

SUBJECT: GAVI 5.0: THE ALLIANCE'S 2021-25 STRATEGY

Agenda item: 06

Category: For Decision

Section A: Introduction

- **Since its creation in 2000, the Alliance has helped countries to vaccinate over 700 million children, with 430 introductions of new and under-used vaccines, thereby saving more than 10 million lives.** The Alliance owes this achievement to its unique capabilities in supporting countries to improve access to vaccines and strengthen immunisation delivery systems. In doing so, the Alliance has pioneered the concept of country ownership and financial sustainability through its co-financing and transition model. It has also developed a powerful market shaping model for vaccines pooling demand from countries, currently accounting for almost 60% of the global birth cohort.
- **The Alliance's 2021-25 strategy ("Gavi 5.0") will build on these successes and aim to accelerate the journey towards universal immunisation.** Immunisation already reaches more households than any other health intervention. Every child ought to receive a full package of vaccines and there is a real possibility that immunisation could be truly universal by 2030 – but achieving this requires an **urgent acceleration** of this journey. This would provide a strong platform for primary health care (PHC) as a pathway to universal health coverage (UHC) and the SDG vision of 'leaving no-one behind'.

Gavi 5.0's contribution to the Sustainable Development Goals:

Immunisation is a strong contributor to SDG 3 which aims to “ensure healthy lives and promote well-being for all at all stages”. SDG 3 targets include:

- *By 2030, end preventable deaths of new-borns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births: **Vaccine introductions and accelerated coverage gains could contribute to nearly half of the missing gap in achieving the under-5 mortality target.**¹*

¹ Progressing on vaccine coverage at the current pace would bring under-5 mortality down to 34 per 1,000 live births by 2030 (compared to 39 currently), while improving vaccine coverage through targeted approaches to achieve nearly zero VPD deaths would reduce it to 30 per 1,000 live births.

- *By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases: Several promising vaccine candidates for HIV, tuberculosis and malaria are in late-stage development, and could be game-changers in the fight against these diseases. Moreover, the pentavalent vaccine contributes to Hepatitis B prevention (6 million deaths averted since Gavi inception), the Cholera and Typhoid vaccines are important tools in the fight against food and water-borne diseases, and vaccines such as Measles/Rubella, pentavalent, Yellow Fever, meningococcal and Japanese Encephalitis are critical to combat a number of other communicable diseases with a high disease burden.*
- *By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being: The Human Papillomavirus (HPV) vaccine can prevent up to 90% of all cervical cancer cases. Moreover, the Hepatitis B vaccine also has a protective effect for liver cancer, with Hepatitis B accounting for 60-80% of cases.*
- *Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all: Immunisation is a universal intervention and already reaches more households routinely than any other health intervention. This makes immunisation a well-placed platform to reach everyone with a basic package of primary health care (PHC) interventions. Immunisation also alleviates the financial burden for governments and individuals of paying for treatment and palliative care.*
- *Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks: The Alliance is a key contributor to the global health security agenda with investments of \$1.1B in outbreak preparedness and response approved since 2016².*

Beyond SDG 3 immunisation also has an important role to play. As one of the most cost effective interventions in global health (taking into account the broader benefits of people living longer, healthier lives, the return on investment rises to \$44 per \$1 spent on immunisation³), the benefits of immunisation cut across many aspects of sustainable development. From contributing to addressing poverty (e.g. vaccines will prevent 24 million people falling into poverty by 2030 through the avoidance of healthcare costs), hunger and reducing the health impact of climate change, to promoting equity and education (e.g. healthy children reach higher educational attainment), and building resilient and inclusive societies, immunisation truly reflects the core principles of the SDGs.

- **The reshaping of the global development landscape in pursuit of the SDGs is coming at a time when the political, macroeconomic and health development landscapes are evolving rapidly.** Populism is on the rise and

² Includes vaccines procurement, ops and VIGs for MR, Men A, YF, IPV, TCV and Diphtheria estimate (RI and campaigns) for 2016-2018 period, PEF TCA and SFA for 2016-2018 period, HSS funds for 2016-2017 for VPD surveillance and stockpiles (Men A, YF, OCV, MR). All amounts are approvals.

³ For 94 Decade of Vaccines (DoV) countries

has led some developed countries to be more inward facing and question the value of multilateralism and ODA. The macroeconomic environment has become more volatile, with growth rates slowing down since the early 2000s. The world is experiencing an increase in fragility and conflict, population growth and urbanisation, and climate change is affecting the health and wealth of populations across the world; these developments are also leading to a dramatic increase in infectious disease outbreaks and epidemics. Lastly, technological innovations are flowing more rapidly across borders than ever before. The Alliance's new strategy will speak to these opportunities and challenges.

