

Report to the GAVI Alliance Board

18-19 June 2014

Subject:	GAVI Alliance Strategy 2016-2020
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Agenda item:	09
Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1 Purpose of the report

- 1.1 The report annexed to this paper proposes a new strategic framework for the GAVI Alliance in the period 2016-2020. It builds on a large body of analytical work conducted through the strategy process and on the input provided through the extensive engagement of Board members and constituencies since June 2013.
- 1.2 The latest version of the proposed strategic framework is attached in Annex 1 and results from the extended discussion by the Board at its retreat in April 2014. A "track change" version of this framework is included in Annex 2 and highlights the changes made during and after the Board retreat. Annex 3 includes a narrative describing the elements of the framework.

2 Recommendations

2.1 The Board is requested to <u>approve</u> the framework for the GAVI Alliance strategy 2016-2020 attached at Annex 1 to Doc 09 and further described in Annex 3 to Doc 09.

3 Process to date

- 3.1 The strategy development process has been structured around the following steps:
 - (a) <u>June-November 2013</u>: Identification of areas requiring stronger focus in the 2016-2020 period. During this period, Board members shared their views through one-on-one interviews with the GAVI Alliance Deputy CEO on the areas requiring fine-tuning or stronger focus in the next strategy period. With further input from Board members,

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constituencies, GAVI countries, development partners, and guidance from the Executive Committee in September, the Secretariat continued to refine and test the input emerging from interviews. An in-depth landscape analysis on the 2016-2020 environment was also developed. This phase culminated at the November 2013 Board meeting, where the Board agreed on the strategic directions for the next period and requested the Secretariat to set up a series of further discussions.

- (b) December 2013-February 2014: Long term vision and details on areas requiring stronger focus. During this phase, the Board discussed the GAVI Alliance's long term vision as well the areas related to eligibility and graduation and GAVI's role in immunisation coverage and equity. After a series of teleconferences in December, the Board met for a workshop on 27-28 February where it provided further guidance on these areas as summarised in Annex 1 of this paper. The workshop discussion drew on further in-depth analysis prepared by the Secretariat on eligibility and graduation, as well as coverage and equity. The Board's conclusion at these workshops is captured at a high level in the proposed strategic framework included in this paper, and it will also be used as critical guidance during the development of the relevant policies and programmes in the coming months, which will underpin the implementation of the 2016-2020 strategy.
- (c) <u>March-June 2014: GAVI Alliance strategic framework.</u> This phase focused on synthesising the input provided by the Board in February into a strategic framework for the period 2016-2020. Central to this was the input provided by the Board at its retreat on 8-9 April 2014. Based on the guidance provided by the Board, the Secretariat finalised the framework and narrative attached to this paper.

4 Next steps

- 4.1 The indicators and metrics provided for each Goal in the framework and narrative attached are illustrative and will be further developed. The complete set of targets and indicators relating to the strategic framework will be finalised by mid-2015.
- 4.2 In addition, further work will be needed to develop the policies or approaches required to implement the strategy and to ensure that the Alliance's operating model is fit to deliver against it. This will include amongst others the Alliance supply chain strategy, the review of the eligibility, graduation and co-financing policies, and potentially other approaches in the areas of the strategy that require further detailing. The Secretariat will also coordinate a collaborative exercise with Alliance partners to review and refine the operating model for the next strategy period, including a review of the roles, responsibilities and processes through which the Alliance partners collaboratively implement the GAVI Alliance strategy and support GAVI implementing countries in their immunisation efforts.

Annex 1: Proposed strategic framework for the GAVI Alliance in 2016-2020

	GAVI Alliance strategy 2016-2020								
Mission	To save children's lives and protect people's health by increasing equitable u of vaccines in lower income countries	se Aspiration 2020	 < 5 mortality rate Future deaths averted Future DALYs averted # of children vaccinated wit 		TBD 5-6 million >250 million >300 million	Disease dashboar	 Empirical measurements (TBD) of health impact to which GAVI Alliance contributed in pneumonia, diarrhoea, HepatitisB and measles 		
	 Country-led: Respond to and align with c budget processes and decision-making 	ountry demand, s	supporting national priorities,	Integrated: Foster support by the GA	r integration of i VI Alliance with	mmunisation vother partners	with other health interventions, harmonising s'		
Principles	 Community-owned: Ensure engagement and sustain demand and impact Globally engaged: Contribute to the Glob 2015 global development priorities and im Catalytic & sustainable: Provide support including country self-financing of vaccines 	 Innovative: Foster and take to scale innovation in development models, financing instruments, public health approaches, immunisation-related technologies and delivery science Collaborative: As a public private partnership, convene immunisation stakeholders and leverage the strengths of all Alliance partners through shared responsibility at both global and national level Accountable: Maximise Alliance cooperation and performance through transparent accountability mechanisms 							
Goals	Accelerate equitable uptake and coverage of vaccines	2 efficiency delivery	effectiveness and y of immunisation as an integrated part thened health		sustainabilit al immunisa mes		Shape markets for vaccines and other immunisation products		
Objectives	 immunisation Support countries to introduce and scale up new vaccines Respond flexibly to the special needs of children in fragile countries 	 comprehensive including fixed components Support improve health information and approaches Strengthen en 	mproving integrated and e immunisation programmes, , outreach and supplementary vements in supply chains, tion systems, demand d gender sensitive gagement of civil society, and other partners in	 a Enhance national and sub-national political commitment to immunisation b Ensure appropriate allocation and management of national human and financial resources to immunisation through legislative and budgetary means c Prepare countries to sustain performance in immunisation after graduation 			 Ensure adequate and secure supply of quality vaccines Reduce prices of vaccines and other immunisation products to an appropriate and sustainable level Incentivise development of suitable and quality vaccines and other immunisation products 		
Goal-level indicators	further developed] Coverage by antigen: Pneumo3, Rota last, Penta3, HPV last, Measles, MenA Equity of coverage Wealth equity Geographic equity (within and across countries) Gender equity	immunisation se of vaccines Data quality: e. of reporting, cor sources Service deliver sessions conduc addressed in im Demand: Increa	e.g., vaccine utilisation, % of issions with adequate stocks g., completeness & timeliness isistency among different y: e.g., % of immunisation cted; Gender related barriers munisation plans ise in demand for g., as measured by survey icator TBD	 a <i>timely</i> manner Country investi immunisation 	es meeting comr) ments in vaccin per child (split ng/graduated co coverage after AVI vaccines ma	nitments in nes and puntries) aintained	Indicator on healthy market dynamics (e.g., # of suppliers, # countries obtaining first choice, vaccines and other products) Reduction in price (vaccines and other products) for GAVI countries, access to appropriate prices for graduated countries and LMICs Reduction in the delivery cost of immunisation Indicator on innovation (e.g., thermo- stable vaccines; delivery technologies)		
lers	 A) Country leadership (1) Strengthen institutional capacity for national decision-making, programme management and monitoring management & coordination (2) Support availability and use of quality data for country-level decision making 								
Strategic enablers	B) Resource mobilisation	-		Alliance programmes as a prerequisite for continued success uding through innovative finance mechanisms and contributions from vaccine manufacturers					
Itegic	(1) C) Advocacy (2)								
Stra	U) Monitoring & Evaluation		• • •				g and management (ii) Regular evaluation evidence-based policy development		

