

SUBJECT: 2016-2020 STRATEGY: PROGRESS, CHALLENGES AND RISKS

Agenda item: 04

Category: For Information

Section A: Executive Summary

Context

Gavi's current mission for the 2016-2020 period is to save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries. It is guided by four strategic goals: accelerating vaccine coverage and uptake, strengthening health and immunisation systems, improving sustainability of national immunisation programmes and shaping markets. In June 2019, the Board approved the Gavi 2021-2025 ('Gavi 5.0') strategy, with the vision of 'leaving no one behind with immunisation'.

Questions this paper addresses

This report presents a holistic view of Alliance-wide progress, challenges and potential risks¹ in implementing Gavi's 2016-2020 strategy, and a short update on the ongoing operationalisation of Gavi's 2021-2025 strategy ('Gavi 5.0').

Conclusions

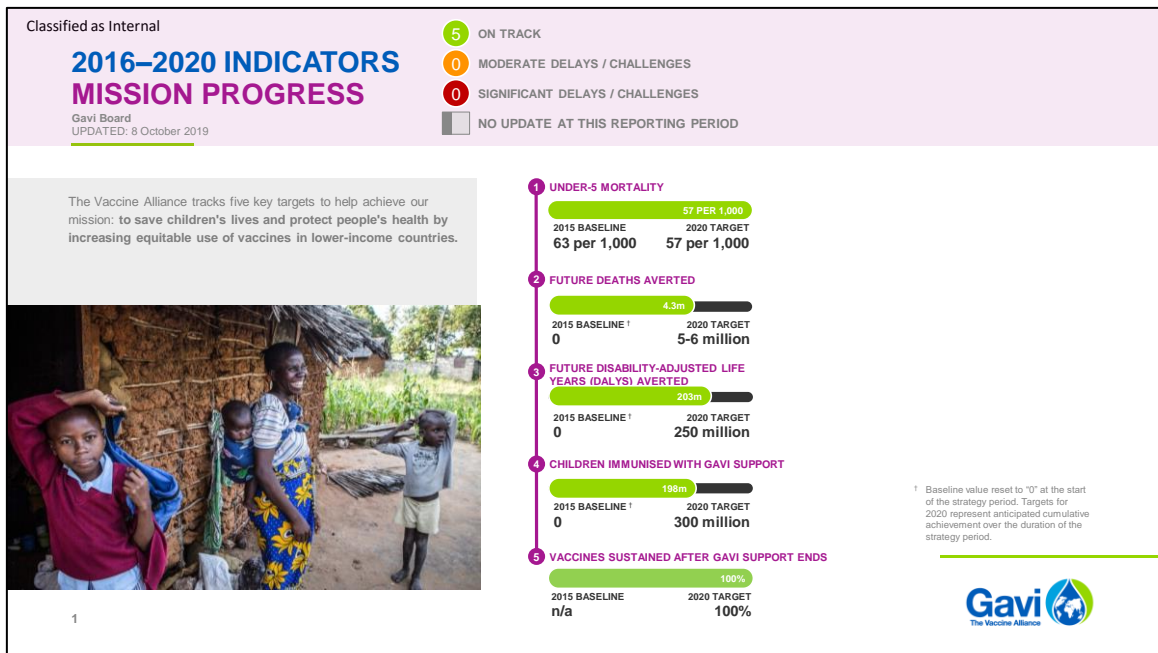
The Alliance is fully **on track on all of its five Mission indicators**. We are also seeing good progress on a number of **key indicators across the four strategic goals**, including breadth of protection, MCV1 (first dose of measles vaccine) coverage, strengthening supply chains, country fulfilment of co-financing commitments and reductions in vaccine prices. However, **challenges also persist**, such as less than targeted improvement in Penta3 coverage and difficulties with measuring progress on our equity indicators.

The six **Gavi 5.0 operationalisation workstreams** are in various stages of development and **generally on track**, with the policy workstream discussed in Doc 09 and a separate update on the measurement framework as Annex B to the pack for this Board meeting.

¹ Associated risks refer to the top risks described in more detail in the Risk & Assurance Report 2019 (see Doc 11).

