SUBJECT:	**STRATEGY, PROGRAMMES AND PARTNERSHIPS: PROGRESS, RISKS AND CHALLENGES**
Agenda item:	03
Category:	For Guidance

Section A: Executive Summary

This is the second report to the Board on progress in implementing Gavi's 2021-2025 strategy and associated risks[1], and the first update reporting against the new Gavi 5.0 measurement framework. This report provides quantitative updates on a limited number of strategy indicators for which new data is available[2] as well as a more qualitative perspective of progress across the four Strategic Goals.

2021 was the first year of the new Gavi 5.0 strategic period and focused on preventing backsliding of routine immunisation in light of the COVID-19 pandemic, as well as establishing strategic and operational alignment towards achieving Gavi 5.0 goals[3]. As discussed by the Board at its retreat in April 2022, the pandemic has placed an incredible strain on immunisation programmes, contributing to a 2.7 million[4] increase in the number of zero-dose children across Gavi-57 eligible countries in 2020. Routine immunisation has continued to show some level of disruption in 2021 as countries have tried to ramp up COVID-19 vaccinations, particularly in the second half of the year. Equity gaps are widening, reversing the pre-pandemic hard won gains. As a result, Gavi's mission is both more important and more challenging than ever.

As the Alliance enters the second year of Gavi 5.0, focus is shifting to 'executing for impact' against the backdrop of continued COVID-19 related disruptions. In 2022 the focus is on supporting in-country programming to both sustain coverage and stretch to reach zero-dose children. For example, India and Pakistan are going through their Full Portfolio Planning (FPP) process, putting unprecedented efforts on identifying zero-dose children and missed communities and developing targeted strategies to reach them. In addition, up to 40 countries are expected to apply for the Equity Accelerator Funding (EAF) to help reach zero-

[1] Associated risks refer to the top risks described in the 2021 Risk & Assurance Report. The AFC update on risk management provides a more detailed update on major changes in Gavi's risk profile since the Risk & Assurance Report was discussed in December.
[2] Noting that the WUENIC coverage data for 2021 will not be released until July 2022, and therefore a more comprehensive update on Strategic Goals 1 and 2 will be provided at the next Board meeting
[3] For example, through the development of new guidelines and application materials to help strengthen country programming, the realignment of existing funding streams, and the creation of a new dedicated funding stream targeting zero-dose children and missed communities (the Equity Accelerator Fund (EAF))
[4] Coverage across Gavi-57 eligible countries, WUENIC, July 2021

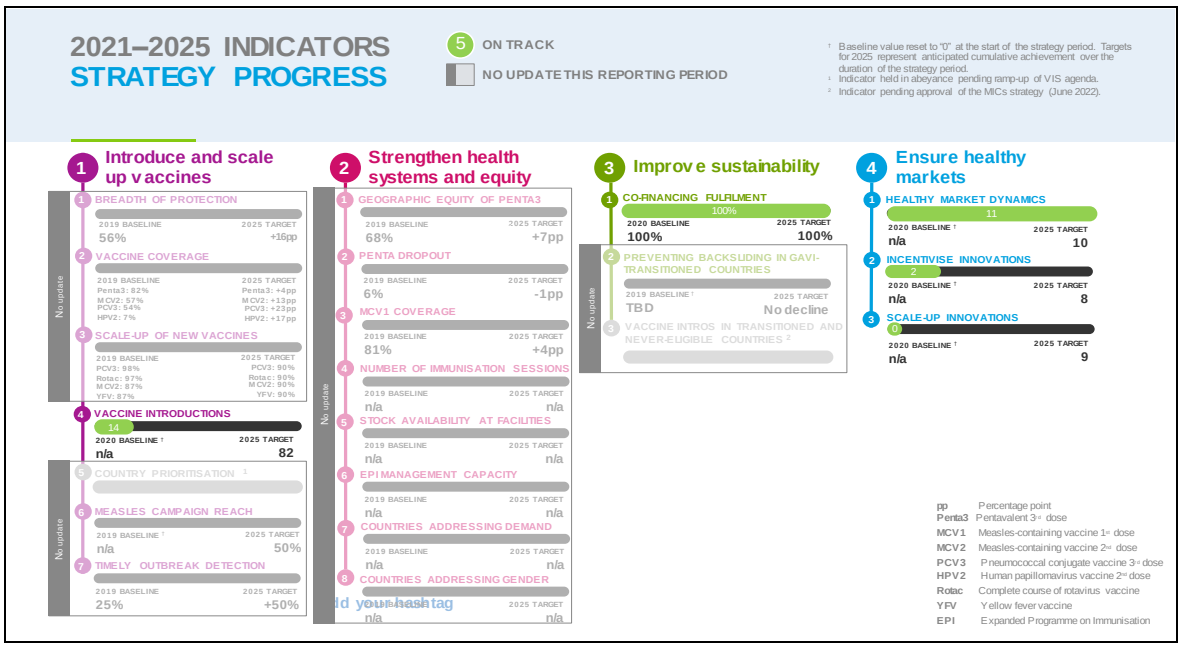
dose children. Increased engagement with local partners and Civil Society Organisations (CSOs) is also a priority to ensure context appropriate partnerships are in place to better address equity challenges. Opportunities to leverage synergies between COVID-19 vaccination and routine immunisation strengthening are also being emphasised.

