

<b>SUBJECT:</b>	<b>GAVI SUPPORT FOR ACCESS TO APPROPRIATE PRICING FOR GAVI GRADUATED COUNTRIES</b>
<b>Report of:</b>	Aurélia Nguyen, Director of Policy & Market Shaping
<b>Authored by:</b>	Wilson Mok, Paolo Sison, Santiago Cornejo
<b>Agenda item:</b>	07
<b>Category:</b>	For Decision
<b>Strategic goal:</b>	SG2 - Health sys, SG3 - Financing, SG4 - Mkt shaping

## **Section A: Overview**

### **1. Purpose of the report**

1.1 The purpose of this report is to seek Board approval of the recommendations by the Programme and Policy Committee (PPC) with regards to access to appropriate pricing (ATAP) for Gavi Phase 3 [graduated] countries. The paper discussed by the PPC at its meeting on 4-6 May 2015, which includes details on the recommendations, is attached to this report.

### **2. PPC recommendations**

2.1 The Programme and Policy Committee recommended to the Gavi Board, subject to endorsement by the Audit and Finance Committee of any funds recommended for approval, that it:

**Approve** the Alliance's approach to ensuring access to appropriate pricing for Phase 3 [graduated] Gavi countries by:

1. Continuing to seek appropriate and sustainable prices through market shaping activities consistent with Gavi's Vaccine Supply and Procurement Strategy.

2. Allowing Phase 3 [graduated] Gavi countries to be included in UNICEF tenders on behalf of Gavi-eligible and Phase 2 [graduating] countries for specific vaccines with the aim of continuing to provide them with access to Gavi prices for a five year period (provided a country commits to key terms to be defined by UNICEF and Gavi), subject to assurance from PAHO that procurement by Phase 3 [graduated] countries in these tenders alongside other Gavi countries is covered under existing exceptions to the lowest price clause (LPC). *This assurance will be forthcoming upon a collaborative agreement between PAHO and Gavi which aims to result, among other things, in price reductions for PAHO's Revolving Fund.*
  3. Providing a catalytic investment of US\$ 5 million towards the capitalisation of UNICEF's Vaccine Independence Initiative (VII), a revolving fund which supports timely availability of financing for countries to meet payment terms. The use of this investment will be prioritised towards Gavi countries, subject to UNICEF approval of each country application to participate in VII. In 2017, the PPC will review the performance of the investment to determine whether there is a need to adjust the amount.
- 2.2 In addition, the Programme and Policy Committee requested the Secretariat to continue developing, in advance of the June 2015 Board meeting, a collaborative agreement between PAHO and Gavi as referenced above and noted that this agreement would involve the Gavi Secretariat and any other relevant partners.
- 3. Update since the May 2015 PPC meeting and updated recommendation**
- 3.1 Since the May PPC meeting, the Gavi Secretariat and PAHO have engaged in further discussions and have finalised the terms of a collaborative agreement, currently being signed (although its entry into force is subject to the Board approving the PPC recommendation on ATAP). This agreement provides the foundation for Gavi and PAHO to work collectively towards both short- and long-term objectives in order to increase access to vaccines and the sustainability of immunisation programmes for countries. Through this agreement, PAHO will provide the assurance for Phase 3 Gavi countries to be able to procure through UNICEF/Gavi tenders under existing exceptions to the PAHO LPC. Ongoing engagement is a component of the successful implementation of the agreement. An update on the signature of the agreement will be provided when the Gavi CEO report will be circulated to the Board. Once the agreement is signed by both parties, Board members may request to view it, subject to commercial sensitivities.
- 3.2 At its meeting on 22 May 2015, the Audit and Finance Committee confirmed that funding recommended for approval for the investment in VII is available.

- 3.3 Given that signature of a collaborative agreement between Gavi and PAHO, which the PPC had requested the Secretariat to develop, is forthcoming, the Board is invited to consider the updated language of the PPC recommendation below:

“[The Gavi Board] **approve** the Alliance’s approach to ensuring access to appropriate pricing for Phase 3 [graduated] Gavi countries by:

1. Continuing to seek appropriate and sustainable prices through market shaping activities consistent with Gavi’s Vaccine Supply and Procurement Strategy.
2. Allowing Phase 3 [graduated] Gavi countries to be included in UNICEF tenders on behalf of Gavi-eligible and Phase 2 [graduating] countries for specific vaccines with the aim of continuing to provide them with access to Gavi prices for a five year period (provided a country commits to key terms to be defined by UNICEF and Gavi).
3. Providing a catalytic investment of US\$ 5 million towards the capitalisation of UNICEF’s Vaccine Independence Initiative (VII), a revolving fund which supports timely availability of financing for countries to meet payment terms. The use of this investment will be prioritised towards Gavi countries, subject to UNICEF approval of each country application to participate in VII. In 2017, the PPC will review the performance of the investment to determine whether there is a need to adjust the amount.”

#### **4. Risk and financial implications – Update**

- 4.1 The risks and financial implications associated with this strategy are described in Sections 4-6 of the attached PPC report.

<b>SUBJECT:</b>	<b>GAVI SUPPORT FOR ACCESS TO APPROPRIATE PRICING FOR GAVI GRADUATED COUNTRIES</b>
<b>Report of:</b>	Robert Newman, Managing Director, Policy and Performance
<b>Authored by:</b>	Wilson Mok, Aurelia Nguyen, Paolo Sison, Santiago Cornejo
<b>Agenda item:</b>	07
<b>Category:</b>	For Decision
<b>Strategic goal:</b>	SG2 - Health sys, SG3 - Financing, SG4 - Mkt shaping

## **Section A: Overview**

### **1. Purpose of the report**

- 1.1 The purpose of this report is to seek Programme and Policy Committee (PPC) endorsement to the Board of the recommended Alliance solution for access to appropriate pricing (ATAP) for Gavi graduated countries and the next steps to implement the solution.
- 1.2 This report was developed in response to the request of the Gavi Board at its November 2013 meeting for the Secretariat 'to conduct analyses and consultations to develop and propose instruments to support access to appropriate vaccine prices for all lower middle income countries (LMICs), including Gavi graduated countries and non-Gavi LMICs', and a request for additional analysis made by the PPC in May 2014.
- 1.3 This report is intended to complement the report on 'Strengthening country transitions out of Gavi support' (Doc 04) in order to create a sustainable transition for Gavi countries to full self-financing of immunisation.
- 1.4 **Terminology:** The complementary report noted above includes a proposal for a new 'Eligibility and Transition Policy', as well as new terminology that aims to better reflect the ongoing transition of countries and responds to stakeholder concerns regarding the term 'graduation' (see Figure 1 below in the Executive Summary). This paper reflects the proposed changes in terminology. In particular, 'intermediate' countries are now referred to as Phase 1 countries, 'graduating' countries are now referred to as Phase 2 countries and 'graduated' or 'fully self financing' countries are referred to as Phase 3 countries for a set period of time.

## 2. Recommendations

### 2.1 The PPC is requested to

**Recommend** to the Gavi Alliance Board, subject to endorsement by the Audit and Finance Committee of any funds recommended for approval, that it approve the Alliance's approach to ensuring access to appropriate pricing for Phase 3 [graduated] Gavi countries by:

1. Continuing to seek appropriate and sustainable prices through market shaping activities consistent with Gavi's Vaccine Supply and Procurement Strategy.
2. Allowing Phase 3 [graduated] Gavi countries to be included in UNICEF tenders on behalf of Gavi-eligible and Phase 2 [graduating] countries for specific vaccines with the aim of continuing to provide them with access to Gavi prices for a five year period (provided a country commits to key terms to be defined by UNICEF and Gavi), subject to assurance from PAHO that procurement by Phase 3 [graduated] countries in these tenders alongside other Gavi countries is covered under existing exceptions to the lowest price clause (LPC). This assurance will be forthcoming upon a collaborative agreement between PAHO and Gavi which aims to result, among other things, in price reductions for PAHO's Revolving Fund.
3. Providing a catalytic investment of US\$ 5 million towards the capitalisation of UNICEF's Vaccine Independence Initiative (VII), a revolving fund which supports timely availability of financing for countries to meet payment terms. The use of this investment will be prioritised towards Gavi countries, subject to UNICEF approval of each country application to participate in VII. In 2017, the PPC will review the performance of the investment to determine whether there is a need to adjust the amount.

## 3. Executive summary

- 3.1 **Successful transition out of Gavi is a core component of the Gavi model and is necessary to ensure that countries are able to sustain and build upon immunisation programmes begun with Gavi support.** As countries transition away from Gavi financial support to full self-financing, there is a risk that they will face significantly higher prices for some vaccines. For some vaccines, the next lowest available price can be up to over four times the Gavi price. Similarly, self-procuring non-Gavi Middle Income Countries (MICs) currently access prices that can be 3-5 times the Gavi price for certain vaccines.<sup>1</sup> This jeopardises the financial sustainability of immunisation programmes after Gavi financial support

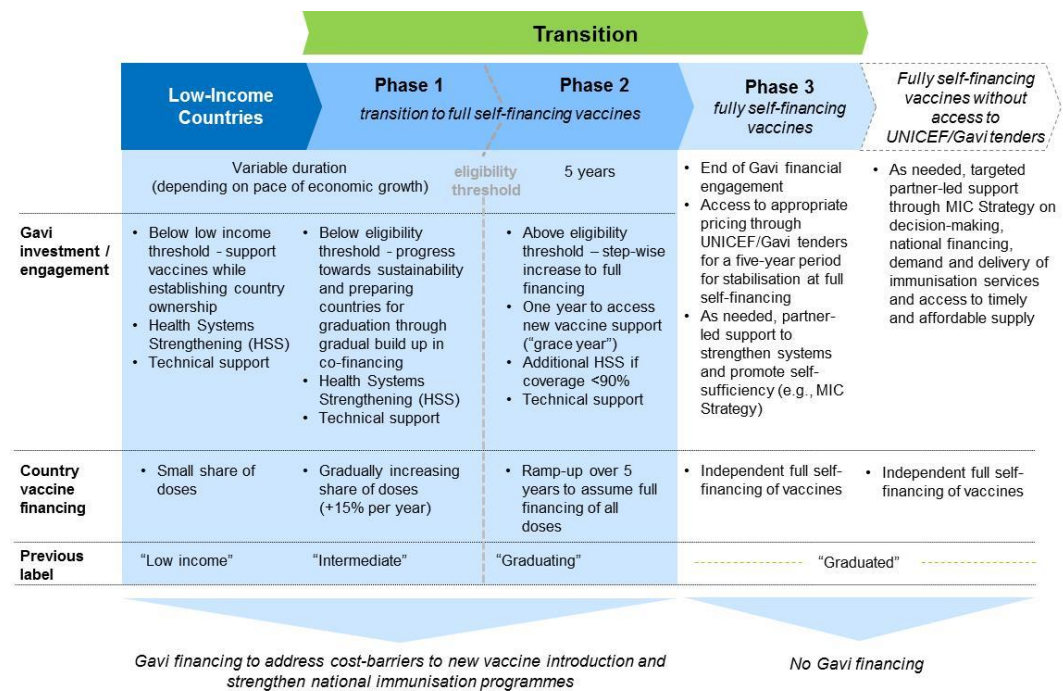
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<sup>1</sup> Price data provided by PAHO Revolving Fund vaccine price list (2013-2015); UNICEF SD; Global Vaccine Action Plan (GVAP) Vaccine Pricing Report 2014.

ends, given countries will have already gone through a rapid increase in funding needs over the course of their transition.