Section B: 2016-2020 Strategy: Progress, Challenges and Risks

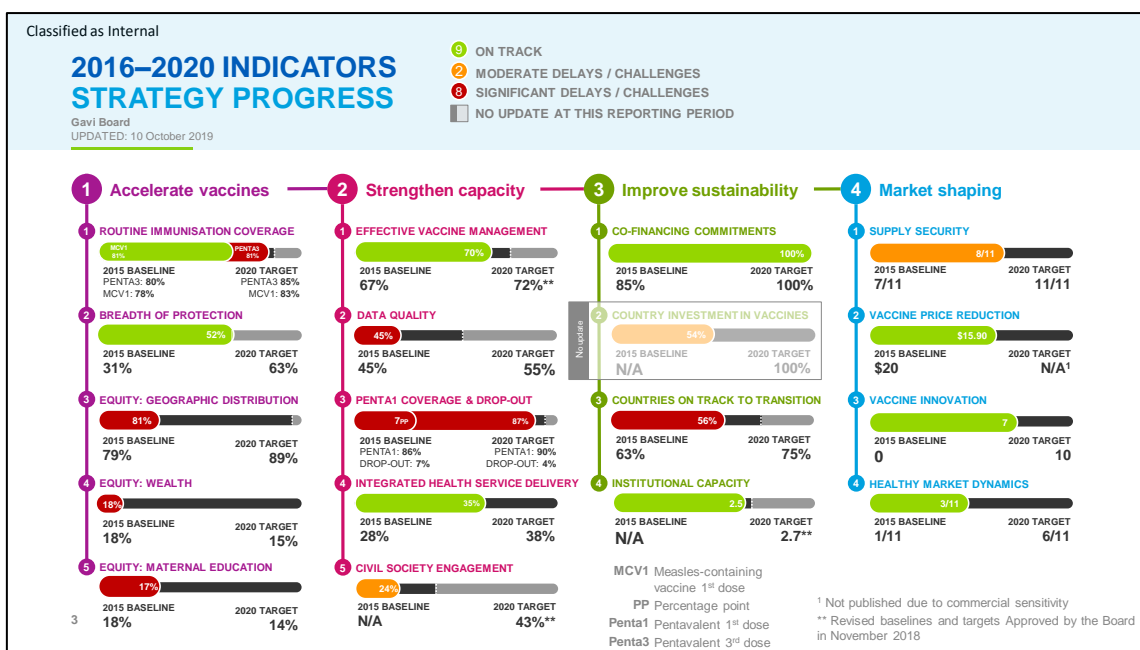
1. Progress against Gavi’s mission aspiration



1.1 **The Alliance is on track to reach all five Mission indicator targets by 2020.** Three years into this five-year strategic period, Gavi has helped immunise nearly 200 million additional children with one or more vaccines, keeping the Alliance ahead of its target to reach 300 million children by 2020. In addition, nearly 370 million people have been reached with SIAs (supplementary immunisation activities) for Yellow Fever, Measles, Rubella, Meningitis and Japanese Encephalitis. The total number of deaths averted so far in this strategic period is 4.3 million, with disability-adjusted life years (DALYs) saved reaching 203 million. These achievements have contributed to reducing under-five mortality in Gavi-eligible countries from 63/1,000 in 2015 to 57/1,000 in 2018², equivalent to our aspiration for 2020. Finally, all countries continue to deliver all recommended vaccines in their routine programmes after they transition out of Gavi support.

² The 2015 baseline and 2020 target have been updated to reflect revisions in historical estimates, as published in the 2019 Child Mortality Report.

2. Progress against Strategic Goals



Strategic Goal 1: Accelerate Vaccines³

- 2.1 **In 2018, more children in Gavi countries were immunised with three doses of DTP-containing pentavalent vaccine (Penta3) and a first dose of measles vaccine (MCV1) than ever before⁴.** Despite growing birth cohorts, the number of under-immunised children⁵ decreased from 15.9 to 15.1 million, and zero-dose children⁶ from 11.3 to 10.4 million between 2015 and 2018.
- 2.2 **The Alliance is on track to achieve its target for MCV1 coverage, which reached 81% in 2018.** This is three percentage points above the 2015 baseline. This is important progress since MCV1 coverage was previously almost stagnant, rising only one percentage point between 2011 and 2015. MCV1 is an important indicator of programmes' ability to reach older infants since it is delivered at a later point in time than other infant vaccines. However, given coverage variations between countries and risk of outbreaks, follow-up campaigns are likely to continue. In order to mitigate the risk of sub-optimally planned campaigns undermining country capacity to manage and deliver routine health and immunisation services, Alliance-wide dialogue and efforts are underway to pivot towards supplemental delivery strategies that specifically target consistently missed children to close immunity gaps.

