

4

The Market Shaping Goal

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

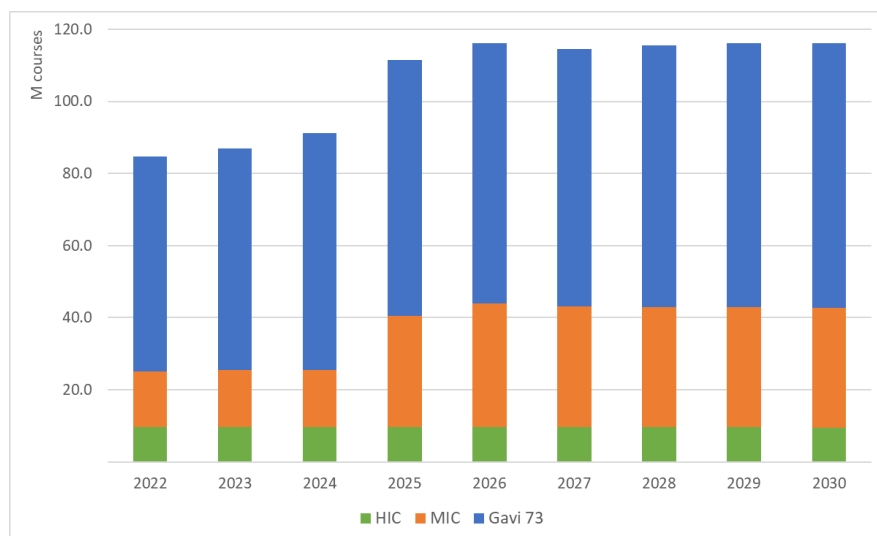
Supply and Procurement Roadmap

Rotavirus

**PUBLIC SUMMARY
MARCH 2022**

Rotavirus is the leading aetiology for diarrhoea mortality among children under five years of age. Unlike other types of diarrhoea, the spread of Rotavirus is resistant to improvements in water and sanitation which means that vaccination is the best way to prevent severe illness.

Fig. 1 : Rotavirus vaccine demand forecast



Gavi has been engaged in supporting Rotavirus vaccination since 2007. As of Q4 2021, 51 Gavi-supported countries accounting for 75% of Gavi73 birth cohort have already introduced a Rotavirus vaccine into routine immunisation programmes and five additional countries have been approved so far for introduction in 2022

onwards. In 2026, global demand is expected to reach 115M courses, including 72M courses in Gavi73. It is estimated that over the period 2018–2027, Rotavirus vaccination will prevent nearly 600,000 deaths in Gavi countries. During the period 2021-2025, Rotavirus is forecasted to represent approximately 12% of Gavi’s total vaccine expenditure.

The magnitude and the duration of the Covid-19 pandemic impact on immunization programmes and Rotavirus vaccine demand is still uncertain. Impact on immunisation has varied across Gavi countries, but disruptions were less severe in 2021 compared to 2020, and generally no more than 5% variability in monthly vaccination rates was experienced versus pre-pandemic levels. From 2023 onwards the forecast assumption is for a return to ‘normal’ activity levels for routine immunisation. However, the emergence of new Covid strains, national lockdown measures, export restrictions, and cold chain capacity constraints have potential to disrupt demand and supply further.

Evolution of the supplier landscape and market health

After years of a supplier duopoly in the Gavi market, new presentations by two new manufacturers based in India were prequalified by WHO in 2018. This helped improve the resilience of Rotavirus vaccine supply, which suffered a disruption in 2018 due to a bulk production issue affecting the most frequently chosen presentation and a decision by another supplier to reduce its allocation to the Gavi market. Three manufacturers are currently offering Gavi-supported countries a total of 12 prequalified presentations covering a diversity of valency, immunization schedules, formulations, number of doses per vial, vaccine vial monitors (VVM) and cold chain volume. Some manufacturers have plans to improve their production capacity in the next three years, which could increase supply availability from 75 million courses to 120 million courses.

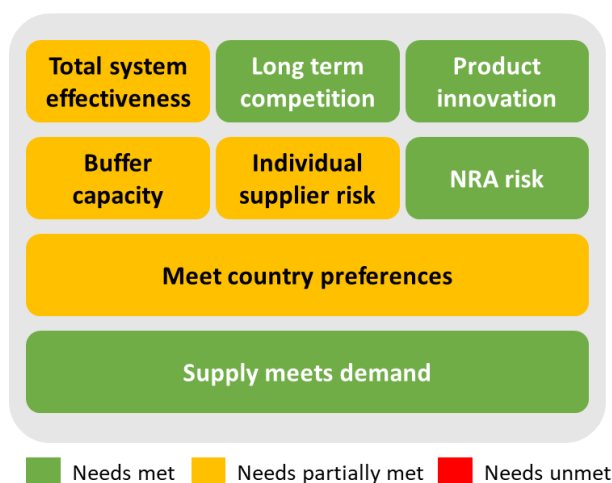
In the longer term, the development of the oral and injectable next generation Rotavirus vaccines (oNGRV and iNGRV) represent genuine scientific progress but their programmatic suitability for

Gavi 73 countries still needs to be confirmed. Their availability in Gavi-supported countries is not expected before 2025.

