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# Rotavirus Vaccine: Supply and Demand Update

UNICEF Supply Division

January 2022

## Rotavirus Vaccine: Supply Demand Update January 2022

This update provides new information on rotavirus vaccine demand, supply, and country introductions. Even though overall rotavirus vaccine supply from three manufacturers through UNICEF is sufficient to meet all confirmed country requirements, UNICEF seeks to accelerate the availability of vaccine presentations suitable for country immunization programmes.

### 1. Summary

- UNICEF procured 232 million rotavirus vaccine (RV) courses over 2011-2021<sup>1</sup>. Most of this volume was for countries supported by Gavi, the Vaccine Alliance (Gavi), with only one per cent supplied to middle-income countries (MICs), not supported by Gavi. UNICEF's procurement has steadily increased over the past eight years from 900,000 courses in 2011 to reach 37 million courses in 2020 on behalf of 56 countries.
- The supply disruptions in 2017-2019 characterised the RV market's imbalance; level of supply insecurity; fragility; low state of health; and identified the need for additional interchangeable products and supplier diversity. It also identified the potential need for technical assistance to support countries to evaluate the available products and their different characteristics. The RV market also witnessed major supply disruptions in 2018 and 2019 due to Merck Sharp & Dohme Corp's (Merck) decision to reduce their allocation to countries supported by Gavi. Another major supplier, GlaxoSmithKline (GSK), suffered technical difficulties with their bulk production.
- The impact of COVID-19 on the market has been limited. However, UNICEF still considers overall demand to have been less than initially anticipated due to the deferment of vaccine introductions by countries having acquired approval from Gavi.
- The availability of RV supply has improved with the increase in presentations offered to countries that have been prequalified by World Health Organization (WHO). In 2018 and 2021, WHO prequalified additional RV products from Bharat Biotech (Bharat) and Serum Institute of India (SII), which, combined with the subsequent resolution of GSK's bulk production issues during the second half of 2019, improved overall supply availability. Currently, three manufacturers offer WHO prequalified vaccines to countries supported by Gavi through UNICEF. Two of these manufacturers, Bharat and SII, also provide RV in support of India's national immunization programme. However, in 2022, GSK will revise its manufacturing plans for RV and reduce its supply through UNICEF by approximately five million courses. In 2021, UNICEF concluded its tender for RV to secure supply from 2022 onwards.
- In MICs, where diarrhoea-associated deaths are relatively infrequent, health authorities often fail to recognise the need for RVs. Country demand from MICs is currently uncertain which makes it a challenge for UNICEF to establish long-term arrangements (LTAs) with suppliers to secure access to affordable prices.

### 2. General Brief and Background

Diarrhoeal diseases are both preventable and treatable, and yet remain the second leading cause of under-five mortality, globally, killing an estimated 525,000 children under five years of age annually.<sup>2</sup> Rotaviruses alone are responsible for 25 to 50 per cent of all severe diarrhoeal cases worldwide, of which 90 per cent occur in Africa and Asia. More than 215,000 children under-five die annually from rotavirus infections,<sup>3</sup> which afflict nearly #ForEveryChild<sup>4</sup> at least once before the age of five, with children aged from six months to two years being the most vulnerable to infection.<sup>5</sup>

Since 2007, WHO has recommended countries to include RVs into their national childhood immunization programmes. It should be part of a comprehensive diarrhoeal disease control strategy, complementing improved water, sanitation, hygiene, and treatment that includes the use of [low-osmolarity oral rehydration salts \(ORS\), and zinc supplementation](#),<sup>6</sup> particularly in countries with high rotavirus gastroenteritis associated fatality rates.<sup>7</sup> Yet, in over 14 years, as of 2020,

<sup>1</sup> As different RVs require different dose schedules to fully immunize a child, RV vaccine data is expressed in *courses* as opposed to *doses*, so that vaccines can be relatable to each other.

<sup>2</sup> World Health Organization, [Diarrhoeal Diseases: Key Facts](#), WHO, Geneva, May 2017.

<sup>3</sup> World Health Organization, [Estimated Rotavirus Deaths for Children Under 5 Years of Age](#), WHO, Geneva, 2013.

<sup>4</sup> Follow UNICEF on Twitter at #ForEveryChild.

<sup>5</sup> World Health Organization, [Rotavirus Vaccines: WHO Position Paper](#), WHO, Geneva, February 2013, p. 50.

<sup>6</sup> UNICEF, [Oral Rehydration Salts \(ORS\) and Zinc](#), UNICEF, Copenhagen, February 2016.

<sup>7</sup> WHO, [Rotavirus Vaccines WHO Position Paper](#), p. 49.

WHO estimates the global immunization coverage for RV to have only reached 46 per cent,<sup>8</sup> against a global WHO vaccination target coverage rate of 90 per cent nationally, and 80 per cent in every district.<sup>9</sup>

WHO has now prequalified 14 RV presentations from four manufacturers, all of which are administered orally. Four new vaccine presentations were recently prequalified in 2021, of which all are liquid presentations (Table 1). These new products now extend additional WHO prequalified vaccine supply options to countries from the previous eight options, to now twelve, from three different manufacturers, noticing that Merck had exited the Gavi market in 2020 and no longer makes their product available through UNICEF.