- **The Board has led the development of the new strategy based on a consultative process involving stakeholders at country, regional and global level.** At its retreat in April 2018, the Board initiated its discussion through a review of the contextual factors and the key themes that should drive the strategy development. The Board further discussed these themes and related high-level strategic questions at its meeting in December 2018, and through a series of telephone conferences held in January 2019. At its retreat in Ottawa in March 2019 and a follow-up call in June, the Board reflected on a more detailed set of strategic questions and options in depth and made trade-offs between them. Feeding into this were extensive consultations conducted by the Secretariat with recipient countries (10 bilateral consultations and 3 regional meetings), Alliance partners (through a retreat with 100+ colleagues and several discussions with the Alliance leadership), civil society organisations (through the CSO constituency), manufacturers and an online survey for over 1,500 immunisation stakeholders at country, regional and global level.
- **The strategic framework for Gavi 5.0 (i.e. the 'one-pager') is included below.** It is based on multiple rounds of input during and after the Board retreat in Ottawa. This paper distils the previous Board discussions and consultations and is structured along the components of the 'one-pager', including the vision and mission, principles and four strategic goals. The paper also introduces some preliminary risk appetite considerations linked to the new strategy. Agenda item 07 describes the high-level roadmap for operationalising the new strategy, including an overview of the key policies, strategic approaches, processes and tools that will need to be reviewed and transformed to be able to launch the new strategy on January 1, 2021, and how the PPC and Board will be involved in this process.

Section B: “Gavi 5.0: the Alliance’s 2021-25 strategy”

Gavi, the Vaccine Alliance strategy 2021 - 2025			
Vision		Leaving no-one behind with immunisation	
Mission 2025	To save lives and protect people's health by increasing equitable and sustainable use of vaccines	Mission indicators	<ul style="list-style-type: none"> • Child mortality reduction tbd • Lives saved tbd • Future DALYs averted tbd • Equity indicator tbd • People (male & female) vaccinated with Gavi support across the life course tbd • People (male & female) vaccinated with Gavi support against outbreak-prone diseases tbd • Economic benefits unlocked tbd
Principles	<ul style="list-style-type: none"> • Missed communities, first priority: Prioritise children missing out on vaccination including among migrants, displaced and other vulnerable populations • Gender focused: Identify and address gender-related barriers to promote immunisation equity • Country-led, sustainable: Bolster country leadership to sustainably deliver and finance immunisation • Community owned: Ensure community trust and confidence in vaccines by engaging communities in planning, implementation and oversight of immunisation • Differentiated: Target and tailor support to national and subnational needs including fragile contexts • Integrated: Strengthen immunisation as a foundation for integrated primary health care to reach unserved communities in support of universal health coverage • Adaptive, resilient: Help countries leverage immunisation to address the challenges of climate change, Global Health Security, antimicrobial resistance and other major global issues • Innovative: Identify and leverage innovative products, practices and services to reach everyone with immunisation • Collaborative, accountable: Collaborate across stakeholders to achieve the SDGs in a transparent, coordinated and accountable manner 		
Goals	1 INTRODUCE AND SCALE UP VACCINES	2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION	3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES
Objectives	<ul style="list-style-type: none"> A Strengthen countries' prioritisation of vaccines appropriate to their context B Support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases C Enhance outbreak response through availability and strategic allocation of vaccine stockpiles 	<ul style="list-style-type: none"> A Help countries extend immunisation services to regularly reach under-immunised and zero-dose children to build a stronger primary health care platform B Support countries to ensure immunisation services are well-managed, sustainable, harness innovation and meet the needs of all care givers C Work with countries and communities to build resilient demand, and to identify and address gender-related barriers to immunisation 	<ul style="list-style-type: none"> A Strengthen national and subnational political and social commitment to immunisation B Promote domestic public resources for immunisation and primary health care to improve allocative efficiency C Prepare and engage self-financing countries to maintain or increase performance
Enablers	<ul style="list-style-type: none"> • Secure long-term predictable funding for Gavi programmes • Use evidence, evaluations and improved data for policies, programmes and accountability • Ensure global political commitment for immunisation, prevention and primary health care • Leverage the private sector, including through innovative finance mechanisms and partnerships 		

1. Gavi’s vision and mission

1.1 **Gavi’s vision of ‘leaving no one behind with immunisation’ recognises the link with the SDG ambition and the critical contribution of immunisation to it.** The vision highlights the opportunity to reach all children with immunisation by the end of the SDG era, as one of the few health interventions where universalism seems realistically achievable within the SDG timeframe. Some Board members have described this vision as ‘90-90-0-0’: More than 90% coverage in 90% of districts, and zero ‘zero-dose’ children in each country by 2030. This would not be used by the Alliance to define specific targets for countries, but rather as an aspiration that would guide the new Immunisation Agenda 2030 and the Alliance’s policies and programmes in their contribution to it.