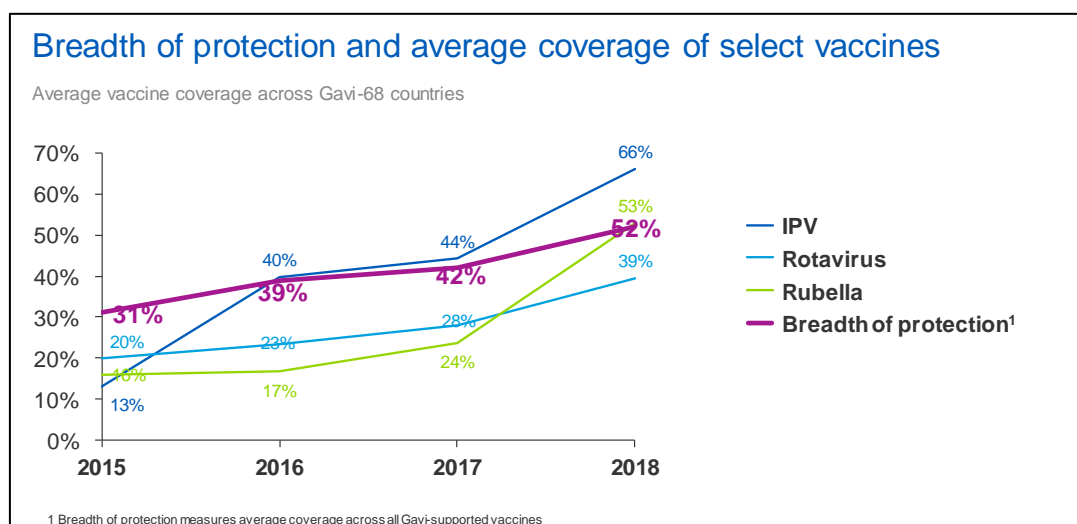
³ This section is informed by the 2018 WHO/UNICEF Estimates of Immunisation Coverage (WUENIC) published in July 2019, along with other data sets.

⁴ From 2015 to 2018: for Penta3, the number of immunised children has increased from 62.2 to 64.6 million, and for MCV1 from 61.2 to 64.5 million.

⁵ Under-immunised children are defined as not receiving at least three doses of pentavalent vaccine

⁶ Zero-dose children are defined as those not receiving any dose of pentavalent vaccine

- 2.3 Penta3 coverage has decreased slightly after two years of steady improvement and achieving our 2020 target will be challenging.** Having increased from 80% in 2015 to 82% in 2017, Penta3 coverage slipped back to 81% in 2018. This decrease was in large part caused by a drop in vaccine coverage in Vietnam (from 94% Penta3 coverage in 2017 to 75% in 2018), which suffered vaccine stockouts after deciding to switch product at short notice. Coverage in Vietnam is anticipated to return to pre-2018 levels next year, similar to the ten-percentage-point rebound experienced in Kenya after a drop caused mainly by health worker strikes in 2017. These examples highlight that coverage can dramatically drop in well-performing countries in the event of any supply or demand related issues.
- 2.4 The ten Tier 1 countries that benefited from higher technical support under the Partners' Engagement Framework (PEF) have increased Penta3 coverage** by three percentage points from 77% in 2015 to 80% in 2018. However, coverage during the same period has slipped back by one percentage point in PEF Tier 2 and fragile countries despite the fact that 4% more children were vaccinated. This highlights the multiplicity of challenges faced by these countries which include conflict, poverty, high birth rates, migration and weak service delivery as well as lack of breakthrough by way of innovative and tailored technical support under PEF. Improving coverage in these countries remains one of the key challenges for the Alliance.
- 2.5 Breadth of protection is on track, having increased by 21 percentage points since 2015 to reach 52% in 2018.** This reaffirms the success of the Alliance in introducing and rapidly scaling-up new vaccines. Since 2015, over 150 vaccines have been introduced with Gavi support. Progress in breadth of protection between 2017 and 2018 is driven largely by inactivated polio, rotavirus and rubella vaccines.