3.2 **Access to appropriate pricing is one aspect of ensuring successful transition out of Gavi, as outlined in the proposed ‘Eligibility and Transition Policy’ (Doc 04).** Transition planning has assumed that countries in Phase 3 of transition will have access to Gavi prices for some time once they begin fully self-financing to allow them to stabilise while they continue to strengthen internal capabilities. As such, ‘appropriate pricing’ for Phase 3 countries is defined as ‘as close to the Gavi price as possible.’

**Figure 1:** Phases of country development and transition out of Gavi support



3.3 **At the January 2015 Gavi replenishment pledging conference, a number of manufacturers renewed or extended commitments to provide continued access to Gavi prices or to freeze prices, for countries for a period of time after they no longer receive Gavi financial support; however, fundamental gaps in access to appropriate pricing remain.** Manufacturer price commitments cover a significant portion of planned procurement by Phase 3 countries for a period of time once they are fully self-financing. However, these commitments are ad hoc, resulting in country perceptions that they are not secure. Price commitments also require countries to procure through UNICEF Supply Division (SD) or the PAHO Revolving Fund, according to manufacturers. Moreover, there are no commitments in place for certain rotavirus and HPV vaccines, and the commitments generally do not cover vaccines that will be introduced by countries with their own financing, including planned introductions of rotavirus and HPV vaccines. Importantly, some countries are also likely to face challenges accessing

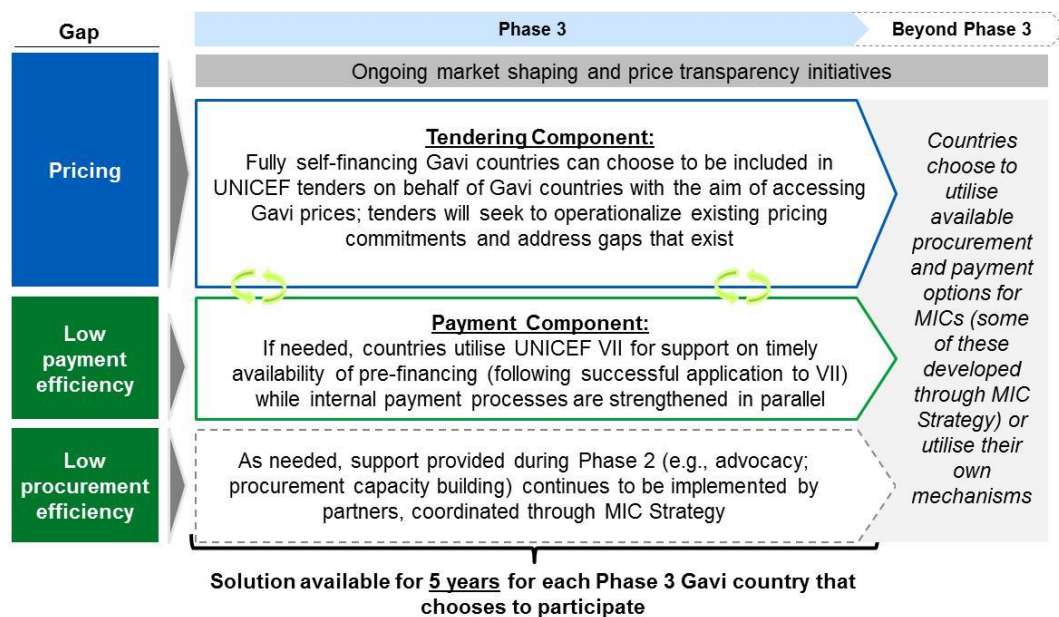
committed prices because of payment challenges<sup>2</sup>, primarily, or barriers to procuring through external agents such as UNICEF SD.

- 3.4 **These gaps create risks to countries' ability to sustain and introduce vaccines once they are fully self-financing.** Overall, many countries are at risk of facing higher vaccine prices: at least 24% of the projected annual procurement volumes across all countries entering Phase 3 between 2016 and 2022 is not covered by manufacturer price commitments and an estimated 94% of projected annual procurement volumes is from countries that have payment challenges. It should be noted that regarding payment challenges, this is considered the maximum magnitude of risk to sustainability of immunisation given that Gavi and Alliance partners are already working with countries during Phase 2 to begin addressing these challenges and thus they may not persist into Phase 3 of transition for all countries.
- 3.5 **To address these gaps, a tender and payment solution has been designed to maximise the ability of Gavi countries to access appropriate pricing once they become Phase 3 countries.** Countries would voluntarily opt in to the mechanism. In return, they would have access to: (i) UNICEF tenders on behalf of Gavi countries (henceforth referred to as 'UNICEF/Gavi tenders') for a five-year period with the aim of securing Gavi prices, which would help to operationalise current manufacturer price commitments and secure appropriate pricing for vaccines not currently covered by commitments, and (ii) support for short-term financing to meet payment terms through UNICEF's VII, where required and subject to an approval process. VII is a revolving fund that provides short-term financing to subscribing countries to bridge the timing gap between when funds are needed to initiate procurement of vaccines through UNICEF and when country funding is available to pay for those vaccines, often after delivery. This solution would provide a platform for countries to comprehensively access appropriate pricing – for both vaccines already introduced with Gavi support and new introductions without Gavi support – in a manner that is highly feasible and low cost to the Alliance. In consultations, most countries indicated a strong interest in accessing UNICEF/Gavi tenders, which they noted would increase their confidence in their ability to access appropriate prices once fully self-financing. In addition, Gavi and partners will continue ongoing market shaping and price transparency efforts, which are foundational to establishing healthy vaccine markets in the long-term.

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<sup>2</sup> This includes legislation that limits the ability to pre-pay for vaccines (i.e., paying in advance of delivery), a requirement of UNICEF SD; limited access to hard currency; and administrative issues preventing timely fund release.

**Figure 2:** Summary of recommended solution to address identified gaps



**3.6 Implementation of the recommended tender and payment solution will rely on Gavi partners, particularly UNICEF, and is intended to complement other partner-led initiatives that address issues beyond vaccine pricing such as the MIC Strategy.** While the Gavi Secretariat can continue to play a supporting role during Phase 3 of transition, UNICEF will lead implementation of the proposed tender and payment mechanisms. Furthermore, while the proposed solution helps to address one critical issue for sustainability of immunisation programmes in Phase 3 countries, some countries may continue to require continued engagement by partners during Phase 3 of transition and beyond to strengthen decision-making, enhance political commitment or address other challenges. Such support from partners can help to secure and expand upon the investments that the Alliance has already made in Gavi countries. This would also include strengthening of MIC pooled procurement mechanisms, which could support Gavi countries after they transition out of Phase 3. These partner-led efforts would be coordinated through the MIC Strategy, being developed by the MIC Task Force convened by the World Health Organisation (WHO). The MIC Strategy would be a platform for support to all MICs, including those that have never been eligible for Gavi support. As funding for these partner-led activities will not come via Gavi in Phase 3, it will be critical that the MIC Strategy be adequately resourced so that partners can provide this support.

#### **4. Risk implication and mitigation**

**4.1 There are several potential risks associated with this recommended mechanism.** To ensure that these risks are managed appropriately, the Secretariat has developed a set of mitigating actions that the Alliance can



take. These risks and accompanying mitigating actions are detailed in the following paragraphs.

- 4.2 **Once Phase 3 countries are included in UNICEF/Gavi tenders, manufacturers could offer higher prices, limit volumes or elect not to participate in these tenders.** Given the large, secure, donor-funded base of demand provided by Gavi-eligible countries and the relatively low volumes from Phase 3 Gavi countries (constituting approximately 1 to 8 percent of the tender volume from 2016-2020<sup>3</sup>), it is relatively unlikely that manufacturers will take these actions. However, in order to further mitigate this risk, UNICEF and Gavi will work with countries during the Phase 2 transition period to establish demand forecasts which manufacturers view as secure and UNICEF will coordinate with countries to regularly update demand forecasts. It is also important that partners are resourced to engage with countries to build capacity for addressing factors that impact robustness of country plans and demand forecasts (e.g., decision-making, domestic financing). Finally, UNICEF SD and Gavi will monitor tender results over time to track any unintended consequences and continually engage with manufacturers as partners to find ways to adapt the tender, as needed, to ensure optimal outcomes. There are also two other related risks associated with manufacturer participation in UNICEF/Gavi tenders. First, manufacturers may view demand to be uncertain if delays in payment impact the timing of procurement; this is mitigated by providing countries that have payment timing issues with access to support through VII, if they successfully apply to VII. Second, there is a risk for manufacturers of increased price referencing to Gavi prices with inclusion of Phase 3 countries in these tenders. It should be noted that Gavi prices are already a fairly visible reference price for countries and this risk is mitigated by limiting countries' participation in these tenders to five years.
- 4.3 **Limiting Phase 3 Gavi country volumes from the overall MICs pool could weaken the ability of non-Gavi MICs to secure an appropriate price.** Given that the volume of Phase 3 Gavi country demand is small, it is unlikely that this volume would significantly impact the pricing achieved in any future pooled MIC tender(s). Furthermore, the MIC Strategy being developed by the WHO-convened MIC Task Force aims to create certain, consolidated demand across MICs through a variety of initiatives, which may improve procurement options for these countries independent of Phase 3 Gavi country volumes. In addition, for specific vaccines where the market is already mature or has sufficient competition to allow Phase 3 Gavi countries to access appropriate pricing without the tendering components of the recommended solution, further pooling of demand across Phase 3 Gavi countries and non-Gavi MICs may support more attractive pricing for all of these countries.

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<sup>3</sup> From 2016-2020, the projected volume of procurement of HPV vaccines for Phase 3 Gavi countries would not exceed 8% of the overall UNICEF/Gavi tender volume. Similarly the projected procurement of rotavirus vaccines by Phase 3 Gavi countries would not exceed 5% of the overall UNICEF/Gavi tender volume.

- 4.4 **The PAHO LPC<sup>4</sup> could be applied to manufacturers that have offered price commitments and/or that make offers on Phase 3 Gavi country volumes as part of future UNICEF/Gavi tenders.** The recommendation in this report is subject to assurance from PAHO that procurement by Phase 3 [graduated] countries in these tenders alongside other Gavi countries is covered under existing exceptions to the LPC. This assurance will be forthcoming upon a collaborative agreement between PAHO and Gavi which aims to result, among other things, in price reductions for PAHO's Revolving Fund.
- 4.5 **Capitalising VII to provide support for timely availability of financing to countries may alter the Gavi model as funds could provide some financial support to Phase 3 Gavi countries.** The US\$ 5 million investment that Gavi would provide to VII would be used primarily to extend short-term credit to subscribing Gavi countries that is then repaid to VII within 30 days following invoicing for a delivery. This would facilitate bridging of the timing gap between when funds are due to initiate procurement and the countries' actual payment of vaccines, typically after delivery. As with a standard revolving fund, upon reimbursement by a subscribing country, that capital can then be utilised by other Gavi countries, creating improved efficiency. To further mitigate this risk, UNICEF and Gavi will clearly communicate to countries the terms of accessing VII during country missions and other engagement.
- 4.6 **For some countries, providing access to the tender and payment mechanisms may create perverse incentives, which could limit country ownership, as well as the desire and/or capacity to self-procure.** There is a concern that this could limit government incentives to invest in developing their domestic resources and technical expertise to support sustainable vaccine procurement, which could make it difficult for countries to exit from the recommended solution. The recommended solution is intended to preserve ownership by allowing countries to choose their own path depending on the state of their procurement capabilities as they transition. Some countries with strong procurement capabilities or domestic supply ambitions may choose not to participate; several countries consulted have already indicated a preference to self-procure. Other countries are likely to opt in to the recommended solution, but the risk of perverse incentives would be mitigated by ensuring strong country ownership and progression towards procurement self-sufficiency. First, countries will be required to fully self-finance their vaccine purchases. Second, Gavi and UNICEF SD will require countries to continue paying UNICEF SD's standard procurement fees (a requirement of co-financing), develop and submit long-term plans (e.g. demand forecasts) for participation in UNICEF/Gavi tenders, support commitments from and

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<sup>4</sup> The lowest price clause (LPC) is a clause included in PAHO Revolving Fund vaccine supply contracts with manufacturers which obligates the manufacturer to provide the Revolving Fund with the lowest global price for a given vaccine. PAHO has granted exceptions to the LPC for supply to Gavi for pneumococcal, rotavirus and HPV vaccines.

coordinate processes between the Ministries of Health and Finance for those countries utilising VII (as part of the normal subscription process), and develop a detailed plan to transition towards independent payment practice over time. Progress against these transition plans will be monitored by UNICEF SD in consultation with Gavi. UNICEF and Gavi will also further discuss additional key terms and requirements for participation in UNICEF/Gavi tenders prior to implementation.

