

**SUBJECT: RISK MANAGEMENT UPDATE**

**Agenda item: 05**

**Category: For Guidance**

### **Section A: Summary**

- This paper provides a high-level update on major changes in Gavi's risk profile since the Risk & Assurance Report was discussed by the Gavi Alliance Board at its December 2021 meeting, as well as an update on progress in strengthening risk management across the Alliance. This paper incorporates inputs from respective risk owners across the Secretariat and was reviewed by the Gavi Executive Office.

### **Section B: Risk Management update**

#### **1. Changes in Gavi's risk profile since December**

- 1.1 Gavi's last Risk & Assurance Report<sup>1</sup> prioritised 19 top risks and showed that Gavi's overall risk profile had remained stable with most top risks continuing to be elevated due to the current environment, Gavi's ambitious strategy and the mission of the COVAX Facility. Three risk exposures were deemed to be outside of Gavi's updated risk appetite for which intensive mitigation is ongoing.
- 1.2 As flagged in the December report, COVAX risks have now shifted from upstream procurement and supply to downstream delivery risks. This is not only due to the anticipated absorption challenges in COVAX Advance Market Commitment (AMC) countries, but also because the epidemiology has changed (from Delta to the milder Omicron variant). This results both in a reduced sense of urgency for uptake in AMC countries (due to a change in disease risk perception), as well as in a global oversupply situation (with High Income Countries (HICs) similarly experiencing decreased demand and having reached high coverage levels) and an urgency in donor countries to donate doses before expiry. The COVAX Facility is managing **risks of supply-demand mismatches and vaccine expiry** to the extent possible, using all levers within its power to optimise the use of all doses in global oversupply, but it is also expecting that these mismatches and expiries will happen nonetheless. This is in line with the level of risk the Board has accepted as necessary to take in order to fight the pandemic (which required upfront procurement at risk while demand was still unknown

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<sup>1</sup> See <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2021>

and continued to evolve with the pandemic)<sup>2</sup>. It is important to note that there is still a risk that a **next virus variant or a new wave** (e.g. due to waning immunity) reverses the current situation and would bring procurement and supply risks back to the fore. Gavi's risk awareness and robust risk management continues to put it in a good position to take, anticipate and mitigate these evolving risks and achieve balanced outcomes in this uncertain context (e.g., minimising waste while allowing a buffer for unexpected supply and demand shocks). But it does also include an ongoing acknowledgement that previously flagged **elevated inherent risks exist and continue to materialise**. Gavi will continue to transparently communicate on such risks and mitigate these to the extent possible, including through reactive mitigation actions when preventive actions are not possible.

- 1.3 The past disruption and ongoing uncertainty from COVID-19 is also putting at risk some of the **Alliance's targets for Gavi 5.0**, which may require baselines and ambitious 5.0 targets to be revisited after the WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) estimates are released in July (Gavi's Board-approved Risk Appetite Statement had already acknowledged that the ambitious 5.0 strategy would require a higher acceptance of risks). Besides COVID-19, the economic situation has also become more challenging, with **inflationary pressures continuing and rising interest rates** potentially leading to debt distress in Gavi-supported countries and risking a global recession. The **Russia-Ukraine crisis** is further exacerbating economic risks through rising food and energy prices, and poses additional regulatory (sanctions), reputational (geopolitical), supply, donor support and cyber risks. The crisis may also affect immunisation programmes in (former) Gavi-supported countries (including through COVAX and Middle Income Countries (MICs) approach) due to the refugee flows and potential resulting disease outbreaks, potential food insecurity, as well as distracted focus and capacity of countries and partners.
- 1.4 Overall risk exposures as defined in the last Risk & Assurance Report remain elevated. While there are no significant changes in overall risk levels, the beforementioned factors as well as new developments and actions taken have been captured for the following top risks:
- 1.5 **Country management capacity** – The risk that many countries may have insufficient Expanded Programme on Immunization (EPI) capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities remains elevated and outside of risk appetite. Countries continue to have difficulties managing competing priorities with COVID-19 vaccinations ramping up. This could be seen in Asian countries such as India or Pakistan where COVID-19 response including the rapid scale-up of COVID-19 vaccination contributed to a slowing down of routine immunisation (RI) services. African countries