Moreover, Gavi is starting to explore how COVID-19 vaccination and COVID-19 learnings will come together with Gavi's core 5.0 strategy and operating model. This interim period of integrating Gavi 5.0 and COVAX, being referred to as 'Gavi 5.1', will serve as a bridge to the Gavi 6.0 strategy. Gavi 5.1 will also be an opportunity to confirm the existing Gavi 5.0 recalibrated strategic priorities. Section C describes the key questions that the Alliance will explore when designing Gavi 5.1, to be brought to the Board for decision at its December 2022 meeting. The Board is asked to provide guidance on the scope of these questions.

Section B: Gavi 5.0 2021-2025 Strategy: Implementation and Progress

1. Progress against Strategic Goals

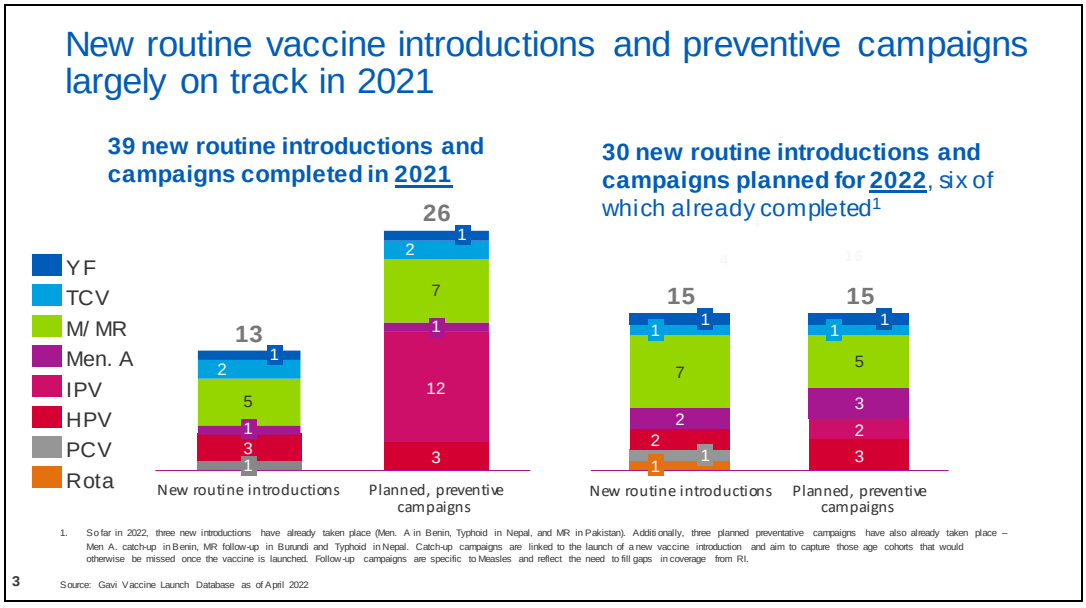
An update on progress against Mission Indicators will be provided in October 2022, once WHO-UNICEF coverage estimates (WUENIC) are available in July. Going forward, this update will be supported by a set of more operational strategy implementation indicators[5] which will be tracked to help interpret the Board-approved 5.0 Mission and Strategy indicators. A draft list of these implementation indicators was shared in May 2021 and October 2021 PPC papers, and will be finalised through Alliance consultations.



[5] Strategy implementation indicators will replace the Alliance KPIs (Key Performance Indicators) used in Gavi 4.0

Strategic Goal 1: Introduce and scale up vaccines

1.1 **Despite the ongoing COVID-19 pandemic, there is an encouraging trend in countries' ability to introduce new routine vaccines and conduct preventive [6] campaigns.** Against 13 planned new vaccine introductions into routine immunisation programmes, 13 occurred in 2021 across six vaccines. In addition to routine introductions, 26 preventive campaigns were planned and conducted by year end across seven vaccines[7]. **Looking forward to 2022, 15 new routine introductions are targeted with three of these already having taken place to date**. Additionally, 15 preventive campaigns are planned with three already conducted. Whilst new routine vaccine launches in 2021 were in line with expectations, as per the Board-approved recalibration of Gavi 5.0 priorities, the new launches of 2018 Vaccine Investment Strategy (VIS) vaccines have been paused since 2020. The earliest launch of VIS vaccines is now expected in 2024.



1.2 **Improving the quality of measles campaigns continues to be an area of focus.** Measles/Measles-Rubella campaigns should now be grounded in a differentiated delivery strategy. Countries are expected to put a more deliberate focus on identifying target populations, for example based on past outbreak data, implementing tailored strategies for reaching zero-dose and under-immunised children during the campaign, and bringing them into

[6] Preventive vaccination campaigns take the form of 'catch-up' activities that aim to vaccinate the main target population responsible for disease transmission when a new vaccine is introduced to the routine programme or 'follow-up' activities, specifically for measles/measles-rubella that target un and under-immunised children missed through routine immunisation services. These preventive campaigns are in contrast to outbreak response campaigns which are reactive.

