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# Rotavirus Vaccine: Supply and Demand Update

UNICEF Supply Division

February 2020

## Rotavirus Vaccine Supply & Demand Update - February 2020

This update provides new information on rotavirus vaccine demand, supply, and country introduction. 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 172 million rotavirus vaccine (RV) courses over 2011-2019.<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 steadily increased over the past eight years from 900,000 courses in 2011, to reach 38.7 million courses in 2019 on behalf of 52 countries. Annual aggregate demand channelled through UNICEF is expected to reach 48.5 million courses in 2020.
- The recent supply disruptions in 2017-2019 characterize the RV market's imbalance, level of supply insecurity and fragility, low state of health, and identify the need for additional interchangeable supply and supplier diversity.
- Insufficient readiness in some countries and their prolonged review of possible alternative products due to supply disruptions, have delayed the introduction of RV resulting in low programmatic uptake, which has in turn undermined forecast accuracy and created uncertainty of demand. The support for country preparations and planning for realistic introduction timelines is required to optimize supply.
- Asymmetric supply and demand of country preferred product presentations have historically created supply constraints for one product leading to delays in RV introductions in several large countries. It also presents a high supply security risk, particularly in an environment characterized by increasing demand and a lack of confirmed supply availability. However, projected supply availability in 2020 and beyond has improved, which will enable countries to introduce the vaccine.
- In MICs where diarrhoea-associated deaths are relatively infrequent, health authorities often fail to recognize the need for rotavirus vaccines. Country demand from MICs is currently uncertain and makes it a challenge to establish long-term arrangements (LTAs) 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, 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 globally, 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, the World Health Organization (WHO) has recommended countries to include RV into their national childhood immunization programmes as part of a comprehensive diarrhoeal disease control strategy, complementing improved water, sanitation, hygiene, and treatment that includes the use of [low-osmolality 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 ten years, as of 2018, WHO estimates the global immunization coverage for RV to have only reached 35 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>

<sup>1</sup> As rotavirus vaccines require different dose schedules to fully immunize a child, RV vaccine data is expressed in *courses* instead of *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> WHO, [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.

<sup>8</sup> World Health Organization, [Immunization Coverage: Key Facts](#), WHO, Geneva, December 2019.

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

WHO has now prequalified eight RV presentations from four manufacturers, all of which are administered orally (Table 1).<sup>10</sup> Four new vaccine presentations were recently prequalified in 2018 and an additional one in 2019. The vaccine WHO prequalified in 2019 was a liquid monovalent RV (RV1) from GlaxoSmithKline (GSK), presented in a strip of five one-dose plastic tubes. It offers a 30 per cent reduction in cold chain capacity compared with their one-dose tube presentation. These new products now extend additional WHO prequalified vaccine supply options to countries from a previous three options to now eight quality assured RV products, and sourcing from two to now four different manufacturers.

**Table 1 WHO Prequalified Rotavirus Vaccines**

Manufacturer	Doses/ Course	WHO PQ	Presentation	Formul.	Shelf life	VVM	Cold Chain Vol / Course	Storage
Bharat Biotech (India)	3	2018	5-dose vial	Liquid	60 months	2	12.6 cm <sup>3</sup>	-20°C
	3	2018	10-dose vial	Liquid	60 months	2	9.6 cm <sup>3</sup>	-20°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	23.6 cm <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

**Note** \*: WHO recently amended GSK's vaccine prequalification reducing the shelf life to 24 months, and the VVM category to 7 (see footnote <sup>10</sup>). Source: World Health Organization

Rotavirus vaccines are administered four weeks apart beginning at six weeks of age. For detailed WHO recommended immunization schedules, refer to WHO's position paper on RV,<sup>11</sup> and detailed information on each manufacturer's WHO prequalified rotavirus vaccines, 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 3-dose schedule, or if the vaccine product is unknown for any dose, a total of 3 doses of rotavirus vaccine should be administered for a complete vaccination series.*

The guidance should support countries that wish 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 (all except Serum Institute of India's (SII) one-dose vial and GSK's 1-dose applicator) on behalf of countries and donors in support of routine childhood immunization programmes.

As of December 2019, 76 per cent of RV demand through UNICEF has been for GSK's 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, as well as it also having a significantly smaller cold chain requirement. These product characteristics have been advantageous for immunization programmes in terms of vaccine administration and costs, for example when compared to Merck's alternative pentavalent RV (RV5) single-dose tube presentation, which has been successfully marketed in many high-income countries (HICs) and MICs, including in Europe, Mexico, and the United States of America (USA).