Table 1: List of the 12 prequalified Rotavirus vaccine presentations available on the Gavi menu as of November 2021

	GSK (Belgium)	Bharat (India)	SII (India)
WHO Prequalified	1-d/plastic tube, liquid (VVM7)	5-d/vial, frozen (VVM2)	1-d/vial, lyophilised (VVM30)
	1-d/BFS, liquid (VVM7)	10-d/vial, frozen (VVM2)	2-d/vial, lyophilised (VVM30)
		1-d/vial, liquid (VVM7)	1-d/vial, lyophilised (VVM+250)
		5-d/vial, lqd (VVM7)	2-d/vial, lyophilised (VVM+250)
			1-d/plastic tube, liquid (VVM7)
			2-d/vial, liquid (VVM7)

Fig. 2: Market Health Framework (2022)



Even with the increased number of available presentations, Rotavirus market health in Gavi 73 is expected to be low in 2022 with only four healthy market attributes met. Four remaining attributes are partially met due to supply constraints that limit countries' access to their preferred presentation and a lack of buffer capacity for this presentation. Recent supply disruptions due to production and delivery issues highlight increased supplier risks as well that need to be monitored.

Moving forward, market health is expected to be low to moderate depending on multiple factors, including:

- Manufacturers successfully increasing their production capacity to improve buffer.
- Availability of new vaccine presentations meeting country preferences and improving affordability.
- Improvement of individual supplier risks by reducing supply disruptions.
- Limited impact of potential product switches on business sustainability.
- Suitability of the next generation of Rotavirus vaccines (oNGRV and iNGRV) and integration in the product mix with limited impact on other market health attributes.

Key challenges

The greatest challenge currently facing the Rotavirus market is ensuring continuity of supply of preferred presentations for ongoing programmes. This will only be possible if Rotavirus vaccine suppliers remain in the market and avoid supply disruptions due to production/quality issues, business decisions and other vaccine development plans. Since 2017, these disruptions have impacted at least 20 countries, forcing them to switch to other vaccines or delay their introductions.

The introduction of programmatically improved vaccines increased the number of presentations offered to Gavi73 which is an opportunity for manufacturers to cater to different country preferences. However, it resulted in a challenging situation for country decision makers that need

to navigate a complex product menu to choose the most appropriate presentation, and potentially for manufacturers who could face reduced efficiency of their production lines.

Two of the three prequalified suppliers of Gavi 73 are based in India and also provide vaccines to the national market. As a result, the health of the Rotavirus market is disproportionately impacted by the dynamics in the Indian national market and by potential pressure to prioritize supply from these two manufacturers to the local market.

Next generation Rotavirus vaccines (oNGRV and iNGRV) that are currently under development could bring improvements in terms of efficacy but will result in some programmatic changes compared to the currently well-established live oral attenuated vaccines. The oNGRV are administered at birth followed by two doses with one month interval (total of three doses) which is different to the current oral vaccines administered starting at 6 weeks of age with subsequent 2nd and 3rd doses at an interval of 4 weeks each¹. Due to their parenteral administration route, iNGRV will also represent a major change in Rotavirus immunization based so far on orally administered vaccines and should be evaluated taking into consideration the already existing parenteral vaccines administered at the same time, i.e., at 6, 10 and 14 weeks of age. Combining iNGRV with other antigens might be a solution, but such a product is not expected to be prequalified by WHO before 2030.

Strategy to sustainably improve market health

Gavi Partners defined a long-term strategy for the Rotavirus market to address these challenges, by reviewing different scenarios in terms of available suppliers, long term business sustainability and product suitability and affordability. It translates into the following strategic market objectives and target outcomes:

- **Objective 1** – Ensure supply availability and timely delivery of Rotavirus vaccine from viable suppliers.
 - A minimum of three viable suppliers remain in the Rotavirus vaccine market.
- **Objective 2** – Scale up new presentations to provide countries with programmatically improved vaccines and optimize the weighted average price (WAP).
 - The number of presentations from each manufacturer on the Gavi menu is consolidated to provide a rationalized product menu of vaccine presentations with best attributes for countries and improve production economics.
 - New presentations with programmatic benefits are offered to Gavi-supported countries at affordable prices to create a viable product mix and healthy competitive dynamics, while providing adequate implementation support to these countries.

¹ Rotarix recommended schedule is 2 oral doses given 4 weeks apart beginning at 6 weeks of age; Rotavac and Rotasiil recommended schedule is 3 oral doses given 4 weeks apart beginning at 6 weeks of age.

- **Objective 3** – Accommodate future innovative vaccines in the Rotavirus market strategy if programmatically suitable for Gavi-supported countries.
 - The programmatic suitability and market impact of new products such as oNGRV and iNGRV are evaluated to guide future development and support decisions.

A concerted action plan ensures the coordination between Gavi Partners and facilitates the achievement of the above strategic market objectives by:

- Getting clarity and alignment from manufacturers about their current and future viable volumes of Rotavirus vaccine, taking into consideration their vaccine portfolios in Gavi-supported countries, their other development programs and potential risks of supply disruptions.
- Monitoring countries whose product decisions can impact market health and integrating into presentation level forecasts and strategic demand scenarios (SDS).
- Monitoring price dynamics and tender awards in India and evaluating potential impacts on UNICEF/Gavi market.
- Monitoring the development and supply availability of new presentations with programmatic benefits to Gavi-supported countries.
- Strengthening predictability of demand by routinely briefing National Immunization Technical Advisory Groups (NITAGs) and Expanded Programs on Immunization (EPIs) on new options and collecting their feedback.
- Working with countries and suppliers to pursue more efficient product mix options, processes to change presentations and timelines.
- Aligning with Gavi partners on a position regarding the potential support of oNGRV and iNGRV, taking into account their programmatic suitability and market impacts.