**Table 1 WHO Prequalified Rotavirus Vaccines**

Manufacturer	Doses/ Course	WHO PQ	Presentation	Formul.	Shelf life	VVM <sup>10</sup>	Cold Chain Vol / Course	Storage
Bharat Biotech (India)	3	2018	5-dose vial	Liquid-frozen	60 months	2	12.6 cm <sup>3</sup>	-20°C
	3	2018	10-dose vial	Liquid-frozen	60 months	2	9.6 cm <sup>3</sup>	-20°C
	3	2021	5-dose vial	Liquid	60 months	7	12.6 cm <sup>3</sup>	2-8°C
	3	2021	1-dose vial	Liquid	60 months	7	48.0 cm <sup>3</sup>	2-8°C
GlaxoSmithKline (Belgium)	2	2009	1-dose tube	Liquid	24 months	7	34.2 cm <sup>3</sup>	2-8°C
	2	2009	1-dose applicator	Liquid	24 months	n/a	170.6 cm <sup>3</sup>	2-8°C
	2	2019	5 x 1-dose tubes *	Liquid	24 months	7	23.6cm <sup>3</sup>	2-8°C
Merck (USA)	3	2008	1-dose tube	Liquid	24 months	n/a	138.9 cm <sup>3</sup>	2-8°C
Serum Institute of India	3	2018	1-dose vial	Lyophilised	30-months	30	52.71 cm <sup>3</sup>	2-8°C
	3	2018	2-dose vial	Lyophilised	30-months	30	31.62 cm <sup>3</sup>	2-8°C
	3	2021	1-dose vial	Liquid	24-months	7	60.2 cm <sup>3</sup>	2-8°C
	3	2021	2-dose vial	Liquid	24-months	7	42.90cm <sup>3</sup>	2-8°C
	3	2000	1-dose vial	Lyophilised	30 months	250+	52.71 cm <sup>3</sup>	<25 °C
	3	2000	2-dose vial	Lyophilised	30 months	250+	31.62 cm <sup>3</sup>	<25 °C

Source: UNICEF Supply Division

Note \*: GSK's blow-fill seal presentation

Rotavirus vaccines are administered four weeks apart beginning at six weeks of age. For detailed WHO recommended immunization schedules, please refer to WHO's position paper on RV.<sup>11</sup> Detailed information on each manufacturer's WHO prequalified RVs are accessible [here](#).<sup>12</sup> WHO prequalified RV products can differ from each other in formulation, presentation, cold chain requirement, and dose schedule. A recent WHO guidance document has assessed the interchangeability of these vaccines.<sup>13</sup>

*WHO recommends that the rotavirus vaccination series for each child be completed with the same product whenever feasible. However, if the product used for a prior dose is unavailable or unknown, the series should be completed with any available licensed product. Restarting the vaccine series is not recommended. If any dose in the series was from a product that has a three-dose schedule, or if the vaccine product is unknown for any dose, a total of three doses of rotavirus vaccine should be administered for a complete vaccination series.*

The guidance should support countries seeking to switch between products from different manufacturers after vaccine introduction into their national immunization programmes, whether based on availability, price, or to introduce more than one product concurrently. UNICEF has procured six of WHO's prequalified presentations on behalf of countries and donors in support of routine childhood immunization programmes.

As of December 2021, 74 per cent of RV demand through UNICEF has been for GSK's RV monovalent (RV1) single-dose tube presentation.<sup>14</sup> This preference can largely be explained by the fact that it is administered in a two-dose schedule compared to other available products that all require a third dose, with all the programmatic implications that it entails. Prior to arrival of new product presentations in 2018, it had a significantly smaller cold chain requirement than alternatives. These product characteristics have been advantageous for immunization programmes in terms of vaccine administration and costs, for example when compared to Bharat or SII's alternative RV presentations.

<sup>8</sup> World Health Organization, [Immunization Coverage: Key Facts](#), WHO, Geneva, July 2021.

<sup>9</sup> World Health Organization, [Global Vaccine Action Plan 2011-2020](#), WHO, Geneva, May 2013, p. 133.

<sup>10</sup> A vaccine vial monitor is a small sticker that adheres to vaccine vials and changes colour as the vaccine is exposed to heat, letting health workers know whether the vaccine can be safely used for immunization.

<sup>11</sup> WHO, [Rotavirus Vaccines WHO Position Paper](#), p. 54.

<sup>12</sup> World Health Organization, [WHO Prequalified Vaccines](#), WHO, Geneva, October 2018.

<sup>13</sup> World Health Organization, [WHO Guidance Note on Interchangeability of Rotavirus Vaccine Products](#), WHO, Geneva, November 12, 2019.

<sup>14</sup> The numbers associated with the vaccine (RV1, or RV5) describes the number of virus strains contained in each vaccine. RV1 has one rotavirus strain, whilst RV5 has five. Whereas Bharat and GSK both have one virus strain, they are different strains, G9P[11] and G1P[8], respectively.



Any country seeking to choose an alternative vaccine from a different manufacturer will require time to adopt any new product and make the necessary programmatic changes. UNICEF and partners are working with countries facing sustainable supply challenges to review their product choices and are seeking to diversify global supply sources to strengthen supply security.

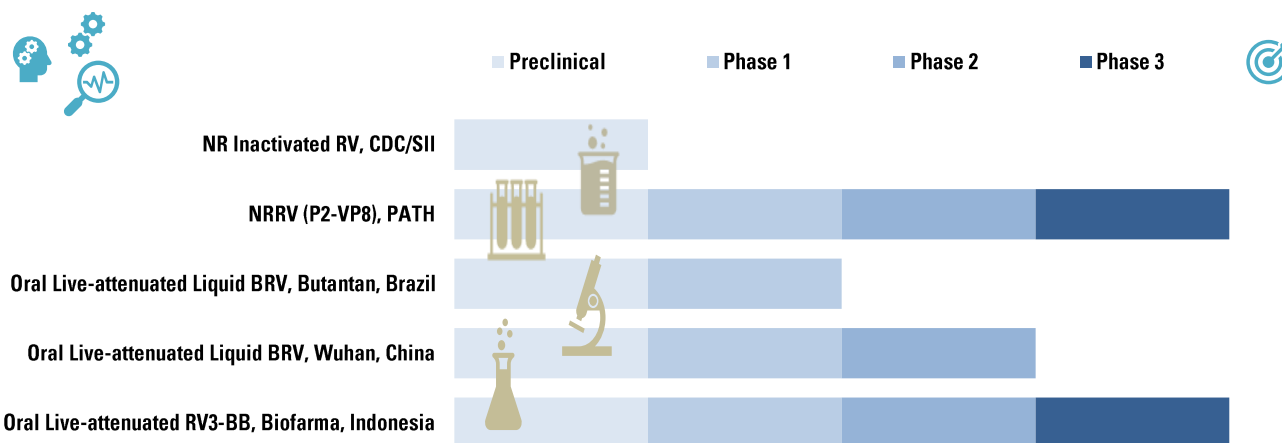
UNICEF only procures vaccines that are prequalified by WHO. In addition to WHO's list of prequalified RV products, there are other RV products licensed in selected markets. UNICEF knows of two other non-prequalified vaccines that are produced by the Centre for Research and Production of Vaccines and Biology in Viet Nam (POLYVAC), and Lanzhou Institute of Biological Products in China, each marketed in their respective countries.<sup>15</sup>

### 3. Innovation and Product Development

Currently, several manufacturers are developing a number of RV candidates to improve the product suitability of their existing presentations for country immunization programmes, of which Bharat and SII, which recently acquired WHO prequalification (Table 1).