- 4.7 **The intended impact of the recommended mechanisms may not be achieved in some countries unless partners are sufficiently resourced to assist them in addressing issues beyond pricing.** Gavi recognises the importance of partners continuing to engage with some countries to provide assistance beyond access to appropriate prices. These efforts would be coordinated through the MIC Strategy – currently being developed by the WHO-convened MIC Task Force – which includes a menu of potential support to all MICs, including those that transition out of Gavi financial support. It is critical that resources are made available to allow for effective partner engagement with countries and implementation of the MIC Strategy, and Gavi will advocate for sufficient resources.

## 5. Risk of inaction

- 5.1 **Failing to act on the issue of access to appropriate pricing for Phase 3 Gavi countries will put millions of vaccinations at risk.** Without a comprehensive approach to transition that includes access to appropriate pricing, there are significant risks to Phase 3 Gavi countries' ability to sustain and introduce vaccines. Specifically, countries risk increased price and potential inability to procure at least 13 million vaccine courses projected to be procured annually without being covered by manufacturer pricing commitments and up to 50 million vaccine courses projected to be procured annually by countries with known payment efficiency challenges. The recommended solution to support countries in accessing appropriate prices – which complements other efforts for sustainability – is critical to mitigating this risk.

## 6. Financial implications: Business plan and budgets

- 6.1 **In order to implement the recommended solution, Gavi and UNICEF would amplify engagement with countries during Phase 2 [graduation] missions and assessments.** UNICEF, the Gavi Secretariat, and other partners as necessary would work with individual interested countries to both determine their needs for UNICEF/Gavi tenders and support access to VII. Additional resources through the Gavi Partners' Engagement Framework will be required to support increased engagement by UNICEF in Alliance-led country missions and to support implementation of VII. This limited resource request is included in the financial request as part of the broader strategy to strengthen country transitions out of Gavi support (Doc 04).

- 6.2 **To support the success of VII as a payment solution for Gavi countries, US\$ 5 million would serve as a catalytic investment in VII to support timely availability of financing for Gavi country needs.** By providing this investment, Gavi will help support VII's coverage of a portion of demand from Gavi countries, with the expectation that separate funding will also come from other donors as part of ongoing UNICEF resource mobilisation activities for VII generally. The Gavi investment would be prioritised towards meeting Gavi country needs. In addition, given countries would pay back the fund after use of any pre-financing, Gavi's investment would be re-used continuously to support Gavi countries on their payment challenges. It is critical that Gavi countries that are transitioning out of financial support have access to an effective mechanism that can support them in addressing payment efficiency challenges for their vaccine procurement. As such, a review by the PPC of Gavi's investment to VII will take place in 2017, including examination of how well the investment has met the financing needs of Gavi countries, the financial health and performance of the fund (e.g. number of times the fund has revolved per year, length of payment cycles), and additional needed capital based on UNICEF's fundraising to date. The future projected VII needs of Gavi countries will also be assessed. Based on this review, Gavi's investment in VII may be adjusted. Any adjustment to the investment would require Gavi Board approval.

## **Section B: Content**

### **7. Background**

- 7.1 **In November 2013, the Gavi Board requested that the Secretariat develop a recommendation to facilitate access to appropriate pricing for countries that no longer receive Gavi financial support.** Specifically, the Secretariat was requested 'to conduct analyses and consultations to develop and propose instruments to support access to appropriate vaccine prices for all LMICs, including Gavi graduated countries and non-Gavi LMICs.'
- 7.2 **In May 2014, the Gavi Secretariat put forward a recommendation to the PPC based on an initial assessment of country needs and potential options; the PPC requested further analysis.** Specifically, following discussion, the PPC 'requested the Secretariat, working closely with Alliance partners, countries and key stakeholders, to conduct consultations and analyses to develop proposal(s) for a pooled procurement facility. This may include tiered pricing, a revolving fund, demand guarantees or similar risk-mitigating structures in contracting, taking into account comments and issues raised at the PPC. The pooled procurement facility would apply to Gavi graduated countries and potentially to non-Gavi LMICs. The analyses should include the roles, responsibilities, financial and legal requirements, sources of funding, risks and costs. The proposal(s) would take into account a phased approach to solutions for short-term and long-term timeframes.'

7.3 **In June 2014, the Gavi Board approved the Gavi 2016-2020 strategy, which includes a commitment to address the issue of vaccine pricing and sustainability.** In particular, Strategic Goal 3 – improve the sustainability of national immunisation programmes – includes a specific objective to prepare countries to sustain performance in immunisation after Phase 2 [graduation]; and, Strategic Goal 4 – shape markets for vaccines and other immunisation products – includes a specific objective to achieve appropriate and sustainable prices.

## 8. Process and analytical approach

8.1 **Two cross-Alliance groups – a Senior Advisory Group and a working level Task Force – provided guidance and direction to this work, while manufacturers, countries and civil society were also consulted.** More details on the roles of the Task Force and Senior Advisory Group and the stakeholder consultations are included in Section 16 and a full list of advisory group members is included in Annex A.

8.2 **The Secretariat, in collaboration with the Task Force and supported by consultants from Dalberg Global Development Advisors, developed and implemented an analytical approach, beginning with a gap analysis that led to identification of potential options.** First, existing pricing-related gaps were analysed to understand which vaccines were most at risk of increased prices among Phase 3 countries, given current manufacturer price commitments and the health of various vaccine markets. The gap analysis further considered other challenges that might influence pricing for Phase 3 countries (i.e. payment and procurement related challenges). Then, the full suite of potential pricing, procurement and payment options to address these gaps was identified, considering opportunities to build off existing initiatives. Potential options were then assessed based on a set of assessment criteria agreed upon by the Senior Advisory Group and Task Force. In accordance with the Senior Advisory Group's guidance, the design of options was specifically focused on addressing the needs of Gavi countries transitioning to full self-financing; the costs and benefits of including non-Gavi LMICs were then separately considered in the options assessment. Finally, prioritised options were packaged into a solution that maximised efficiency. See Annex C for the full gap analysis; the detailed options assessment is available on myGavi.

## 9. Development of recommended solution

### *Context*

9.1 **Gavi Alliance and country planning have always assumed that countries would initially have access to Gavi prices when they transition from Gavi financial support to full self-financing.** Having access to Gavi prices would provide countries with a period of stabilisation following a rapid increase in budgetary requirements during Phase 2 of transition. During this stabilisation period, countries could continue to

strengthen internal capabilities in the initial years of full self-financing and prepare for future increases in cost. This work on access to appropriate pricing is intended to complement other initiatives that may also support countries in transition, in particular the report on ‘Strengthening country transitions out of Gavi support’ (Doc 04); the MIC Strategy being developed by the WHO-convened MIC Task Force<sup>5</sup>; and the ongoing Equitable Access Initiative.<sup>6</sup>

- 9.2 **Twenty-four countries are projected to enter Phase 3 between 2016 and 2020 and another seven countries are expected to enter Phase 3 before 2022.**<sup>7</sup> Facilitating access to appropriate pricing for this set of countries is essential in order to protect over US\$ 2.8 billion in investments that have been committed by the Alliance to support introduction of vaccines in these countries (as well as additional investments by the countries themselves); ensure that approximately 14 million children annually in these countries do not lose access to vaccinations; and, maintain confidence in Gavi’s mission, model and ability to deliver sustainable outcomes. Further detail on these countries is provided in Annex B.

***Objectives, assumptions and principles***

- 9.3 **The objective of this work is to support access to appropriate pricing so that countries can sustain immunisation programmes begun with Gavi support and continue to introduce new life-saving vaccines.**
- 9.4 Several key assumptions underlie efforts to achieve this objective:
- (a) Vaccine prices are a necessary aspect of supporting countries to sustain immunisation programmes and introduce new vaccines after they no longer receive Gavi financial support (although not the only aspect);
  - (b) In most cases, an ‘appropriate vaccine price’ for a Phase 3 country that has recently begun fully self-financing is as close to the Gavi price as possible in order to avoid further rapid increase of budgetary requirements following the Phase 2 transition period and to improve countries’ ability-to-pay; and,

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<sup>5</sup> This strategy focuses on financing, decision making, systems strengthening, and procurement activities for all MICs. The report “Sustainable Access to Vaccines in Middle-Income Countries (MICs): A Shared Partner Strategy” was submitted to the Strategic Advisory Group of Experts on Immunisation (SAGE) for its April 2015 meeting.

<sup>6</sup> The Global Fund’s Equitable Access Initiative is building a policy framework regarding the health needs and constraints of countries. It held an initial meeting on 23 February 2015, results of which are publicly available on the Global Fund’s website: [http://www.theglobalfund.org/en/equitableaccessinitiative/updates/2015-02-23\\_the\\_initial\\_meeting/](http://www.theglobalfund.org/en/equitableaccessinitiative/updates/2015-02-23_the_initial_meeting/)

<sup>7</sup> Of these countries, Indonesia and India are excluded from the gap analysis given their preference for procuring from local manufacturers and Cuba and Ukraine are also excluded from the gap analysis because they have never received Gavi funding for vaccine procurement.

(c) A solution should focus on meeting the needs of countries that will enter Phase 3 in the next five to ten years, but should also provide a platform for addressing issues that arise longer term.

9.5 **A set of four key principles guided the design of solutions to address access to appropriate pricing.** These principles are incorporated in the options assessment criteria described in paragraph 9.15. Principles include:

- (a) supporting the creation of long-term healthy markets,
- (b) supporting country ownership and long-term sustainability in terms of financing,
- (c) providing countries with a pathway towards self-sufficiency as markets become healthy and countries experience economic growth, and
- (d) building on existing efforts and initiatives where possible and leveraging the capabilities of the Alliance.

#### ***Summary of gaps to be addressed***

9.6 **The magnitude of the price-related risk that countries are expected to face upon transition from Gavi financial support to full self-financing is significant for a number of specific vaccines.** For countries in scope for this gap analysis (see Annex B), the cost of procurement of pentavalent, pneumococcal, rotavirus and HPV vaccines is projected to be over US\$350 million annually (assuming current Gavi prices), accounting for over 85% of total vaccine costs across the Gavi portfolio vaccines in these countries. For countries that no longer receive Gavi financial support, there is risk that prices for these vaccines could increase significantly from current Gavi prices: for some vaccines the next lowest available price can be up to over four times the Gavi price; similarly, self-procuring non-Gavi MICs currently access prices that can be 3-5 times the Gavi price for certain vaccines..