[7] For M/MR, of the 7 preventive campaigns in 2021, 5 were follow-up campaigns and two were wide age-range MR catch-up campaigns (targeting children 9 months – 14 years) that accompanied MR introduction into the routine programme. Catch-up vaccination activities for IPV are necessary to address a gap in coverage from pre-existing supply constraints at the time of switching from trivalent to bivalent oral polio vaccine (OPV) in April 2016. In 2021, 11 of 12 activities were conducted as campaigns with one carried out through expanded routine services.

the routine immunisation programme following campaigns. Countries are also expected to plan and deliver campaigns integrated with other vaccines or primary health care (PHC) interventions where feasible. Ten applications for measles campaigns have been approved under these guidelines by the Independent Review Committee (IRC)[8] with implementation starting in Q4 2022. However, 12 applications were rejected or removed during application pre-screening in line with the Board's low risk appetite for poor quality campaigns. While acknowledging an upward trajectory in the quality of campaign plans and budgets, the IRC continues to observe areas for improvement such as more consistent use of data in planning campaigns and better linking identification of barriers to immunisation and specific strategies to reach missed children.

1.3 **Despite new introductions in 2021, the human papillomavirus vaccine (HPV) programme faces challenges. Severe supply constraints due to limited global manufacturing capacity compounded by pandemic-related disruptions led to a decline in global HPV coverage in 2020.** COVID-19 disruptions such as school closures, decreased fiscal space and the subsequent de-prioritisation of HPV vaccination meant that the limited supply of HPV vaccines to countries was not used optimally. To help address supply constraints, manufacturers are ramping up production but absorption in countries will also need more concerted attention. In addition, in April 2022, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) announced that a single dose of HPV vaccine is highly effective in preventing HPV infections. As this is currently an off label usage, countries may not switch to a single dose regimen yet. This has the potential to accelerate HPV scale-up in Gavi-supported countries. It could help reduce the financial cost of the vaccine, increase the ease of delivery, and rebalance supply and demand. The Secretariat will come back to the Board (December 2022) with a proposal to help accelerate scale-up of HPV coverage.

1.4 **The fight to eradicate all forms of polio virus continues, with previous timelines for eradication in 2022 delayed until at least 2026**. Whilst 2021 saw the lowest number of wild poliovirus (WPV) cases ever reported (six), one was an importation into Malawi[9], putting Africa's polio free status at risk. In 2022, Afghanistan, Pakistan and Mozambique have already reported a total of four cases of WPV[10]. A multi-country regional response to the African outbreak has been effective however, the threat remains that the virus may be circulating elsewhere undetected. In addition to WPV circulation, more than 600 cases of vaccine-derived poliovirus have been detected in the past 12 months[11]. This is symptomatic of gaps in routine coverage and a reminder that there is no substitute for identifying and reaching low coverage communities and zero-dose children. Gavi together with the Global Polio Eradication Initiative (GPEI) will work to ensure that

[8] In its last September, November 2021 and March 2022 application rounds
[9] Malawi detected a case of WPV in November 2021, its first since 1992
[10] Pakistan reported 2 new cases this year; Afghanistan reported 1 case and Mozambique 1 new case this year.
[11] This is across 14 African countries, Afghanistan, Israel, Tajikistan, Ukraine and Yemen.

resources and interventions to address these outbreaks are also leveraged to identify and reach zero-dose children[12].

1.5 **Despite the relatively low number of outbreaks requiring vaccination responses in 2020 and 2021, there are indications that some Vaccine-Preventable Diseases (VPD) outbreaks, such as measles and yellow fever, are on the rise.** 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 risk could be increasing further. In the case of measles, WHO has already received 22 reports of large, disruptive outbreaks by April 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[13]. Root cause analyses are now a requirement for measles outbreak response support and encouraged for yellow fever, since outbreaks of both diseases result from routine immunisation delivery gaps. However, there has been variability in systematising this approach to inform programme and management responses beyond the outbreaks. Moving forward, this will require stronger collaboration and follow-up across the Alliance partnership to determine why this is not systematic, and take specific steps to make necessary improvements.

Strategic Goal 2: Strengthen health systems to increase equity in immunisation

1.6 **As discussed by the Board at its April 2022 retreat, the COVID-19 pandemic has continued to strain health systems and disrupt routine immunisation services, highlighting and exacerbating inequities both within and between countries**. The poor and most marginalised populations have been more severely impacted by pandemic-related disruptions, contributing to worsening inequities.