- 2.6 The inability to reach the under-immunised is a top risk for the Alliance but measuring progress on equity related indicators has been challenging.** There have been only 11 new household surveys since 2015 and if all countries were improving at the same average rate as these 11, Gavi would be ahead of target on both wealth and maternal equity. New

analyses including the 2019 Child Mortality Report and Universal Health Care (UHC) Global Monitoring Report show that immunisation remains the most equitable health intervention, reaching the largest proportion of poor households. WUENIC estimates also point to ongoing reduction in the number of both zero dose and underimmunised children as reflected in 2.1 above.

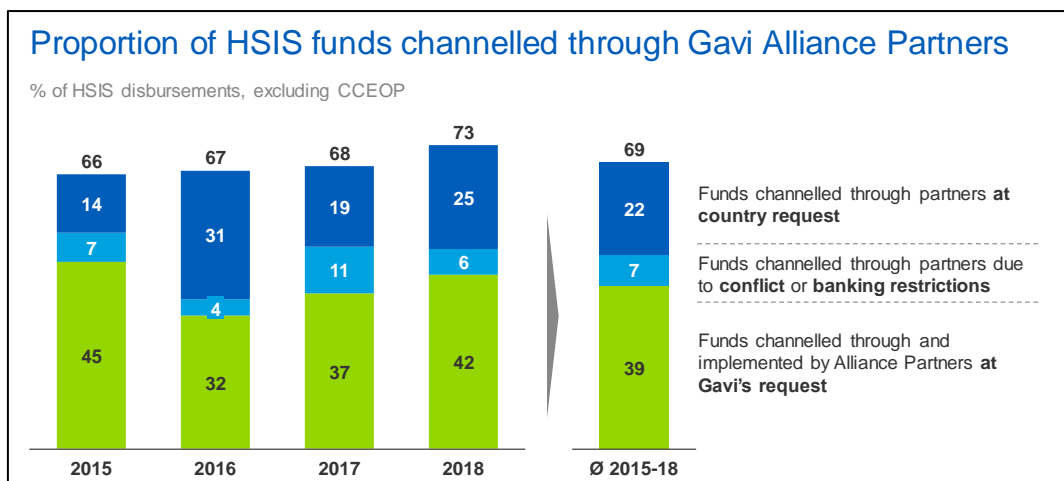
Strategic Goal 2: Health System Strengthening

- 2.7 **Countries continued to make progress in strengthening their supply chains in 2018**⁷. All countries with new EVM (effective vaccine management) assessments in 2018 showed improvement by an average of 12 percentage points since their last assessment.
- 2.8 **The quality of immunisation coverage data at country level remains a significant challenge and a top risk for the Alliance.** 45% of countries met the data quality target in 2018 as compared to 47% in 2017, relating to a net decrease of one country. Gavi continues to support countries to invest in strengthening data systems, tools and capacities, often in collaboration with the Global Fund. For example, DHIS2 (District Health Information Software 2) is now in use in more than 50 Gavi-eligible countries, with immunisation programme data now integrated in more than 30 countries, and 19 Gavi-supported countries now have a costed and funded data improvement plan. Efforts are also underway to promote use of data for action.
- 2.9 **Drop-out rates between Penta1 and Penta3 have remained flat at 7% and insufficient demand, including service quality and experience issues, remain a top risk for the Alliance.** Since 2016, the Alliance has invested approximately US\$ 72 million in demand generation through health system strengthening (HSS) and PEF targeted country assistance (TCA), and in 2018 a more strategic approach to addressing demand-side challenges was initiated under the Demand Strategic Focus Area (SFA). As part of this SFA, the Demand Hub, a new partner coordination mechanism, is rapidly gaining momentum and delivering early results. Demand side interventions can have a profound impact as exemplified by the Gavi-Unilever partnership in India which brings together immunisation and handwashing. This project has led to an increase in age-appropriate compliance of Penta and Measles vaccination by 14.3% and 30.1% respectively in two pilot districts of Uttar Pradesh, a low coverage province. In addition, WHO is leading an expert working group to measure the behavioural and social drivers for immunisation with new tools being validated in the field this year, and UNICEF has launched a global interpersonal communication skills-building package for frontline workers. At the Secretariat, work on demand, communities and gender has been brought together under a central team to ensure a common approach for these interlinked areas. Addressing gender-related barriers is a critical

⁷ A detailed assessment of Gavi's efforts in strengthening supply chains was provided at the June 2019 Board meeting.

factor for demand, and Annex C provides a detailed update on progress made in 2019 on implementing Gavi's Gender Policy.