9.7 **Manufacturer price commitments have done a great deal to establish appropriate prices for vaccines which were introduced with Gavi support, but are likely not sufficient.** At the January 2015 Gavi replenishment pledging conference, a number of manufacturers renewed or extended price commitments, as outlined in Figure 3 below. Among the 27 countries in the gap analysis that enter Phase 3 between 2016 and 2022, up to 70% of projected procurement (by value) in the first year of full self-financing is covered by current manufacturer price commitments. However, manufacturer price commitments are ad hoc and as a result, countries do not perceive them as providing sufficient security and predictability on pricing once they no longer receive Gavi support. The terms of the price commitment can also be complex and challenging for countries to understand and incorporate into decision-making. In addition, some manufacturer price commitments may be contingent on securing agreement from PAHO that procurement by Phase 3 Gavi countries will be

covered under existing exceptions to the LPC and countries must be able to procure through UNICEF SD or the PAHO Revolving Fund, according to manufacturers.

Figure 3: Summary of existing price commitments<sup>8</sup>

	Manufacturer	Commitment to Phase [graduated] countries
Pentavalent*	Crucell / Janssen	• Access to Gavi price through 2020
	Sanofi Pasteur / Shantha	• Access to Gavi price through 2018**
	Biological E	• Access to Gavi price through 2019
	Panacea	• 5 years price “freeze” post-graduation
	LG Life Sciences	• No commitment
	Biofarma	• No commitment
	Serum Institute	• No commitment
Pneumococcal	GSK	• Access to AMC “tail price” (AMC supply significantly diminishes from ~2023) • 10 years price “freeze” post-graduation
	Pfizer	• Access to AMC “tail price” (AMC supply significantly diminishes from ~2023) • Access to \$3.10/dose price for 4-dose presentation through 2025
Rotavirus	GSK	• 10 years price “freeze” post-graduation
	Merck	• No commitment
HPV	GSK	• 10 years price “freeze” post-graduation
	Merck	• No commitment

9.8 Furthermore, there are no price commitments for certain key vaccines from specific manufacturers, which countries will need to sustain or plan to introduce with their own financing. There are no manufacturer price commitments for HPV vaccines other than GSK’s, which will affect eight of the 27 countries entering Phase 3 between 2016 and 2022 (representing 1 million courses of projected procurement annually) and for rotavirus vaccines other than GSK’s, which will affect three countries (approximately 7 million courses each year). In addition, current manufacturer price commitments do not provide access to Gavi prices, or frozen Gavi prices, for countries that introduce new vaccines without Gavi financial support, with the exception of GSK’s commitment which allows countries that entered Phase 2 [graduation] in 2011 to introduce GSK’s HPV vaccines by the end of 2017 and access frozen prices. This gap affects a number of countries that are projected to introduce HPV and rotavirus vaccines without Gavi support before 2025 (11 countries projected to procure 3 million HPV courses and 8 countries projected to procure 2 million rotavirus courses, annually). Without access to appropriate pricing, it is unclear if these projected introduction timelines can be met.

<sup>8</sup> Gavi is currently engaging with manufacturers to define the operational details regarding these commitments. \*GSK is not expected to supply pentavalent vaccine to Gavi countries after 2014. \*\* Commitment also applies to yellow fever and oral cholera vaccines. Commitment applies to first set of 20 graduating countries amongst the 73 Gavi countries.



- 9.9 **Importantly, some Phase 3 countries are likely to have challenges accessing existing price commitments because of domestic payment challenges or legislative barriers to procuring through external agents such as UNICEF SD.** Fourteen out of 27 countries that will enter Phase 3 between 2016 and 2022 have been assessed as facing some barrier that could limit their ability to pay for vaccines efficiently once they stop receiving Gavi financial support and assume full self-financing.<sup>9</sup> This could put at risk these countries' ability to procure over 50 million courses of vaccines annually at an appropriate price. Eleven countries also have national laws or regulations which could impede their ability to utilise UNICEF SD Procurement Services when they no longer receive Gavi support. Finally, a number of countries have a stated preference for self-procurement, but may face challenges associated with low self-procurement efficiency and capacity, at least in the short term, which could put at risk countries' ability to procure over 20 million courses of vaccines at an appropriate price annually. While UNICEF, Gavi and other Alliance partners are currently working with countries to overcome these barriers and have seen that countries can, at times, quickly adapt legislation or processes to overcome some of these challenges, many countries are likely to continue facing challenges in accessing manufacturer price commitments.
- 9.10 **Although more manufacturers will enter these vaccine markets in the future, pneumococcal, rotavirus and HPV vaccine markets are unlikely to be sufficiently competitive in the near-term to support appropriate prices for Phase 3 countries.** The pneumococcal, rotavirus and HPV vaccine markets only have two pre-qualified suppliers each at the moment. While both the rotavirus and HPV vaccine markets could each see up to three new suppliers by 2020, this is dependent on successful product development. New manufacturers are particularly important for rotavirus vaccine, as there is currently a supply shortage, derived from a product preference imbalance. Additionally, one or two new pneumococcal conjugate vaccines are expected to reach the market between 2018 and 2024. Competition in the pentavalent vaccine market is more robust compared to other vaccine markets, with Gavi procuring from six manufacturers of pre-qualified vaccines. Thus, while new manufacturers are expected to enter less competitive vaccine markets in the coming years, based on Gavi's current demand forecasts, most new introductions by countries without Gavi support will occur in a timeframe during which these markets are still relatively immature and lacking robust competition.
- 9.11 **These gaps are likely to affect countries as soon as they begin fully self-financing, starting in 2016.** The most urgent gaps to address in the short-term are low payment and procurement efficiency, as these will impact the ability of countries to access existing manufacturer price

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<sup>9</sup> Known payment challenges include difficulty accessing hard currency, administrative issues preventing fund release and laws against pre-payment.

commitments immediately. Furthermore, gaps in existing manufacturer price commitments are expected to pose challenges related to sustaining vaccines introduced with Gavi support beginning in 2020 (when one country will begin fully self-financing Merck's HPV vaccine), and to pose challenges to countries introducing vaccines without Gavi financial support beginning in 2018 (when four countries are planning to introduce rotavirus vaccine and one country is planning to introduce HPV vaccine).

### ***Options to address identified gaps***

- 9.12 **Two specific areas were identified for further intervention to facilitate access to appropriate pricing for countries that transition to fully self-financing.** These included a tendering mechanism to improve countries' ability to secure an appropriate price by operationalising manufacturer price commitments and addressing gaps in these commitments, and a payment mechanism to ease countries' payment challenges and further enable access to appropriate pricing.
- 9.13 **A number of tendering mechanisms were considered to support countries in securing appropriate prices to sustain and introduce vaccines.** These included: UNICEF/Gavi tenders in which UNICEF SD tenders on behalf of all Gavi countries including Phase 3 Gavi countries; and, existing or new pooled procurement mechanisms, where the demand of Phase 3 Gavi countries could be pooled with other non-Gavi MICs, either regionally or globally.
- 9.14 **A number of options for a payment mechanism were considered to address countries' challenges with payment efficiency and, thereby, allow them to access appropriate prices.** Two broad options were considered: revolving funds and short term loan facilities. A revolving fund is a capital fund that pre-finances vaccine purchases on behalf of a country to manufacturers, mitigating impediments to pre-payment (which is a requirement of UNICEF SD). A short-term loan would allow countries to take on debt in order to facilitate pre-payment for vaccines. Within each payment option, the possibility of leveraging an existing mechanism or creating a new mechanism was considered.
- 9.15 **Beyond these two mechanisms, a number of existing initiatives were recognised as important to support access to appropriate pricing.** These included: market shaping initiatives to increase the supply base, foster competition and encourage lower prices (supported by the Alliance, including the Gavi Secretariat, the Bill & Melinda Gates Foundation and UNICEF SD); price transparency efforts (such as WHO's Vaccine Product, Price and Procurement initiative, or V3P) which give countries greater knowledge of vaccine prices and potential increased bargaining power; and technical assistance and advocacy which support countries to enhance their ability to self-procure or procure through UNICEF SD.

### ***Assessment criteria***

- 9.16 **Options were assessed using criteria agreed upon with the Task Force and Senior Advisory Group.** Assessment criteria consisted of: projected impact of the solution on pricing that countries would access; feasibility of successfully implementing the solution given the capacity of the likely implementing organisations; estimated cost of implementing the mechanism; and, potential positive externalities and risks associated with country ownership, market health, pricing for other MICs and pricing for Gavi-eligible countries. Core guiding principles (see paragraph 9.4 above) factored heavily into the development of these assessment criteria.

### ***Assessment of options***

- 9.17 **A tendering mechanism in which UNICEF SD continues to tender on behalf of all Gavi countries, including Phase 3 countries for a limited period of time, is most likely to secure appropriate prices by operationalising manufacturer price commitments and addressing gaps in these commitments, particularly for rotavirus and HPV vaccines.** This UNICEF/Gavi tender is likely to have the highest impact on price. First, it has a strong demand base of large, assured donor-funded volumes pooled across countries with the lowest incomes. In addition, manufacturers broadly acknowledged the rationale for including Phase 3 Gavi countries in this tender, although three of nine manufacturers consulted expressed reservations on inclusion of demand associated with new vaccine introductions as they considered this beyond the mandate of Gavi.
- 9.18 **By comparison, analysis of an alternative tendering option where Phase 3 Gavi countries' demand is pooled with other non-Gavi MICs' demand suggests that it is very unlikely to deliver prices similar to existing Gavi prices.** This is due to lack of security regarding non-Gavi country demand, particularly associated with new vaccine introductions. Consultations with manufacturers indicated that tenders with this structure would likely lead to higher price offers for Phase 3 countries compared to UNICEF/Gavi tenders. Costs to the Alliance and partners were anticipated to be very similar across all tender options assessed, with few incremental costs required to implement them. However, in the assessment it was recognised that even if Phase 3 Gavi countries are not included in pooled tender mechanisms for non-Gavi MICs, it is critical that these mechanisms continue to be strengthened. This work is coordinated through the MIC Strategy.
- 9.19 **To address payment challenges, leveraging UNICEF's VII is most likely to maximise impact at the lowest cost, and allow for operational efficiencies by linking payment and procurement through UNICEF SD.** To arrive at this assessment, the Task Force and Gavi Secretariat drew on lessons learned from the development of the PAHO Revolving Fund and its operations over the last 35 years. This included acknowledgement that efficiencies can be gained from linking payment

and procurement mechanisms and that the impact of a revolving fund can be magnified by further integration with capacity building and advocacy activities. A joint assessment by Gavi and UNICEF SD indicated that VII, assuming sufficient capitalisation, would be able to effectively serve the pre-financing needs of Gavi countries, which are estimated to be 15-40% of anticipated VII capitalisation by 2020 (see Annex E). VII is a revolving fund meant to facilitate countries' ability to pay for vaccines. Following UNICEF Executive Board approval, there is a new commitment for VII to grow in size and effectiveness. In addition to the planned expansion of the VII capital base from US\$ 10 million to US\$ 100 million, UNICEF has improved operational efficiency by reducing payment cycles through more intensive monitoring and country follow-up; improved the VII application process to ensure that countries understand what is expected of them as VII subscribers and can sufficiently plan for transition out of VII; and, is exploring other opportunities and instruments to appropriately manage risks and protect the capital base against default. Furthermore, given that UNICEF will be the procurement agency tendering on behalf of Gavi for the recommended solution on access to appropriate price, there will be strong efficiencies from the linkages across the procurement and payment mechanisms.

