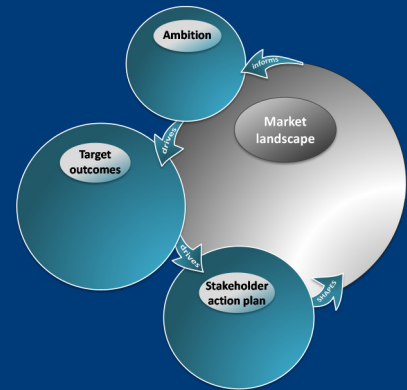


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The Market Shaping Goal

Shape vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries.



Gavi Supply and Procurement Roadmap Pentavalent (DTwP-hepB-Hib)

PUBLIC SUMMARY

Pentavalent vaccine remains the cornerstone of the expanded program on immunisation and Gavi, the Vaccine Alliance engagement. It combines five different vaccines in a single presentation to protect against five diseases: diphtheria, pertussis, and tetanus (DTP); hepatitis B (hepB); and *Haemophilus influenzae* type B (Hib). Since Gavi began offering support in 2001, the increase in hepB and Hib vaccination through the uptake of pentavalent routine immunisation represents the most significant achievement of the Gavi Vaccine Alliance. The number of additional children immunised annually with hepB and Hib through pentavalent will continue fast growth during the period 2013-2016 and will stabilise thereafter. Pentavalent is a 'pioneer vaccine' for Gavi, as it is the first vaccine to have been introduced in all 73 Gavi countries and it will be one of the first vaccines for which a country will experience a graduation from Gavi support in 2016. The next 2 years is a critical period for Gavi, to continue efforts to accelerate roll-out and further improve coverage and equitable access, with a target to reach 77% coverage with the 3rd dose of pentavalent vaccine across all Gavi countries by the end of 2015. The market is also unique in that the whole-cell pertussis containing pentavalent (wP-pentavalent) vaccine was developed and targeted by industry primarily for the 'Gavi' market, thus profits are not being made in high income countries, and only to a limited degree in middle income countries.

Market overview

- Global demand for wP-pentavalent products has grown significantly since 2009 and is expected to start to stabilise from 2015 at ~300M doses per year.
 - Gavi countries will continue to be the world's largest market for wP-pentavalent vaccines through 2020. However, Gavi share of the global market volume is estimated to decrease from more than 85% in 2014 to about 57% across 2016 to 2020, as countries graduate from Gavi support and start to self-fund and/or self-procure.
 - India, when it assumes responsibility for its own procurement, is estimated to account for approximately 25% of global demand in the period 2016-2020.
 - Today, country presentation preferences have increased the 10-dose share of market to approximately 70%, and it is expected that the preference for multi-dose vials will increase to roughly 80% by 2017.
- Theoretical global supply of prequalified 1- and 10-dose wP-pentavalent vaccines now likely exceeds 400M doses per year and is expected to remain greater than demand over the long term (2020 and beyond). However, a turbulent supply history (including supply interruptions linked to WHO de-listings of multiple pentavalent vaccines) shows that the balance of supply and demand can be disrupted.
- Seven manufacturers currently have WHO prequalified wP-pentavalent vaccines. UNICEF SD last tendered for pentavalent supply in 2012 for offers covering the period 2013-2016 and awards were made to six suppliers; three accounting for approximately 95% of total awarded volumes. The exit or withdrawal from the market of one of these key manufacturers (i.e. through quality failure, supply issues or for commercial reasons) would remove the current overcapacity and could negatively impact Gavi pentavalent programmes.
- By 2017, additional liquid multi-dose presentations are anticipated from one to four manufacturers of different NRAs, providing diversified supply of prequalified vaccines.
- The UNICEF/Gavi 2013-2016 tender was successful in obtaining lower prices, with WAP dropping 6% from 2012 to 2013 and then ~3% per year until 2016. During the 2013-2016 tender period, prices range from USD 1.19 to USD 2.95 per dose.
- The market shaping challenge is to bring down the cost per vaccination, to reach appropriate and sustainable levels for each presentation, whilst embracing beneficial product innovations and preserving a healthy and secure market.

Supply and procurement objectives

The supply and procurement objectives were analysed and weighted according to timeframe, to potential market shaping impact and to Gavi's potential capacity to influence the market.