GAVI Alliance strategy 2016-2020

Annex 2: "Track changes" version of the proposed strategic framework following the April 2014 Board retreat Blue font: Changes agreed upon by the Board at the April retreat (vs. original version attached to the April Board retreat paper) Green font: Additions/changes made based on input received at the April Board retreat

davi Alliance Mission	To save children's lives and protect <i>people's</i> health by increasing equitable use of vaccines in lower income countries	Aspiration 2020 • < 5 mortality rate • Future deaths averted • Future DALYs averted	TBD 5-6 million >250 million d with GAVI support >300 million				
Principles	 Country-driven-led: Respond to and align with budget processes and decision-making Community-owned: Ensure engagement of c demand and impact Targeted: Focus support on lower-income could Aligned Globally engaged: Contribute to the 2015 global development priorities [in harmony Catalytic & sustainable: Provide support to g country self-financing of vaccines through the global development priorities [in harmony 	ommunities to increase accountability and sustain intries where the need is greatest Global Vaccine Action plan, align with the post ⁴ and implement aid effectiveness principles] enerate long term sustainable results including	 Integrated: Encourage Foster integration of immunisation with other health interventions, harmonisi support by the GAVI Alliance with other partners' 				
Goals	Accelerate equitable access to and use uptake and coverage of vaccines	2 Strengthen and modernise Increase effectiveness and efficiency of immunisation programmes delivery within as an integrated part of integrated strengthened health systems	3 Improve sustainability of national immunisation programmes	4 Shape markets for vaccines and other immunisation products			
Objectives	 a Increase coverage and equity of immunisation b Support countries to introduce and roll-out- scale up new vaccines c Respond flexibly to the special needs of children in fragile countries 	 Contribute to improving integrated and comprehensive immunisation eystems programmes, including fixed, outreach and supplementary components Support improvements in supply chains, dat health information systems, demand generation, and access to immunisation services through-gender sensitive approach Strengthen engagement of civil society, private sector and other partners in immunisation 	 political commitment to immunisation b Ensure appropriate allocation and management of national human and financial resources to immunisation through legislative and budgetary means c Prepare countries to sustain performance in immunisation after 	 a Ensure adequate and secure supply of quality vaccines b Reduce prices of vaccines and other immunisation products to an appropriate and sustainable level c Incentivise development of appropriate suitable and quality vaccines and other immunisation products 			
Goal-level indicators	 % Fully immunised children [to be further developed] Coverage by antigen: Pneumo3, Rota last, Penta3, HPV last, Measles, MenA Equity of coverage Wealth equity Geographic equity (within and across countries) Gender equity Number of additional children reached 	 Supply chain : e.g., vaccine utilisation, % of immunisation sessions with adequate stocks of vaccines Data systems: e.g., quality, completeness & timeliness of reporting, consistency among different sources Service delivery: e.g., % of immunisation sessions conducted; Gender related barriers addressed in immunisation plans Demand: Increase in demand for immunisation, e.g., as measured by survey Integration: Indicator TBD 	• Fulfilment of co-financing commitments (e.g., % countries meeting commitments in a <i>timely</i> manner)	 (e.g., # of suppliers, # countries obtaining first choice, vaccines and oth products) Reduction in prices (vaccines and other products) for GAVI countries, access to appropriate prices for 			
Strategic enablers	A) Country leadership management & coordination (1) Strengthen institutional capacity for national decision-making structures, programme management and monitoring capabilities B) Resource mobilisation (1) Secure long-term predictable funding for GAVI Alliance programmes as a prerequisite for continued success (2) Harness the capacity of the private sector, including through innovative finance mechanisms and contributions from vaccine manufication						
		 Strengthen national political and subnational commitment for immunisation Strengthen global political commitment for immunisation, health and development 					

Annex 3:

Proposed strategic framework for the GAVI Alliance in 2016-2020 – Accompanying narrative

GAVI ALLIANCE STRATEGY 2016-2020

1) GAVI Alliance environment 2016-2020

The focus of the GAVI Alliance strategy for 2016-2020 is to consolidate and to build upon the impact achieved during 2011-2015 and adapt to the changing environment in which the Alliance and the countries it is supporting will operate.

1.1- Impact to date

The GAVI Alliance's third strategy phase, covering 2011-2015, has been characterised by a dramatic increase in vaccine introductions, particularly rotavirus and pneumococcal; a shift in emphasis from broad health systems strengthening to more focused investments to improve immunisation outcomes within an integrated health system; and an increased focus on shaping vaccine markets. In this phase, the Alliance has also forged new advocacy networks and formed new partnerships such as those with the Measles Rubella Initiative and the Global Polio Eradication Initiative and, as such, it has played a critical convening and alignment role for multiple organisations involved in routine immunisation. Overall, the Alliance expects to have contributed to significant public health impact, immunising an additional 243 million children and averting more than 3.9 million future deaths.