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<sup>2</sup> See Gavi's Risk Appetite Statement for the Board-approved higher risk appetite <https://www.gavi.org/news/document-library/risk-appetite-statement>

witnessed a slower rollout of COVID-19 vaccination so far, but are still at risk of disruptions to RI going forward as COVID-19 vaccinations ramp up. Full Portfolio Planning (FPP) and Equity Accelerator Funding (EAF) applications have been delayed in many countries due to COVID-19, which may result in delays of key preparatory activities (e.g., zero-dose identification) for Gavi 5.0 outcomes. To manage this risk, in addition to Partners' Engagement Framework (PEF) Targeted Country Assistance (TCA), US\$ 58 million has been invested through COVAX TA in 2021 to provide surge capacity – including additional Leadership, Management & Coordination (LMC) capacity – dedicated to COVID-19 vaccine rollout and thereby limiting the disruption on routine work. There is also continued engagement of Ministries of Health to ensure sustained prioritisation of RI. Country dialogues and advocacy efforts focus on integrated planning for COVID-19 and RI (microplans, budget, and delivery strategies). There will also be an intense focus on FPP in 2022 with up to 22 countries applying, and a step-back exercise to review pain points in the process and how to accelerate and streamline. Furthermore, targeted additional support for zero-dose identification will be deployed.

- 1.6 **COVAX delivery** – The risk of significant COVID-19 delivery issues and impact on routine immunisation remains very high as the roll out of COVID-19 vaccine doses has scaled up (while human and cold chain capacity in-country remains limited) and a substantial volume are dose donations – which offer less flexibility to meet country preferences and may have shorter shelf lives. Together with potential displacement by non-COVAX supply, this increases the risk of countries refusing doses (there is already an upward trend of refusals) and poses a very high risk of above-country vaccine expiries if the Facility cannot find enough homes for increasing supply at hand. Demand by the population in-country is also affected by a changed risk perception due to the milder Omicron variant and vaccine hesitancy in some cases (there is currently a downward vaccination trend in 46 AMC participants), which could lead to in-country vaccine expiries and wastage. To mitigate this, the allocation mechanism is being adapted with a focus on using enhanced demand planning (based on vaccination plans and country coverage targets), and by combining dose sharing and APA supply sources. To further accelerate uptake of COVID-19 vaccines towards reaching national coverage targets and with a renewed focus on high-risk populations, COVID-19 Vaccine Delivery Support (CDS) needs-based funding requests have been approved (although oversubscription of CDS funds has required prioritisation and rationing of funds to countries), funds have been disbursed in a timely manner, and activities are being implemented. The Vaccine Delivery Partnership (VDP) helps to increase vaccination coverage by flagging lagging countries for deep dives to identify and resolve bottlenecks, by enhanced country level intelligence (especially needed to track coverage in high-risk populations and vaccine expiries and wastage), by supporting and monitoring country specific action plans with actionable next steps, owners and timelines, and by coordinating in country and across Alliance partners and other COVAX stakeholders (especially important to reduce transaction costs for countries). Furthermore, insights from monthly reports from Monitoring Agents are being used for course

correction. In order to further mitigate the impact on routine immunisation (RI), countries are being supported to do integrated planning of COVID-19 and RI.

- 1.7 **COVAX supply** – The risk of significantly reduced and unpredictable COVID-19 supply has reduced substantially given that most vaccines have been granted regulatory approval, most manufacturers have successfully scaled-up production, export restrictions have eased, and demand for vaccines in HICs has waned. Together with lower than expected vaccine candidate attrition and evolved demand due to the Omicron variant, this has led to a current global oversupply situation. However, the supply risk can quickly increase again in case of a resurgence of the pandemic (e.g., due to waning immunity) or the emergence of a new virus variant requiring COVAX to compete again for places in the queue with manufacturers. While uncertainties persist around future demand (e.g., potential new waves and variants; evolving coverage targets; and policy recommendations on boosters and paediatric doses) as well as future supply (e.g. level of non-COVAX supply and new dose donations; the effect of domestic manufacturing efforts; vaccine market developments and changes in manufacturer confidence; and access to next generation and new variant-adapted vaccines), the Facility is actively mitigating the current likely risk of having more supply than demand by rephasing and reducing Advance Purchase Agreement (APA) supply as well as encouraging donors to rephase their own excess supply to delay and reduce additional dose donations. Since APA doses are those within the Facility's control and the most direct lever to adjust supply, current efforts to mitigate risk and minimise wastage will make the Facility more dependent on dose sharing, making its portfolio more vulnerable to external supply and demand shocks. The Facility aims to hold an above country stock 'buffer' (currently 400-600m doses) to be able to respond to a pandemic upswing or variant of concern (knowing that these doses would be at risk of expiry if they were never needed) and may draw on the Pandemic Vaccine Pool for contingent funding in case of a shock.
- 1.8 **Secretariat disruption and COVAX Facility** – The risk of significant disruption of Secretariat operations and disruptions specific to the COVAX Facility functioning remains high with a high workload due to the COVID-19 delivery scale up, and with continued organisational changes due to optimisation and integration of COVAX and Gavi core processes. The Secretariat is also beginning to transition towards a new hybrid Way of Working with a new workspace and remote working guidelines, and despite ongoing dialogue and adoption of best practice, such a large change may carry risks around productivity, culture and staff engagement. Also, with the current Chief Executive Officer completing his term of appointment in 2023 and the Deputy CEO due to retire in the same year, the Secretariat may be exposed to disruption if the transition to new leadership does not go smoothly. Following a recent pulse survey on staff engagement, the Secretariat's Health & Wellbeing Committee is rolling out initiatives to better understand root causes (by engaging an external expert), to provide additional support to staff, and to prevent issues (i.e., burn-out, increasing