- 2.10 **In June 2018, the Board approved flexibilities to allow countries to fully benefit from the Health System Strengthening (HSS) envelope in the 2016-2020 period.** Non-fragile countries are eligible to access up to an additional 25% of their HSS ceiling, while countries identified as fragile can access up to an additional 50% under the Fragility, Emergencies, Refugees (FER) policy. 18 non-fragile countries have applied for additional HSS funding so far, of which 15 with a total amount of US\$ 101 million were recommended for approval by the Independent Review Committee (IRC) based on demonstrated need and ability to invest additional funds in targeted coverage and equity interventions. Eight out of 15 fragile countries have applied for additional grants, of which the IRC has recommended seven for approval with total funding of US\$ 78 million. Further flexibilities have also been accessed by countries under the FER policy, such as funds to cover vaccines and operational costs to reach refugees in Rwanda, Tanzania, Uganda and Bangladesh.
- 2.11 **The Alliance has made progress in improving the timely disbursement of its HSIS grants.** The average time from IRC recommendation to disbursement in 2019 is 11.5 months, significantly lower than the 17.5 months reported in 2018, although still above the target duration of nine months. On excluding those grants that were impacted by vaccine supply constraints, the average further drops to 10.6 months. This partly reflects the fact that averages in 2017 and 2018 were negatively impacted by the learning curve of enhanced fiduciary risk management processes introduced in 2016. The Secretariat continues to make progress in streamlining its risk mitigation and grant monitoring processes. As part of the Gavi 5.0 strategy operationalisation, the Secretariat has also initiated a full-fledged review of its portfolio management processes with focus on simplification and agility (see Section C).
- 2.12 **A significant portion of HSIS support continues to be channelled through Alliance partners, as the Alliance aims to balance the desire to build country-owned systems with a low appetite for fiduciary risk.** 69% of funds were channelled through partners on average between 2015 and 2018, out of which approximately one third were at country request.



The proportion of funds channelled through partners is increasing in the short term as earlier funding decisions work their way through into disbursements. In accordance with the guidance from the Board in November 2018, Gavi is prioritising exploring alternative mechanisms to enable funds to flow through governments, and is focused on reducing the proportion of funds channelled via partners. This is a key priority, noting that the speed of change and the type of solutions will need to be informed by Gavi's appetite for fiduciary risk.

- 2.13 **The top risk that routine immunisation is adversely impacted by polio resurgence is increasing**, with a resurgence of wild poliovirus transmission in Pakistan and Afghanistan and the increasing number of vaccine-derived poliovirus type 2 (cVDPV2) outbreaks occurring. See Doc 11 for more detail in the Risk & Assurance Report.

Strategic Goal 3: Improve Sustainability

- 2.14 **In 2018, Gavi-eligible countries invested a record amount in the procurement of Gavi-supported vaccines, and the number of countries not meeting co-financing commitments in a timely manner remains at an all-time low.** Total country financing⁸ increased from US\$ 298 million in 2017 to US\$ 407 million in 2018 – the highest level on record. 52 out of 55 countries completed their latest co-financing requirements on time⁹. This represents a significant increase in the allocation of domestic public resources¹⁰, as less than 1% of annual co-financing requirements has been paid from Official Development Assistance (ODA) sources between 2013 and 2018.
- 2.15 **Sustainable transition remains a closely monitored top risk for the Alliance, but the risk is decreasing.** High-risk countries have now tailored

⁸ Includes Gavi-vaccine costs fully self-financed by countries, including India.

⁹ 2018 obligations include Ethiopia, Kenya and Pakistan whose co-financing obligations are aligned with their fiscal years ending on 30th June. Cameroon, Ghana and Sierra Leone were in default for 2018 obligations, however have now made appropriate payments and are out of default.

