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The Market Shaping Goal

Shape markets for vaccines and other immunisation products to achieve moderate or high levels of healthy markets dynamics.

Supply and Procurement Roadmap

Pneumococcal Vaccine

Public Summary

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Pneumococcal disease caused by *Streptococcus pneumoniae* is the leading cause of pneumonia, which results in the greatest number of deaths in children under five years of age worldwide. WHO recommends that pneumococcal vaccines be introduced into all national immunisation programmes, particularly in countries with high child mortality. Pneumococcal conjugate vaccines (PCVs) are currently the only vaccines for childhood protection.

The aim of Gavi's PCV programme is to facilitate the rapid introduction of pneumococcal immunisation into countries' routine immunisation programmes. Gavi is currently in a second market phase focused on securing long-term sustainable access to pneumococcal vaccines by reducing costs and on supporting the introduction of PCV vaccines in India.

- By the end of 2016, Gavi had approved support to a total of 59 countries for PCV introduction with a combined surviving infant population of approximately 43 million children.
- It is projected that the continued scale up of PCV vaccination will result in the prevention of 1 million deaths by 2020. PCV accounts for approximately 11% of total projected deaths averted across Gavi's portfolio of vaccines during 2016-2020, representing the second highest impact after the pentavalent vaccine.
- The introduction of an appropriate PCV vaccine for Gavi countries was incentivised by an innovative finance instrument – the pilot Pneumococcal Advance Market Commitment (AMC). Donors committed $1.5 billion in funding and the AMC was launched in June 2009 to help achieve Gavi's goal of promoting access to pneumococcal vaccines. To date, six AMC supply agreements have been entered into, to supply a total of 146 million doses per year from 2016 until 2020. To date Gavi has disbursed 73% of AMC funds ($1,095 million).
- However, despite recent PCV price reductions, PCV remains the most expensive vaccine per child within the Gavi-supported portfolio at $3.05 per dose and $9.15 for a full course.

Market Overview

The total demand for PCV vaccines for the Gavi 73(*) countries in the base case scenario is expected to range from approximately 150 million doses in 2016 to approximately 190 million doses in 2020 and to further grow to approximately 250 million doses in 2026.

There are uncertainties around introductions and programme scale up particularly in India and Indonesia but demand in these countries will drive the volume increase from 2017 to 2026.

SAGE recommendations on vaccine schedule (e.g. potential changes from 3+0 to 2+1 and 1+1) will not have an impact on short- to mid-term demand (2017-2025) but may have a significant impact on long-term demand (after 2026).

(*) Note: Gavi 73 countries are the seventy-three countries eligible for Gavi support in 2003 based on a GNI/capita of ≤ USD 1,000. They include currently eligible, transitioning and transitioned countries. All are eligible to procure through UNICEF Supply Division and the AMC mechanism.

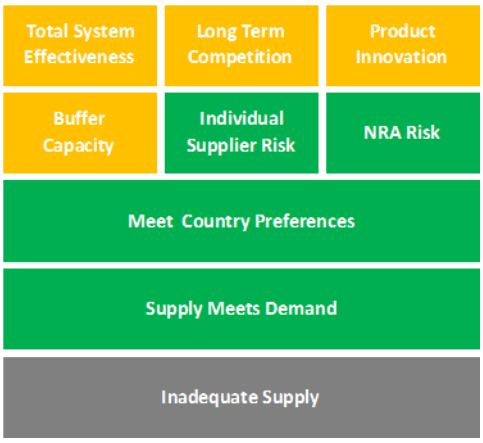
Supply available to Gavi73 is expected to reach more than 200 million doses by 2020 and over 300 million doses by 2026. However, there are uncertainties on the timing of additional supply and the volumes resulting from industrial scale-up of potential new entrants from 2020.

- Supply available to Gavi72 (Gavi73 excluding India) is expected to meet demand whatever the demand or supply scenario.
- When Indian demand is added, supply will meet demand only if a new supplier enters the market around 2020.
- The buffer capacity across PCV presentations is expected to range 10-25% for the period 2017-2020 and 15-35% for the period 2021-2026.
- Balance of supply and demand for PCV13, in particular, will be very tight during the period 2017-2020, with a buffer capacity of -3% to +7% depending on demand scenarios. A switch from PCV10 to PCV13 by a large country would result in supply shortfalls during the period 2018-2020 until a new entrant supplies India with sufficient volume.
- Under current assumptions, AMC funds will be fully used only if the Government of India procures for its self-funded PCV programme through UNICEF after the end of Gavi support.