1.2- The 2016-2020 environment

The landscape in 2016-2020 will be very different than in 2000, when GAVI was created, and in 2010, when the current strategy was developed. Rapid economic growth in emerging economies means that "recipient countries" will assume increasing financial responsibility for their own essential social infrastructure. Yet, the benefits of economic growth are often unequally distributed within countries, such that most poor people today live in countries that are now classified as middle income. The same is true when looking at the benefits of immunisation; some of the countries with high GNI growth experience important challenges in immunisation. About 56% of the world's under-immunised children live in Indonesia, India and Nigeria – countries now classified as middle-income countries and expected to graduate from GAVI support in the next strategic period. **Sustainability will therefore be central to the next strategy period to ensure that graduating countries maintain and continue to improve the performance of their immunisation programmes after graduation.** This will also require GAVI to evolve its support model and consider the types of support other than vaccine subsidies that it could provide to its 'alumni countries' to ensure that they sustain immunisation results.

There has also been significant progress globally in reducing child mortality, partly due to increased immunisation rates. Immunisation coverage against the most basic vaccines (as measured by the third dose of a DTP-containing vaccine) in GAVI countries has grown from 61% to 75% from 2000 to 2010. However, average coverage rates have stagnated in the past 3 years -- primarily due to challenges in a number of large countries – and in 2012, close to 20 million children (26%) in countries supported by GAVI did not receive a full course of a DTP-containing vaccine. Within developing countries, children who die before the age of five and who miss out on life-saving

vaccines are often those living in the hardest-to-reach areas, in marginalised communities and in the poorest households. Improving equity in access to immunisation both between and within countries continues to be a key priority for the Alliance. After a period of unprecedented number of vaccine introductions in 2011-2015, the GAVI Alliance's next strategy will need to focus strongly on consolidation and integration to increase coverage and equity of all life-saving vaccines.

2) Strategic framework for the period 2016-2020

2.1- Executive summary

Throughout the strategy development process, Board members have commented that the current GAVI Alliance strategic framework has served the Alliance well and should remain a strong foundation for 2016-2020. At the same time, Board members have suggested refining the strategic framework (e.g. mission, goals, indicators) in order to reflect lessons learned in the current strategic period, and to ensure focus on the challenges ahead.

The strategic framework attached in Annex 1 is the result of Board guidance. The main innovations are detailed in the box below. The following section provides more details on the framework.

Overview of major innovations in the proposed strategic framework

The main changes reflected in the new strategic framework proposed in this paper include:

- A refined set of principles: To reflect the Alliance's aspiration with regards to its operating model and better align with aid effectiveness principles.
- A strengthened focus on coverage and equity: The mission is modified to include a reference to "equitable use of vaccines". The first strategic goal evolves from a focus on introducing of new and underused vaccines to an emphasis on improving coverage and equity of immunisation.
- Focus on effectiveness and efficiency of immunisation delivery: Strategic Goal 2 articulates the focus of the GAVI Alliance on immunisation programmes and the importance of effectiveness, efficiency and integration with national health systems. Progress will be tracked through a set of intermediate indicators related to the strength of immunisation programmes, including supply chain, data systems, service delivery, demand generation and integration. The ultimate objective of GAVI support in this area is to improve coverage and equity, which will be tracked in Goal 1. GAVI support will not be limited to these specific areas, but be based on a thorough analysis of country bottlenecks.
- A holistic emphasis on sustainability: Sustainability becomes the third Goal in the strategy. It keeps the co-financing element which links with financial sustainability and also includes an element of programmatic sustainability. Resource mobilisation becomes one of the new 'strategic enablers'.
- A broad market shaping role: The market shaping goal includes a mention of sustainable pricing for 'alumni' countries, as well as immunisation-related commodities other than vaccines.
- A focus on leadership, management and coordination at country level: Recognising the critical importance of this aspect in sustainability, system performance and decisions to introduce new vaccines, this area becomes one of the new 'strategic enablers'.
- A "disease dashboard": To complement model-based health impact monitoring with empirical measurements of the Alliance's contribution to alleviating the burden of vaccine-preventable diseases.

2.2- Details of the strategic framework

The section below provides more details on each element of the draft framework.

<u>Mission – To save children's lives and protect people's health by increasing equitable use of</u> <u>vaccines in lower income countries</u>

The mission emphasises GAVI's focus on **saving children lives** by contributing to address some of the highest causes of mortality in children in lower income countries (including diarrhoea and pneumonia) through immunisation. It also includes a reference to **protecting health** and saving lives at a later stage in life, by preventing certain cancers triggered by vaccine-preventable infections (e.g. cervical cancer from HPV and liver cancer from hepatitis B).

The mission also makes equity more central, as GAVI will aim to **increase the equitable use of vaccines.** Beyond ensuring fairness amongst different populations, ensuring equity in immunisation coverage (whether based on wealth, geography or gender) will also contribute to maximising impact on mortality and morbidity, as children missed by immunisation services often lack access to both curative and other preventive services.

Lastly, the reference to "lower income countries" does not intend to match a specific income categorisation by other organisations, but rather reemphasises the focus of the GAVI Alliance's financial support on countries with limited ability to pay for immunisation programmes.

By working to achieve the GAVI Alliance Mission, GAVI Alliance partners support the Decade of Vaccines vision: "a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases".

Aspirations for 2020

Consistent with the "mission level indicators" in the 2011-2015 strategy, the GAVI Alliance strategic framework 2016-2020 sets both (a) an aspirational target to which GAVI's efforts will contribute (but not be directly attributable): the estimated under-five mortality rate in GAVI-supported countries; and (b) targets more directly attributable to the Alliance's efforts: the estimated number of children vaccinated with GAVI support (aspiration: over 300 million children over the 2016-2020 period), the estimated number of future deaths averted (aspiration: between 5 and 6 million future deaths averted thanks to immunisations delivered over the period 2016-2020) and the estimated number of future Disease Adjusted Life Years (DALYs) averted through GAVI programmes (aspiration: over 250 million DALYs averted thanks to immunisations delivered over the period 2016-2020).