1.2 **In delivering on its vision, Gavi’s mission will be:** “To save lives and protect people’s health by increasing coverage and equitable use of vaccines”. The mission puts ‘equity’ at the heart of the strategy. ‘Coverage’ includes attention to individual antigens but also the concept of the fully immunised child. The mission also recognises the fact that vaccines protect people at all stages of life, by preventing both the primary causes of mortality in children (including diarrhoea and pneumonia) and preventing cancers later in life triggered by vaccine-preventable infections (such as cervical cancer from HPV and liver cancer from hepatitis B).

2. Principles: Gavi 5.0 will be grounded in a number of operating principles

- **Missed communities, first priority:** Prioritise children missing out on vaccination including among migrants, displaced and other vulnerable populations
- **Gender focused:** Identify and address gender-related barriers to promote immunisation equity
- **Country-led, sustainable:** Bolster country leadership to sustainably deliver and finance immunisation
- **Community owned:** Ensure community trust and confidence in vaccines by engaging communities in planning, implementation and oversight of immunisation
- **Differentiated:** Target and tailor support to national and subnational needs including fragile contexts
- **Integrated:** Strengthen immunisation as a foundation for integrated primary health care to reach unserved communities in support of universal health coverage
- **Adaptive, resilient:** Help countries leverage immunisation to address the challenges of climate change, Global Health Security, antimicrobial resistance and other major global issues
- **Innovative:** Identify and leverage innovative products, practices and services to reach everyone with immunisation
- **Collaborative, accountable:** Collaborate across stakeholders to achieve the SDGs in a transparent, coordinated and accountable manner

- 2.1 Most importantly, there will be an **increased focus on equity, which will be the key organising principle** of Gavi's support. This will entail ensuring that services are extended as a priority to communities that are currently missed including refugees, displaced and other vulnerable populations. To deliver on this principle, the Alliance will apply a strong **gender** lens to address immunisation barriers, recognising the strong connection between gender-related barriers and immunisation inequities and therefore the central role that gender should play in the next strategy period to reach under-immunised communities. Similarly, the new strategy will take a renewed emphasis on **increasing community ownership, trust, and demand** for immunisation services, and improve **service delivery** for under-served populations.
- 2.2 A stronger focus on **programmatic sustainability** will guide Gavi's investments and complement the existing focus on financial sustainability. In reaching the 'missed communities' the Alliance will take a more deliberate approach to find the right balance between short-term health systems support and long-term health systems strengthening, and bolster **country leadership** to sustainably deliver and finance immunisation.
- 2.3 **To deliver on equity and sustainability, the Alliance will:**
- (a) **Further differentiate interventions**, targeting and tailoring them to the specific national and sub-national context in each country. The remaining Gavi-eligible countries (54 countries at the beginning of the next strategic period) will have a wide range of performance, with an increasing share facing significant health system challenges. While maintaining a **country-led approach** for all countries, the Alliance will adapt its interventions and support model based on local context to ensure maximum impact. This will include helping countries and communities leverage immunisation to address **major global developments** including climate change, Global Health Security, antimicrobial resistance (AMR) and urbanisation.
 - (b) **Innovate**. Innovation is part of Gavi's DNA and – as a means of reaching its goals and objectives – will be mainstreamed into Gavi's support. The Alliance will develop a more deliberate approach to accelerate innovation across immunisation products, practices and services. This will notably include: (a) a broader strategy for vaccine-related products; and (b) a path to scale up innovative practices and services that can unlock equity bottlenecks at local level.
 - (c) Work with countries to **prioritise Gavi support**. In particular, while continuing the vaccine introduction agenda, the Alliance will assist countries in identifying vaccines that are most appropriate for their local context and ensure that health systems and technical support are focused on the marginalised and underserved communities.

- (d) Engage with countries through **lean and efficient processes**. This will entail a redesign and simplification of Gavi’s portfolio management processes. It will also necessitate refining the Alliance’s risk appetite to find the right balance between speed and limited transaction costs on one hand, and diligence through checks and balances and accountability and measurement on the other hand.
- (e) Enhance **partnerships and collaboration with other global health institutions**. As an Alliance, Gavi has collaboration as a core principle for all of its work. The Alliance will continue to expand its collaboration beyond the core partnership, with new ‘expanded’ partners bringing crucial new skills relevant for country needs. Gavi will also enhance its collaboration with the Global Polio Eradication Initiative (GPEI). To maximise its impact, reduce duplication and transaction costs for countries, the Alliance will also more systematically coordinate with other donors and financing institutions, most notably the Global Fund, World Bank and its Global Financing Facility (GFF) including by continuing to engage in the SDG3 Global Action Plan for Healthy Lives and Wellbeing for All. The Alliance will also explore new partnerships to promote integration and multisectoral approaches to disease control and prevention.

