

4

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

Rotavirus Vaccine

Public Summary

Gavi engagement and market shaping implications

Gavi has been engaged in supporting rotavirus vaccination since 2007 when the Vaccine Alliance opened a window to help Gavi-supported countries in the Americas and Europe introduce rotavirus vaccines into their infant immunisation programmes. Gavi expanded this support in 2009 allowing for introduction of the vaccine in all Gavi-supported countries.

It is estimated that each year, the use of rotavirus vaccines in Gavi-supported countries could prevent 180,000 deaths and avert 6 million clinic and hospital visits, thereby saving USD 68 million annually in treatment costs. The purchase of Rotavirus vaccines is expected to represent approximately 12% of Gavi vaccine expenditure for the 2016-2020 strategic period.

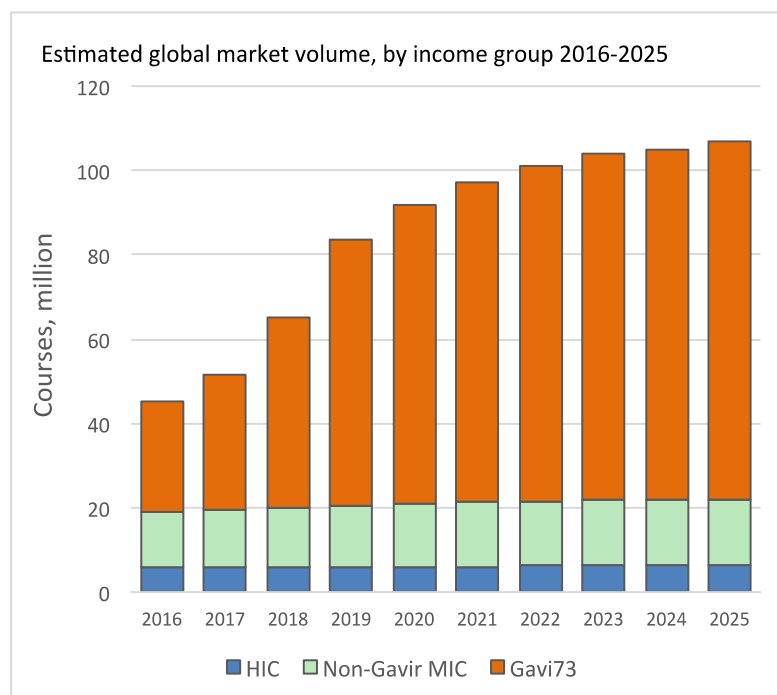
Two critical market related issues need to be addressed to optimise Gavi support.

1. Slower than anticipated introductions of rotavirus vaccines in large countries. Gavi73 coverage did not meet 2011-2015 targets due to delays in introduction by large countries. Some of the reasons for the slower introduction are linked to concerns over vaccine prices and sustainability, and concerns over supply capacity, as well as cold chain capacity constraints.
2. Availability in sufficient volumes of the vaccine preferred by countries. One vaccine has been preferred by the majority of countries due to a more attractive product presentation profile than the other available vaccine in terms of programmatic considerations and price.

Market overview

Note: One vaccine requires a 2-dose schedule while the other current and potential future vaccines require a 3-dose schedule. Due to this difference, volume data are expressed in courses per year throughout this summary.

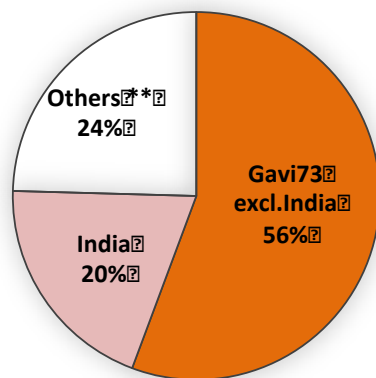
- The global market for rotavirus vaccines has grown from 12 million courses in 2010 to 36 million courses in 2015. The growth is driven by introductions in Gavi-supported countries that accounted for 51% of the global market volume in 2015.
- Two vaccines are WHO prequalified and available for Gavi supported countries. RotaTeq (produced by Merck) is a live-attenuated vaccine administered in a 3-dose schedule, produced in a 1 dose liquid presentation, with no Vaccine Vial Monitor (VVM), and it requires 139 cm³ of cold chain space per course. Rotarix (produced by GSK), is a live-attenuated vaccine administered in a 2-dose schedule, produced in a 1 dose liquid presentation, with a VVM14, and it requires 34 cm³ of cold chain space per course.
- In 2015, demand for Rotarix represented approximately 78%



of global volume and 92% of Gavi volume.