In addition, the framework will include a 'disease dashboard' to empirically measure the GAVI Alliance's contribution to alleviating the burden of vaccine preventable diseases. The intention of the "disease dashboard" is to monitor health impact indicators using empirical measurement to supplement the other health impact indicators which are predominantly based on models¹. It is important to note that these empirical indicators should be interpreted as evidence of the Alliance's contribution to health impact: they should not be interpreted as implying attribution of such impact solely to the Alliance. To the extent possible, the disease dashboard will leverage existing Alliance partner investments and attempt to align with indicators for other global and regional initiatives (e.g.

¹ Most of the GAVI Alliance health impact indicators are model-based, but informed by empirical data where available, to allow for consistent measurement and reporting across the GAVI vaccine portfolio and countries eligible for support.

GVAP monitoring and regional hepatitis B control initiatives). Indicators for vaccines comprising the greatest proportion of health impact projected in GAVI countries will be prioritised. The list of indicators, definitions and data sources will be developed in the upcoming months.

Principles

The strategic framework includes eight principles, intended to define the Alliance's characteristics, its business model and its aspirations:

- Country-led: Highlights that GAVI Alliance programmes respond to and align with country demand, supporting national priorities, budget processes and decision-making;
- Community-owned: Recognises that, while country governments bear the responsibility to guarantee access to immunisation for all, communities play a key role advocating for vaccine uptake, advising the government in decision making, supporting it in service delivery and holding it accountable;
- Globally engaged: Places the GAVI Alliance in the broader context of the international community's collective efforts. In particular the GAVI Alliance will contribute to the Global Vaccine Action Plan, align with the post 2015 global development priorities and implement the aid effectiveness principles, which includes, among others, the IHP+ framework;
- Catalytic and sustainable: Clarifies that GAVI support is time limited, intended to catalyse long-term sustainable results, including through country co-financing and the graduation process;
- Integrated: Underscores the importance of integration of immunisation programmes with other health interventions, as well as the integration/ harmonisation of GAVI support with that of other development partners;
- Innovative: Emphasises that the Alliance will foster innovation, including through collaboration with the private sector, with the intent to take it to scale. The Alliance will strive to foster innovation in development models, financing instruments, public health approaches, immunisation-related technologies and delivery science;
- Collaborative: Highlights that, as a public private partnership, the GAVI Alliance convenes immunisation stakeholders and leverages the strengths of all Alliance partners through shared responsibility at both global and national levels;
- Accountable: Stresses that the Alliance will maximise cooperation and performance through transparent accountability mechanisms.

Goal 1 - Accelerate equitable access to and use of vaccines

Increasing coverage and in-country equity of immunisation is the centrepiece of the Alliance's next strategy, and is the first objective in Goal 1. This goal reflects the need for programme consolidation in the period 2016-2020 after the high number of introductions in 2011-2015 and the need for more comprehensive and new approaches in immunisation programmes. It also reflects the fact that some of the 'new vaccines' are now part of routine immunisation in most GAVI countries (most notably, pentavalent).

The three objectives proposed under this goal are as follows:

- Increase coverage and equity of immunisation: The Alliance will work with countries and incountry partners to support the implementation of strategies to reach all currently unreached children and to ensure high coverage of all vaccines across all subsets of the population, reducing disparities where they exist, across wealth groups, geographies and gender.
- Support countries to introduce and scale up new vaccines: The Alliance will also continue to support countries that have planned to introduce GAVI-supported vaccines in their schedule. This objective has evolved from the current period to reflect increased emphasis on successful roll-out beyond actual introduction. Leveraging its various grants, technical assistance and other core processes, the GAVI Alliance will support countries in funding vaccines, preparing their introductions and ensuring successful roll out in a way that strengthens routine immunisation.
- Respond flexibly to the special needs of children in fragile countries: The Alliance will continue to devote particular attention to the needs of countries facing instability and/or particularly entrenched challenges in immunisation. The Alliance will take flexible approaches to adapt to these exceptional contexts.

Of note, vaccine support will continue to represent the majority of the Alliance's expenditure. The GAVI Alliance will continue to support the Board-approved vaccines including those in the most recently approved Vaccine Investment Strategy (VIS). The VIS, developed through a fact-based and consultative process, will be conducted on a regular basis to ensure that GAVI focuses on the vaccines with highest public health impact and cost-effectiveness.

Support for vaccine financing will be provided to GAVI-eligible countries on the basis of criteria related to their ability to pay. GAVI might also consider, on an exceptional basis, catalytic investments (e.g., for certain states in large countries) beyond this eligibility criterion for countries facing disproportionate public health needs. The exact scope and modalities for this support would be brought to the Board for its consideration in 2015, as part of the revision of the eligibility, graduation and co-financing policies.

The Alliance will track progress against Goal 1 through indicators reflecting coverage of individual GAVI-supported vaccines (including, but not limited to, those already tracked in the current period: pentavalent, PCV, rotavirus), as well as through an indicator on the 'Fully Immunised Child' -- tracking the percentage of children being reached by a full suite of WHO-recommended vaccines. Further development of the latter will be needed, to identify a definition of "fully immunised" that is acceptable to Alliance Partners and GAVI implementing countries, and to ensure that robust data is available to track progress. Progress would also be measured through strengthened indicators reflecting equity in immunisation coverage across various dimensions, including wealth, geography and gender.

<u>Goal 2 - Increase the effectiveness and efficiency of immunisation delivery as an integrated</u> part of strengthened health systems

Strong and efficient immunisation delivery, drawing on modern technologies and approaches as appropriate, will be critical to ensure that the Alliance reaches its ultimate goals on coverage, equity and sustainability. The wording for Goal 2 reflects the increased focus of GAVI health systems support on immunisation and also emphasises the need for integration with other primary health care interventions, and with other interventions targeting the same health needs.

Governments are responsible for their national health systems and immunisation programmes, and the GAVI Alliance has a clear role in working with them to build strong routine immunisation delivery. The support should be provided in a way that reinforces overall health system capacity through strong integration and system-wide improvements which have positive effects beyond immunisation.