2.4 **As a learning organisation the Alliance has already tested a number of these principles in the current strategic period.** The relative change in the next strategic period will be the focus on reshaping and more deliberately applying and scaling up the approaches.

3. Strategic Goal 1: Introduce and Scale up Vaccines

1 INTRODUCE AND SCALE UP VACCINES

- A** Strengthen countries’ **prioritisation of vaccines** appropriate to their context
- B** Support countries to **introduce and scale up coverage of vaccines** for prevention of endemic and epidemic diseases
- C** Enhance **outbreak response** through availability and strategic allocation of vaccine stockpiles

3.1 **Introduction and scaling-up coverage of high-impact vaccines in eligible countries will continue to be at the heart of the Gavi strategy**, as a clear comparative advantage for the Alliance. With Gavi support, all Gavi-eligible countries have now introduced pentavalent vaccine, 82% of Gavi-eligible countries have introduced Pneumococcal (PCV) vaccine and 64% have introduced Rotavirus vaccine ⁴. While significant progress has been made, a number of countries are still missing some key vaccines (e.g. only 16% have introduced the

Human Papilloma Virus (HPV) vaccine). The Alliance needs to continue its introduction agenda particularly in the most fragile countries where vaccines

⁴ As of end 2018 in Gavi-73 countries

can have the highest impact on child mortality. As such the Alliance will offer more flexibility to countries on vaccine introductions, e.g. by removing the pre-requisite ‘programme filter’ of 70% DTP3 coverage before introducing new vaccines (whilst also paying attention to sustainability) and allowing initial sub-national introductions, especially in large, federated states – where the disease burden can vary significantly between regions.

- 3.2 **As part of the introduction agenda, the Alliance will provide support for 18 vaccines**, including inactivated polio vaccine (IPV) and vaccines identified under the new Vaccine Investment Strategy⁵ (VIS; as approved by the Board in November 2018). As the Alliance will offer a wider range of vaccines, it will assist countries in identifying and **prioritising those vaccines** that are most appropriate for their local context, capacity and disease burden while also taking into account long-term programmatic and financial sustainability.
- 3.3 **The new VIS vaccines will be an opportunity to support countries in taking a life-course and integrated approach to immunisation.** Through its support for new vaccine introductions, the Alliance will incentivise countries to build or strengthen the immunisation touchpoints at various stages in life (e.g. Hepatitis B birth dose, or Td boosters at 4-7 years, Rabies at any age). These touchpoints would also provide the opportunity for countries to roll out other health interventions that would be part of a broader PHC package. Such new or under-used touchpoints along the life course may also be needed in future to roll out potential new ‘blockbuster’ vaccines for major diseases such as HIV, TB and Malaria which may be outside of the infant schedule. Vaccines against these three diseases are in advanced stages of clinical trials and could have a significant public health impact by 2030.
- 3.4 **The Alliance is already a key contributor to Global Health Security.** Gavi’s engagement in outbreak preparedness and response in countries includes its routine immunisation support for epidemic diseases, its funding of global vaccine stockpiles for outbreak response and its investments in surveillance for vaccine-preventable diseases. The Alliance will continue to ensure access to vaccines for outbreak prone diseases and develop a more deliberate and flexible approach to respond to outbreaks and emergencies. This will entail more streamlined and efficient processes to prepare and respond quickly to outbreaks and strengthened approaches to stockpile management including demand projections and efficient procurement. The Alliance will also continue to scale up vaccines for diseases prone to AMR such as the pneumococcal and Typhoid vaccines and also some of the VIS vaccines including Cholera and multivalent meningococcal vaccines.

⁵ Diphtheria, tetanus & pertussis-containing boosters; hepatitis B birth dose; A, C, W-containing multivalent meningococcal conjugate vaccines; oral cholera vaccine; rabies post-exposure prophylaxis; and respiratory syncytial virus immunisation products

4. Strategic Goal 2: Strengthen Health Systems to Increase Equity in Immunisation

2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION

- A** Help countries extend immunisation services to regularly **reach under-immunised and zero-dose children** to build a stronger primary health care platform
- B** Support countries to ensure **immunisation services** are **well-managed, sustainable, harness innovation** and meet the needs of all care givers
- C** Work with countries and communities to build resilient **demand**, and to identify and address **gender-related barriers** to immunisation

4.1 | **Gavi-supported countries reached a record 64 million children with a full course of basic vaccines (based on DTP3-containing vaccines) in 2017, up from 41 million in 2000.** Yet, even though the absolute number of children immunised has constantly been increasing, the rate of Penta coverage growth has slowed and, in particular, stagnated in fragile countries. Moreover, the number of children who are ‘zero-dose’ and have not received any routine vaccines (which are estimated to be 25-50% of the under-immunised) has hardly changed since 2010. This is indicative of the

challenge of reaching children living in communities that are often the most marginalised in their societies and suffer from multiple deprivations: It may require entirely new approaches and be more expensive. At the same time, these are the communities who most need immunisation as they are least likely to have access to treatment, are most likely to be exposed to disease due to low population immunity, are sites where epidemics begin and can least afford to cope with the cost of illnesses.