- 9.20 **Alternative payment options were either ill-suited to address the needs of countries overcoming payment inefficiencies or were considerably more costly and less feasible in the short- and medium-term.** For example, loan facilities often do not result in improved payment efficiency due to disbursement issues; and, establishing a new revolving fund was considered much more costly and less feasible in the near term. Over the long term, if other credit and financing facilities arise and are appropriate for Phase 3 Gavi country needs, they could potentially be considered for Gavi countries.
- 9.21 **A five year timeframe for inclusion of fully self-financing Gavi countries in UNICEF/Gavi tenders was identified as most appropriate.** Three different exit options were considered for individual countries: allowing countries to access UNICEF/Gavi tenders for five years; allowing countries to access these tenders for ten years; or, allowing countries to access these tenders until they reach upper middle income country (UMIC) status, which would result in countries having access to these tenders for different amounts of time depending on their rate of economic growth. Senior Advisory Group and Task Force members agreed that five years would provide an appropriate transition period for countries while upholding the principles of encouraging country ownership and creating healthy markets. Moreover, over half of countries that are projected to enter Phase 3 of transition between 2016 and 2022 are anticipated to reach UMIC status within five years. This option also limited inequities between Phase 3 Gavi countries and non-Gavi countries relative to the two alternative options with longer timeframes. A timeframe of less than five years for certain countries (e.g. through an income level-based threshold) was considered too short to allow countries to stabilise at full self-financing after the increase in costs during Phase 2 of transition. With

regard to VII, access is not defined by the Gavi transition timeline, although VII can assist countries in successfully completing the transition from Gavi. Each country will have ongoing access according to the plan developed together with UNICEF SD, which outlines a transition out of VII to independent payment practice.

- 9.22 **Input from country consultations was heavily incorporated during the assessment of various options.** Nineteen countries projected to enter Phase 3 in the next 10 years were consulted to assess interest in a potential solution to address access to appropriate pricing. Fifteen of these countries expressed a preference for procuring through UNICEF SD over self-procurement, and all of these countries expressed interest in participating in UNICEF/Gavi tenders if it provides them with access to Gavi prices. Of these 15 countries, 14 indicated that UNICEF/Gavi tenders provide greater confidence that they would have access to appropriate prices once fully self-financing than other tender/procurement options and manufacturer price commitments. Regarding potential payment mechanisms, 11 out of 15 countries expressed interest in utilising a revolving fund such as VII, and two are either already utilising VII or currently finalising plans to do so.

#### ***Recommended solution***

- 9.23 **Based on this assessment, a tender and payment solution has been designed to maximise the ability of countries to access appropriate vaccine pricing as Phase 3 Gavi countries in a manner that is highly feasible and low cost for the Alliance.** Countries that wish to use this mechanism would opt in and be required to commit to key terms designed to strengthen country ownership, which UNICEF and Gavi would define prior to implementation. In return, countries will have access to: (i) UNICEF/Gavi tenders that would aim to provide countries with access to Gavi prices for a five year period after they begin fully self-financing to both sustain existing vaccines and introduce new vaccines without Gavi support where desired, as a means of operationalising existing manufacturer price commitments and addressing gaps where commitments do not exist; and, (ii) for those countries that require it, support through UNICEF's VII in pre-financing for vaccines procured through UNICEF provided the country successfully applies for access to the fund. Each country would have the option of accessing UNICEF/Gavi tenders with or without payment support through VII, based on its specific needs. To maintain robust demand forecasts for UNICEF/Gavi tenders – and thereby continue to provide manufacturers with a secure demand base to facilitate attractive pricing offers – UNICEF SD and Gavi will support countries in developing demand forecasts during Phase 2, and UNICEF SD will continue to coordinate with countries on an ongoing basis to regularly update and refine the demand forecasts as part of their annual forecasting exercise. However, it was acknowledged that pooled procurement mechanisms for MICs broadly need to be strengthened simultaneously to support not only non-Gavi MICs, but Gavi countries after

transitioning out of Phase 3. This work will be coordinated through the MIC Strategy.

- 9.24 **Gavi's proposal relies on an assurance from PAHO that Phase 3 Gavi countries' procurement through UNICEF/Gavi tenders is covered under existing exceptions to the LPC.** This assurance will be forthcoming upon a collaborative agreement between PAHO and Gavi which aims to result, among other things, in price reductions for PAHO's Revolving Fund.
- 9.25 **While the principles of the tender component of the recommended solution are broadly defined, a number of operational details still need to be determined jointly by UNICEF and Gavi.** First, UNICEF and Gavi will need to consider the timing of upcoming tenders given that Phase 3 Gavi countries would only be included in UNICEF/Gavi tenders going forward, as new tenders are issued. Second, UNICEF and Gavi must determine for which specific vaccines Phase 3 Gavi countries would be allowed to participate in UNICEF/Gavi tenders, recognising that for vaccine markets that are mature and have robust competition, Phase 3 countries can already access appropriate vaccine pricing without utilising these tenders. Third, while the objective is to provide Phase 3 countries with access to the Gavi price for the specific vaccines in scope, it is acknowledged that there may need to be flexibility in structuring individual tenders. For example, certain manufacturers have made commitments to stabilise Phase 3 countries at a frozen price (i.e. the last Gavi price the country accessed while receiving Gavi financial support in Phase 2 of transition), which may be different from the Gavi price negotiated in a future tender. UNICEF/Gavi tenders would accommodate, and encourage, such stabilisation/frozen prices for Phase 3 countries. Finally, it should be noted that, as part of the supply and procurement strategy for each vaccine, Gavi could selectively decide to use risk-mitigating tools such as volume guarantees using Gavi funds and other innovative procurement tools to provide better tender outcomes. Gavi already considers use of these instruments in ongoing UNICEF/Gavi tenders on a case by case basis, and use of such tools would continue to require Gavi Executive Committee approval. These issues, and others, will be addressed by UNICEF and Gavi in the development of the implementation plan or in execution of individual future tenders.
- 9.26 **Access to UNICEF/Gavi tenders would be limited to fully self-financing Gavi countries, given the significant risk of elevated pricing in UNICEF/Gavi tenders if non-Gavi MICs are also included.** The demand from non-Gavi MICs is considered much less certain, and the majority of manufacturers consulted were not supportive of their inclusion in UNICEF/Gavi tenders at Gavi prices, indicating that they may consider limiting volumes or not bidding on the tenders.
- 9.27 **Any country with a programme of work with UNICEF can apply for access to VII, including Gavi countries in all phases of transition.** In the application to VII, countries must demonstrate pre-financing need and

the capacity to repay borrowed funds. Each application is subject to the approval of the UNICEF SD Director and UNICEF's Comptroller; countries will be assessed against certain criteria while also taking into consideration availability within the fund's capital base. UNICEF and Gavi will work closely to support timely payment of subscribing country obligations to the revolving fund.

- 9.28 **The recommended solution is intended to provide countries with access to appropriate pricing through a five-year period as they transition out of Gavi support to a long-term fully self-financing state.** During this five-year period, fully self-financing Gavi countries would have greater stability as they take on full responsibility for financing and procuring vaccines while continuing to strengthen internal capabilities. Furthermore, vaccine markets are expected to become healthier over this time, creating an environment that allows countries to access appropriate prices independently or through other means after this period. Additionally, the Alliance recognises the acute need to simultaneously continue to strengthen vaccine procurement capacities of MICs as well as the procurement mechanisms available to all MICs, which is spearheaded by partner organisations and coordinated through the MIC Strategy currently being developed by the WHO-convened MIC Task Force. This will provide Gavi countries complementary support during and after Phase 3 of their transition from Gavi.
- 9.29 **Some countries may choose to self-procure and/or procure from local producers rather than utilise UNICEF/Gavi tenders.** For countries that choose to self-procure, procurement capacity-building may help with accessing appropriate vaccine prices. This type of support is provided by Alliance partners during Phase 2 of Gavi countries' transition and can continue as a component of the menu of support being proposed for all MICs in the MIC Strategy. In addition, ongoing Gavi Alliance market shaping efforts should help to establish healthy and competitive vaccine markets that support access to appropriate pricing for all countries, including those that choose to self-procure after Gavi support ends. Other countries have shown a commitment to procure vaccines from local producers; while they would also have the opportunity to access appropriate vaccine prices through the proposed solution, such countries may choose to wait for local manufacturers to develop these vaccines. It should be noted that a separate report is being submitted to the PPC regarding a strategy for India (Doc 10), one of the countries that prefers procuring from local manufacturers.

#### ***Anticipated costs of solution***

- 9.30 **The additional operational resources required to implement the recommended solution are expected to be limited and would be included in the Gavi Partnership Engagement Framework as part of the broader strategy to strengthen country transitions out of Gavi support (Doc 04).** In order to implement the recommended solution, UNICEF, together with the Gavi Secretariat and other Alliance partners,

would engage with countries during Phase 2 [graduation] missions and assessments and other Alliance-related activities. To support inclusion of Phase 3 countries in UNICEF/Gavi tenders, UNICEF and Gavi will work with individual interested countries to prepare for their participation in UNICEF/Gavi tenders (e.g. clarifying commitment to procure through UNICEF; longer-term procurement planning; demand forecasts including product preferences; introduction planning for new vaccines; etc.). Similarly, to support subscription to VII, UNICEF will regularly engage with countries during Phase 2 and 3 of transition, with support from Secretariat teams, particularly Financial Sustainability and Graduation, to prepare VII applications, conduct payment monitoring and provide update on subscriptions and operational planning. Where relevant, UNICEF will consult with the Gavi Secretariat prior to a country submitting the VII application to assess the country's plans and readiness for participation. Additional resources are required for UNICEF to support increased engagement in Phase 2 [graduation] missions, to conduct regional workshops focused on financing and to implement VII and UNICEF/Gavi tenders.

- 9.31 **Separately, to support the success of VII as a payment solution for Gavi countries, US\$5 million would be required as a catalytic investment towards the increased capitalisation of VII to support Gavi countries' timely access to pre-financing.** This investment would help ensure that Gavi countries' pre-financing needs would be at least partially supported. The investment would be prioritised towards meeting Gavi country needs, and it is anticipated that Gavi's incremental US\$ 5 million capitalisation would be able to support more than US\$ 5 million of annual short-term financing given the revolving nature of the mechanism. The US\$ 5 million figure was determined based on anticipated demand for VII among Gavi countries through 2017, as detailed in Annex E, recognising some uncertainty regarding the exact demand that will materialise. Other contributions to the VII capital base are anticipated to come from other donors as part of ongoing UNICEF resource mobilisation activities. UNICEF and Gavi will work together to develop precise terms regarding the application of these funds and how both organisations will work together to support successful country subscription to VII. As noted earlier, a review by the PPC of this investment in VII will take place in 2017, which may lead to an adjustment in the funding amount, subject to Board approval.