GAVI support to countries in this domain will continue to be driven by country context and country priorities. Recognising that GAVI health systems support is relatively small in comparison to the cost of delivering immunisation in-country, GAVI will continue to effectively target its investment in this area. This will include support for national bottleneck analysis, a review of the allocation formula for the HSS grant to enable a greater focus on countries with significant needs, and access to health systems specific technical competence. In addition, the Alliance will develop strategies and approaches in critical areas of immunisation delivery where, as a global Alliance, it can bring value in addition to the direct financial support it provides to countries (e.g. through market shaping interventions, dedicated technical assistance, and incentives to countries). All these elements would follow the standard decision-making processes, including reviews by relevant committees and ultimately decision by the Board. Performance based HSS support will remain the main instrument for GAVI to provide its support for this purpose, as already approved by the Board.

This goal will be structured around three objectives:

- Contribute to improving integrated and comprehensive immunisation delivery: GAVI Alliance will support countries in designing and implementing comprehensive approaches to immunisation programmes, and support better coordination of the various components of immunisation strategies (including fixed, outreach and supplementary/campaigns components). Support by the GAVI Alliance will continue to fit in the broader context of national health strategies and to support the integration of immunisation in health systems. Based on individual countries' needs and priorities, the GAVI Alliance will provide support through grants and technical assistance to tackle the health systems constraints to delivering immunisation. This support will be based on country-driven and fact-based analysis to identify the bottlenecks in all areas of immunisation systems. Particular attention will be paid to integration and how this support reinforces health systems more broadly.
- Support improvements in supply chains, data systems, demand generation and gender-sensitive approaches: As a global Alliance, GAVI will explore how to better leverage its comparative advantage to develop, catalyse or scale up potential solutions in the areas of supply chain, data systems, demand generation and gender-sensitive approaches to immunisation. These areas are critical constraints to the delivery of immunisation services and domains where the Alliance could add value through initiatives such as market shaping; development and use of global tools and digital technologies; elaboration of norms and standards; dedicated technical assistance; and further use of incentives built into application and guidelines for GAVI support.
- Strengthen engagement of civil society, private sector and other partners in immunisation: Civil society and the private sector have critical roles to play in improving immunisation and increasing coverage and equity at country level. As a public-private partnership, the GAVI Alliance will further encourage the engagement of civil society organisations in immunisation programmes and actively seek engagement with the private sector to leverage their capabilities and expertise in areas that would be beneficial to the implementation of national immunisation programmes.

Ultimately, the expected outcome under this Goal is to improve coverage and equity, which will be tracked in Goal 1. Progress against Goal 2 will be more directly tracked through intermediate health systems performance indicators reflecting GAVI's investments. Specific indicators will be used for selected areas, such as supply chain (e.g. vaccine utilisation rate); data systems (e.g., quality, completeness and timeliness of reporting, consistency among different sources, deployment of

appropriate systems for birth registration etc.); service delivery (e.g., percentage of immunisation sessions conducted, gender-related barriers addressed in immunisation plans); demand for immunisation services (e.g., increase in demand for immunisation services as measured by surveys); and an indicator to measure the integration of immunisation with other health interventions.

Goal 3 - Improve the sustainability of national immunisation programmes

As an increasing number of GAVI-supported countries graduate or enter the graduation period between 2016 and 2020, ensuring sustainability through successful graduation will be central to the GAVI Alliance's next strategy period. Goal 3 centres on the sustainability of immunisation programmes, including after GAVI support ends. This issue has been repeatedly stressed by Board members as needing increased emphasis in the next strategic period, including through early engagement with countries well before they start the graduation process. It includes the co-financing element, as well as an emphasis on political commitment, leadership, management and sustained performance of the immunisation programme after graduation. Global resource mobilisation, a critical pre-requisite for GAVI programmes included in Strategic Goal 3 of the 2011-2015 strategy, has been positioned in the proposed draft as a 'strategic enabler' (see below).

One of the cornerstones of the GAVI Alliance's development model is that funding is time-limited and catalytic, and that countries graduate out of GAVI support as their economy grows. As of 2014, 20 countries have entered the five-year graduation process. Overall, most of the countries currently graduating are successfully laying the foundations for self-sufficiency and sustained performance of immunisation once GAVI support ends. A limited number of graduating countries are, however, expected to face financial and/or programmatic challenges in the next period, including three large countries: Indonesia, India and Nigeria. At the workshop in February, there was a majority view that the GAVI Alliance should keep its eligibility criteria (i.e. the 'entry' criteria) but refine its graduation approach to ensure a successful glide path towards sustainability, both financial and programmatic (i.e., the 'exit' criteria). In particular, the Alliance should ensure that the graduation process is tailored to countries' specific needs and includes early engagement to identify bottlenecks and to design and implement country-specific graduation plans. The GAVI Alliance will also further develop the tools and improve the quality of technical assistance that it makes available to countries in this process.

This goal is structured around three objectives:

- Enhance national and sub-national political commitment to immunisation: Political commitment is critical to ensure sustainability of immunisation programmes, not only government budget allocations but also with regards to sustainable performance of immunisation programmes in terms of coverage and equity. This will require engagement with country decision-makers, including Ministers of Health, Ministers of Finance, parliamentarians and heads of states, such that immunisation is firmly represented in the national political agenda. This will be done through advocacy at all levels, including close engagement of local communities and civil society organisations.
- Ensure appropriate allocation and management of national human and financial resources to immunisation through legislative and budgetary means: The GAVI co-financing policy will continue to require countries to contribute financially to the cost of the vaccines that the GAVI Alliance supports, with a holistic view to all national investments in immunisation, including co-financing as well as funding for vaccines not supported by the Alliance. The Alliance will also support countries during the graduation phase, to ensure that they allocate enough resources to meet and sustain the full GAVI price of the vaccines and the other costs related to immunisation programmes when GAVI support ends. This could include advocacy towards increasing the

share of the national budget dedicated to health, consistent for example with the Abuja declaration by African countries.

 Prepare countries to sustain performance in immunisation beyond graduation: Based on the Board's guidance to revisit "exit criteria" and to consider tailored engagement with graduating countries, the new graduation approach will be designed to maximise the potential for countries to sustain results beyond graduation. Although GAVI vaccine support will end once a country has graduated, the Alliance will continue to engage with 'alumni' countries to assist them in maintaining the results gained through GAVI support and may continue to play a supportive role, e.g., in terms of facilitating favourable pricing arrangements or providing technical assistance. Sustaining these results should also be an integral part of the commitment that countries make when deciding to introduce vaccines with GAVI support.