UNICEF also knows of several manufacturers, including Bio Farma (Indonesia), the Institute Butantan (Brazil), and Wuhan Institute of Biological Products (China),<sup>16</sup> that have products in different stages of clinical development, of which some are in advanced clinical trials (Figure 1).

Figure 1 Pipeline for RV Pipeline Vaccines Known to UNICEF



Source: BMGF

Whereas some manufacturers are developing live-attenuated oral vaccines, others are developing products using non-replicating RV (NRRV) technologies. Products targeting neonatal vaccination are also currently in clinical trials, although without a clear date for prequalification and launch. These new vaccine candidates aim to meet or exceed the performance of current licensed products. UNICEF does not anticipate that any of these new vaccine products will be licensed and WHO prequalified before 2024, based on its assessment of product development timelines.

Some vaccine product development efforts have also experienced challenges. In 2017, Sanofi's Indian subsidiary, Shantha Biotechnics, discontinued their RV development projects,<sup>17</sup> and Hilleman Laboratories together with MSD discontinued their RV product development in 2018.

### 4. Current Market Situation

In 2021, the Global Vaccine Market Model (GVMM),<sup>18</sup> estimated that total market revenues for RV reached approximately USD 2.432 billion.<sup>19</sup> Figure 2 provides an indicative breakdown of the global RV market revenues. Ninety per cent of severe diarrhoeal cases globally occur in Africa and Asia, of which rotaviruses alone account for 25 to 50 per cent of the cases. However, in terms of World Bank country classifications, HICs account for approximately 83 per cent of the RV market by value, with low-income countries (LICs) making up only four per cent, and MICs making up 13 per cent. In

<sup>15</sup> Kang, Gagandeep, *An Update on Rotavirus Vaccines*, WHO, Geneva, March 2018, p. 9.

<sup>16</sup> Steel, D, et al, *Next Generation Rotavirus Vaccines*, WHO, June 2018.

<sup>17</sup> Access to Medicine Foundation, *Vaccines Index 2017: How Vaccine Companies are Responding to Calls for Greater Immunisation Coverage*, Amsterdam, 2017, p. 38.

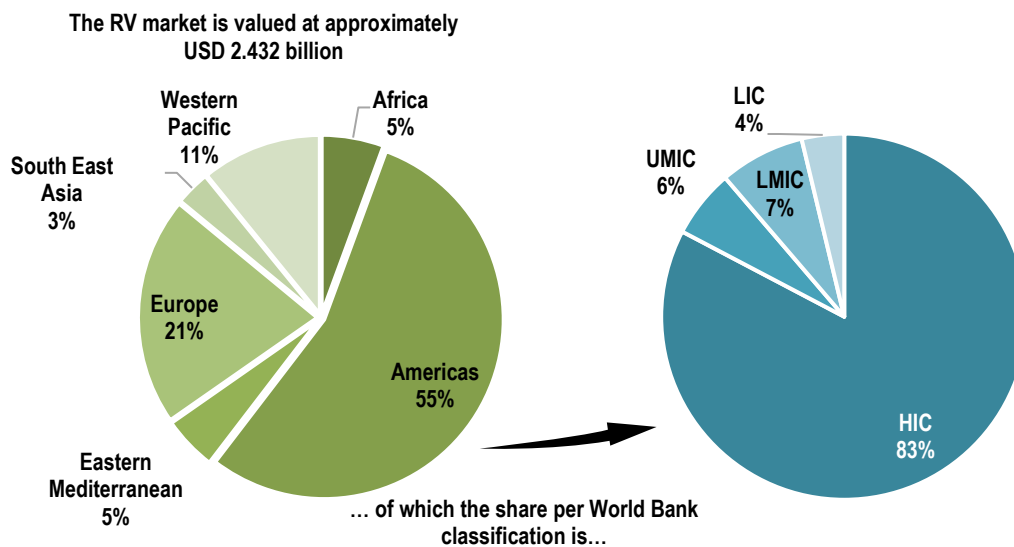
<sup>18</sup> Global Vaccine Market Model is a data-sharing collaboration between BMGF, Gavi, UNICEF and WHO managed by Linksbridge.

<sup>19</sup> Linksbridge, *Vaccine Almanac January 2021*, Linksbridge, Seattle, December 2021.

aggregate, the Americas account for approximately 55 per cent of market share, followed by Europe with approximately 21 per cent of the market. The Western Pacific countries have increased their market share to 11 per cent, whereas the Eastern Mediterranean, Africa, and South East Asia make up on average between three to five per cent of market share each.

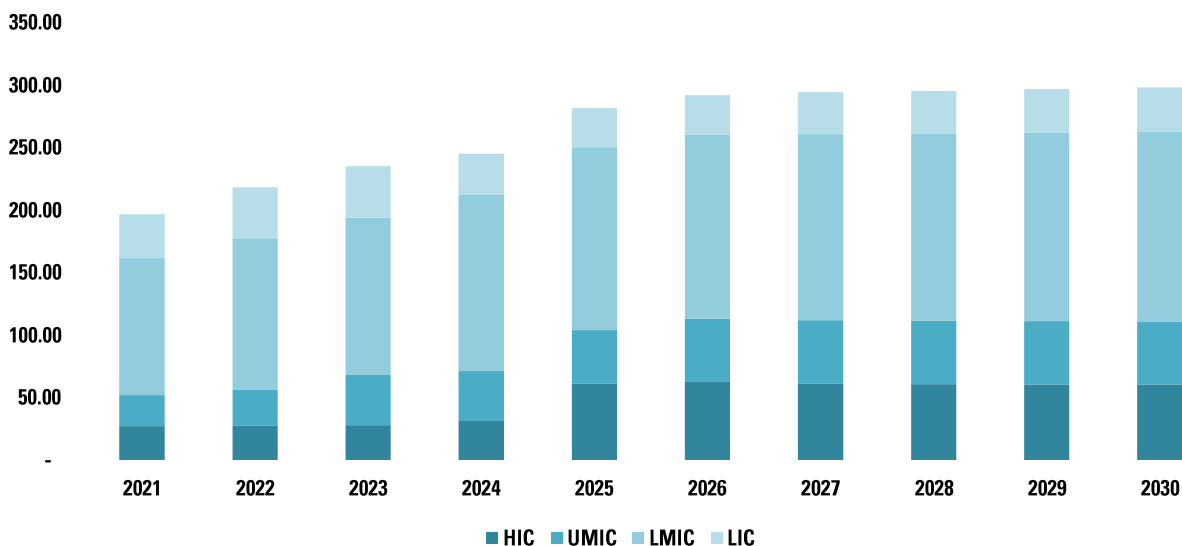
UNICEF anticipates significant growth from the Asia Pacific region, notably in China, India, and Indonesia due to vaccine introductions, as well as growth due to country introductions supported by Gavi.<sup>20</sup> Gavi expects an increase in global RV market to be largely driven by the demand from Gavi-eligible countries and India, which could collectively represent 56 per cent of the total projected global demand in volume.

