible range – to ensure availability of sufficient supply and funding. There is a lower appetite for the risk that such variability might reduce manufacturer or donor confidence.

# Gavi's Risk Appetite Statement

## The amount of risk the Alliance is willing to take, accept, or tolerate to achieve its goals

The Alliance is accepting to face risks required to achieve its goals, enabled by robust risk management to ensure these stay within the Board-approved risk appetite

Mission	<ul style="list-style-type: none"> <li>The Alliance <b>embraces the need to take risk</b> to achieve its ambitious mission of leaving no-one behind with immunisation in the world's poorest countries</li> <li>It acknowledges risks inherent in its <b>operating model</b> relying on many partners and in its <b>business model</b> requiring country ownership</li> <li>It acknowledges that during the <b>COVID-19 crisis</b> risks may increasingly materialise, and is willing to take risk needed to respond flexibly and timely to special needs</li> <li>It understands that operating the <b>COVAX Facility</b> carries risks worth taking, and seeks to find the right balance to minimise risks to core resources and programmes</li> </ul>			
Strategic Goals	<p>The Alliance adopts an <b>overall high risk appetite to achieve its strategic goals</b>, acknowledging the aspirational ambition of the Gavi 5.0 strategy, requiring more and novel support to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments</p>			
	<p><b>1</b> <b>INTRODUCE AND SCALE UP VACCINES</b></p> <p><b>High</b></p> <ul style="list-style-type: none"> <li>Risks required to introduce and scale up coverage in fragile/emergency settings</li> <li>Risks required for equitable allocation and timely delivery of COVID-19 vaccines</li> </ul> <p><b>Balanced</b></p> <ul style="list-style-type: none"> <li>Vaccine-preventable disease outbreaks</li> </ul> <p><b>Low</b></p> <ul style="list-style-type: none"> <li>Vaccine introduction decisions exacerbating inequities or affecting sustainability</li> <li>Campaigns undermining routine immunisation or being of low quality</li> </ul>	<p><b>2</b> <b>STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION</b></p> <p><b>High</b></p> <ul style="list-style-type: none"> <li>Risks required to strengthen health systems and increase equity</li> <li>Risks of working with new partners</li> <li>Risks of exploring innovative strategies</li> </ul> <p><b>Balanced</b></p> <ul style="list-style-type: none"> <li>Building immunisation-critical management capacity in-country</li> <li>Improving data quality to find and target zero-dose children</li> <li>COVID19 roll-out adversely affecting routine immunisation or missed opportunities for synergies</li> </ul> <p><b>Low</b></p> <ul style="list-style-type: none"> <li>Fraudulent misuse of Gavi support</li> <li>Drop or insufficient increase in vaccine demand and confidence</li> <li>Weak systems jeopardising vaccine and immunisation safety</li> </ul>	<p><b>3</b> <b>IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES</b></p> <p><b>Balanced</b></p> <ul style="list-style-type: none"> <li>Countries transitioning without sufficient financial and programmatic capacity</li> <li>Significant reduction in performance post-transition</li> </ul> <p><b>Low</b></p> <ul style="list-style-type: none"> <li>Drop in political will and social commitment for immunisation</li> <li>Countries defaulting on co-financing obligations</li> </ul>	<p><b>4</b> <b>ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS</b></p> <p><b>High</b></p> <ul style="list-style-type: none"> <li>Risks required to transform markets</li> <li>Risks required to incentivise innovation for vaccine development and scale up of related products</li> </ul> <p><b>Balanced</b></p> <ul style="list-style-type: none"> <li>Supply shortages impacting existing programmes</li> <li>Risks required for securing access to and sufficient supply of safe and efficacious COVID-19 vaccines</li> </ul>
Organisation	<p>The Alliance has <b>overall a lower appetite for organisational risks</b> that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners</p>			

### OPERATIONAL RISK

#### Low

- Quality and robustness of Secretariat processes, facilities and business continuity
- Critical information systems or data being compromised
- Risks related to staff health and safety, engagement and capacity, including harassment and exclusion

### PERFORMANCE RISK AND OVERSIGHT

#### Balanced

- Risks related to the capacity and performance of Alliance partners
- Risks related to the increasing complexity of managing many partners at country level
- Risks related to grant performance in-country

#### Low

- Risks undermining accountability and transparency

### REPUTATIONAL, FUNDING AND FINANCIAL RISK

#### High

- Risks required for attracting new donors

#### Balanced

- Risks affecting Gavi's image and confidence of its stakeholders

#### Low

- Immunisation becoming a lower priority on policy agendas
- Risks affecting the sustainability of donor funding
- Risks affecting Gavi's finances (accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk)
- Forecasting variability reducing manufacturer or donor confidence