1.7 **Initially, the disruptions to routine immunisation services were largely driven by early interventions in response to the pandemic such as strict lockdowns.** As these measures were eased, strong recovery was seen in the second half of 2020. However, **further disruption in routine immunisation was seen in the latter half of 2021 as countries ramped up COVID-19 vaccinations** whilst simultaneously trying to maintain and extend the reach of routine immunisation services. The difficulty in managing these competing priorities can be seen in Asian countries such as India or Pakistan where the rapid scale-up of COVID-19 vaccination contributed to a slowing down of routine immunisation services. In contrast,

[12] An update on the co-financing approach for inactivated polio virus co-financing will be provided to the Board in December 2022 as part of the broader Funding Policy review. The Board will also be provided with an update on Hexavalent and whether the five conditions the Board set for approval of Gavi support to Hexavalent have been met

[13] The 6 emergency requests were from Ghana (2), Cameroon, Central African Republic and Chad (2). This is approximately the same number of requests expected over a 12 month period based on historical pre-pandemic data.

African countries witnessed a slower rollout of COVID-19 vaccination and a lower drop in routine immunisation coverage on average, still resulting in an increase in the number of unreached children. As discussed at the Board retreat, this highlights the need for leveraging opportunities for integration between COVID-19 vaccination and routine immunisation programmes more deliberately and maintaining the focus on reaching zero dose children.

1.8 **Despite continued pandemic-related disruption, the Alliance has built further momentum on its ambitious zero-dose agenda.** The US$ 500 million Board-approved Equity Accelerator Funding (EAF) provides dedicated, additional funding to countries to reach zero-dose children. Up to 40 countries are expected to apply for EAF funding in 2022[14]. In addition, through the EAF, Gavi has selected two consortia to receive up to US$ 100 million to implement new multi-country partnerships to reach zero-dose children and missed communities in fragile, conflict and cross-border settings outside government reach. Together with a revised Fragility, Emergencies and Displaced populations policy (see Doc 07), Gavi is differentiating engagement in fragile and conflict settings in order to improve coverage and reach zero-dose children.

1.9 **Gavi's funding levers continue to be holistically leveraged to support countries to reach zero-dose children and missed communities.** For example, following the Board's approval of Gavi's 2022-2026 strategic partnership with **India** in December 2021, the country is currently conducting sub-national level consultations to identify appropriate interventions to reduce the number of zero-dose children by 30% by 2026 against a 2019 baseline[15]. **South Sudan** is proposing tailored interventions to reach children in different contexts, including conflict-affected areas, highly dispersed and mobile populations, areas affected by seasonal flooding and remote rural areas. And **Pakistan**, has leveraged a Measles-Rubella campaign covering 92 million children, to identify zero-dose children and missed communities. All three countries are using human-centred design to identify barriers and tailor interventions and include a focus on demand and gender-related strategies. FPP is also ongoing in 15 other countries with the total number anticipated to complete the process in 2022 currently expected to be 14[16]. Progress is being monitored as COVID-19 is limiting some countries' bandwidth to complete FPP processes and health system strengthening (HSS) disbursements are below forecasted levels as a contributing factor. Competing priorities arising from COVID-19 are stretching country management capacity which remains an area of very high risk and will require on-going engagement by the Alliance (see Annex B for further details).

[14] Based on intelligence and engagement with countries and as of April 2022
[15] Interventions will focus on demand-side barriers and on improving data, with limited supply-side investments
[16] Two countries finalised their FPP process in 2021 – Kyrgyzstan and Northwest of Syria. There are a total of 17 countries with active FPPs currently, of which Benin, Burkina Faso, Burundi, CAR (Central African Republic), Cote d'Ivoire, Ethiopia, Mauritania, Madagascar, Mali, PNG (Papua New Guinea), Pakistan, Tajikistan, Uganda and Zambia are expected to complete their FPP in 2022.

1.10 **In Nigeria, progress on improving coverage and equity as measured through the Board-approved Nigeria accountability framework has been mixed.** In 2018, the Board agreed to an extended transition timeline for Nigeria and committed US$ 1.03 billion[17] to support Nigeria through 2028. A high-level mission in February 2022 found that despite the pandemic, Nigeria has increased national DTP3 (three doses of diphtheria, tetanus and pertussis vaccines) coverage to 56% in 2021, up from 33% in 2016[18] and has consistently met co-financing obligations. However, it also highlighted **sub-optimal progress made across other accountability framework indicators** such as the proportion of states that reached expected coverage rates for DTP3, IPV (inactivated polio vaccine), and MCV (measles-containing vaccine). Nigeria hosts 2.5 million zero-dose children, 20% of all zero-dose children in Gavi-supported countries. Gavi is working with the Government of Nigeria on defining a strategy to reach zero-dose children and missed communities by focusing efforts at subnational levels. Gavi has also begun working with the Government and partners to conduct a mid-term review of the national strategy (NSIPSS)[19] and refining the Accountability Framework based on feedback from the high-level mission. The outcomes of this review and refined Accountability Framework will be summarised for the Board's information in December 2022.

1.11 **Recognising the central role of addressing gender-related barriers in reaching zero-dose children, countries have been making progress in integrating a gender lens into their programming**[20]. For example, interventions proposed in South Sudan include integrating outreach and mobile services with other child survival programmes (nutrition, education, WASH) to reach every child. This takes into consideration the reality of mothers who need necessary services to be co-ordinated and provided in an efficient manner. In the Democratic Republic of the Congo (DRC), identifying male vaccination champions who promote the importance of father's role in child care and specifically to support children's vaccination has led to increased demand by marginalised communities for vaccinations services.