## 10. Implementation and next steps

- 10.1 **If approved by the Board, Gavi will work closely with UNICEF SD and other Alliance partners, as needed, to facilitate implementation of the solution beginning in 2016 for the first cohort of fully self-financing Gavi countries.**
- 10.2 **Given that there are a number of operational considerations that both Gavi and UNICEF SD must address to implement this solution, UNICEF and Gavi will jointly develop a plan for implementing the**



**solution, working with other partners as necessary (June-July 2015).** As UNICEF and Gavi already work closely together on tenders for Gavi countries, and VII is an ongoing UNICEF initiative with processes already in place, developing this plan will build heavily upon collaboration and processes already established. For UNICEF/Gavi tenders, key elements of this plan will include taking into account the timeline of upcoming tenders, determining the process for including Phase 3 Gavi country demand, and defining roles and responsibilities with regards to engagement with countries and other implementation activities. UNICEF and Gavi will also consider key terms for countries to participate in UNICEF/Gavi tenders. For VII, key elements of this plan will include agreeing on the specific terms associated with Gavi's investment of US\$ 5 million.

**10.3 UNICEF SD and Gavi must ensure integration of the proposed solution into the broader Supply and Procurement Strategy (Q3, 2015).** Gavi, together with other Alliance partners including UNICEF SD, will need to incorporate this solution into the overarching Supply and Procurement Strategy. The review of the 2011-2015 Supply and Procurement Strategy and development of the 2016-2020 strategy will commence in Q3 of 2015.

**10.4 UNICEF SD, Gavi and other relevant partners must then consistently communicate the recommended solution to Gavi countries, especially those in Phase 2 as they prepare for transition to Phase 3 (Q3/Q4, 2015).** Communication to Gavi countries regarding these mechanisms would include discussion of benefits, risks, requirements and fit with long-term country objectives. These discussions would take place as part of Phase 2 [graduation] missions and other Alliance-related activities that seek to engage with countries on longer-term transition planning. Should countries be interested, both organisations would support countries in development and review of plans for participation. Partners could also support countries in overcoming challenges to utilising UNICEF SD as a procurement agent in Phase 3, should countries wish to do so.

**10.5 Finally, UNICEF SD will implement the UNICEF/Gavi tenders and VII according to the plan that will have been developed and in coordination with Gavi (Q4, 2015).**

## **11. Measurement & evaluation framework**

**11.1 Gavi and UNICEF SD would monitor a number of specific indicators on an ongoing basis.** These indicators are part of a broader measurement and evaluation framework to assess the transition of countries out of Gavi support, further described in Doc 04. The number of Phase 3 Gavi countries that procure at Gavi negotiated prices will be monitored for each Gavi portfolio vaccine. With regards to UNICEF/Gavi tenders, the number of countries that participate in tenders will be monitored for each relevant vaccine. The number of countries that commit

to participate, but decide to utilise an alternative procurement mechanism will also be tracked. With regards to VII, the number of Gavi countries that participate will be tracked. The performance of Gavi countries on repayment to VII will also be monitored. Finally, Gavi prices in UNICEF/Gavi tenders will continue to be monitored as part of Strategic Goal 4 indicators. The additional annual reporting requirements would be integrated into the existing memorandum of understanding (MoU) between Gavi and UNICEF SD, as appropriate.

- 11.2 **A review of the recommended solution will take place in four years, as part of a broader review of the Eligibility and Transition Policy.** Based on the mechanism's performance and the gaps faced by Gavi countries at that time, the mechanism could be adapted to best meet countries' needs. As noted earlier, a separate review of Gavi's investment in VII will be conducted in 2017.

### **Section C: Implications**

#### **12. Impact on countries**

- 12.1 **If implemented successfully, Gavi countries would have an improved ability to sustain vaccination programmes started with Alliance support and to implement new vaccination programmes, as well.** The birth cohort of countries that are projected to enter Phase 3 between 2016 and 2022 is nearly 18% of the total current birth cohort across the 73 Gavi countries.<sup>10</sup> As such, it is critical to ensure that they do not lose the ability to access appropriate prices and continue to procure vaccines once they no longer have access to Gavi financial support. Furthermore, as more and more countries transition out of Gavi, the recommended solution will become even more crucial to Gavi's legacy.
- 12.2 **In order for countries to fully participate in and make use of the recommended solution, sufficient political will is required.** For some countries, participation may require changes to national laws and regulations (specifically those laws requiring national tenders and/or laws prohibiting pre-payment).

#### **13. Impact on Gavi stakeholders**

- 13.1 **Impact on donors:** Gavi donors will not be asked to provide additional resources to fund implementation of the recommended option.
- 13.2 **Impact on UNICEF SD:** Both the tendering and payment mechanisms build off existing initiatives currently being implemented by UNICEF SD. Implementing aspects of the recommended solution will, however, result in additional workload for UNICEF SD (e.g. participation in Phase 2

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<sup>10</sup> This figure is based on 2013 birth cohort figures. Note that the 18 percent figure excludes Cuba, Ukraine, India and Indonesia, which would not be expected to utilise the recommended solution.

[graduation] missions; serving additional countries' utilisation of VII). Thus, moderate operational costs will be incurred, as described as part of the overall budget request to strengthen country transitions out of Gavi support (Doc 04, Financial Implications).

#### 14. Impact on Secretariat

14.1 The Secretariat will continue to engage with countries to enhance their transitions out of Gavi support and will build upon current collaboration with UNICEF SD to support them in implementation of the UNICEF/Gavi tenders and VII-related activities. The Secretariat will continue to engage with Gavi countries as part of Phase 2 [graduation] missions to assess country interest in, and support country preparations for, participation in the recommended solution. The Secretariat will also coordinate with UNICEF SD to ensure that Phase 3 Gavi country demand is integrated into overall Gavi demand forecasts and to support UNICEF SD on follow-up with these countries, as needed. Also, as described earlier, the Secretariat will continue ongoing market shaping activities to support creation of healthy vaccine markets that enhance access to appropriate vaccine prices.

#### 15. Legal and governance implications

15.1 Subject to PPC recommendation and Board approval, appropriate legal arrangements will be made with partner organisations including specifically with UNICEF regarding Gavi's US\$ 5 million investment to support capitalisation of VII.

15.2 If adopted, the recommendations in this paper will need to be implemented in a manner that is consistent with applicable regulatory and legal requirements, including relevant anti-trust and competition laws.

15.3 In 2017, the PPC will review Gavi's investment in VII. In 2019, after four years of implementation, the PPC and Board will conduct a review of the recommended solution in this report, as part of the broader review of the Eligibility and Transition Policy.

#### 16. Consultation

16.1 **Two cross-Alliance groups – a working level Task Force and a Senior Advisory Group – were constituted to guide the development of a recommendation.** The purpose of the Task Force was to provide general expertise to this work; review and give feedback and guidance to the Secretariat on the analyses and materials developed; provide input on their respective agency position; and, lead discrete pieces of work, as appropriate. The Senior Advisory Group was requested to provide overall direction for this work, including both process and content, and provide oversight for the Task Force. Membership in advisory bodies included Alliance partners, country representatives, donors, civil society, industry experts and academia as outlined in Annex A.

- 16.2 **A highly consultative approach was utilised for both groups to ensure robust input.** The Task Force convened nine times over the course of four months and worked closely with the Secretariat to conduct and review analyses, including the gap analysis, options assessment and recommendation development. The Senior Advisory Group convened three times over the course of five months to provide overall guidance. The Secretariat also held bilateral conversations with each institution represented on the Task Force and Senior Advisory Group to ensure that all views were being incorporated into solution design.
- 16.3 **The Secretariat also conducted consultations with 28 countries that are projected to enter Phase 3 between 2016 and 2022.** Recognising the importance of country ownership of this solution, the Secretariat consulted with country representatives throughout the process. A first round of consultations sought input from countries on general issues relating to pricing after they no longer receive Gavi financial support. A second round of consultations sought perspectives on potential specific approaches to support countries in access to appropriate prices. In total, 28 countries across all regions provided input into this process, including 19 countries that provided feedback on specific options. In addition, representatives from Moldova and Ghana participated in the Task Force and Senior Advisory Group and provided detailed perspectives throughout the process as part of those bodies. Summary findings from country consultations are included in Annex D.
- 16.4 **The Secretariat consulted with nine industry partners and with civil society organisations.** Nine individual manufacturers and two industry groups, the Developing Countries Vaccine Manufacturers Network (DCVMN) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), were consulted to ensure that industry input was incorporated into the development of the recommendation. The Secretariat also surveyed civil society organisations and five individual CSOs shared their perspectives through responding to the survey. Summary findings from these consultations are included in Annex D.

## 17. Gender implications

- 17.1 One of the vaccines within the scope of this work is HPV vaccine. HPV is a leading cause of cervical cancer, the second most common cancer among women in less developed regions. By helping to make HPV vaccine introduction viable for countries that no longer receive Gavi financial support through access to appropriate pricing, Gavi can help reduce the incidence of cervical cancer for women and girls living in these countries.

## **Section D: Annexes**

Annex A: List of members of ATAP Senior Advisory Group & Task Force

Annex B: Information on Gavi countries projected to enter Phase 3 between 2016 and 2022

Annex C: Gap analysis

Annex D: Industry, country and civil society organisation (CSO) consultation feedback

Annex E: Demand sizing for VII

Further documents available on myGavi:

- Description of ongoing initiatives
- Detailed options assessment

### Annex A: List of members of ATAP Senior Advisory Group & Task Force

The Senior Advisory Group was requested to provide overall direction for this work, including both process and content, and provide oversight for the Task Force. The purpose of the Task Force was to provide general expertise to this work; review and give feedback and guidance to the Secretariat on the analyses and materials developed; provide input on their respective agency position; and, lead discrete pieces of work, as appropriate.

Affiliation	Senior Advisory Group Member	Task Force Member
Bill & Melinda Gates Foundation	Orin Levine	Greg Widmyer
DfID (UK)	Donal Brown	Jason Lane, Ross Leach
French Foreign Ministry	Marianne Barkan-Cowdy	Julia Blau
Gavi Secretariat	Seth Berkley	Santiago Cornejo, Wilson Mok, Eduard Molnar, Aurelia Nguyen, Paolo Sison, Eelco Szabo
Ghana Ministry of Health	Victor Bampoe	John Dadzie
Independent	John Grundy	-
MSF Access Campaign	Manica Balasegaram	Kate Elder
Moldova Ministry of Health	Andrei Usatii	Cristina Gaberi
PAHO	Francisco Becerra	Francisco Becerra, Daniel Rodriguez
Princeton University	Adel Mahmoud (Chair)	
UNICEF PD	Mickey Chopra	Gian Gandhi
UNICEF SD	Doreen Mulenga	Gian Gandhi, Philipp Kalpaxis
William Davidson Institute	Prashant Yadav	Andrea Bare
World Bank	Tim Evans	Karima Saleh
WHO	Michel Zaffran	Tania Cernuschi