- 4.2 **As a result, increasing equity in immunisation delivery will be the priority of Gavi’s HSS support in the next strategic period** with a high ambition to reduce the number of under-immunised and an intensified focus on reaching the unreached, especially **‘zero-dose’ children** who tend to be clustered in communities without any basic services. Strengthening subnational data systems to identify these ‘zero-dose’ children and extending immunisation services to reach them can also serve as a platform for countries’ **integrated delivery** of other PHC services, laying a solid foundation for progressively universalising PHC in support of universal health coverage.
- 4.3 **Reaching marginalised communities will require continued efforts to strengthen delivery systems for immunisation** (e.g. by extending provision of **immunisation services**, strengthening supply chains and data systems), build **leadership and management capacity**, and also an increased focus on the **demand side**. While the latter has been an emerging focus in Gavi 4.0, the Alliance will need to scale-up its efforts significantly in this next strategic period particularly with the global epidemic of increasing **vaccine hesitancy**. This will include building and maintaining trust and confidence in immunisation, helping to ensure communities actively demand immunisation and designing services which respond to the specific **needs of care givers** in each community.

- 4.4 While immunisation is one of the most gender equal interventions there are still differences in coverage between boys and girls in specific communities that needs to be further understood and addressed. Moreover, **given the strong connection between gender and immunisation inequities the Alliance will prioritise, leverage and mainstream gender** into all its funding and approaches to ensure that gender dynamics contribute to, rather than inhibit, positive immunisation outcomes. Across these areas, the Alliance will need to bring new thinking and **innovative approaches**.

Examples of gender related barriers:

Some care givers face gender related barriers that prevent both them and their children from accessing immunisation and other healthcare services. These include demand-related aspects – for example with mothers and primary care givers not being able to leave the home alone or not having access to family finances, leading to an inability to bring their children to a facility to be immunised. They also include service delivery aspects, linked, for example, to a lack of female healthcare workers.

Examples of demand related barriers:

Demand related barriers range from a lack of awareness (e.g. on immunisation schedule) or low acceptance (e.g. due to concerns about minor side-effects, cultural, social or religious beliefs against vaccination), through to supply-side challenges which impact demand for services (e.g. because services are hard or costly to access, of low quality or not offered at times which are suitable for caregivers).

- 4.5 **Learning from the current strategy period, the Alliance will take a more deliberate approach to programmatic sustainability in Gavi 5.0.** While the Alliance has been successful in building financial sustainability into its programmes, it has become clear as countries have begun to transition that programmatic sustainability is a significant risk in some cases. The Alliance will therefore bring a greater focus to ensuring that countries deliver immunisation in a sustainable manner, that the programmatic approaches are efficient and cost-effective and that they have the strong institutions required to maintain performance after transitioning out of Gavi support. This will also entail a more deliberate approach to finding the right balance between short-term health systems support and long-term health systems strengthening as countries move along the development continuum.
- 4.6 **In line with its high ambition of reducing the number of under-immunised children, the Alliance will differentiate its support model** across varying country contexts (noting a tailored approach will be needed for each country as many countries will have multiple different contexts within their borders). This would include in particular:
- (a) Lighter requirements, processes and resourcing in relatively strong performing countries;

- (b) Higher resourcing and intensified engagement in countries with weaker systems (this will entail a review of the Alliance’s risk appetite in both settings and would likely entail accepting more risk in lower priority countries);
- (c) Working more extensively at sub-national level in large, federated states; and
- (d) Exploring new partnerships and models of working in conflict settings, prioritising reaching children while laying the foundations for sustainability where possible.

5. Strategic Goal 3: Improve Sustainability of Immunisation Programmes

3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES

- A** Strengthen national and subnational **political and social commitment** to immunisation
- B** Promote **domestic public resources for immunisation and primary health care** to improve allocative efficiency
- C** Prepare and engage **self-financing countries** to **maintain or increase performance**

5.1 **At the heart of the Gavi model is a unique approach to sustainability, domestic public resource mobilisation for vaccines and transition out of Gavi support.** The model has been highly successful so far in bolstering country ownership of vaccine programmes and in driving domestic public resource allocation towards immunisation. From 2011 to 2018, countries have increased their resources for Gavi-supported vaccines from US \$36 million to US\$ 475 million, representing 37% of Gavi’s and countries’ combined investments into

routine Gavi vaccines. At the end of 2018, 16 countries had fully transitioned out of Gavi support and self-financed 33 vaccine programmes. An additional three are expected to transition by the end of this the 2016 – 2020 strategic period. Across all transitioned countries, domestic public resource allocation for vaccines continues to increase and all eight countries that have transitioned for more than one year have been able to maintain or increase coverage. Strategic Goal 3 builds on the successes and challenges experienced so far.