1.12 **Gavi has begun to operationalise the Board-approved Civil Society and Community Engagement (CSCE) approach to ensure local partners and CSOs can be better leveraged to tackle the zero-dose agenda.** The Secretariat is reviewing its business processes to enable effective engagement of CSOs, a prerequisite to implementing the CSCE approach. At country level, guidance has been embedded in the latest

[17] US$ 1.03 billion has been allocated for Nigeria until 2028, as part of a joint commitment with the Government of over US$ 3 billion over the 10-year period to fund vaccines procurement and health system strengthening interventions.
[18] Change from 2016 Multiple Indicator Cluster Surveys/National Immunization Coverage Survey (MICS/NICS) to the preliminary NICS/MICS 2021 data
[19] Gavi made a commitment to the Board to conduct the mid-term review of the Nigeria Strategy for Immunisation and Primary Health Care Strengthening (NSIPSS) 2018-2028 as part of the approval for support
[20] Gender analysis is being systematically conducted to help shape strategic immunisation programming including in the Democratic Republic of Congo (DRC), Afghanistan, Kenya, Pakistan, and South Sudan.

release of Gavi's application kit to support countries to meet the Board requirement that 10% of their combined targeted country assistance (TCA), HSS and EAF ceilings are allocated for CSO implementation. In addition, a new hosting organisation for the CSO Steering Committee and the CSO Constituency has been appointed - Amref Health Africa, the first Gavi CSO host from the global south and located in a Gavi-supported country.

1.13 **The PEF Targeted Country Assistance (TCA) invested a total of US$ 82 million in 2021** against a budget of US$ 100 million, to provide countries with technical assistance to support their immunisation programmes. In addition to PEF TCA, US$ 58 million was allocated through COVAX Technical Assistance (TA) in 2021 to provide surge capacity, and help limit the disruption of COVID-19 vaccine rollout on routine work. Given COVID-19 vaccination efforts will likely continue in the near term, PEF TCA and COVAX TA are being co-ordinated and will be managed together in the future. **Partner performance against programmatic milestones in TCA for 2021 continues to lag behind Gavi 4.0.** Partners reported 68% milestone achievement[21] for 2021[22], demonstrating that the negative impact of the pandemic on partner performance seen in 2020[23] has persisted (the 2019 baseline for comparison was 79% milestone achievement). As of November 2021, partners' milestone achievement was 85% in High Impact countries, 70% in Conflict & Fragile countries, and 62% in Priority & Standard countries. Partners have reported that the high number of competing priorities due to the COVID-19 pandemic have resulted in difficulties to hire staff and provide the required TA.

1.14 **Multi-year planning of PEF TCA support for 2022-2025 was launched in April 2022.** This reflects a key shift for PEF TCA away from annual planning cycles to multi-year applications, specifically aligned with the HSS grant period. This allows for longer term planning of PEF TCA to sustainably strengthen health systems, with a focus on reaching zero-dose children, multi-sectoral collaboration, and context specific partnerships. Recognising the importance of localised partnerships to better identify and reach zero-dose children and missed communities, a target has been set to allocate 30% of TCA funds to local partners. Further, a global Expression of Interest has helped identify a prioritised list of global and local partners for PEF TCA in Gavi 5.0. **At the global and regional level, PEF investments through Foundational Support (FS) and Strategic Focus Areas (SFA) have also shifted to multi-year planning with a clear focus on zero-dose children and missed communities.** The Partnerships Team has also approved a new approach for performance monitoring and management of these investments to improve accountability and transparency and help keep partner performance on track for successful delivery of Gavi 5.0.

[21] Milestone achievement defined as completed or on track

[22] In 2021, milestone achievement for core partners was 76.5%, and for expanded partners was 48.4%. This is in-line with funding utilisation (95% for core partners, 60% for expanded partners).

[23] 65% milestone achievement in 2020. The 2019 baseline for comparison was 79% milestone achievement.

Strategic Goal 3: Improve Sustainability of Immunisation Programmes

1.15 **Despite a challenging fiscal context in 2021, most Gavi-supported countries have been able to maintain or increase domestic resources for co-financing of Gavi-supported vaccines.** Countries contributed US$ 161 million in 2021, bringing total co-financing contributions to US$ 1.3 billion since the introduction of the co-financing policy in 2008.