The GAVI Alliance will track the sustainability of immunisation programmes through indicators on the timely fulfilment of co-financing commitments (for fully eligible and graduating countries). In addition, it will look at the amount of country investments in immunisation (covering both vaccines and non-vaccine costs). Possible indicators to reflect to what extent the Alliance ensures that countries are prepared for graduation and sustain performance thereafter include immunisation coverage in 'alumni' countries and vaccines maintained in the EPI schedule after graduation.

Goal 4 - Shape the markets for vaccines and other immunisation products

Shaping vaccine markets will remain a key goal for the Alliance in 2016-2020. Beyond shaping the markets for vaccines, the wording of Goal 4 reflects the role that the Alliance has played in the past for other immunisation-related products, such as auto-disable syringes, and could potentially play in the future for products such as cold chain equipment (subject to Board decision through the relevant processes), with the objective of reducing price, securing supply or influencing technological developments and innovations to better address the needs of GAVI countries. This goal also reflects the Alliance efforts to support 'alumni' countries and, potentially, other Lower Middle Income Countries (LMICs) to access appropriate and sustainable prices for vaccines. This goal is structured around three objectives:

- Ensure adequate and secure supply of quality vaccines, by sourcing a sustainable supply through a diverse supplier base. This will entail, among others, encouraging a wide base of manufacturers to produce quality vaccines required and ensuring that countries with manufacturers that have the potential to become GAVI Alliance suppliers have the relevant regulatory capacity to control quality of national production.
- Reduce prices of vaccine and other immunisation products to a sustainable level: The GAVI Alliance will leverage its purchasing power, predictable financing and procurement capabilities to drive down vaccine prices to levels that are sustainable in the sense of both (a) being affordable for GAVI-supported countries, 'alumni' countries, and potentially other LMICs, and (b) enabling the industry to ensure continuous supply of quality vaccines. The Alliance is developing options for a mechanism to ensure access to appropriate pricing for 'alumni' countries and potentially other LMICs, which will be brought to the Board for consideration.
- Incentivise development of suitable and quality vaccines and other immunisation products by setting up the relevant Alliance mechanism to encourage or advocate for presentations, products and technologies that are appropriate to the context of the countries that the GAVI Alliance supports.

To track progress against this Goal, the GAVI Alliance will use indicators related to price reductions for GAVI-eligible countries, potentially adding access to appropriate prices for 'alumni' countries and other LMICs. In addition, it will look at indicators around supply security and healthy market dynamics (e.g. number of suppliers, uninterrupted supply), delivery cost of immunisation in GAVI countries (with clear links to the efficiency of immunisation programmes referred to in Goal 2), and innovations (e.g. on thermo-stable technologies, or new delivery technologies).

Strategic enablers

The new strategic framework includes four 'strategic enablers'. These are defined as critical elements that the GAVI Alliance, including countries, need to put in place to successfully achieve the four Goals of the strategy. These enablers include: In-country Leadership Management & Coordination, Advocacy, Resource Mobilisation and Monitoring & Evaluation.

A) Country Leadership, Management & Coordination

Strong leadership, management and coordination at national and subnational levels, based on quality data, are critical to implementing effective, efficient and sustainable immunisation programmes. This area was identified as one of the critical barriers in the in-depth analysis of bottlenecks to immunisation coverage and equity developed ahead of the February workshop. This strategic enabler underpins the proposed Goals: country leadership, management and coordination are essential in the decision to introduce and in the roll out of new vaccines (Goal 1); to drive improvements in immunisation delivery systems (Goal 2); and to guarantee the sustainability of immunisation programmes (Goal 3).

This enabler is structured around two areas of work:

- Strengthen institutional capacity for national decision-making, programme management and monitoring: Decision-making bodies in countries such as NITAGs², NRAs³ ICCs⁴ and HSCCs⁵ play a critical role in collaboration with the Ministries of Health in the performance and sustainability of immunisation programmes. Regular reviews of performance at various levels and supportive supervision are also important drivers of immunisation performance. Through its country grants, technical assistance and other non-financial tools, the Alliance will further encourage the development and implementation of such structures and processes and contribute to build capacity to better manage, plan, execute and monitor multiple aspects of the immunisation programme. This also includes the Alliance's role in convening Alliance partners and other immunisation and health stakeholders at country level to help ensure collaboration and alignment between them; and the aspect of fiduciary control and procurement systems incountry, which GAVI will continue to reinforce through its Transparency and Accountability Policy.
- Support availability and use of quality data for country-level decision making: To be effective, the
 country structures and processes described above must have robust data to ensure effective
 decision making. The GAVI Alliance will support countries in selecting and using the relevant
 instruments and processes for generating quality data for decision-making, and encourage
 appropriate in-country feedback loops to drive performance improvement at all levels of the
 system.

² National Immunisation Technical Advisory Groups

³ National Regulatory Authorities

⁴ Inter-agency Coordinating Committees

⁵ Health System Coordinating Committees

Although the GAVI Alliance is already engaged in this field in the current strategic period, this enabler is a new feature in the strategic framework. It pulls elements from different Goals and brings them together as an enabler critical for fulfilling GAVI's mission.

B) Resource Mobilisation

The GAVI Alliance's ability to mobilise the resources necessary to implement its programmes is and will remain a critical pre-requisite to reach each of the Goals and to deliver on the mission. The unprecedented impact of the current period outlined in Section 2 above would not have been possible without the pledges of over US\$ 4 billion to GAVI during a replenishment conference held in June 2011. Continued commitment of development partners is crucial if GAVI Alliance is to secure and further advance this public health impact in 2016-2020. Together with countries' co-financing and health systems investments and with manufacturer's commitment to offer affordable vaccine prices, financial commitments from development partners, public and private, represent one of the three cornerstones of the GAVI Alliance's long-term funding strategy.