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

<sup>10</sup> WHO initially prequalified GSK's single-dose tube presentation with a vaccine vial monitor (VVM) 14 and a 36 months' shelf life. A VVM is a thermochromic (heat sensitive) label put on vials containing vaccines that gives a visual indication of whether the vaccine has been kept at a temperature that preserves its contents. It changes colour when exposed to heat and determines the extent to which a vaccine has been subject to warmer ambient temperatures. In January 2018, after the review of additional stability data, WHO revised this vaccine's prequalification with a lower VVM category (VVM 7), and a 24 months shelf life.

<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.

sustainable supply challenges to review their product choices and is 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, and are marketed in their respective countries.<sup>15</sup>

### 3. Innovation and Product Development

Currently, several manufacturers are developing a number of RV vaccine candidates to improve the product suitability of their existing presentations for country immunization programmes. Two manufacturers, Bharat and SII have new product presentations that UNICEF anticipates WHO to prequalify by 2020-2021 (Table 2). All new vaccines will provide additional options for countries although oral live-attenuated liquid bovine RV products are easier to use as they do not require diluent.

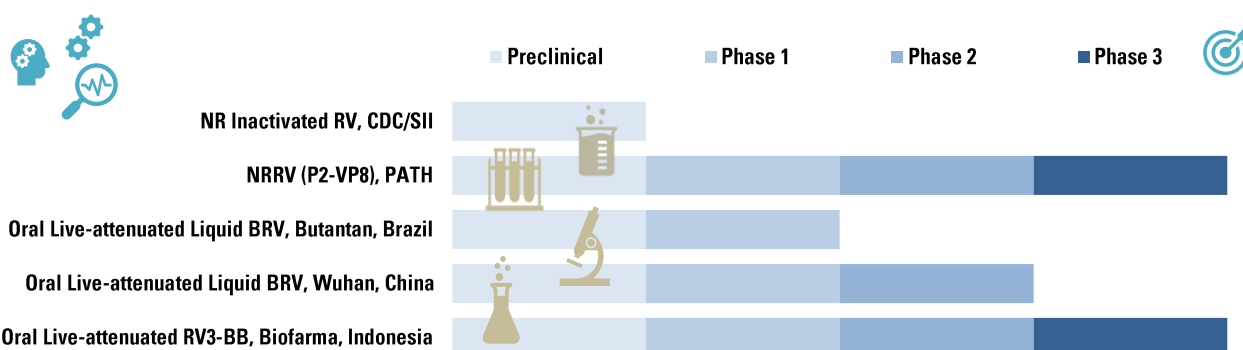
**Table 2 New Vaccines Expected in 2020**

Manufacturer	Dose Course	Est WHO PQ	Presentation	Formulation	VVM	Cold Chain Vol / Course	Storage
Bharat Biotech (India)	3	2020	1-dose vial	Liquid	2	48.0 cm <sup>3</sup>	2-8°C
	3	2020	5-dose vial	Liquid	2	12.6 cm <sup>3</sup>	2-8°C
Serum Institute of India	3	2020	1-dose vial	Lyophilised	250+	52.71 cm <sup>3</sup>	25°C
	3	2020	2-dose vial	Lyophilised	250+	31.62 cm <sup>3</sup>	25°C
	3	2020	1-dose tube	Liquid	7	31.62 cm <sup>3</sup>	2-8°C

Source: UNICEF Supply Division

UNICEF also knows of several other manufacturers, including Bio Farma (Indonesia), the Institute Butantan (Brazil), and Wuhan Institute of Biological Products (China),<sup>16</sup> that have other products in different stages of clinical development, of which some are in advanced clinical trials (Table 3).

**Table 3 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 rotavirus vaccine (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 and / 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 UNICEF's 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.

<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.