1.16 **For those six countries[24] that were granted an exceptional COVID-19 co-financing waiver in 2021, Gavi absorbed a cost of US$ 7.8 million.** This represents a decrease compared to 2020 which saw nine countries submit a waiver for their co-financing obligations, totalling US$ 28.9 million[25]. This reduction in the number and volume of waivers reflects the economic rebound in 2021 seen in most countries as well as the active engagement of the Secretariat and wider Alliance with countries to protect past gains in domestic financing for vaccine procurement. **Payment of Gavi co-financing obligations through funding from other donors has remained an exception**. In 2021, it was limited to one country, Malawi.[26]

1.17 **Increasing debt levels in particular in initial self-financing countries are hampering their capacities to invest sufficiently in health.** The economic impact of the pandemic has contributed to a ten-percentage point increase in debt to gross domestic product (GDP) ratio from 62% in 2019 to 72% in these countries. With public finances under stress, per capita government health spending is expected to drop and remain below pre COVID-19 levels until 2026 in more than a quarter of Gavi-eligible countries. Significant strain on countries' capacity to maintain co-financing is anticipated and the Alliance will need to consider carefully how to best support countries to sustainably finance their vaccination programmes. This should include ensuring global health agencies collaborate further to unlock efficiencies in health spending at country level. At its recent retreat in April 2022, the Board discussed the risk of rising debt levels and noted that it will be essential to continue to strongly advocate to protect domestic financing for health and immunisation. However, the Board also noted that Gavi will need to reflect on the right timing and criteria for transition for countries with specific challenges such as fragility.

1.18 **The impact of the COVID-19 pandemic on routine immunisation is also increasing the risk of backsliding in former Gavi-eligible countries**. Despite strong pre-pandemic performance, from 2019 to 2020, average DTP3 coverage in former-Gavi countries declined by 5 percentage points, with some countries experiencing even more significant declines, e.g. a fall of 15 percentage points in Azerbaijan. In December 2020, **the Gavi Board**

[24] Six countries received an exceptional waiver as per the Board approved COVID-19 co-financing flexibilities. These were Afghanistan, Sierra Leone, Somalia, South Sudan, Sudan and Syria.
[25] Including the US$ 16 million waiver for Pakistan which was submitted in 2020 but applicable to 2021
[26] In addition, World Bank and UNICEF grants were used to fund 2.5% of the overall co-financing requirements in 2021 in specific challenging country contexts, as an option preferable to waivers.

approved the Middle-Income Country's (MICs) Approach and corresponding budget envelope of US$ 281 million for Gavi 5.0. The detailed approach to MICs will be discussed at this Board meeting (see Doc 09).

Strategic Goal 4: Ensure healthy markets for vaccines and related products

1.19 **In 2021, the number of markets exhibiting acceptable levels of healthy market dynamics for vaccines and immunisation products improved from 10 to 11,** exceeding the target for the year (see Annex A for a full breakdown of Strategic Goal targets and reporting across Strategic Goal 4). This was driven by an improvement in demand in the Typhoid Conjugate Vaccine (TCV) market. This has led to three countries[27] successfully applying for new introductions of TCV. Two markets, HPV and the Oral Cholera Vaccine (OCV), continued to exhibit unacceptable levels of market health in 2021. For HPV, supply constraints persisted and Gavi was unable to meet accumulated demand despite an additional supplier as countries' product preference remains skewed towards the established product[28]. For OCV, supply satisfied demand but only tightly, with limited buffer capacity. Given limited demand predictability, the market continued to face supply planning and investment challenges.

1.20 **In 2021, Alliance partners came together to resolve Pneumococcal Conjugate Vaccine (PCV) supply disruptions with minimal impact on programme continuity**. Supply challenges in 2021 included 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. As a result, the PCV market remained healthy.

1.21 **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: at least nine countries have had to switch to different presentations. Further pressure has also been experienced due to constraints experienced by another Rotavirus supplier. Despite fast decision making by most countries, and partner efforts, these supply disruptions have generated a very high risk of stockout. Whilst these risks have not impacted the market health in 2021, impact is anticipated to be seen in 2022 and the situation will continue to be monitored closely.

1.22 **The Cold Chain Equipment (CCE) market saw unprecedented demand in 2021, driven by cold storage needs for COVID-19 vaccines[29].** The

[27] Pakistan, Liberia and Zimbabwe introduced by the end of 2021. In 2020, two additional countries applied - Nepal and Malawi - and will introduce in 2022.
[28] Established product in the market is HPV4
[29] Over 50,000 units of refrigerators/freezers procured through UNICEF in 2021, compared to ~25,000 in 2019; however, the Gavi-funded portion of demand was considerably higher as a share of the total UNICEF market in 2019 (~80%) compared to 2021 (~35%).

CCE market has the supplier capacity to meet the surge demand, although equipment lead times in some cases were longer given supply chain challenges for specific components. **Supplier volumes were generally healthy and aligned to roadmap targets**.

1.23 **Innovation-related market shaping indicators are largely on track**. The number of innovative products within the pipeline of commercial-scale manufacturers increased by two in 2021 as two Measles-Rubella Micro-Array Patch (MAP) Phase 1 studies were initiated. Moving into 2022, preparations for clinical trial launches are underway for several flu and COVID-19 vaccine candidates on MAPs. **The Alliance efforts on MAPs forms part of the Vaccine Innovation Prioritisation Strategy (VIPS) which also focuses on innovations pertaining to Heat Stable and Controlled Temperature Chain qualified vaccines as well as barcodes on primary packaging.** A five-year roadmap has been developed and published for MAPs. The roadmap for Heat Stable and Controlled Temperature Chain will be finalised in 2022, followed by the roadmap for barcoding.

