



## Gavi – The Vaccine Alliance

### KEY RECOMMENDATIONS OF STRATEGIC IMPORTANCE EVALUATION MANAGEMENT RESPONSE

**Business Owner: Pneumococcal AMC Secretariat**

**Evaluation Title: Endline evaluation of Gavi's pilot Advanced Market Commitment (AMC) for Pneumococcal Conjugate Vaccine (PCV)**

**Evaluation Year: 2021**

1.	FINDING/S	RECOMMENDATION	RESPONSE	ACTION
	<ul style="list-style-type: none"> <li>The PCV AMC pilot did not achieve the objective of accelerating new product R&amp;D amongst those in the pipeline, despite one new TPP-compliant PCV product coming to market during the PCV AMC pilot.</li> <li>Taking a broader interpretation of 'accelerating' new product R&amp;D102, the PCV AMC pilot was successful at signaling the value of the LMIC PCV market.</li> <li>The PCV AMC pilot was very successful at driving presentation innovation, in terms of Multi-Dose Vials (MDVs). These were key to scaling up supply and driving down cost per dose in LIC and</li> </ul>	<p>The design of subsidy mechanisms in future AMCs or other market shaping instruments could benefit from both understanding the incentive structures the mechanism will create if the market develops as expected, and how it will influence market actors in other plausible scenarios.</p>	<p>Partially agree In comparative terms across the Gavi supported vaccine markets, Pneumococcal conjugate vaccine development is one of the most complex undertakings with numerous challenges along the pre-clinical and clinical pathway. The AMC has certainly accelerated the availability and uptake of PCV as of Objective 2 and 3 and hence, created a very attractive market for both, incumbent and pipeline manufacturers with a large predictable demand due to the RI nature. The fact that pipeline manufacturer kept their programmes and reached market (e.g. SII, Walwax, Merck) or are in late stage development (e.g. BioE, EuBio, Panacea and BioFarma) demonstrates the attractiveness of the PCV market provides the necessary incentives for R&amp;D investment and offers the "pull factor" for R&amp;D. To note, some manufacturers halted their PCV programme due to patent challenges and other technical aspects.</p>	<p>None</p>



	<p>LMIC markets.</p>		<p>In addition, the AMC encouraged incumbent manufactures to not only expand their production capacity but also encouraged them to keep investing as we could see with both, GSK and Pfizer, who invested in Multi Dose presentations and launched a 4 dose Multi dose vial presentation, which significantly reduced the cold Chain Capacity requirement for countries.</p> <p>Pfizer also invested heavily in the next generation, high valency candidate (Prenar20), which got recently licensed by the US FDA.</p> <p>Finally, the evaluation seems to have overly relied on literal interviewee responses and lacked triangulation of data or modelling, which could have been supportive of the above mentioned facts and could have led to a different conclusion. Further, the lack of evaluator engagement with the designers of the mechanism suggest that relatively important perspectives have been missed in assessing the initial design process (partially described in the retrospective working paper by Michael Kremer, Jonathan Levin, and Christopher Snyder titled "Advance Market Commitments: Insights from Theory and Experience"). While Finding 1 seems possible, the Gavi Secretariat questions the basis on which Finding 1 was concluded as it lacks of substantial evidence. Findings 2 and 3 are agreeable and the recommendation overall serves as good general guidance for any new market shaping mechanism bus is nevertheless an obvious conclusion irrespective of any particular insights gleaned from this particular evaluation and opens up the need for further, more third party evaluation of thorough and technical nature.</p>	
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2.	FINDING/S	RECOMMENDATION	RESPONSE	ACTION
	<ul style="list-style-type: none"> <li>The PCV AMC pilot achieved the objective of scaling up PCV supply in Gavi-73 markets – especially between 2010 and 2015/6 – by increasing manufacturer confidence in market demand.</li> <li>The PCV AMC pilot was not successful at avoiding supply shortage issues common for antigens in Gavi-73 markets – there were significant supply shortages in the first three or four years of the PCV AMC pilot.</li> <li>The Gavi/UNICEF demand forecasts were structurally optimistic, and this has led to a reduction in confidence amongst manufacturers.</li> <li>The PCV AMC pilot was relatively ineffective at driving price competition, likely due to the late entry of SII’s PCV10 and the subsidy design.</li> </ul>	<p>Gavi could benefit from delivering more accurate and informative demand forecasts to manufacturers, focusing in particular on when demand is likely to materialize.</p>	<p>Reject</p> <p>Gavi recognises the historic (and structural) tendency towards optimistic demand forecasts during the time period referenced, especially in the shorter term. Would also highlight, however, the inherent uncertainty around demand forecasting in a new product development and adoption cycle, and would urge caution around expectations for high forecast precision in such situations. It may also be worth pursuing in tandem other instruments which e.g., could include supplier commitments to provide more certainty, and/or a stronger commitment of intention from countries around introduction dates and demand volumes. Gavi also continues to pursue several initiatives towards continuous improvement of demand forecast accuracy, which include increased scrutiny and firmer benchmarking of short term country forecasts and increased flexibility and a longer time-horizon towards dose approval levels, lessening the structural incentives towards optimistic demand forecasts</p> <p>On the third finding, the report does not show any current, accurate and data driven evidence to support this conclusion. Gavi SDF is the official AMC forecast but there is no comparison of various versions of the SDF and actual doses procured in this report. Page 31, 1st paragraph of the report has inaccurate statements and data points which is the basis for this inaccurate conclusion. Contracted doses are not the AMC forecast and UNICEF does</p>	<p>None</p>