stress levels) with a focus on reducing stigma, health promotion, respectful behaviour and onboarding. While the COVAX Facility has effectively shifted its focus on operationalisation, with formalised processes, increased resourcing and a dedicated organisational structure, the design and strategy of the Facility needs to continue to adapt to the evolving pandemic and global strategy to remain fit for purpose, and may require further integration with Gavi core processes and routine immunisation programmes in the future. There is also an operational impact of the COVAX Pillar refresh, partnership realignment, and establishment of the COVID-19 Vaccination Delivery Support steering committee and Vaccine Delivery Partnership. The current uncertainty around the future of the pandemic and vaccination requirements, and resulting requirements for the operating model, combined with the ongoing high workload, poses risks to staff morale, recruitment and retention of high performing staff, and succession and knowledge management. With COVAX staff on temporary contracts (to retain necessary flexibility in the Secretariat) that end at the end of 2022, key personnel is already leaving due to the lack of security, with implications on Secretariat capacity to deliver and staff workloads.

- 1.9 **Sustainable transition and Unresolved co-financing default** – The risk that some countries may fail to sustain progress of their immunisation programmes after transition remains high despite the positive trend of successful transitions, post-transition support having been rolled-out and an increased focus on programmatic sustainability under Gavi 5.0. COVID-19 now combined with high inflation, interest rate rises, and economic uncertainty related to the Russia-Ukraine crisis, has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' transition trajectories, their fiscal space for domestic financing and risks of backsliding in already transitioned countries. Countries at greatest risk of backsliding have been identified and the first phase of implementing the Middle-Income Country's (MICs) Approach has started with a focus on mitigating backsliding in former-Gavi countries (with a defined theory of change and learning agenda) and building relationships with select never-Gavi-eligible countries via COVAX. Whilst all Gavi countries have recorded an increase in debt levels compared to pre-COVID-19, countries in the initial self-financing phase have recorded a ten-percentage point increase in debt to GDP ratio in only two years from 62% in 2019 to 72% in 2021 due to the economic impact of the pandemic. With public finances under stress, the share of public spending in GDP is expected to fall by 2026 in all Gavi-eligible countries and remain below pre COVID-19 levels in more than a quarter. Significant strain on countries' capacity to maintain co-financing is anticipated and at its recent April 2022 retreat, the Gavi Board agreed that it will be essential to continue to strongly advocate to protect domestic financing for health and immunisation, as well as to ensure global health agencies collaborate further to unlock efficiencies in health spending at country level. Gavi proactively engages in a dialogue with countries to assess the risk of countries not paying their co-financing, supports engagement with Ministries of Finance and partners, and advocates for alternative sources of funding through close collaboration with the World Bank (and is further exploring similar engagement with the

International Monetary Fund (IMF). Active monitoring of immunisation expenditures is critical, and requires that countries are able to report accurately on domestic expenditures for immunisation. The risk of faulty reporting is being mitigated by rolling out the standardised System of Health Accounts (SHA) methodology co-financed by the Global Fund and the Gates Foundation.