Figure 2 RV Global Estimated USD Revenues and Market Share 2018



Source: GVMM

Figure 3 Trend in Global Demand Forecast Estimates in Vaccine Doses per World Bank Income Group 2021-2030



Source: GVMM

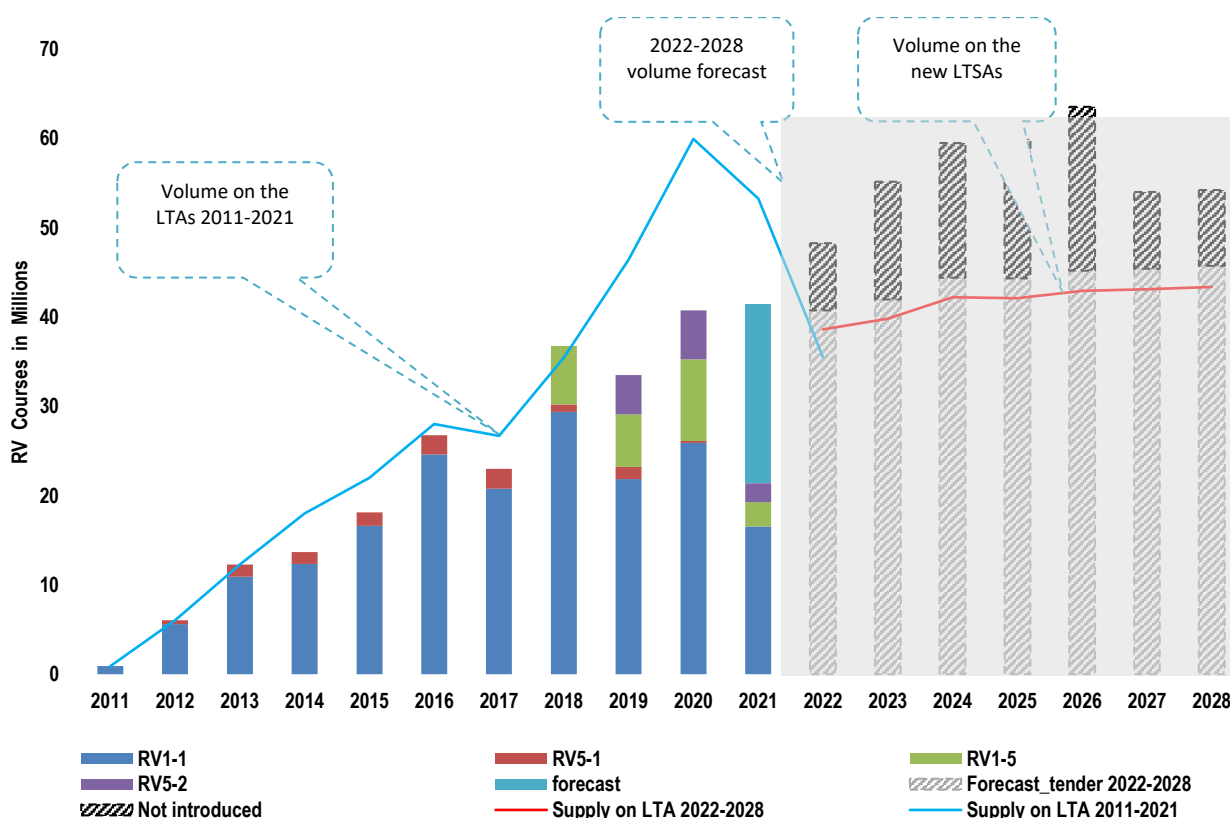
In terms of volume, GVMM estimates the global demand for 2021 could reach approximately 196.6 million doses (Figure 3) and grow at an anticipated compound aggregate growth rate (CAGR) of 4.71 per cent a year to reach 298.2 million doses by 2030. The information is subject to change and is to provide an indicative global outlook, as it does not encompass all potential vaccine introductions, especially where countries have not communicated future plans.

<sup>20</sup> Gavi, the Vaccine Alliance, [Supply and Procurement Roadmap: Rotavirus Vaccine](#), Gavi, Geneva, 2016, p. 2.

Even though HICs account for just 13 per cent of the RV vaccine volume, they account for 83 per cent of the market value, whereas LICs and lower middle-income countries (LMICs) account for 75 per cent of the market volume but only 11 per cent of market value.

Over the past ten-years (2011-2021), UNICEF has procured in aggregate a total of 232 million courses (Figure 4). In 2020 alone, UNICEF procured a total of 37 million RV courses, representing 96 million doses at a value of USD 153.9 million. This represents approximately 44.8 per cent of the global volume, and eight per cent of global revenue. UNICEF's anticipated procurement will be on behalf of all LICs and 56 per cent of the demand from LMICs (Figure 3).