5.2 **Broad-based political and social commitment to immunisation at both national and subnational levels is critical for countries** to maintain and further improve the performance of immunisation programmes. The Alliance has progressively sharpened its approach and tools to building political will at national level during the current strategic period. In Gavi 5.0 the Alliance will place greater emphasis on subnational political will as this is the level where much of the funding for immunisation delivery lies (e.g. due to devolution) and where immunisation programmes are operationally managed. Strong social commitment of communities for immunisation can significantly bolster the sustainability of political commitment, and hence the Alliance will put an enhanced focus in working with civil society organisations to foster this commitment.

- 5.3 Domestic public funding for immunisation remains vital for well-functioning immunisation programmes and successful transition from external support.** Therefore, it will continue to be a key priority in Gavi 5.0. The Alliance will refine ongoing approaches to secure domestic public resources for vaccines, maintaining the approach of increased country ownership for immunisation through co-financing while recognising the need to apply co-financing more flexibly in a set of conflict/emergency and fragile countries. The Alliance will also seek to more purposefully promote prioritisation of and domestic public funding for PHC, recognising that immunisation services reach children most sustainably when embedded into strong PHC. As part of its commitment to this approach, Gavi is working with The Global Fund and the World Bank to lead on the Financing Accelerator for domestic resource mobilisation under the umbrella of the SDG3 Global Action Plan. In this context, the Alliance will expand its collaboration with key multilateral technical and health financiers for advocacy, policy dialogue, technical assistance and funding to ensure sustainable immunisation programmes.
- 5.4 Ensuring successful transitions will remain at the heart of the Alliance's strategy in Gavi 5.0, with the objective to enable countries to maintain or increase performance sustainably after transition.** The Alliance's approach will be grounded in lessons learned from the cohort of countries already transitioned from Gavi support, also recognising the challenges in countries with growing GNI per capita but with deeply rooted systems issues. To ensure a more systematic and purposeful preparation for transition, the Alliance will continue to engage countries earlier on transition ensuring the appropriate sequencing and prioritisation of support (including a focus on programmatic sustainability as described in section 4.4). As part of this approach the GNI per capita indicator will remain the main criterion for transition but the Alliance will include additional considerations on programmatic sustainability to suitably adjust the duration of the accelerated transition phase in case of substantial programmatic challenges.
- 5.5 While most transitioned countries are maintaining immunisation performance, some countries have gaps in programmatic capacities or have not yet introduced critical high impact vaccines.** In response, the Alliance has been providing targeted support to post transition countries including voluntary time-limited vaccine price commitments provided by vaccine manufacturers, catalytic support to incentivise new vaccine introductions and targeted technical assistance to mitigate the risk of backsliding in performance. The Board has agreed that the Alliance will institutionalise this support and take a more deliberate approach to post-transition engagement. This approach would potentially include a market shaping mechanism pooling country demand, coupled with targeted technical support to accelerate new vaccine introductions where appropriate, and prevent immunisation coverage from backsliding. With countries self-financing their newly introduced vaccines after a short initial period of financial catalytic support, such an approach would aim at helping countries maximise the impact of their domestic public resources for immunisation.

5.6 A range of never Gavi-eligible MICs with comparable income levels to post-transition MICs (i.e. less than US\$ 6,000 GNI p.c.) face similar programmatic challenges. Despite higher immunisation investments on average, some never Gavi-eligible MICs are lagging behind on introductions of critical vaccines and/or are facing coverage and equity challenges. In fact, by 2030, 70% of the world's under-immunised will be living in MICs. The Board agreed that in the SDG era this poses an 'inter-country' equity challenge that is difficult to disregard. There are multiple drivers behind these challenges, such as weak political will for immunisation, fragility, gaps in decision making and regulatory processes, higher vaccine prices, and limited programmatic and institutional capacities. Thus, the Board agreed that a more deliberate engagement of the Alliance with post transition countries could be explored for some never Gavi-eligible MICs with GNI p.c. below US\$ 4,000. The Board also agreed that Gavi should explore options to engage with never Gavi-eligible MICs with GNI p.c. of between US\$ 4,000 and US\$ 6,000 (including countries facing conflicts and emergencies), although based on the needs, the modalities of engagement may be different. The scope and approach of this engagement, once developed, would need to be reviewed by the Programme and Policy Committee and approved by the Board and would ensure that:

- (a) Gavi's main focus will remain on its core portfolio of eligible countries;
- (b) engagement with former and never-eligible Gavi countries should account for no more than 3.0% of Gavi planned expenditure in the 2021-2025 period;
- (c) the approach does not create adverse consequences for the support being provided to eligible countries and for Gavi's current transition model;
- (d) attention to healthy market dynamics is maintained;
- (e) the goal would be that countries make better use of their domestic public resources including fully self-financing the new vaccines after a potential short initial period of financial catalytic support;
- (f) Gavi would prioritise high impact vaccines including HPV, PCV, Rota, Cholera and Typhoid; and that
- (g) careful communication and engagement be applied to avoid unreasonable expectations

Taking into account these guiding parameters the Secretariat will revert to the PPC and Board with a more detailed approach in 2020.