- 1.10 **VPD outbreaks and Polio disrupting immunisation** – The risk of sizeable outbreaks of vaccine-preventable diseases in some Gavi-supported countries remains high. This is in part due to disruptions in routine immunisation services arising from the pandemic resulting in missed children and delays in planned vaccination campaigns. With the easing of COVID-19-related restrictions the cumulative risk could be increasing further. In the case of Measles, by March WHO has already received 16 reports of outbreaks this year. The situation is also concerning for Yellow Fever, especially in West Africa where six emergency requests have been received in the last two quarters in response to confirmed outbreaks in the region. Close monitoring will continue to be needed as well as an assessment of the link between an outbreak occurrence and gaps in routine immunisation to better develop recovery plans that strengthen routine immunisation services and prevent future outbreaks. In addition, a revised TCA grant to support timely International Coordinating Group (ICG) on Vaccine Provision applications has been signed with WHO and root-cause analyses are being encouraged, especially when immunisation gaps are likely at the source of outbreaks. Whilst 2021 saw the lowest number of wild poliovirus (WPV) cases ever reported (six), Malawi reported a case of WPV in February, its first since 1992, linked to polio circulation last seen in Sindh province, Pakistan. A multi-country regional response to this outbreak has been effective so far with no additional cases detected. However, the threat remains that the virus may be circulating elsewhere undetected. In addition to WPV circulation, more than 500 cases of vaccine-derived poliovirus have been detected in the past 12 months across 17 African countries, Afghanistan, Pakistan, Ukraine, Yemen and Israel. Gavi and the Global Polio Eradication Initiative (GPEI) are working closely together in priority countries to ensure that resources and interventions to address these outbreaks are leveraged to also identify and reach zero-dose children and communities with multiple interventions through integrated immunisation activities.
- 1.11 **Global supply shortages** – The risk that shortages in global vaccine supply affect Gavi-supported countries remains high. 2021 saw risks of shortages linked to COVID-19 disruption, country demand volatility and manufacturers holding low buffer inventory. To avert country stock-outs and programme interruptions, partners successfully worked with countries and suppliers to accelerate country decisions on alternative products and to fragment shipment plans ensuring minimal impact on programme continuity. These supply shocks highlight the need for continuous review and improvement of Gavi processes to avoid bottlenecks in time-sensitive situations where country product switches are often the only immediate solution. For 2022 high risks of Rotavirus vaccine stockout are being flagged by Cameroun,

Kenya, Senegal, Sudan, Tanzania, Zambia and Zimbabwe due to supply constraints and forced product switches (the supplier of the most used rotavirus product has reduced its offer to Gavi-supported countries and is halting the production of its new presentation). This has caused significant supply pressures and at least ten countries have had to switch to different presentations. To reduce the risk of stock-outs, some countries are being offered an alternative presentation to bridge the gap for a few months. This interim solution however carries a high transaction cost as the healthcare workers will need to be trained twice due to a high risk of confusion between the two presentations. Despite fast decision making by most countries, and UNICEF Supply Division's efforts to ship smaller quantities across more countries, this sequence of disruptions has generated a very high risk of stockout. Furthermore, the Russia-Ukraine crisis has underlined the need to geographically diversify vaccine supply and stockpiles in order to be resilient against geopolitical and related supply shocks and potential sanctions being imposed on manufacturers. The Secretariat is taking actions to further diversify Yellow Fever supply (the only vaccine affected so far) over time while minimising the immediate impact on public health outcomes, and continues to monitor any dependencies and concentration risks in the portfolio. In the longer term, initiatives to increase regional and local manufacturing on the African continent may also contribute to better diversification and hence supply security. However, if not carefully planned, this could also serve to undermine some existing market-shaping efforts and create new risks of market distortions and price increases.

## **2. Risk Management update**

- 2.1 The Risk function continues to engage actively with the business to identify and frame new risks, maintain awareness of existing risks and ensure progress in mitigation. It is routinely participating in COVAX Facility Leadership and Delivery Leadership Team meetings to highlight risk aspects of discussion items, and to provide monthly reviews of the dynamically evolving COVAX risk profile. It is also working with the Finance team to review its Finance Risk and Control Matrix, which defines key internal controls in finance operations, and is a member of the standing Treasury risk committee. Through the Cybersecurity steering committee it engages regularly on IT risks.
- 2.2 The Risk function furthermore has been part of the Situation Response Team set up in the Secretariat following the Russia-Ukraine crisis, and prepared a cross-cutting review of associated impacts and risks to Gavi's programmes, supply, positioning, donor support, cyber security and staff. This was discussed in-depth in the Secretariat's Risk Committee (chaired by the CEO with senior leadership from across the organisation).
- 2.3 The Risk function has also been working with the Policy team to inform the risk and risk appetite aspects of the Fragility, Emergencies and Refugees (FER) policy; with the Secretariat's Health & Wellbeing Committee on clarifying people risk drivers and mitigation; and with the Country Programmes department and the Secretariat's Monitoring and Performance

Management (MPM) Task Force on defining common country programme risks and inclusion of risk indicators into a new programmatic monitoring tool. It also engages through regular meetings with the Global Fund, WHO and UNITAID on safeguarding risk, including through a public health collaboration workshop and a joint three-day safeguarding training.

### **Section C: Actions requested of the AFC**

This report is for information only.