- From 2016 to 2025, the global rotavirus vaccine market is projected to grow 136%, reaching approximately 107 million courses by 2025. The growth will be driven mostly by demand for Gavi73 countries projected to peak in 2025 with approximately 85 million courses, of which 24 million courses is for India, 6 million courses for other self-procuring countries, 1 million courses for countries who procure through the PAHO revolving fund, and 54 million courses for the 64 countries (Gavi64) that will procure through UNICEF.

Estimated global market volume for rotavirus vaccines 2016-2025 (million courses)



Global market

<i>Estimates</i>	2016-2025 (courses million)	
Gavi*	474	56%
India	168	20%
Others **	209	25%
Total	851	100%

* Gavi73 less India

** HICs + Non-Gavi MICs

- From 2017 onwards, demand for the vaccine presentation preferred by Gavi countries (Rotarix) is estimated to exceed existing supply capacity available. Supply capacity of the other prequalified, but less preferred vaccine (RotaTeq) is higher than the anticipated Gavi demand.
- Up to four new prequalified vaccines from two Indian manufacturers may enter the market between 2017 and 2020; a frozen vaccine presentation followed by a liquid presentation; and a lyophilised vaccine presentation followed by a liquid presentation. Availability of these future vaccines to Gavi countries are subject to the development, regulatory and manufacturing scale-up risks that all new vaccines face.

None of these vaccines are expected to completely meet the preferred product presentation profile requirements of the majority of Gavi countries vis-à-vis a combination of price, dose/course, stability, all-in-one dispenser, etc.

- The 2015 rotavirus weighted average price (WAP) for Gavi was USD 4.80 / course, with the price for Rotarix USD 4.17 /course and the price for RotaTeq USD 10.50 / course.
- The global market for Rotavirus vaccines reached approximately USD 1.3 billion in 2015; of which USD 87 million (7%) for Gavi64. The global market value is anticipated to reach approximately USD 1.9 billion by 2025, of which approximately USD 232 million for Gavi64 and USD 107 million for India.

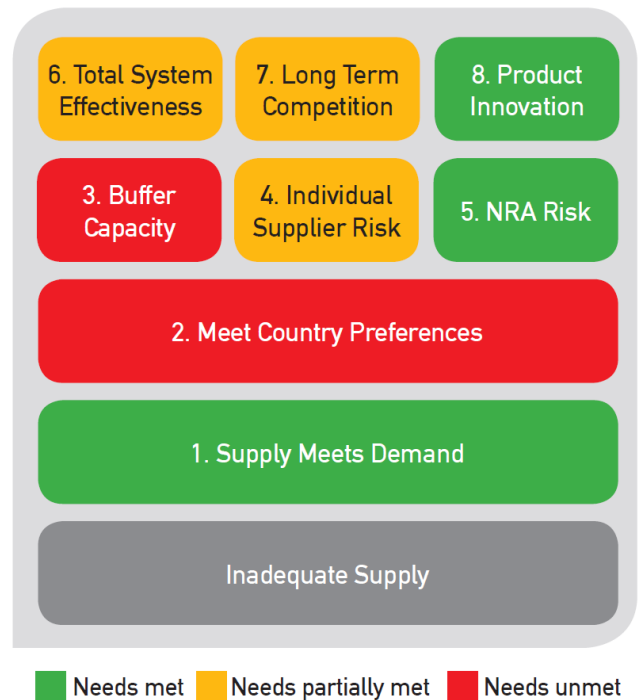
Healthy Market Framework Evaluation

The current Rotavirus market is in an unsatisfactory state of health with a dominant-supplier structure that may not have the future production capacity to meet country vaccine preferences. Three of eight healthy market attributes are met (highlighted green), three are partially met (highlighted amber), and two are not met (highlighted red).

The “country vaccine preference” market attribute is not met because of the current country preference for Rotarix. In the context of rotavirus vaccines, failure to achieve this market attribute has negative implications on Gavi’s rotavirus goal because countries have chosen to delay introduction rather than accept the less preferred presentation.

The rotavirus market functions as if there is insufficient supply of antigen despite supply theoretically meeting demand. It will continue to function in that way unless there are market interventions.