¹⁰ This includes World Bank lending and funding from mixed domestic and donor sources, which cannot be clearly differentiated.

strategies in place, Gavi is engaging with countries earlier on sustainability and transition (issues which are now mainstreamed into Gavi systems and processes), post-transition support is being rolled out and programmatic sustainability is at the core of the Gavi 5.0 strategy¹¹. **Five of the nine countries in accelerated transition are on track for successful transition out of Gavi support.** The four countries that missed the criteria are Nigeria, Papua New Guinea (PNG), Solomon Islands (fluctuating Penta 3 coverage) and Vietnam (because of drop in Penta 3 coverage). Nigeria and PNG have Board-approved tailored transition strategies with targeted investments to improve coverage outcomes in place. For Solomon Islands, the 2018 coverage level increased as compared to 2017, and in Vietnam coverage is expected to recover after one-off supply challenges (see above). **15 out of 18¹² countries projected for this strategic period have now transitioned out of Gavi support.** The majority perform well and are sustaining the vaccines introduced with Gavi support, as evidenced by continuing high or improving coverage levels. To address country-specific challenges, the Alliance continues to roll out time-limited, catalytic post-transition support. In addition, regional and global-level initiatives supporting post-transition engagement, such as the development of a peer learning platform for transitioning countries, are also underway.

Strategic Goal 4: Shape Markets

2.16 **While Gavi's efforts on market shaping are mostly on track, global supply shortages remain a top risk for the Alliance.** As indicated in the detailed update provided to the Board in June 2019, Gavi continues to make progress on reducing vaccine prices and increasing product innovation. On market dynamics, three of 11 markets continue to be assessed as exhibiting moderate to high health, meaning the 2020 target of six markets remains ambitious, particularly in the context of **global supply constraints which have recently eased for rotavirus vaccine, but persist for human papillomavirus vaccine (HPV).** Following major supply issues in 2018 and the first half of 2019, rotavirus vaccine supply has started to improve with products from new manufacturers prequalified by WHO and previous bulk production issues resolved. Countries that suffered delays due to the lack of supply are expected to start introducing the vaccine in Q4 2019. On HPV, however, country demand is still outpacing supply and challenges are expected to persist in the short- and mid-term. Although 90% of global deaths from cervical cancer are in low and middle-income countries, projected supply for Gavi countries has further reduced from previous forecasts for 2019 and 2020, despite a global increase in use. Though Alliance partners are continuing to prioritise single age cohorts and delay multi-age cohort (MAC) implementation and are closely engaging and communicating with both current and pipeline manufacturers, HPV

¹¹ For more information regarding the risk on sustainable transition please refer to the Risk & Assurance Report under Doc 11.

¹² The number of countries expected to transition by the end of the strategic period was reduced from 20 to 18 because Congo Republic has regained Gavi eligibility in 2019, and due to the extension of the accelerated transition phase to 2025 for Papua New Guinea.

coverage and impact would fall significantly short of targets for the current strategic period.

- 2.17 **Cold chain equipment (CCE) markets have been affected by market concentration and limited price decrease due to country familiarity with certain brands and relative lack of price sensitivity.** Two manufacturers in both the mains powered ice-lined refrigerators (ILRs) and solar direct drive (SDD) segments has ~80% of the market share in 2018. Actions undertaken by the Alliance to address these issues, such as interventions to generate experience with alternative brands and access volume-based discounts, are expected to establish a more competitive market for the future and are starting to show results. Market concentration has decreased by 5% in the first three quarters of 2019, and preliminary cost savings generated over the first five months of 2019 include 5% savings for CCE compared to pricing of initial country CCE preferences and 12% savings for service bundles as compared to service bundle bids. In addition, eight ice-lined refrigerator (ILR) models from a leading cold chain equipment supplier that were suspended by WHO Performance, Quality and Safety (PQS) in late June have now been reinstated following the supplier successfully redesigning the models and developing an in-field fix solution to countries for all impacted models.
- 2.18 **Since the Board approved funding in 2018, Gavi has made progress in strengthening yellow fever diagnostic capacity in Africa.** UNICEF Supply Division (SD) was selected as the procurement partner for the introduction and distribution of at least one validated yellow fever diagnostic assay test kit. To ensure a reliable distribution system is in place and to address urgent supply gaps until a validated assay test kit is available, UNICEF SD is also organising the supply of reagents and equipment for the current first-line yellow fever test protocol in Africa. Of the 24 African countries that are eligible for Gavi support and are considered to be at high risk for yellow fever outbreaks, six have applied for procurement support, and the IRC has recommended all six for approval. The IRC has also confirmed the importance of Gavi's yellow fever laboratory network support and efforts to ensure its sustainability, and recommended that Gavi seek to address laboratory needs for a wider range of relevant diseases. Four other countries are actively working on applications. The Alliance has also made progress in decreasing the time needed to confirm yellow fever cases in Africa and increasing the number of laboratories able to reliably detect and confirm yellow fever cases. This helps to mitigate the **risk of disease outbreaks disrupting immunisation programmes, which remains a top risk for the Alliance.**