6. Strategic Goal 4: Ensure Healthy Markets for Vaccines and related Products

4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS

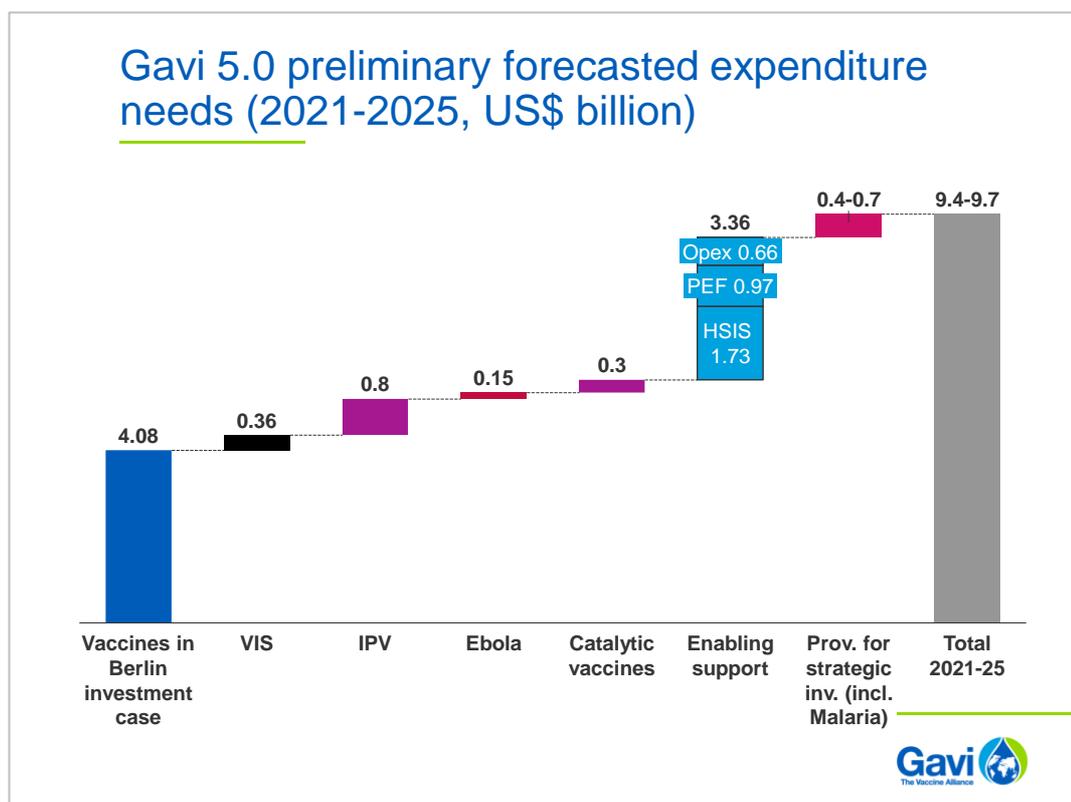
- A** Ensure sustainable, **healthy market dynamics** for vaccines and immunisation-related products at affordable prices
- B** Incentivise **innovation** for the development of **suitable vaccines**
- C** Scale up **innovative immunisation-related products**

6.1 **The market shaping model for vaccines and immunisation-related products will remain key to the Alliance in Gavi 5.0.** In the past, Alliance market shaping efforts have helped attract new manufacturers, improve supply security and decrease vaccine prices. The average price to fully vaccinate a child with pentavalent, rotavirus and pneumococcal vaccines has come down from ~US\$ 35 in 2010 to ~US\$ 17 in 2017. The Alliance

has expanded the number of vaccine manufacturers supplying Gavi-eligible countries from 5 in 2000 to 17 today (including multiple developing country vaccine manufacturers) ensuring scale and diversity of supply. In some cases, vaccine prices have come so low that they threaten healthy supply. Also, challenges persist on supply security in some vaccine markets. The Alliance will continue to work on balancing all the elements necessary to ensure **sustainable and healthy market dynamics** for vaccines and immunisation-related products, focusing on reliable, consistent and affordable supply as an overarching objective.