1.24 **During 2021, the development of regional vaccine manufacturing has come to the fore as a health security priority, especially in Africa.** The COVID-19 pandemic highlighted the supply shortfalls faced by many lower-income countries arising from COVAX' initial dependence on a single manufacturer for substantial volumes and from export restrictions. At its recent retreat in April 2022, the Board discussed that Gavi's role could be to orient ongoing efforts, providing strategic guidance and partnership to support sustainable and healthy markets for COVID-19 vaccines as well as other key routine vaccines. Regional manufacturing could have implications for Gavi, including on its financing and operating model, and will need to be assessed accordingly. This will be a key question explored for Gavi 5.1 (see Section C), and is discussed further under Agenda Item 6.

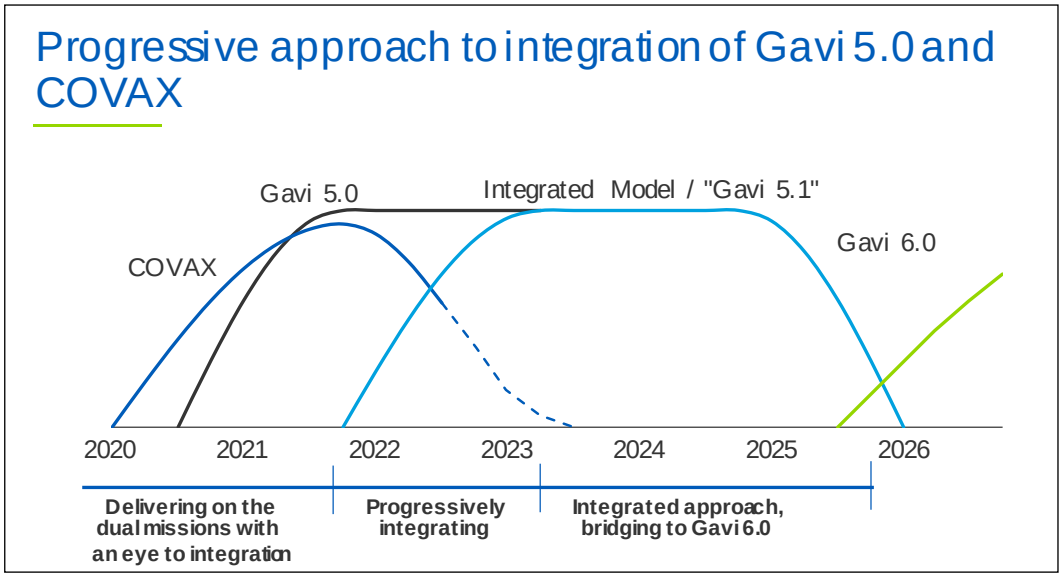
Section C: 'Gavi 5.1' – integrating the Gavi 5.0 and COVID-19 vaccination agendas

1.25 **The COVID-19 pandemic has dramatically transformed the global health and immunisation landscape.** With COVAX, Gavi has played a significant role in the world's response to the pandemic, helping AMC countries introduce and rollout COVID-19 vaccines at unprecedented speed. While the work on scaling up COVID-19 vaccines in countries is far from over, Gavi now needs to start exploring how its role in COVID-19 vaccination is to evolve from 2023 onwards and how COVID-19 vaccination and COVID-19 learnings will come together with Gavi's core 5.0 strategy and operating model, while recognising that there are still uncertainties in the trajectory of the pandemic.

1.26 **As discussed at the May 2022 PPC meeting, we are referring to this interim period of the integrating Gavi 5.0 and COVAX as 'Gavi 5.1'.** Gavi 5.1 takes as its core the Gavi 5.0 strategy with the integration of COVAX and its learnings and will serve as a bridge to the Gavi 6.0 strategy, the

development of which will start next year. Gavi 5.1 will also serve as an opportunity to confirm Gavi's recalibrated 5.0 strategic priorities. Gavi 5.1 discussions will take into account the independent evaluations underway and other lessons learned[30]. This section describes the key questions that the Alliance will explore in articulating 5.1, to be brought to the Board for decision at its December 2022 meeting. The Board is asked to provide guidance on the scope of these questions.

Figure 1: Gavi 5.1 as a progressive approach to integration of Gavi 5.0 and COVAX



1.27 **Four key questions will guide the articulation of Gavi 5.1:**

a) What are the implications of the COVID-19 pandemic (including COVID-19 vaccination, COVID-19 learnings and the impact on routine immunisation) on Gavi's strategic priorities?
b) What is the possible design of a COVID-19 vaccine programme and how should future COVID-19 vaccine support align with core Gavi programmes?
c) Building on Gavi's historic contributions to pandemic preparedness and response (PPR) and new learnings from COVID-19, how might Gavi's role in PPR evolve?
d) How will Gavi's integrated organisational set up and business processes evolve?