Figure 3 UNICEF RV Gavi-eligible and Transitioned Supply and Projected Demand 2011-2028



Source: UNICEF Supply Division

#### 4.1 Gavi supported Country Demand and Forecast

Fifty-three countries have been eligible for Gavi RV support through UNICEF procurement since 2011. Another fourteen countries have transitioned from Gavi support and can still access RV through UNICEF, even though they have to fully self-finance their procurement (Table 2, next page). These numbers do not include the six countries in Latin America and the Caribbean that access RV through the Pan American Health Organization's (PAHO) Revolving Fund, and that are Gavi-eligible or have transitioned.<sup>21</sup> Six countries are pending introduction in 2021, including Bhutan, which will self-finance its supply, leaving seven countries eligible to apply to Gavi for RV support, but which have not yet done so due to a lack of programme readiness, cold chain capacity, and concerns over long-term pricing.

UNICEF demand from Gavi-eligible and transitioned countries, excluding those in the PAHO region, reached 41.0 million courses in 2020 (Figure 3). This was slightly less than the 48.5 million courses UNICEF had initially anticipated. In 2021, the demand through UNICEF from countries eligible for Gavi support and transitioned countries dropped to 23 million courses. This was due to the fact that from 2021 India self-procures its own RV requirements. Also, UNICEF expects Indonesia and Viet Nam to self-procure domestically produced RV after having introduced the vaccine. Despite the number of successful RV introductions to date, UNICEF still considers overall demand to have been less than initially anticipated due to the deferments in vaccine introduction by some large countries.

<sup>21</sup> The six PAHO countries are Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua.

Table 2 RV Introduction Status of Countries Supported by Gavi (Excluding Countries Under PAHO) 2021

2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Others
Sudan	Armenia*	Burkina Faso	Angola*	Guinea-Bissau	Liberia	Côte d'Ivoire	Afghanistan	DR Congo	Myanmar	Azerbaijan*
	Ghana	Burundi	Cameroon	Kiribati*	Sao Tome & Pr.	India	Uganda	Benin	Nepal	Bhutan*
	Malawi	Ethiopia	Congo*	Mozambique		Lesotho		Kyrgyzstan	Solomon Island	Cambodia
	Moldova*	Gambia	Djibouti	Tajikistan		Pakistan			Timor-Leste*	Chad
	Rwanda	Georgia*	Eritrea						Bangladesh	Comoros
	Tanzania	Zambia	Kenya						CAR	Guinea
	Yemen		Madagascar						Lao PDR	Indonesia*
			Mali						Nigeria	Korea, DPR
			Mauritania						Viet Nam	Mongolia*
			Niger							Papua New G*
			Senegal							Somalia
			Sierra Leone							Sri Lanka*
			Togo							South Sudan
			Uzbekistan							Ukraine*
			Zimbabwe							

Introduced  
 Approved pending introduction  
 Countries not yet applied  
 Transitioned country - cannot apply

Source: UNICEF Supply Division

**Note**\*: Transitioned countries must fully self-finance RV procurement.

Overall supply projections based on production capacity are adequate to meet projected requirements, reaching an estimated 51 million courses by 2028 (Figure 3); and actual supply availability through UNICEF during the period from 2022-2028 is currently sufficient. Countries should confirm their supply requirements include the demands of countries pending for introduction, and ensure respective programmatic arrangements for manufacturers with newly WHO prequalified liquid vaccines presentations to scale up their production and ensure sufficient supply availability.

## 4.2 Gavi supported Country Supply

UNICEF seeks to secure a sufficient and sustainable supply of quality-assured RV to meet Gavi-supported country requirements. Based on its landscape assessment of the market and funding availability, UNICEF uses several procurement approaches to secure supply to achieve the best value for money on behalf of countries, including the use of longer-term contracting arrangements, phased additional supply awards, volume commitments, and contracting in different currencies (US dollars and Euros).

GSK had faced manufacturing issues with its vaccine vial monitor (VVM) compliance and manufacturing issues when producing the vaccine. As a result, nine countries had to postpone their planned RV introductions in 2018 and 2019 and some switched from GSK's vaccine to vaccines from Bharat and SII. Such complications serve as a reminder that the chemical and biological processes required to produce live virus vaccines, such as RV, are complex and can often face challenges that are not always predictable.<sup>22, 23</sup>

In 2022, GSK will reduce its manufacturing plans for RV and reduce the supply it makes available through UNICEF by nine million doses of RV1. This is due to GSK discontinuing their blow-fill-seal (BFS) production presentations until its reintroduction in 2024. It will disrupt the supply of RV on the market, as thirty-four countries supported by Gavi, in addition to three transitioned countries, procure GSK's RV through UNICEF. The average annual volume in terms of demand for this product is estimated to reach 55 million doses, requiring some of these countries to switch to another product in 2022. GSK will be reducing their supply availability through UNICEF to approximately 46 million doses.

To identify which countries would be most suitable to switch product, Gavi assessed the impact of the switch on each country's co-financing cost and cold-chain volume. It identified that countries could save 18-60 per cent of vaccine co-financing cost and up to 70 per cent of their cold chain volume requirements by switching to other options. UNICEF is supporting countries to diversify their supply options and to choose alternative WHO prequalified products. In 2022, Cameroun, Kenya, Senegal, Zambia, and Zimbabwe will switch to Bharat's vaccine product.

The LTA awards for 2017-2021 include Bharat's and SII's newly WHO prequalified presentations (Table 3). GSK's RV1-1 BFS will only be available from 2024, while their RV1-1 tube will be discontinued from 2026, and all subsequent RV1-1 supply will only be in BFS presentations. SII will experience challenges to supply its RV5-1 dose liquid for 2022, due

<sup>22</sup> Gavi, the Vaccine Alliance, [The Development of Live, Attenuated, Rotavirus Vaccines: A Manufacturer's Resource Guide](#), Gavi, Geneva, 2006, p. 5.

<sup>23</sup> World Health Organization, [Statement on Rotarix® and Vaccine Vial Monitor \(VVM\) Compliance](#), WHO, Geneva, February 2017.

to an incident of fire occurring in the month of January 2021. SII are still working on targeting the third quarter of 2023 to restore their damaged plant.