Balance of supply and demand. Despite the healthy balance of supply and demand, this remains an important market-shaping objective, as major supply disruptions would have a severe disruptive effect on routine immunisation against five important diseases. There remain three main supply interruption risks: (1) Downgrading of India's NRA from "functional" (its current WHO categorisation) would put at risk up to three quarters of global wP-based supply. (2) Supply failure related to production of either bulk-components or finished product or process non-compliance. (3) Key suppliers exit the wP-based market judging it commercially unattractive. This objective spans the short, mid and long-term out to 2020 and beyond. The market shaping targets for this area are:

- India, Indonesia and South Korea NRAs maintain continued functionality
- Planned global prequalified supply capacity from manufacturers is achieved and sustained
- Retain, over the long-term, a minimum safety level of redundant global annual production capacity to cover supply interruption/exit of any pentavalent supplier: ≥150 million doses of appropriate and prequalified presentations
- Retain a minimum of three Gavi suppliers from at least two different releasing-NRAs, with no more than two thirds procured from one releasing NRA. This should constitute:
 - A minimum of three Gavi suppliers of 10-dose pentavalent presentations
 - A minimum of one Gavi supplier of a 1-dose presentation

Cost of vaccine to Gavi and countries. Gavi has been successful in significantly reducing pentavalent prices over the past six years. However, it is critical that the price reduction trend is continued through harnessing benefits from increasing competition. Targeting improved prices as a result of a new 2015-2016 tender could be an important step in consolidating a favourable pricing trend for Gavi and an increasing focus on lowest-price procurement. Sustainable prices are targeted to ensure: no key manufacturer exits the market; anticipated new manufacturers are not discouraged from entry; and important product development projects are not jeopardised. Moreover, total cost to Gavi can potentially be reduced by encouraging usage of appropriate presentations. As such, the market shaping targets for this area are:

- Achieve improved prices for unawarded 2015-2016 demand and explore opportunities to discount prices on awarded doses
- Achieve significant Gavi price reductions from 2017
- Prices reach a low but sustainable level for both countries and manufacturers
- Optimise presentation mix according to coverage and cost per child vaccinated

Appropriate and innovative vaccines. Current vaccines satisfy the medical impact requirements. This objective is incremental and not game-changing in nature for pentavalent in the short- to mid-term, but may become more important towards the later stages of the polio endgame when wP-combinations vaccines containing inactivated polio may become available. The market shaping efforts should

encourage new entrants and efforts to improve presentation options. As such, the market shaping targets for this area are:

- Availability and prequalification of Crucell's 'blow-fill-seal' 1-dose presentation, which may reduce wastage and improve programmatic implementation in certain settings, at a total cost comparable to 1-dose vial presentations
- Manufacturer's strategies for hexavalent are influenced by a unified Gavi / GPEI strategic position on hexavalent vaccines

Information. Information is a cross-cutting objective and enabler for all vaccines. As such, the market shaping target for this area is:

- Comprehensive pentavalent forecasts for Gavi and non-Gavi LMICs are reviewed, adjusted and shared with manufacturers on a regular basis.

Supporting stakeholder action-plan

An action plan agreed upon by Gavi stakeholders optimises coordination and maximises achievement of the above supply and procurement objectives and target outcomes. The highlights of that action plan are segmented by time period:

Short-term (2014-2016):

- Encourage manufacturers of new multi-dose and 'blow-fill-seal' presentations to attain prequalification and production scale-up targets. Ensure India, Indonesia and Korea NRAs maintain functionality.
- Explore different tendering options for fulfilling 2015-2016 demand.
- Communicate strongly to manufacturers the importance of making competitive offers and an increasing emphasis on low prices.
- Make awards on all remaining 2015-2016 doses, with a strong focus on lowest price allocation, whilst balancing the need for new (re)entrants and supplier diversity.
- Provide guidance to countries on presentation suitability, in relation to optimal coverage and cost.
- Carefully monitor and understand demand trends per presentation and communicate to manufacturers.

Longer-term (2017+):

- Engage manufacturers to seek ways to significantly reduce offered prices in 2017+ tender.
- Maintain a strong focus on lowest price procurement, whilst retaining a mix of Gavi suppliers that ensures at least a minimum level of supply security. Also seek to maintain a healthy global wP-pentavalent market.
- Examine different tendering options for demand in 2017 and beyond.
- Develop a joint Gavi / GPEI hexavalent strategic position on the conditions for potential usage. Provide guidance to manufacturers, enabling them to make informed strategic/product development decisions.
- Maintain regular, complete and transparent forecast communication with current and future suppliers to enable effective planning.

Pentavalent - Summary visual roadmap

Gavi Supply & Procurement Strategy