**Annex B: Information on Gavi countries projected to enter Phase 3 between 2016 and 2022**

Country	Income class	GNI/capita (US\$ 2013)	Birth cohort (2013)	Introduced vaccines	Planned introduction by 2020
Angola	UMIC	5,010	948,958	Penta, pneumo, rota	HPV
Armenia	LMIC	3,790	40,786	Penta, pneumo, rota	-
Azerbaijan	UMIC	7,350	167,318	Penta, pneumo	Rota
Bhutan	LMIC	2,460	14,740	Penta, HPV	Pneumo
Bolivia	LMIC	2,550	274,638	Penta, pneumo, rota	HPV
Congo, Rep.	LMIC	2,660	166,929	Penta, pneumo, rota	HPV
Cote d'Ivoire	LMIC	1,380	744,941	Penta, pneumo	Rota, HPV
Djibouti	LMIC	Exact figure unavailable	24,007	Penta, pneumo, rota	HPV
Georgia	LMIC	3,570	57,809	Penta, pneumo, rota	-
Ghana	LMIC	1,760	799,552	Penta, pneumo, rota, HPV	-
Guyana	LMIC	3,750	16,180	Penta, pneumo, rota	HPV
Honduras	LMIC	2,180	209,027	Penta, pneumo, rota	HPV
Kiribati	LMIC	2,620	2,385	Penta, pneumo	HPV
Lao PDR	LMIC	1,460	181,078	Penta, pneumo, HPV	Rota
Lesotho	LMIC	1,550	57,014	Penta, pneumo HPV	Rota
Moldova	LMIC	2,460	42,364	Penta, pneumo, rota	-
Mongolia	LMIC	3,770	64,280	Penta	Pneumo, Rota, HPV
Nicaragua	LMIC	1,780	138,275	Penta, pneumo, rota	HPV
Nigeria	LMIC	2,760	7,173,020	Penta, pneumo	Rota, HPV
Papua New Guinea	LMIC	2,010	211,555	Penta, pneumo	Rota
Sao Tome	LMIC	1,470	6,538	Penta, pneumo	Rota, HPV
Solomon Islands	LMIC	1,610	17,293	Penta, pneumo	Rota, HPV
Sri Lanka	LMIC	3,170	380,009	Penta	Pneumo, Rota, HPV
Timor-Leste	LMIC	3,580	40,645	Penta	Pneumo, Rota, HPV
Uzbekistan	LMIC	1,900	621,686	Penta, pneumo, rota	HPV
Vietnam	LMIC	1,730	1,423,991	Penta	Pneumo, Rota, HPV
Zambia	LMIC	1,480	624,919	Penta, pneumo, rota	HPV

### Annex C: Gap analysis

Figure C1: Gap analysis focuses on countries projected to enter Phase 3 between 2016 and 2022

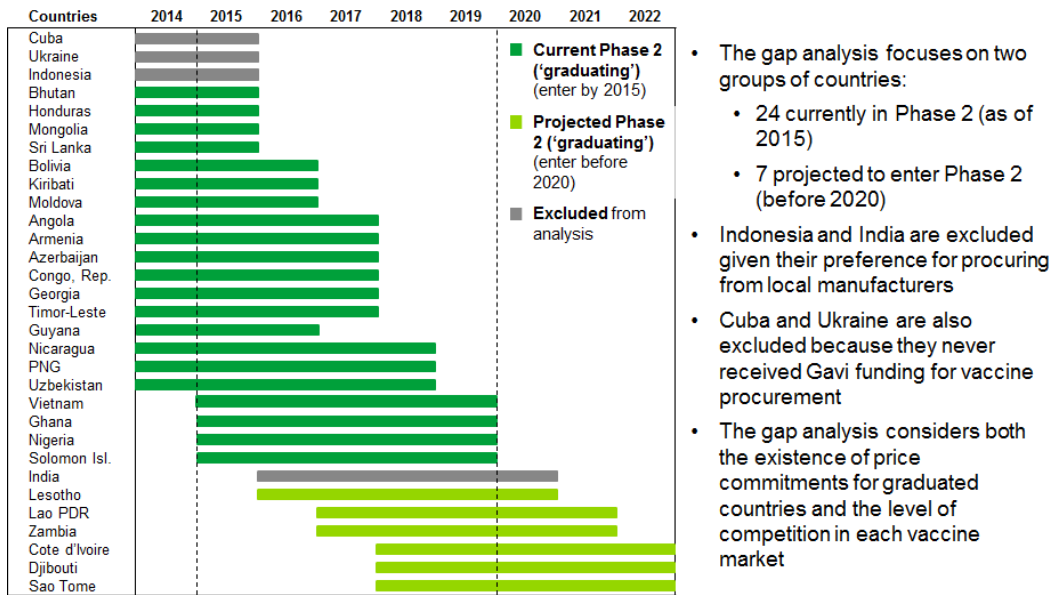


Figure C2: Gap analysis focuses on four high-priced vaccines in the portfolio that are used in routine immunisation programmes

To focus gap analysis on a limited number of highest priority vaccines, vaccines having the highest cost implications for countries were selected

- Price:** does the vaccine have a high price per course, implying a significant impact on country vaccine budgets if price were to increase?
- Usage:** is the vaccine introduced by countries for routine or campaign use (rather than procured for stockpile)?

	Vaccine	Approximate current Gavi price per course	Usage	Focus vaccine for gap analysis?
Current portfolio	Cholera	~\$1.90	Stockpile	No
	HPV	\$9.00-9.20	Routine	Yes
	IPV	~\$0.90 (10-dose)	Routine	No
	Japanese encephalitis	Low price (not yet publicly available)	Routine, campaign	No
	Measles	\$0.22-0.25	Routine, campaign	No
	Measles rubella	~\$0.50-0.60	Routine, campaign	No
	Meningitis A	\$0.60	Routine, campaign	No
	Pentavalent	~\$3.60-6.30 (10-dose)	Routine	Yes
	Pneumococcal	\$9.90-10.50	Routine	Yes
	Rotavirus	~\$5.20 (GSK)	Routine	Yes
Pipe-line	Yellow fever	~\$1.00	Routine, campaign	No
	Ebola	TBD	Stockpile	No
	Malaria	TBD	Routine	No
	Typhoid	TBD	Routine, campaign	No



Figure C3: Gaps in access to pricing among countries projected to enter Phase 3 between 2016 and 2022

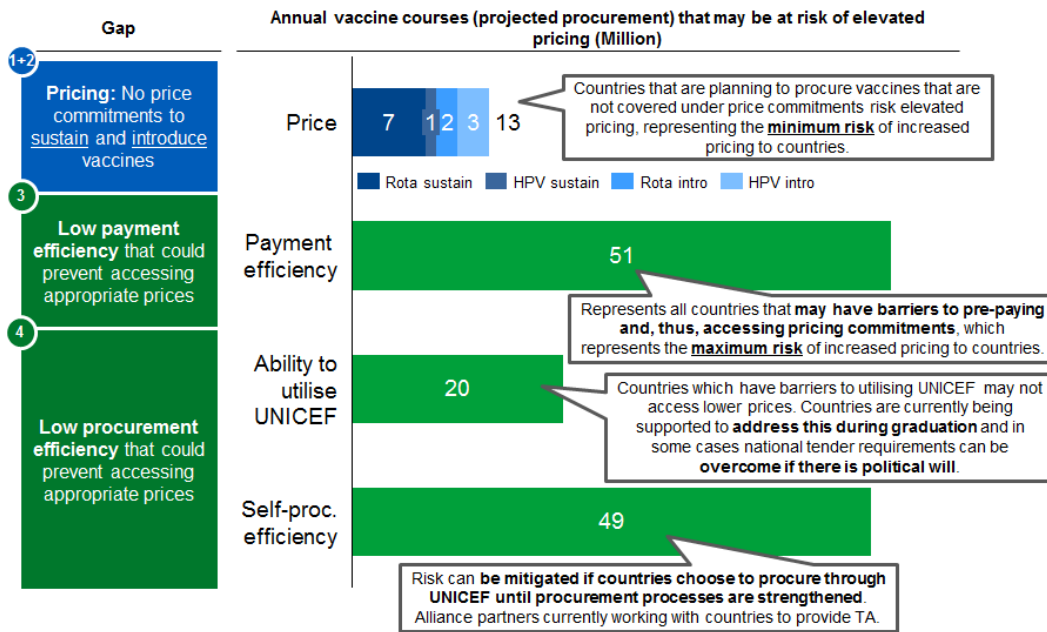
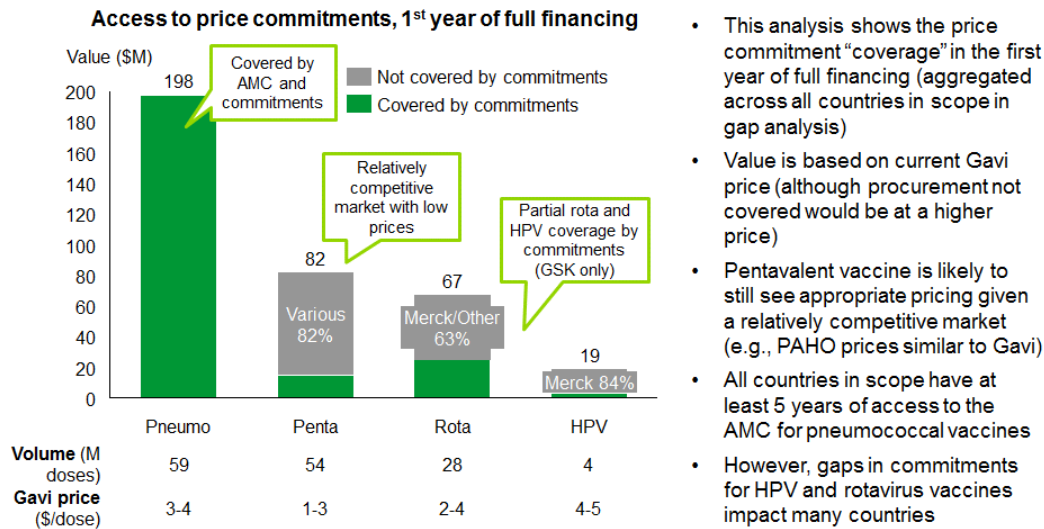
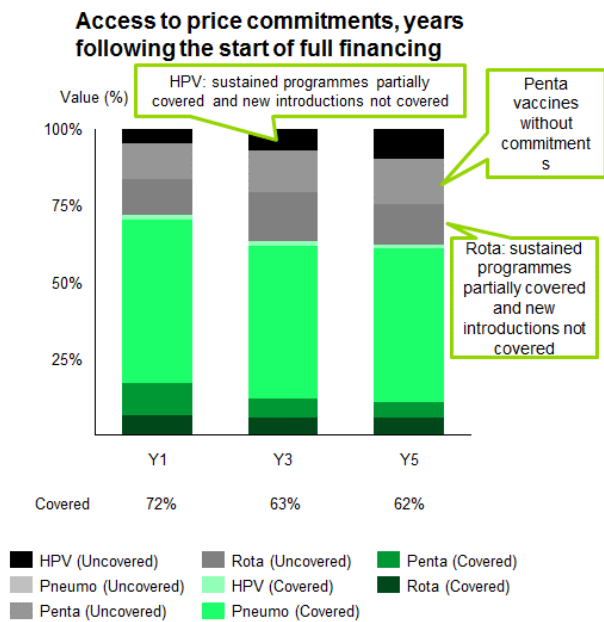


Figure C4: Countries entering Phase 3 between 2016 and 2022 have access to commitments, but significant gaps still exist



Source: Extended ADF v10 (revised October 214) – 27 current and projected graduating countries, 1 year after graduation Notes: Does not include vaccine volumes already procured by countries outside of GAVI mechanism

Figure C5: Among countries entering Phase 3 between 2016 and 2022, manufacturer price commitments have secured Gavi price for 60-70% of planned procurement



- This analysis shows the price commitment “coverage” for countries’ projected vaccine procurement
- Value is based on current Gavi price (although procurement not covered would be at a higher price)
- Pricing commitments cover the majority of planned procurement
- However, payment and procurement efficiency challenges may be a barrier to countries being able to access pricing through commitments
- Specific vaccines are also not covered under pricing commitments (e.g., some rotavirus and HPV vaccines)
- Pentavalent vaccines are also largely not covered but the market is relatively competitive market