			<p>not refer to contracted AMC doses as the forecast, Dalberg did not understand the terminology of “contracted” doses. Page 27, figure 9, the report distinguishes contracted doses from forecast but from page 29, figure 11, erroneously refers to contracted doses as the forecast. Very inconsistent.</p> <p>Supply constraints until 2014 caused delayed introductions but BCG evaluation report in 2015 indicated overoptimistic Forecast, which is now the main reference of this report as seen on page 31 first paragraph. Both manufacturers have new teams managing PCV and when presented with the findings from BCG evaluation of 2015 with leading questions, they reiterated the same findings in a different context which should not be the case. Over-forecasting in a time of severe supply constraints and claim of excess inventory is contradictory.</p>	
<b>3.</b>	<b>FINDING/S</b>	<b>RECOMMENDATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
	<ul style="list-style-type: none"> <li>The PCV AMC pilot achieved the objective of accelerating vaccine uptake, though it is plausible demand for PCV would have been high without an AMC, on account of the disease burden and context.</li> <li>The sharp increase in late payments during preparatory transition (PT) suggests countries in initial self-financing (ISF) are not fully internalizing the co-financing strategy.</li> <li>The drop in late payments</li> </ul>	<p>Gavi could benefit from adopting a more coordinated and intentional approach to shaping healthy demand – as proposed in the new market shaping strategy.</p>	<p>Agree</p>	<p>Gavi and Alliance partners will operationalize the approach agreed in the Market Shaping Strategy to support a Healthy Demand.</p>

	during accelerated transition (AT), and the overall reduction in late payments since 2016, suggest that Gavi-73 countries are broadly on track for sustainable co-financing.			
<b>4.</b>	<b>FINDING/S</b>	<b>RECOMMENDATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
	<ul style="list-style-type: none"> <li>• The PCV AMC pilot likely was successful at driving higher coverage of PCV than has been seen with other antigens. This increased coverage led to more lives saved.</li> <li>• There are a significant number of non-price sensitive countries who would likely have introduced PCV on account of the disease burden, and Gavi support.</li> <li>• The PCV AMC pilot was perceived to be a success by almost all stakeholders, which is hugely important given that that making and stabilizing markets is as much about confidence, trust, and signaling as about legal agreements and vaccine procurement.</li> </ul>	N/A	<p>Partially agree</p> <p>The AMC's fourth objective was to pilot the effectiveness of the AMC mechanism as innovative finance mechanism and significant thought and stakeholders worked on the structure of the mechanism. It seems a missed opportunity that the external evaluation did not draw lessons learned informing future innovative finance mechanisms which could be constructed to support other antigen markets or address current or future market failures from a demand or supply side perspective. While it is indeed undeniable that some countries may have introduced PCV, that other designs may have in retrospect created more impact, or that Gavi would have offered PCV regardless of the AMC, the evaluation fails to assess the incremental value of the AMC over other possible approaches to shaping behaviors in a vaccine market. In addition, the modelling and analysis regarding the counterfactual scenario, i.e., the development of the PCV market without the PCV AMC does not provide necessary substance to meaningfully inform new financial mechanisms. While the evaluation highlights the value and impact of a subsidy-based mechanism for vaccine</p>	None



			markets, the evaluation lacks important secondary analysis and the perspectives of original designers of the mechanism which are necessary to offer recommendations that could lead to meaningful improvements on the original mechanism.	
	FINDING/S	RECOMMENDATION/S	RESPONSE	ACTION/S
5.	It was necessary to use very robust legal structures for the first AMC, because of the innovative nature of the partnership. However, with Gavi’s capabilities, and especially its credibility, now firmly established, Gavi and its partners can take advantage and have a nimbler legal structure that reduces (transaction) costs while still providing the right level of confidence and protection for both sides.	Legal structures of future AMCs could be designed to allow for appropriate flexibility, and to minimize transaction costs for all parties involved.	Partially agree.  The complexity of the legal structures for the PCV AMC was necessary because of the many different stakeholders involved, including Gavi, UNICEF, the World Bank, donors and some external reviewers. The robust legal agreements were successful in that they provided protection to Gavi from legal and financial liability. For example, the agreements protected Gavi against liability resulting from default by a donor to the AMC PCV. However, the financing structure of any future AMC could likely be streamlined, reducing the complexity of the legal agreements. Effective legal arrangements must balance "flexibility" with clarity around the roles and responsibilities, deliverables and accountability of the various stakeholders.	In future agreements and legal structures, Gavi's legal team will seek to balance "flexibility" in legal agreements with clarity around the roles, responsibilities, deliverables and accountability of the various stakeholders.

***The full detailed version can be accessed by request to Gavi Secretariat.***