Table 3 UNICEF LTA Awards for 2017-2021 - continued next page

	Year	2022	2023	2024	2025	2026	2027	2028	Total
RV1-1 tube*	Millions of courses	24.50	24.50	23.50	12.25				84.75
	Euro Price	4.10	4.10	4.10	4.10				
RV1-1 BFS*	Millions of courses			1.00	12.25	24.50	24.50	24.50	86.75
	Euro Price			3.58	3.58	3.40	3.40	3.40	
RV1-5 frozen**	Millions of courses	5.71	6.82	8.78	8.52	9.13	9.18	9.31	57.45
	USD Price	2.55	2.55	2.55	2.10	2.10	2.10	2.10	
RV1-5 liquid**	Millions of courses	2.44	2.48	2.53	2.57	2.62	2.66	2.69	17.99
	USD Price	3.45	3.45	3.45	3.45	3.45	3.45	3.45	
RV1-1 liquid**	Millions of courses	0.51	0.52	0.53	0.54	0.55	0.55	0.56	3.76
	USD Price	4.05	4.05	4.05	4.05	4.05	4.05	4.05	
RV5-2 lyophilised**	Millions of courses	5.29	5.33	5.70	5.81	5.96	6.04	6.13	40.26
	USD Price	2.85	2.85	2.85	2.85	2.85	2.85	2.85	
RV5-2 liquid**	Millions of courses	0.16	0.16	0.17	0.17	0.16	0.16	0.16	1.15
	USD Price	2.40	2.40	2.40	2.40	2.40	2.40	2.40	
<b>Volume award</b>	<b>Millions of courses</b>	<b>39.00</b>	<b>40.00</b>	<b>42.00</b>	<b>42.00</b>	<b>43.00</b>	<b>43.00</b>	<b>43.00</b>	<b>292.00</b>

Source: UNICEF Supply Division

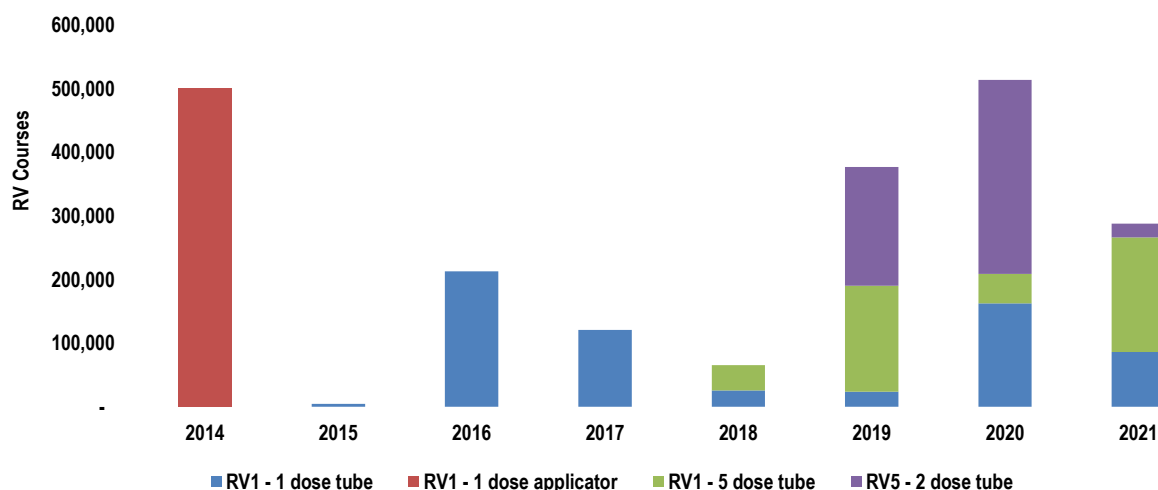
Note \*: Schedule: Two doses

Note \*\*: Schedule: Three doses

### 4.3 Middle-income Country Demand and Supply

Looking beyond UNICEF's procurement for Gavi-supported countries, RV demand through UNICEF from MICs has been modest, but increased significantly over the last three years. Sixteen MICs procured their RV requirements through UNICEF since 2014, of which nine are Pacific Islands Countries (PICs). The MICs are Albania, the Cook Islands, Fiji, the Kingdom of Eswatini, Kiribati, Namibia, Nauru, the Philippines, Samoa, Seychelles, the State of Palestine, Tokelau, Tonga, Turkmenistan, Tuvalu, and Vanuatu, representing in aggregate two million courses, of which UNICEF procured 50 per cent between 2019 and 2021 (Figure 4).

Figure 4 UNICEF RV Procurement for Middle-income Countries 2014-2021 (as of end-October)



Source: UNICEF Supply Division

From 2019, UNICEF secured all supply quantities for MICs through an LTA specifically for MICs, which included PICs, while from 2014 to 2018 the supply for MICs were secured through ad-hoc tenders as the demand materialised from countries. As for the next seven years from 2022, UNICEF has secured supply quantities for MICs through LTA awards with the three current RV suppliers.



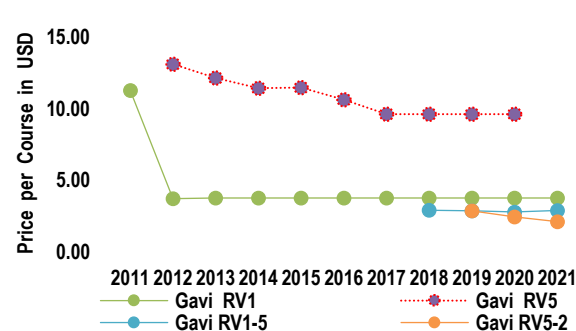
In some MICs, where diarrhoea-associated deaths are relatively infrequent, health authorities have not prioritised the need to immunise children against rotaviruses, despite significant rotavirus-associated outpatient consultations, hospitalisations, as well as medical and emergency room visits.<sup>24</sup> UNICEF procurement can play an important enabling role for MICs seeking to introduce new vaccines. It maintains ongoing discussions with countries to secure multi-year commitments to allow UNICEF to keep active LTAs already established with manufacturers to secure supply for MIC countries. However, the aggregate demand for RV through UNICEF from self-financing MICs remains uncertain from year to year. Most MICs procuring through UNICEF tend to confirm their demand annually, rather than making any multi-year commitments. The lack of longer-term solid demand from MICs, together with the comparatively high tiered prices from some manufacturers, makes it difficult to ensure effective procurement interventions. Moreover, based on historical procurement, while UNICEF expects the use of RV vaccines by some MICs to continue, MICs may not always channel their needs through UNICEF.