The Resource Mobilisation enabler will entail two areas of work:

- Secure long-term predictable funding for GAVI Alliance programmes as a prerequisite for continued success: In accordance with the Long Term Funding Strategy adopted by the Board in 2012, particular emphasis will be placed on the predictability of funding, a core component of the GAVI Alliance development model which enables it to provide countries with the predictability necessary to plan in the long term and to shape vaccine markets by increasing certainty around demand for vaccines and ability to fund. The Alliance will aim to extend the existing financial commitments from development partners and to expand its donor base to new partners, including from emerging countries.
- Harness the capacity of the private sector, including through innovative finance mechanisms and contributions from vaccine manufacturers: In a context of a global evolution of the official development assistance model, the Alliance will continue to explore how to harness the private sector's contributions, advocacy power and capabilities, including through IFFIm, through the development of potential new innovative finance mechanisms, through the contribution from vaccine manufacturers through affordable and sustainable pricing and through expanding Alliance partnerships with private sector companies (see also Goal 2.c concerning the opportunity to leverage private sector capabilities and expertise in areas that would be beneficial to the implementation of national immunisation programmes).

C) Advocacy

While there remain significant technical barriers, reaching pockets of under-immunised children down to the district and community level will, to a large extent, rely on political commitment at the global, national and sub-national level. In the last five years, there has been a surge in global advocacy related to immunisation due to a variety of factors: the heightened impact and prominence of the GAVI Alliance; efforts of individual Alliance partners, including the Bill & Melinda Gates Foundation, UNICEF, WHO and Civil Society Organisations; and the development and launch of the Global Vaccine Action Plan. The Alliance model enables coordinated advocacy at a scale greater than any single organisation could accomplish. As part of this enabler, the GAVI Alliance will aim to:

 Strengthen national and sub-national political commitment for immunisation: Strong political leadership will be critical to enable improvement in coverage and equity, as well as to ensure the sustainability of immunisation programmes once GAVI support ends. Strengthening political commitment requires the engagement of national and sub-national political leaders and influencers, including civil society organisations, faith-based organisations, and communities to build momentum for immunisation and to ensure appropriate attention and resources are dedicated to it. This element is also related to the increased emphasis on demand generation activities (see Goal 2.b).

Strengthen global political commitment for immunisation, health and development: Considering
the scale of GAVI programmes, the growing strength of the Alliance and its increasing
recognition as a model for new approaches to development, the GAVI Alliance is well placed to
further leverage collective advocacy efforts to ensure global political commitment for health (in
general) and immunisation (in particular) as core and integrated development issues in the post
2015 agenda. In doing so, the Alliance will further promote innovation in development and
immunisation approaches, including products, technologies, financing mechanisms and the
value of multi-sectorial partnerships. The Alliance's global advocacy role also supports resource
mobilisation efforts (see previous enabler).

D) Monitoring & Evaluation

As a learning Alliance, GAVI will continue to place a strong emphasis on Monitoring & Evaluation (M&E), which will be essential to ensure that the GAVI programmes are delivering their expected results and that the Alliance is using its resources effectively and continually improving the way it does business. This will be achieved through:

- Effective routine surveillance, programme monitoring and management: The Alliance will continue to support countries improve their surveillance systems to track the epidemiological evolution of the diseases prevented by GAVI-supported vaccines. In addition, the implementation of an improved grant application and monitoring review process and the on-going monitoring of key performance indicators will contribute to ensure that the programmes funded in-country are being implemented effectively and that Alliance investments are producing the expected results. Where necessary, changes would then be made to programmes structures and processes.
- Regular evaluations of the relevance, effectiveness, impact, and efficiency of the GAVI Alliance's investments to inform evidence-based policy development. Through regular evaluations leveraging innovative approaches, the Alliance will continue to regularly evaluate the impact of its programmes. This will include targeted studies on specific areas of investments, as well as large-scale public health effectiveness evaluations, such as the 'full country evaluation' currently underway, designed to comprehensively measure the effectiveness and cost-effectiveness of GAVI's support in a subset of countries. The findings from these evaluations will be critical in the regular revision of GAVI policies to ensure that they are fit-for-purpose to help the Alliance deliver on its Mission.

Annex 4: Summary of the strategic direction provided at the Board workshop in February 2014

During the Board workshop conducted in Geneva on February 27-28, Board members and alternates provided guidance on the Alliance's direction over the long term, on its future plans regarding eligibility and graduation and on potential approaches to help countries improve immunisation coverage and equity.

A) Alliance's role and focus in the long term.

One theme that emerged in that discussion is the need to clarify the <u>Alliance operating model.</u> Many noted that the Alliance's value-add goes much beyond its financing support to countries. It brings together the contribution from the main partners in the field of immunisation, provides a place for coordination and mutual accountability and sets up the relevant mechanism and incentives to ensure that the support ultimately reinforces routine immunisation systems in GAVI supported countries. Board members noted that in the current period good progress has been made, especially at global level, to clarify the roles of the Secretariat and Alliance partners, but that there was a need to review how to maximise the added value of the Alliance (including core implementing partners, but also bilateral partners and civil society) at country level. While there was consensus that flexibility is necessary and it would be neither possible nor advisable to list exhaustively all the roles and responsibilities ("positive ambiguity"), participants agreed that it will be important to clarify roles and responsibilities of Alliance partners as well as the operating model of the Alliance for the next strategy period.

The discussion on the Alliance's focus in the long term focused on three questions:

- Question 1 The GAVI Alliance's role to ensure access to immunisation in fragile eligible countries: As countries graduate in the coming decades, a growing share of the portfolio of remaining GAVI countries is projected to face deep and sometimes entrenched challenges requiring more intensive and comprehensive support. The Board agreed that the Alliance should develop further country-by-country approaches to support these countries, but that more work would be necessary to determine more precisely how to best support them. The Board was also open to the ideas of exploring "graduation" of certain vaccines in the long term, meaning that GAVI would progressively cease support for vaccines that had become sufficiently affordable.
- Question 2 The GAVI Alliance's role to contribute to improving access to immunisation • for the poor and vulnerable in 'Alumni' countries (and potentially countries that were never GAVI-eligible): As an increasing number of countries graduate from GAVI support, and the overall global burden of poverty shifts to middle income countries, a majority of the world's 'poor people' and under-immunised children will live in countries that are no longer GAVI-eligible. The Board discussed whether GAVI should consider providing non-financial support to these countries (e.g. access to more sustainable prices, technical assistance etc.). Several positions emerged on this question. Overall, participants recognised the importance of considering access to vaccines for the great number of poor and vulnerable people living in countries no longer eligible for GAVI support. This discussion was continued in the session on eligibility and graduation (see below), but most participants agreed that the Alliance could potentially expand its market shaping role to these countries. This would include continuing to support countries' access to appropriate prices through a negotiated stabilisation period of access to GAVI prices, possibly followed by a tiered pricing approach, and potentially providing technical assistance when required. The overall objective would be to ensure sustainability of immunisation programmes after Alliance support ends and also to continue to increase equitable access to vaccines.