Healthy Market Framework Evaluation

The PCV market (base case) currently *meets* four of the healthy market attributes and *partially meets* four.

Of partially met attributes, ***Buffer capacity*** will be improved with new manufacturers entering the market, ***Long-term competition*** is anticipated to move towards met as new products enter the market, ***Product innovation*** is unlikely to improve during 2017-2021, ***Total systems effectiveness*** is partially met at current price levels and could be improved through reduced cost per person vaccinated and through product innovations. Vaccine price is the most critical element to improve for a healthier pneumococcal market.



Supply Meets Demand: **Met.** Total market supply is currently sufficient. In a base case supply situation, it will continue to meet Gavi73 demand for the antigen during the period 2017-2026. However, if new manufacturers are late to market, India cannot completely scale-up its PCV programme.

Country presentation preference: **Met.** Two manufacturers have programmatically suitable vaccines. However, if a large country or countries change preference to PCV13 this will result in a possible shortage of 5% of PCV13 demand 2017-2020 and a buffer capacity of only 8% 2021-2026.

Buffer capacity: **Partially met.** In a base case scenario, there is 19% buffer capacity above Gavi73 demand for the period 2017-2020, increasing to 25% for the period 2021-2026 as new manufacturers bring products to market 2020-2025.

Individual supplier risk: **Met.** The risk profile of the current manufacturers is low from a technical and financial perspective. However, there is a risk that manufacturers may consider leaving the market over the longer term.

NRA risk: **Met.** NRA risk is low with current manufacturers. New manufacturers are expected to provide further NRA diversity that carry moderate risk profiles.

Long-term competition: **Partially met.** There is a rich pipeline of new products but a lack of certainty on development timelines and the timing of new market entrants.

Product innovation: **Partially met.** The entry of 4-dose vials with preservative represents an important step in product innovation. New technology may decrease the cost of manufacturing and protect more universally against pneumococcal strains. It is unlikely to be available before 2025.

Total systems effectiveness (TSE): **Partially met.** TSE is partially met at current price levels as PCV vaccines are safe, efficacious and cost effective but PCV is the highest cost per course for countries as compared with other Gavi-supported vaccines. More data is required to understand the cost trade-offs as countries move to a preserved multi-dose vial presentation, including the monitoring of wastage in different use settings. New SAGE recommendations on schedule optimisation are expected in 2017 and 2021.

Supply and Procurement Objectives

The supply and procurement objectives were analysed resulting in the following target outcomes:

- New 4-dose presentations are offered at a lower price per dose by 2017.
- New suppliers enter the market with a lower price per dose (as a 'tail-price' if AMC still applies and/or as a price beyond the AMC).
- No manufacturers exit the market before 2025.
- The market's buffer capacity reaches ≥25% from 2021 and maintains this minimum level.
- Changes to country presentation preference during 2017-2020 are evidence-based and dependent on supply availability.
- Multi-dose presentations usable in multiple sessions are available from all manufacturers by 2018 and from new manufacturers as they gain licensure.
- One new manufacturer supplies Gavi from 2020 and at least one other enters the market by 2025. The new entrant(s) can supply a total of at least 20 million doses per year from 2020 and 80 million doses per year from 2023.
- AMC stakeholders agree on timelines and process for winding down the AMC by its closure on 31 December 2020.

Supporting Stakeholder Action Plan

An action plan ensures the coordination between Gavi Alliance stakeholders and is designed to facilitate the achievement of the above supply and procurement target outcomes. The action plan includes the following items:

- Engage pipeline manufacturers to increase their supply capacity targets to ensure that the buffer capacity target is met. Identify potential market shaping activities that would support such an evolution.
- Limit unnecessary presentation switches by asking countries to make requests for PCV presentation choices based on the epidemiology and presentation that would meet their programmatic needs. Gavi will share evidence-based product data and information on supply availability that helps countries and the Independent Review Committee (IRC) make the best product preference decisions.
- Support pipeline manufacturers to develop candidate pneumococcal vaccines that are appropriate for the Gavi market to be ready for market between 2020-2025.
- Maintain close dialogue with the Government of India to ensure clarity on rollout plans and procurement options and responsiveness to their implications.
- Engage pipeline manufacturers on price targets during their PCV development and identify appropriate activities that may support selected manufacturers to reach the Gavi target.