UNICEF will continue to engage partners to analyse the cost-effectiveness of rotavirus vaccination for MICs, as well as to strengthen country advocacy, decision making, financing and supply chains. Depending on the outcome, UNICEF will continue to develop a RV MIC procurement strategy based on supporting supply to MICs. It will consolidate credible RV demand where there is interest to channel such demand through UNICEF.

#### 4.4 Pricing

The weighted average price (WAP) per course through UNICEF for Gavi-supported countries decreased gradually for Merck's RV5, by around 26 per cent over the past six years from 2012 (Figure 5). The WAP for GSK's RV1 through UNICEF for Gavi-supported countries initially declined sharply in 2012 (67 per cent), in large part as a result of using longer-term special contracting arrangements, and has since remained stable (Figure 5). Bharat's RV1-5 frozen and SII's RV5-2 lyophilised were introduced in 2018 and 2019, respectively; bringing in an improved weighted average price (WAP) per course.

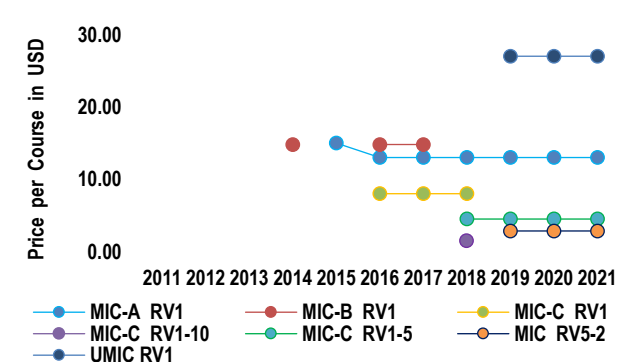
Figure 5 RV Price through UNICEF for Gavi Supported Countries 2011-2021



Source: UNICEF Supply Division

The Gavi market remains with three suppliers, following Merck's exit from the market in 2020. Bharat, GSK, and SII have all committed to continue to provide countries that have transitioned from Gavi support access to vaccines at prices similar to those they paid when they were Gavi-eligible, albeit under specific conditions, and for a limited period of time.<sup>25</sup> Also, SII has committed to apply price parity to all countries that procure RV through UNICEF, including for MICs.

Figure 6 MIC RV USD WAP Price per Course through UNICEF 2014-2021



Source: UNICEF Supply Division

Generally, RV prices for MICs are still high compared with Gavi-supported countries, and they can vary significantly between countries depending on the manufacturers' pricing policies. Prices offered by manufacturers to LMICs and UMICs that self-finance their RV vaccine purchases through UNICEF have reached up to USD 18.00 per course and USD 27.00, respectively, which is a multiple of the costs of Gavi-supported procurement through UNICEF (Figure 6).

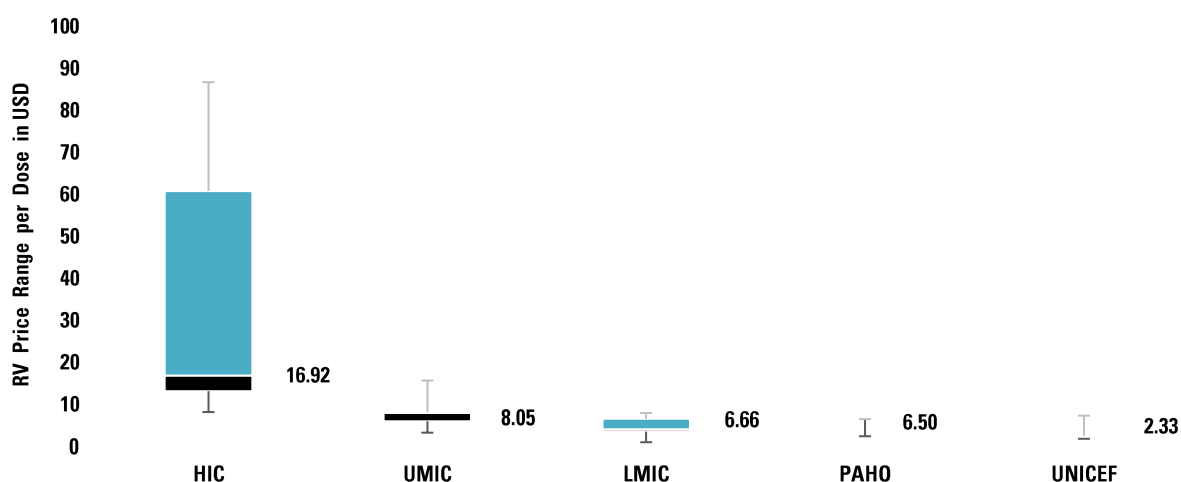
<sup>24</sup> O'Ryan, Miguel, *Rotavirus Vaccines: A Story of Success with Challenges Ahead*, PubMed Central, US National Institutes of Health, Bethesda, August 2017.

<sup>25</sup> World Health Organization, *Vaccine Pricing: Gavi Transitioning Countries*, WHO, December 2017.

With new additional product availability and competition on the market, there is an opportunity for some price improvements. SII's price per course for Gavi-eligible countries and for MICs is USD 2.85. The price of Bharat's new WHO prequalified RV1 five-dose vaccine for Gavi-eligible countries is USD 2.55 per course, while their MIC price for the State of Palestine is USD 4.50 per course.

UNICEF highlights the notable variances in prices per dose offered to countries in different income classification tiers, as well as to countries in the same tier, which is a growing concern for UNICEF and countries (Figure 7).<sup>26</sup> The Access to Medicine Foundation analysed the cost to fully immunise children. They assessed newer vaccine price evolution over the years, their proportion of national immunization programme costs, as well as the extent of adoption by LICs and MICs. The foundation identified that vaccines against rotavirus and pneumococcal disease make up approximately three quarters of the total cost of vaccinating a child based on assessing the 12 required vaccines.<sup>27</sup> Some MICs have reported that the cost of some vaccines, including rotavirus, are too high for them to consider to be sufficiently cost-effective to introduce into their country's national immunization programme schedule.<sup>28</sup>

Figure 7 RV Price per Dose Ranges per Income Group 2013-2021 <sup>29</sup>



Source: MI4A: Market Information for Access to Vaccines, UNICEF Supply Division

As noted earlier, demand from MICs through UNICEF is low and variable. With more certainty in demand from MICs, and longer-term commitments, pricing to support MIC access has improved with the tender 2022-2028.