Gavi’s aim is to support actions that will result in the greatest number of children immunised. Given existing knowledge on the current and future vaccines and future market (demand, supply, potential new vaccines and associated characteristics, price dynamics, and the healthy market analysis), the market shaping interventions that will have the greatest positive impact on the rotavirus market will increase supply in line with current country preferences while supporting the availability of new vaccines to satisfy the demand from India. Gavi also aims to support vaccines with the combination of product characteristics that will meet Gavi country preferences.



Supply and Procurement Objectives and Target Outcomes

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.

1st priority Objective: balance of supply and demand. Based on the current supply availability to Gavi countries, a supply gap of approximately 8 million courses is expected in 2018 that increases to approximately 22 million courses in 2025. Gavi aims to ensure that sufficient supply of vaccine is available to meet total Gavi demand and country presentation preference, through four market shaping target outcomes:

- Supplies for country preferred vaccines reach 55 million courses/year or more by 2023.
- Domestically produced vaccines satisfy demand in self-procuring countries in line with country product preferences.
- New vaccines are WHO prequalified 2017-2020.

2nd priority Objective: cost of vaccine to Gavi and countries. Costs must be reduced long-term to ensure country sustainability, especially as countries transition from Gavi support. To minimise the costs of immunisation, Gavi should seek competitive prices for future suitable vaccines and allocate supply to manufacturers offering the best value considering country product presentation preference. This results in three market shaping target outcomes:

- WAP is decreased to a (confidential) Gavi target value or lower by 2020.

- Future suitable vaccine manufacturers offer prices in line with the above Gavi target value.
- The programmatic feasibility of introducing non-liquid, non-all-in-one (e.g. require steps to reconstitute/deliver) vaccines are thoroughly assessed.

3rd priority Objective: appropriate and innovative vaccines. The increased cold chain capacity linked to the introduction of rotavirus vaccination is a challenge for countries that needs to be minimised.

- The supply capacity for innovative new lower volume presentations is increased in the mid-term.

There is a need to improve the vaccine efficacy rates beyond that provided by the current generation of replicating rotavirus vaccines (RRVs) while ensuring that other features of the desired product profile are met such as cold chain volume and programmatic convenience.

- Innovative vaccines targeting the Gavi-desired profile (e.g. that improve the protective efficacy and/or costs compared to current rotavirus vaccines) enter Phase III clinical trials by 2019.

Information is a cross-cutting objective and strategic enabler for all vaccines. Specific to rotavirus:

- The speed of country uptake is lower than initially anticipated. Therefore, short-term demand forecasts should be updated and shared quarterly to ensure transparency and synchronization among Alliance partners, countries, and relevant manufacturers. Demand forecasts are shared annually and detailed assumptions are discussed with the stakeholders that are relevant to market shaping outcomes.
- The desired product profile for new rotavirus vaccines must be clearly communicated to all relevant stakeholders in 2017.
- Optimised communication between Gavi partners and potential new suppliers.
- UNICEF-SD deliver timely rotavirus market notes to help inform Alliance partners (https://www.unicef.org/supply/index_70173.html).

Supporting Stakeholder Action Plan

A concerted action plan ensures the coordination between Gavi Alliance stakeholders, designed to lead to the achievement of the above supply and procurement objectives.

- Engage the manufacturers of the rotavirus vaccines preferred by countries to facilitate decisions on long-term supply capacity.
- Engage suppliers to find practical short-term supply solutions that reduce the risk of countries postponing rotavirus introduction.
- Support the development, registration, scale-up and roll-out of appropriate new rotavirus vaccines for India and other Gavi countries.
- Engage potential future suppliers of rotavirus vaccines to develop vaccines with product characteristics and prices that are competitive against the vaccine that is currently preferred by countries.
- Undertake further reviews of progress on potential new vaccines, identify potential issues that may delay or prevent their access to the Gavi market, and explore their potential as alternative supply options.
- Undertake an independent evaluation of the programmatic implications related to frozen and lyophilised candidate vaccines in relevant countries and with relevant partners.

- Update quarterly short-term forecasts and communicate with relevant stakeholders to ensure transparency and synchronisation between Alliance partners, countries, and manufacturers.
- Agree between Gavi partners an updated Gavi-desired product profile for new rotavirus vaccines and clearly communicate it to all relevant stakeholders in 2017.
- Support the development of new technologies that target innovative vaccines, potentially through R&D investments, technical support, and identification of commercial partners.