## GAVI Secretariat Management Response to the Process and Design Evaluation of the Pilot Advance Market Commitment for Pneumococcal Vaccines

Advance Market Commitments (AMCs) for vaccines aim to encourage the development and production of affordable vaccines tailored to the needs of developing countries. Following the announcement of the Governments of Italy, the United Kingdom, Canada, the Russian Federation, Norway and the Bill & Melinda Gates Foundation, who collectively pledged a total of US\$ 1.5 billion to fund the programme, the pneumococcal AMC pilot was designed to stimulate the late stage development and manufacture of affordable pneumococcal vaccines for the poorest countries.

The pilot AMC is currently in its fifth year of operation and all operational activities have been implemented as designed. Since the 1<sup>st</sup> GAVI-funded introduction in Nicaragua in 2010, 24 countries have introduced pneumococcal conjugate vaccines resulting in more than 13 million children being vaccinated against pneumococcal disease,<sup>1</sup> a leading cause of pneumonia, the largest killer of children worldwide.<sup>2</sup> An additional 26 countries have already been approved and plan to introduce in the near future.<sup>3</sup> Two products have been made available, with a total of 960 million doses of pneumococcal vaccines already contracted under this AMC.<sup>4</sup>

In order to assess the impact of the programme and uncover learning that could be valuable for the Alliance members and for the international development community, the pilot has included a Monitoring and Evaluation framework with four key components: (a) a Baseline Study (completed in 2010<sup>5</sup>); (b) an annual monitoring Report published on the GAVI website each year from 2010<sup>6</sup>; (c) an independent Process and Design Evaluation; and (d) independent Impact Evaluations to be undertaken every four years starting from 2014. This paper provides the GAVI Secretariat's response to the Process and Design evaluation, completed by Dalberg in February 2013.

The one for pneumococcal vaccines represents the first ever AMC implemented and has demonstrated the ability of the international development community to design, establish and administer such a facility. This Process and Design Evaluation provides therefore important lessons relating to both the current pilot and how to utilize AMCs in future market shaping initiatives. Among the points identified, the following are in our opinion the most relevant:

• With regards to the evaluation's findings on pricing, the Alliance believes that the long-term impact of the AMC can only be fully evaluated once all of the AMC funds have been allocated and additional vaccines from developing countries' manufacturers have reached the market.

<sup>&</sup>lt;sup>1</sup> WHO Report on GAVI Progress 2000-2011 & Projected Achievements 2012, Department of Immunization, Vaccines, and Biologicals, October 2012.

<sup>&</sup>lt;sup>2</sup>Black R, Cousens S, Johnson H, et al for the CHERG Reference Group. Global, regional, and national causes of child mortality in 2008: a systematic analysis. Lancet. 2010 Vol.375. Published online May 12, 2010.

 <sup>&</sup>lt;sup>3</sup> 52 of 73 countries have applied for support since the programme started (including one resubmission)
<sup>4</sup> As of February, 2013.

<sup>&</sup>lt;sup>5</sup>Available at: <u>http://www.gavialliance.org/results/evaluations/baseline-study-for-amc/</u>

<sup>&</sup>lt;sup>6</sup> Available at: <u>http://www.gavialliance.org/funding/pneumococcal-amc/</u>

- We agree that ensuring the participation of the only two manufacturers with AMC-eligible products was essential to meet short term demand from countries, allowing countries to introduce the life-saving vaccine as quickly as possible, and to provide reliable supply, which is important due to implications on manufacturing processes of the biological nature of vaccines.
- In addition, we agree that the binding commitments from donors were an important part of the AMC design, as they provided a source of predictable funding to GAVI and to the countries, built momentum with stakeholders and contributed to the success of the GAVI Alliance's 2011 pledging conference. The existence of these funds provided GAVI eligible countries with the necessary assurance of the long term viability of the programme. This has been demonstrated by the high number of applications received, even during the period ahead of GAVI's 2011 replenishment round, when its financial situation was uncertain.
- As recommended by the evaluation, the Secretariat will review the indicators used to track progress in the AMC to identify opportunities for further increasing their relevance, timeliness and usefulness. Furthermore, as part of its preparatory work for the 2014 AMC Impact Evaluation, the Secretariat will assess various evaluation design options to enhance the ability of the evaluation to generate learning about the current and future impact of the AMC. The Secretariat will consult with partners on these design options and other methodological issues.

In November 2011 the GAVI Alliance Board approved the Vaccine Supply and Procurement Strategy for the period 2011-2015 with the goal of ensuring sufficient and uninterrupted supply of highquality vaccines, promote low and sustainable costs for developing countries, and foster an environment for innovation. At the core of the strategy is the recognition that each vaccine has its specific market environment and that prioritisation of supply and procurement objectives, as well as the interventions and tools used to influence the market, need to be tailored to each vaccine. Depending on the circumstances, the strategy may include catalysing or brokering push-funding methods and technology transfers to overcome development and production barriers, developing innovative finance tools, and using a wider set of procurement mechanisms and tactics. As such, an Advance Market Commitment is included in the toolbox of potential interventions to shape vaccine markets.

The GAVI Secretariat is committed to continuing to share the results of the pilot AMC evaluations so that the potential designers of future AMCs will have access to the full range of lessons learned from the experiences of the design, implementation and evaluation of this innovative financing and procurement mechanism.

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