Source: Extended ADF v10 (revised October 214) – 27 current and projected graduating countries, 1 year after graduation Notes: Does not include vaccine volumes already procured by countries outside of GAVI mechanism. \*With the exception of GSK’s HPV commitment to the 2011 graduating country cohort if they introduce before 2018

## Annex D: Industry, country and civil society organisation (CSO) consultation feedback

### Industry consultation feedback

The Gavi Secretariat conducted a second round of industry consultations in February/March 2015. These consultations followed a first round of industry consultations that took place in Q1 2014, findings from which were presented to the PPC in May 2014. The second round of consultations included nine manufacturers, five based in high-income countries and four based in developing countries. The main findings were as follows:

- **Nearly all manufacturers acknowledged the rationale to include Phase 3 Gavi countries in UNICEF/Gavi tenders to sustain existing immunisation programmes.** Four manufacturers preferred this concept to other tenders for fully self-financing Gavi countries.
- **Nearly all manufacturers indicated support for the principle of tiered pricing.** Despite this, six have made commitments to continue providing the Gavi price to countries after Phase 2 and two others have offered single prices across countries in practice.
- **Six manufacturers noted that continued Gavi support for demand forecasting would be beneficial in a UNICEF/Gavi tender,** particularly if a single-price was requested.
- **Most manufacturers were also comfortable with inclusion of Phase 3 Gavi countries in alternative UNICEF tenders not including other Gavi countries.** However, many advised that overall demand certainty would be significantly lower – which would increase pricing offered – and noted that there is no exceptions to the PAHO LPC for mechanisms beyond Gavi.
- **Three manufacturers raised concerns with Phase 3 Gavi countries being able to introduce new vaccines at Gavi prices.** Most manufacturers were aligned with the principle of allowing these countries to introduce new vaccines at Gavi prices, however three manufacturers raised concerns on the principle of equity and ability to apply tiered pricing. Six manufacturers noted that increasing certainty around volumes for this set of countries, particularly with new introductions, is vital to maintaining low prices for the whole UNICEF/Gavi tender.
- **The majority of manufacturers (seven of nine) strongly opposed the inclusion of other LMICs in a UNICEF/Gavi tender.** Many manufacturers saw non-Gavi LMICs as “riskier demand” and three manufacturers explicitly warned that their inclusion would risk Gavi achieving the lowest possible price for Gavi-eligible and Phase 2 countries. However, two developing country manufacturers saw an opportunity to reach more of the MIC market.

- **All manufacturers supported providing access to UNICEF's VII for Gavi countries with two manufacturers suggesting it could result in lower prices.** Most indicated that it would not impact the prices they offer, given UNICEF's existing payment terms already address risk to manufacturers, but recognised the benefits to countries.

### Country consultations feedback

**In November 2014, eight EURO countries and six PAHO countries were consulted regarding access to appropriate pricing.** The objectives of this first round of consultations were to: gain input from in-country stakeholders regarding the impact vaccine prices may have on the ability to sustain immunisation programmes once Gavi financial support has ended; better understand the main bottlenecks to country introduction of new vaccines after Phase 2; understand how countries currently procure non-Gavi vaccines and the factors that are important in accessing the best price for these vaccines; understand perspectives on pooled procurement; and understand how PAHO countries, specifically, benefit most from the PAHO Revolving Fund. Key findings were as follows:

- **Nearly all countries (both EURO and PAHO) expressed concerns regarding pricing after they become fully self-financing.** There was a strong desire from countries, especially those close to completing Phase 2, to have some certainty and security regarding what the long-term price will be for vaccines. For EURO countries, there was particular concern about newer vaccines: pneumococcal, rotavirus and HPV.
- **Countries indicated a desire for access to Gavi prices for at least 5 years, with some noting as much as 10 years.** 1-2 PAHO countries noted that they would require access to the Revolving Fund to sustain access to pricing after they no longer receive Gavi financial support.
- **Vaccine price and low domestic immunisation budgets were named as key bottlenecks to introduction of new vaccines.** Most EURO countries noted that vaccine price/cost and the domestic budget for immunisation were key bottlenecks to introduce new vaccines after Phase 2. Evidence of disease burden and vaccine effectiveness / cost-effectiveness and procurement capacity were also noted by many EURO countries to be bottlenecks for new vaccine introduction. PAHO countries also cited vaccine price/cost and domestic budget for immunisation as key bottlenecks to introduction. Additionally, evidence of burden of disease and vaccine effectiveness / cost-effectiveness was cited by many countries as a key barrier to address.
- **EURO countries rely on various tools to access best pricing for non-Gavi vaccines.** The procurement mechanism utilised to procure non-Gavi supported vaccines varies across countries. While two countries self-procure for non-Gavi vaccines, most other EURO countries use UNICEF SD to some extent. Reasons for not using UNICEF SD include local legislation barriers and UNICEF SD not supplying certain vaccines (e.g.,

rabies). There was wide variability on what countries noted was the most important factor in securing best possible prices for non-Gavi supported vaccines. Some of the factors most frequently noted include publication of prices other countries are paying, data and information on vaccines, reference prices provided by the manufacturer and local product registration and national regulatory authority (NRA) functionality.

- Many EURO countries expressed strong interest in participating in a pooled procurement mechanism through UNICEF.** Countries desired a more detailed understanding of how a pooled procurement mechanism would operate (e.g., requirements) and an estimate of pricing in order to provide further feedback on interest in participating in a pooled procurement option. Most EURO countries have requirements for national tenders, although many have been able to obtain exemptions for procurement through UNICEF SD. The most significant barrier to pooled procurement that was cited was not having a guarantee of receiving vaccine in the preferred presentation or from the preferred manufacturer. For EURO countries, payment in hard currency and pre-payment of vaccines (in advance of delivery) was noted by most countries as not being a major barrier, although some country-level processes may need to be changed to address these issues. Paying a fee to participate was generally not seen to be a major barrier.
- PAHO countries expressed satisfaction with the Revolving Fund's ability to access low prices.** PAHO countries indicated that demand forecasting, country planning and budgeting and access to pooled procurement were the factors most important to their ability to access vaccines at low prices. A broad manufacturing base indicative of competition, payment facilities and local production were also noted as important factors by at least one country. Countries expressed appreciation for the Revolving Fund's ability to bring a variety of tools and services to member countries. Countries expressed that the Revolving Fund provides a country demand forecasting form which aids in their planning and budgeting processes; offers a credit line to countries that need payment support; pools demand on their behalf to access a better price; and ensures timely delivery of quality vaccines.

**In March and April of 2015, a second round of country consultations were conducted, focused more specifically on gauging country interest in participating in a proposed mechanism for support.** These consultations included input from 19 countries: seven countries from the Africa region (AFRO), four countries from the Western Pacific region (WPRO), three countries from the Southeast Asia region (SEARO), and five countries from the Europe region (EURO). Key findings were as follows:

- The majority of countries (15 out of 19) expressed a preference for procuring through UNICEF over self-procurement,** with nine of those indicating a strong preference for utilising UNICEF.

- **Fourteen of these countries indicated that a UNICEF/Gavi tender provided greater confidence that they would have access to appropriate prices in Phase 3 than other tender/procurement options.** Only one country indicated that an alternative tender/procurement option would be a better option than a UNICEF/Gavi tender.
- **Similarly, fourteen of these countries indicated that a UNICEF/Gavi tender provided greater confidence that they would have access to appropriate prices in Phase 3 than manufacturer price commitments.** Only one country indicated that a UNICEF/Gavi tender and manufacturer price commitments provided the same level of confidence.
- **Four countries indicated that they would likely not utilise a UNICEF/Gavi tender:** one due to laws requiring a national tender and three due to a preference for self-procurement.
- **Countries are generally familiar with the revolving fund concept, with two having specific experience with VII:** One country is already using VII and indicates that it has worked well, while another is currently finalising an MoU to participate.
- **Eleven out of 15 countries preferring to procure through UNICEF expressed interest in utilising a revolving fund.** Seven of these expressed an interest in using the fund routinely for all vaccines, while three expressed interest in using the fund for some vaccines.
- **Several countries expressed the need for other types of support, outside of procurement and payment mechanisms.** Countries cited the need for support on high-level advocacy and sensitisation to gain attention for adequate funding of immunisation; support for combining procurement of devices and syringes with procurement of vaccines; and the desire to examine issues on a regional basis, rather than through a country by country lens.

### CSO consultation feedback

In January 2015, a survey was sent to the members of Gavi's Civil Society Organisation (CSO) Steering Committee. Representatives of five CSOs responded to the survey. Key findings were as follows:

- **All CSO Steering Committee member survey respondents considered access to appropriate pricing as a very important concern.**
- **Access to Gavi prices was the most desired form of support for countries in Phase 3 of transition out of Gavi.** In addition, respondents noted a need for continued health systems support, encouraging competition and a broad supplier base, and support related to pooled procurement and self-procurement capacity.

- **The key bottleneck identified for countries to be able to continue introducing new vaccines in Phase 3 was having sufficient domestic budget allocated to immunisation.** In addition, there is concern over countries' ability to maintain political commitment for the EPI, overall vaccine prices and the strength of national immunisation programmes / health systems.
- **When asked about what factors currently enable countries to secure best possible pricing in their ongoing procurement for non-Gavi vaccines, several factors emerged:** local production facilitated by tech transfer; a broad manufacturer base / competition; publication of prices paid by other countries; and effective country planning / budgeting.
- **Some respondents felt there would be interest from countries in participating in pooled procurement, although some were unsure.** The most important potential barrier to country participation in pooled procurement was noted to be the lack of guarantee that countries would receive their preferred vaccine presentation or brand.

## Annex E: Demand sizing for VII

Year	Number of times fund revolves per year	Low scenario			High scenario		
		Projected annual procurement value (US\$, million)	Capital need (US\$, million)	Percentage of VII fund required for Gavi countries	Projected annual procurement value (US\$, million)	Capital need (US\$, million)	Percentage of VII required for Gavi countries
2016	2	4.5	2.3	11%	21.2	10.6	53%
2017	2	7.7	3.9	10%	30.1	15.0	38%
2018	2.25	13.2	5.9	10%	42.5	18.9	32%
2019	2.25	22.6	10.1	13%	60.2	26.8	33%
2020	2.25	38.7	17.2	17%	85.2	37.9	38%

### Notes and assumptions:

- Countries planning to self-procure and PAHO countries are excluded from these demand estimates.
- Nigeria is excluded from these demand estimates, as alternative near-term payment solutions are currently in development by other partners, including UNICEF and the World Bank.
- Figures account for demand from Phase 2 and Phase 3 countries. Each country receives access to the fund for five years. Figures for projected annual procurement are provided by Gavi.
- Low scenario estimates include countries that are very likely to use VII (includes countries that are current subscribers or that have directly indicated interest in utilising VII; countries that face administrative issues preventing fund release; countries that have poor access to hard currency AND laws against pre-payment; or countries that have serially defaulted on their co-financing requirements).
- High scenario estimates include countries that are very likely to use VII in addition to those that might use VII (these include countries that face at least one payment barrier of any type; and countries that have defaulted on a one-off basis).
- Countries' expected usage of VII as a percentage of their total vaccine spend was estimate as either 33%, 67% or 100%. Percentages were assigned based on each country's 2014 default status (e.g., no default = 33%; partial default = 67%; full default = 100%), and then adjusted as needed based on qualitative feedback from Gavi and UNICEF experts.
- Number of revolutions per year have been assigned as per UNICEF assumptions.
- All figures include a 6% buffer to account for shipping/devices/etc. and a 10% buffer for currency and other risks.