Section C: Operationalisation of Gavi 5.0

- 3.1 **In June 2019, the Board approved the Gavi 2021-2025 ('Gavi 5.0') strategy, with the vision of 'leaving no one behind with immunisation'.** Following Board approval, the Secretariat has launched the operationalisation process to review and transform Gavi's policies, strategic

approaches, processes and tools to ensure alignment with the new strategy. This phase will conclude in the course of 2020 to ensure that the Alliance is ready to deliver on Gavi 5.0 starting 2021 – acknowledging that delivering on Gavi 4.0 will remain the priority over the next year.

3.2 Building on lessons learned from Gavi 4.0, the operationalisation phase is structured around six workstreams with a dedicated Secretariat project management office (PMO) to ensure alignment of deliverables and progress. The Secretariat is engaging stakeholders through appropriate mechanisms (e.g. steering committees, technical working groups) using joined up, cross-workstream approaches wherever possible. Existing forums such as the Alliance Coordination Team (ACT) and regional Expanded Program on Immunization (EPI) manager meetings are also being leveraged where possible, with the Programme and Policy Committee (PPC) and Board as the final guidance and decision-making bodies as required.

3.3 The six workstreams include:

- a) **Measurement & accountability:** The Secretariat, advised by a technical working group of Alliance partners, has developed a first version of the high-level theory of change for Gavi 5.0 and draft architecture of the revised measurement framework, and has started the process of identifying indicators for measurement. Initial concepts were presented to the PPC and a paper with more information is available on BoardEffect as Annex B to the pack for this Board meeting. Board decisions are expected in Q2 and Q4 2020.
- b) **Policies:** This work entails a review of Gavi's core funding policies (i.e. Eligibility & Transition and Co-financing policies, Health System and Immunisation Strengthening (HSIS) Support Framework) and the Cold Chain Equipment Optimisation Platform (CCEOP)). More details are provided in Doc 09.
- c) The Alliance will refine its **programmatic approaches** where needed to ensure alignment with the 5.0 priorities, including current strategic focus areas (including but not limited to supply chain, demand generation, data, leadership, management & coordination (LMC)). As a first step, and based on the Gavi 5.0 strategic priorities, the Alliance will review in which programmatic areas new or refined programmatic approaches and grant programming guidance are required and consider whether new dedicated SFA funding would be necessary for areas of potentially enhanced focus (e.g. gender, service delivery for zero dose children). This work will commence in Q1 2020.

- d) Responding to the Board's request, the Secretariat has started a review of its entire **portfolio management processes**, to make them more differentiated, efficient, simpler and hence a successful platform to deliver on Gavi 5.0 goals and objectives. Work on a comprehensive mapping of existing pain points and a lessons-learned exercise of other funding organisations has concluded, and several redesign options – including radical redesign – are being built and assessed over the coming months. The Secretariat will continue to regularly engage with countries and Alliance partners over the next year and report back to the PPC and Board on progress.
- e) Review of **partnerships** (including the PEF): Gavi will review the approach for engagement with partners in the new strategy period. This includes: a) the overall vision for the Alliance partnership model; b) the future roles of Alliance partners at global, regional and country level; c) the processes of funding and accountability in the Alliance under the PEF; d) a review whether the interaction forums amongst Alliance partners are fit-for-purpose. The Secretariat will consult with the PEF Management Team, countries and Alliance partners for further guidance – with an expected PPC and Board discussion in Q2 2020.
- f) A cross-cutting approach to **innovation** will be developed across immunisation products, services and practices (including private sector partnerships), with a focus on using innovations to unlock equity bottlenecks. The review has started in Q4 2019, along with consultations of key stakeholders – with the new strategic approach expected to be presented for validation at the PPC and Board in the course of 2020.

3.4 **Across all workstreams risk considerations are being captured and discussed to understand how Gavi's risk profile may shift** with the new strategy and operating model, as well as potential implications for Gavi's risk appetite.

Section D: Actions requested of the Board

This report is for information only.

Annexes

Annex A: Updated Alliance KPIs dashboard

Annex B: Strategy Indicators reported as originally defined

Annex C: Gender Policy Update