1.28 **a) What are the implications of the COVID-19 pandemic (including COVID-19 vaccination, COVID-19 learnings and the impact on routine immunisation) on Gavi's strategic priorities?** In light of the integration of COVID-19 vaccination and lessons from the pandemic, the scope of Gavi's strategic goals, objectives and indicators needs to be reviewed and could potentially evolve. For example, Strategic Goal 1 on introduction and scale

[30] There are currently two evaluations underway, respectively focused on Gavi's early response to the COVID-19 pandemic and COVAX, with interim findings expected in the summer. COVAX related evaluations are part of a multi-stage evaluation of the COVAX Facility and COVAX Advance Market Commitment (AMC).

up of vaccines may integrate Gavi's ambition to support countries administer a routine COVID-19 programme, if applicable (see Doc 05). Building on learnings from COVAX and the pandemic, it could also include a reshaped role for Gavi in pandemic preparedness and response (see agenda item 6). There is also an opportunity to reflect whether the recalibrated Gavi 5.0 strategic priorities that the Board had discussed in December 2020 are still fit for purpose[31]. Adjustments to the strategy indicator targets might be required in the context of the continued disruption to routine immunisation (see Section 1.6/1.7). As discussed at the last Board meeting and the Board retreat, the Alliance's ambitious 5.0 targets such as reduction of zero-dose and increase in breadth of protection may be at risk. The existing targets – such as the 25% reduction of zero-dose children from 9.7 to 7.3 million by 2025 – are based on a 2019 baseline and grounded in the assumption that coverage levels would return to 2019 levels in 2021 given evidence of strong recovery in the second half of 2020. If this is not the case across countries, Gavi may need to revisit the targets following the release of WUENIC coverage data in July 2022. At its retreat in April 2022, the Board also supported relaunching the HPV programme.

1.29 **b) What is the possible design of a COVID-19 vaccine programme and how should future COVID-19 vaccine support align with core Gavi programmes?** The design of a potential Gavi-supported COVID-19 programme for 2023 onwards will be informed by the latest scenarios on the future evolution of the pandemic. The programme design would consider financial implications, risks and trade-offs associated with different vaccination strategies, as well as implications for Gavi's programmatic policies. The three WHO pandemic scenarios and the initial considerations for a future Gavi-supported COVID-19 programme are described in agenda item 5 and will be detailed for the December 2022 Board meeting. Moreover, the Alliance is exploring opportunities to pivot the focus of COVID-19 delivery support (CDS) towards leveraging opportunities for integrated planning, delivery and communication of COVID-19 vaccination with routine immunisation programmes, for guidance at this Board meeting (see Doc 05.

1.30 **c) Building on Gavi's historic contributions to pandemic preparedness and response (PPR) and new learnings from COVID-19, how might Gavi's role in PPR evolve?** Gavi has long been a significant contributor to PPR. Through two decades of support to routine immunisation programmes, the Alliance's core work has contributed to building countries' capacity to prepare and respond to outbreaks. Gavi's suite of programmatic and financial instruments and capacity to innovate at pace also mean the Alliance is well positioned to play a key role in a future pandemic response – indeed COVAX was only able to be launched so quickly because of Gavi's existing capacities and expertise and the complementary strengths of the Alliance partners. And with calls for support for regional vaccine

[31] At its December 2020 meeting the Board discussed a set of recalibrated Gavi 5.0 priorities in light of the COVID-19 pandemic. These include a focus on maintaining, restoring and strengthening immunisation services; reaching zero-dose children and missed communities; ensuring access to COVID-19 vaccines; and safeguarding domestic financing for immunisation.

manufacturing, as set out above, Gavi's experience in market-shaping for vaccines could be deployed to improve supply resilience, particularly in Africa. Questions also arise about sustaining adult immunisation platforms outside pandemics, and how this might link to the broader lifecourse agenda and IA2030. As part of Gavi 5.1, Gavi will examine where the Alliance can build on and strengthen any of these core elements – for example through providing greater response capacity with the Pandemic Vaccine Pool. More detail on Gavi's potential future engagement in PPR can be found in Doc 06.

1.31 **d) How will Gavi's organisational set up and business processes evolve?** As the Secretariat continues to monitor and adapt to an evolving environment and manage the transition from a COVID-19 emergency response to more normalised operations delivered via an integrated model, it will need to maintain adequate capacity to ensure Gavi continues to deliver across its core mandate and COVAX. As discussed at the last Audit and Finance Committee (AFC) meeting, this process also presents an opportunity to strengthen the Gavi Secretariat by retaining COVAX top talents for the longer term. US$ 35 million out of the original 2020-2023 COVAX operational budget are available and approved for COVAX operations in 2023. A costed organisational integration plan for 2023-2025 will be presented by the end of the year. It will reflect the update from Gavi 5.0 to Gavi 5.1 resulting from the integration of select COVAX functions, processes and lessons with Gavi's model.

1.32 **The Secretariat will consult PPC and Board members on Gavi 5.1 leading up to the October PPC and December Board meetings.**

Section D: Actions requested of the Board

The Gavi Alliance Board is requested to **provide guidance** on the scope of the questions to be explored for Gavi 5.1 in advance of the December 2022 Board meeting.

Annexes

Annex A: Gavi 5.0 dashboard and update on key metrics

Annex B: AFC update on risk management