Question 3 – The GAVI Alliance's role to ensure equitable access to future breakthrough vaccines: There was consensus that the GAVI Alliance would retain a role in supporting access to breakthrough vaccines when they become available. Participants observed however that by the time these vaccines become available, GAVI might not be supporting the countries with the highest burden and GAVI Alliance's role might evolve from a 'provider of subsidies' to a wider role on market shaping, and/or revisit eligibility for these new vaccines on a case-by-case basis.

B) Review of eligibility and the graduation.

Question 1 - Should the GAVI Alliance consider other eligibility criteria related to public health 'need', in addition to 'ability to pay'? Should the GAVI Alliance consider different criteria for different types of support?

- Participants unanimously agreed that a **commitment to sustainability** should remain key to the GAVI Alliance's investments and should guide its engagement with countries from the outset.
- Participants agreed not to change the fundamental model of country eligibility ("entry" criterion) based on ability to pay. Promoting equal access to life-saving vaccines while recognising sovereign national responsibility is central to the Alliance's development model. The basic elements of the current eligibility and graduation policies are central to this. The need for a simple and transparent measure for 'ability to pay', such as GNI, was underscored.
- Participants however expressed concerns about certain settings where improvements in immunisation programmes are lagging behind growth in GNI. Some of these countries may not be able to sustain the gains of the GAVI Alliance's investments after graduation. To this end, the Alliance should work with countries towards the goal of graduation from the time of the first GAVI grant. Also, the Alliance should work with countries to strengthen their capacity to make evidence-based decisions on vaccine introduction including cost-benefit analyses that take into account the future transition to self-financing. Once programmes have been launched, the Alliance should proactively and regularly engage with countries to discuss potential bottlenecks that could jeopardize 'successful' graduation. Partners on the ground will be critical to this effort.
- Where systems and immunisation outcomes continue to lag behind despite increases in GNI, the Alliance needs to explore more flexible graduation approaches in order to protect the sustainability of its investments. Additional criteria (beyond 'ability to pay') on the 'exit' side could therefore be explored, provided they have robust indicators and do not create perverse incentives. Where countries meet such criteria, the graduation "glide path" could be tailored to address country bottlenecks. Different forms of engagement could be explored during the graduation period (e.g. special Technical Assistance, new financial instruments, duration of the graduation process etc.) and the feasibility and trade-offs of different options will need to be assessed. This flexible graduation approach would be complemented by explicit commitments by countries as to what their contribution towards successful transition would be. It was also recognized that some countries have deeply rooted problems that cannot be solved through immunisation support alone and require concerted action from all development partners. The graduation policy that will be updated in 2014-2015 will need to address to what extent GAVI should extend or intensify support in these settings.
- Participants agreed that a critical element of ensuring self-sufficiency of countries after graduation was access to appropriate prices for vaccines. Therefore, there was strong consensus regarding the need for the Alliance to play and even stronger market shaping role for Alumni countries.

Participants discussed whether policies should be adapted to enable support for **poor people** regardless of national income levels. Recognising that most of the world's poor and under-immunised people live in countries expected to graduate from GAVI support in upcoming years, the Alliance should aim to support these countries to address inequities through a tailored graduation process. Participants generally agreed that the Alliance should not extend vaccine or HSS support to countries that have never been eligible for GAVI support, although some of them may benefit from market shaping efforts to achieve appropriate prices and potentially from technical support.

Question 3: Should the GAVI Alliance consider creating a financial envelope for targeted investments outside basic eligibility?

 The Board recognized that current eligibility policy might prevent the Alliance from playing a role in countries with high GNI but significant public health needs in subsets of the population. The Board concluded that GAVI Alliance should consider **catalytic investments** in the next strategy period (e.g. support to a subset of states for a limited period of time, with commitment that the country would pick up the cost at national level). Such exceptional investments would need to be guided by transparent investment criteria.

C) GAVI's role in improving coverage and equity.

Two critical questions were assessed:

Question 1: To what extent should GAVI focus its health systems support on countries that are facing the most challenges? There was general consensus that the Alliance's efforts to increase coverage and equity should have a stronger focus on countries facing the greatest challenges. This would mean changing the current formula by which health systems support is provided on the basis of countries' GNI and population size. Participants recognised however the need to manage the risk of perverse incentives, inappropriately rewarding countries that have not prioritised investment in immunisation systems specifically and health systems more broadly.

Question 2: To what extent should the GAVI Alliance develop programmes of support in specific areas of immunisation systems, leveraging its comparative advantage? Participants noted that country ownership will remain key and that countries should generally drive the agenda for improvements in immunisation systems. At the same time, they acknowledged that countries would likely welcome proposals from the Alliance for tools and approaches in specific areas, and that there was an opportunity to harness the strengths of Alliance partners to tackle difficult systems issues that affect many if not most GAVI-supported countries.

Participants recognised the opportunity to assist countries in areas that could leverage the Alliance's comparative advantage, such as supply chain and data systems, as well as new approaches to vaccine demand generation. Board members however did not generally support the opening of new completely separate windows of support beyond the existing ones, but also acknowledged that some changes or adaptations in funding mechanisms might be needed. Participants concluded that the Alliance should undertake further work to better define potential approaches in the areas of supply chain, data and demand generation. There was agreement that such 'programmes' would be developed through the relevant decision-making processes, including consultation with key stakeholders and technical experts, review by the relevant Board committees and ultimately decision by the Board.