6.2 **The Alliance will also use its market shaping capabilities to drive innovation in vaccine-related products** funded by Gavi and in vaccine technologies with value-added enhancements in, for example, primary containers, route of delivery, packaging, safety, labelling and formulation. More broadly, **Gavi will continue to invest in innovation as a core part of its model.** Building on its experience so far, the Alliance will develop a more purposeful approach to promote transformational innovations across immunisation products, services and practices to help deliver on Gavi's equity ambition.

7. Financial implications



8.

- 7.1 **The preliminary forecasted expenditure needs for the 2021-2025 strategy period are US\$ 9.4 to 9.7 billion**, with assured resources and the replenishment approach for the next strategic period discussed further in agenda item 05.
- 7.2 **While the Alliance will be expanding the coverage of vaccines in the Berlin investment case (i.e. the ones listed at the Berlin replenishment), vaccine expenditures are projected to decrease** from US\$ 6.48 billion to US\$ 4.08 billion. The main drivers for this decrease are lower vaccine prices and the transition of countries from Gavi support. Additional vaccine investments will include the **VIS vaccines** (US\$ 0.36 billion) which will enable to close the immunity gap (Hepatitis B birth dose, DTP boosters and multivalent meningococcal vaccine), protect vulnerable populations (Cholera, Rabies), reduce outbreaks and/or decrease the risk of AMR (Cholera, multivalent meningococcal). The Alliance has also been asked to continue to support **Inactivated Polio (IPV)**, complementing GPEI eradication efforts (US\$ 0.80 billion), to assure this global public good is in place to protect against polio back-sliding. The Board has also provided in-principle support for the IPV-containing hexavalent vaccine, when available. Gavi will also bring an investment case to the Board for funding of a licensed **Ebola vaccine** (US\$ 0.15 billion). Finally, as per sections 5.5 and 5.6 the Alliance will institutionalise its support to **post-transition countries and will explore engagement with selected never Gavi-eligible MICs** primarily to catalyse

the introductions of high-impact vaccines which would be self-financed by these countries after a potential short initial period of catalytic support. This catalytic support would be in the range of US\$ 0.12-0.30 billion (approximately US\$ 0.12-0.17 billion for post-transition countries and US\$ 0.08-0.13 billion for never Gavi-eligible MICs). The detailed approach will come back to the PPC and Board.

7.3 The ‘enabling support’ (US\$ 3.36 billion) covers Gavi’s investments required to introduce vaccines and increase equity in immunisation delivery. Delivering on the high ambition of the Alliance to reduce the number of under-immunised children will require intensified effort and more innovation. The ‘enabling support’ includes:

- (a) US\$ 1.73 billion for HSIS and CCEOP which corresponds to a level of HSS support slightly below the current allocation formula (total of US\$ 1.10 billion), reduced provision for both vaccine introduction grants and operational support for campaigns (US\$ 0.43 billion), and CCEOP at the current level (US\$ 0.20 billion). Of note, the reduced HSIS allocation assumes a more efficient and effective use of Gavi’s grants. Hence there is a risk that the allocation may not be sufficient to deliver on the Alliance’s equity ambition or cover the increased costs of working in more challenging contexts;
- (b) US\$ 0.97 billion for the Partners’ Engagement Framework (PEF), which corresponds to the level of technical assistance provided in 2018; and
- (c) US\$ 0.66 billion of operating expenditures which correspond to the current resourcing of Secretariat and PEF operating expenditure;

Developing the details on the new HSIS and PEF grants will be part of the Gavi operationalisation process (see agenda item 07) and will come back to the PPC and Board for decision.

7.4 The ‘provision for strategic initiatives’ (US \$ 0.40-0.70 billion) includes

- (a) Additional support for countries with conflicts and weak systems as per approach for Strategic Goal 2: US\$ 0.15 – 0.30 billion;
- (b) Scaling up system innovations as described under Strategic Goal 4: US\$ 0.10-0.25 billion⁶; and
- (c) Investments for malaria vaccine if the implementation pilots are successful and there is a WHO recommendation for its use: ~US\$ 0.15 billion

These initiatives correspond to the Board’s guidance on areas of work that may require additional investment. The funding will require a decision from

⁶ Includes US\$ 25-50 million for technical support for post-transition countries and potentially never Gavi-eligible MICs as per sections 5.5. and 5.6 of this document

the Board on new policies or programmes and will come back to the PPC and Board for decision.

- 7.5 **The financial implications account for a number of trade-offs with regards to strategic priorities that the Board made at its retreat in Ottawa.** This includes decisions not to invest in various programmatic areas that would have had a significant cost impact (including expanded programs in human resources for health, vaccine-preventable disease surveillance, public financial management, funding of PHC platforms, etc.). In case Gavi did not raise all the required funding for the planned programmes, the Board would develop a prioritisation approach outlining what programmes would be funded in priority.