## 5. Healthy Market Framework

The Bill and Melinda Gates Foundation (The Gates Foundation), Gavi, and UNICEF, developed the Healthy Markets Framework (HMF). HMF is a tool to support market shaping and it is used to assess and articulate a market's current and desired future state. UNICEF and partners use it to identify a set of attributes that measure the health of a particular market; to provide a process to value it specifically for vaccines; and to provide a framework to describe its desired state of health. The current revised HMF evaluation for RV (Figure 8, next page) demonstrates that the RV market is now in a low to state of health, with supply largely dependent on one supplier that faced manufacturing issues and a lack buffer capacity.<sup>30</sup>

Even with the increased number of available presentations, RV 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, highlighting unmet country preferences for the most frequently chosen presentation, a lack of buffer capacity by the preferred supplier and some supplier risks following the recent disruptions. Moving forward, market health will be low to moderate depending on

<sup>26</sup> World Health Organization, [MI4A: Market Information for Access to Vaccines](#), WHO, Geneva, March 2018.

<sup>27</sup> AMF, [Vaccines Index 2017: How Vaccine Companies are Responding to Calls for Greater Immunisation Coverage](#), p. 51.

<sup>28</sup> Médecins Sans Frontières. [The Right Shot: Bringing Down Barriers to Affordable and Adapted Vaccines, 2<sup>nd</sup> Edition](#), MSF, Geneva, January 2015, p. 6.

<sup>29</sup> UNICEF uses a "box and whisker" (Figure 8) chart to show data distributed per quartile. It highlights price data and ranges in sections each containing 25 per cent. The blue and black box spans the interquartile range showing 50 per cent of the price data, with the median price (called out) marked by a vertical line inside the box separating the two shaded halves, each containing 25 per cent of the data. The "whiskers" show the minimum and maximum price ranges of the data set. Looked at overall, the chart shows you the spread of a product's price range per country income classification tiers.

<sup>30</sup> Gavi, the Vaccine Alliance, [Rotavirus Vaccine Roadmap: Public Summary](#), Gavi, Geneva, 2016.

multiple factors, including whether the manufacturers increase their production capacity, new vaccine presentations meet country preferences, product switches and their impact on business sustainability, potential market exits and the impact of the next generation of oral RVs (oNGRV) and injectable next generation RVs (iNGRV).

Figure 8 Healthy Markets Framework for RV 2021



The individual supplier risk is also partially met, as there are uncertainties around the risk of supply disruptions due to production issues by GSK and the delivery capacity of new suppliers. Total system effectiveness is also partially met, and there are opportunities to improve costs and wastage rates. Long term competition and product innovation are met, as there is a lack of clarity regarding GSK's decision to scale-up its RV1 BFS presentation, reduce supply capacity of plastic tubes, and increase its price. This would result in a weakened position in the Gavi market and could potentially lead to its exit in the medium to long term.

Source: UNICEF Supply Division

## 6. Issues and Challenges

- The RV market is in a low to state of health characterised by a supply-demand imbalance, high-risk level of supply insecurity and fragility, as portrayed by the recent reduction of supply by GSK anticipated for the period 2022- 2028, which has triggered five countries to switch out of GSK's product in favour of Indian manufacturers.
- Country preparations and planning with realistic introduction timelines are required to optimise supply. This is undermined by forecast inaccuracy and the uncertainty of demand, resulting in low programmatic uptake due to insufficient in-country readiness in some countries, and their prolonged review of possible alternative products.
- The health authorities in some MICs where diarrhoea-associated deaths are relatively infrequent, often fail to recognise the need for RVs. This uncertainty in demand makes it a challenge to establish LTAs to secure access to affordable prices.

## 7. Steps Forward

- UNICEF, Gavi, and partners, will continue to monitor closely the supply capacity and requirements through 2022 and beyond. The demand will be reassessed upon the successful introduction of the RV in Nigeria in 2022, and Bangladesh in 2024, as well as against Gavi's strategic demand forecast projections.
- UNICEF will work with countries to benefit from the increasingly diverse supply base.
- UNICEF, Gavi, and partners, will continue to support country implementation and work with governments to address system readiness to introduce new vaccines or support countries that would like to switch product presentations to another based on countries' preferences.
- UNICEF continues to work with countries, partners, and industry to improve access to affordable and timely vaccine supply for MICs. To secure better RV prices, UNICEF advises self-funding MICs seeking to procure through UNICEF, to forecast and plan their demand and commit to multi-year procurement volumes. Manufacturers may offer better pricing and secure availability if the needs for vaccines are identified, planned, and secured against longer timeline procurement commitments.
- UNICEF will continue to work with countries, partners, and industry to improve access to affordable and timely supply of vaccines, particularly for MICs that self-finance their RV purchases. To this end, UNICEF will seek greater clarity on MIC requirements to provide industry with better visibility and predictability on the evolution of demand. It will also engage with self-financing MICs to consolidate credible demand for RVs, where there is interest to channel such demand through UNICEF.
- UNICEF encourages manufacturers to accelerate new pipeline product developments that are in programmatically suitable presentations for low-resource settings.
- Mitigating COVID 19 impacts on RVs, UNICEF will continue collaborating with countries, WHO, and other stakeholders.
- UNICEF will continue working with manufacturers and countries to increase the transparency in the market. UNICEF has published LTA vaccine pricing as part of its Influencing Markets strategy, and broader commitments to

information and price transparency, recognising that the free flow of information and correcting information asymmetry is critical to underpin an efficient market, and which is accessible [here](#).<sup>31</sup>

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Other UNICEF information notes can be found at: <https://www.unicef.org/supply/market-notes-and-updates>

UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, competitive market landscapes, and product quality that is fit for purpose and in the right form for children.

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<sup>31</sup> UNICEF, [UNICEF Pricing Data](#), UNICEF Copenhagen, November 2021.