The Advance Market Commitment Pilot for Pneumococcal Vaccines: Outcomes and impact evaluation

Independent evaluation conducted by The Boston Consulting Group

The Advanced Market Commitment (AMC) pilot was started in 2005 and officially launched in 2007 to "reduce morbidity and mortality from pneumococcal disease by accelerating the development, availability and uptake of pneumococcal conjugate vaccines (PCVs)” ($1.5 billion from 6 donors – the Bill and Melinda Gates Foundation, Canada, Italy, Norway, Russian Federation and United Kingdom).

Objective of the evaluation:
To assess the extent to which the pilot AMC has achieved its stated objectives and the overarching goal of reducing morbidity and mortality from pneumococcal disease. The evaluation also captures lessons learned in the pilot.

Summary of findings:

Overarching goal: reducing morbidity and mortality from pneumococcal disease

- Introduction of PCVs through the AMC pilot has accelerated immunisation coverage against pneumococcal disease across 53 countries to when the report was completed
- 49 million children have been fully immunised with 3 PCV doses between 2009 and 2014
- 6 to 7.5 million pneumococcal disease cases have been averted and 14 to 17 million DALYs saved through 2015
- PCV’s have averted an estimated 230,000 to 290,000 deaths of children under five years old (U5) through 2015 and it is estimated that over 3 million U5 deaths will be averted by 2030
- AMC pilot contributed to helping increase supply availability and uptake of PCV in developing countries

Objective 1: Accelerating the development of pneumococcal vaccines that meet developing country needs

- AMC pilot stimulated demand and brought forward supply to developing countries but had very little influence on accelerating Research and Development (R&D) outcomes, in particular vaccine licensure (when PCV was selected for the AMC pilot, 2 candidates compliant with the AMC Target Product Profile (TPP) were already in advanced stages of development)
- AMC has not succeeded in accelerating the development timelines of other manufacturers (companies with earlier-stage candidates have faced significant technical and regulatory challenges)
- Two positive R&D effects:
It proved that there would be a large low-income country market after the conclusion of the AMC

The creation of this market stimulated the development of other presentations specifically for Gavi markets by existing suppliers.

**Objective 2: Bringing forward availability of effective pneumococcal vaccines for developing countries**

- Pfizer and GlaxoSmithKline (GSK) made investment decisions to further expand capacity to serve Gavi markets in response to AMC and its supply agreements. These decisions were affected by the long-term demand stimulated by the AMC and supply agreements.
- There have been persistent and notable supply shortages over the past five years (in the context of unprecedented vaccine demand), however they were rectified more quickly than would have happened without the AMC.

**Objective 3: Accelerating vaccine uptake by ensuring predictable vaccine pricing for countries**

- PCV10 and PCV13 became available in Gavi countries just one year after they were available in developed countries.
- Higher number of country introductions than Hib and Rotavirus (Rota) in the analogous time period.
- Accordingly, access and coverage in this time period exceeded that of Hib and Rota vaccine by three to four times.

**Other considerations**

- While AMC played an important role in accelerating supply availability, Gavi country demand and PCV coverage, these positive outcomes were aided by many other factors (e.g. PneumoADIP, Gavi’s Accelerated Vaccine Introduction initiative, strong WHO recommendation for PCV preceding the AMC).
- It is not possible to attribute these results exclusively to the AMC.

**Lessons learned:**

- Proof of concept and validation
  - This pilot provided proof of concept of an advance market commitment (such as the legally binding agreements for donors and the TPP).
  - Garnered significant interest from donors, including 2 countries that had not previously donated to Gavi.
  - Proven to have the desired effect on accelerating supply of vaccines, accelerating uptake in Gavi countries, and contributing to a large reduction in mortality and morbidity from pneumococcal disease.

- Recommendations for possible future AMCs or other innovative financing mechanisms:
o Having clear prioritisation of competing objectives will lead to greater achievement of those outcomes

o Earlier stage products, particularly those that are technically complex, likely require a portfolio of incentive mechanisms to accelerate R&D outcomes

o Successful engagement with the pharmaceutical industry is critical to improve sustainability of initiatives, enabling manufacturers to shift from Corporate social responsibility (CSR)-based approach to a commercially viable strategy

o Complementary forces to an AMC are critical for creating the enabling environment necessary for its success (e.g. Gavi’s Accelerated Vaccine Introduction initiative, WHO recommendations, Gavi co-financing policy, Gavi’s operational partners)

Considerations for future evaluations:

- Challenges inherent in isolating the influence of the AMC from all the other concurrent factors
- Limitations to understanding the true and precise mortality and morbidity impact of immunisation
- BCG recommends some actions to improve this:
  - Continue investment in empirical studies and population surveillance
  - Build uncertainty ranges and sensitivity analyses into academic models
  - Validate models using sub-national data
  - Delineate drivers of differences across mortality revisions

More detailed information is available in the report.