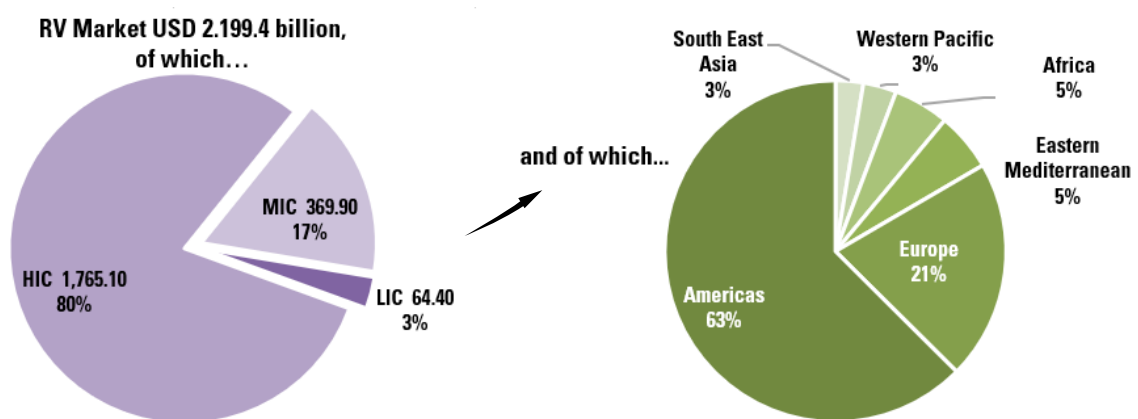
<sup>17</sup> Access to Medicine Foundation, *Vaccines Index 2017: How Vaccine Companies are Responding to Calls for Greater Immunisation Coverage*, Amsterdam, 2017, p. 38.

#### 4. Current Market Situation

In 2018, the Global Vaccine Market Model (GVMM),<sup>18</sup> estimated that total market revenues for RV reached approximately USD 2.199 billion.<sup>19</sup> Figure 1 provides an indicative breakdown of the global RV market revenues. Even though 90 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, in terms of World Bank country classifications, HICs account for approximately 80 per cent of the RV market by value, with low-income countries (LICs) making up only three per cent, and MICs making up 17 per cent. In aggregate, the Americas account for approximately 63 per cent of market share, followed by Europe with approximately 21 per cent of the market, and the Eastern Mediterranean, Africa, the Western Pacific, and South East Asia making up on average between three to five per cent of market share each.

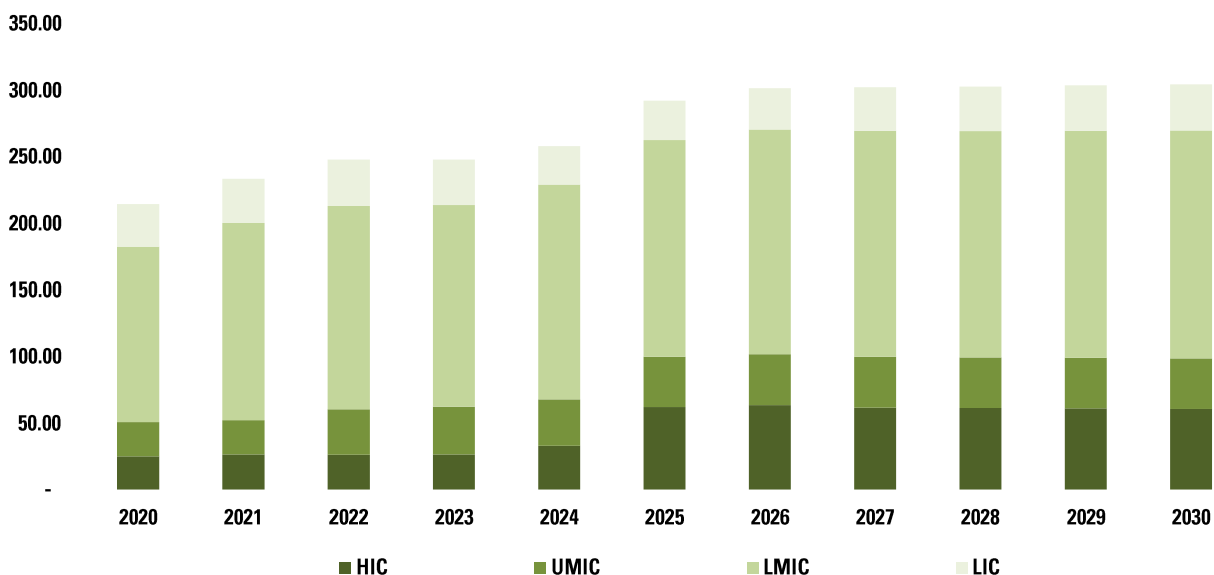
UNICEF anticipates significant growth from the Asia Pacific region, notably in China, India, and Indonesia due to vaccine introductions, as well as growth due to country introductions supported by Gavi.<sup>20</sup> Gavi expects an increase in global RV market to be largely driven by the demand from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

Figure 1 RV Global Estimated USD Revenues and Market Share 2018



Source: GVMM

Figure 2 Global Demand Forecast Estimates 2020-2030



Source: GVMM

<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 2019*, Linksbridge, Seattle, December 2018.

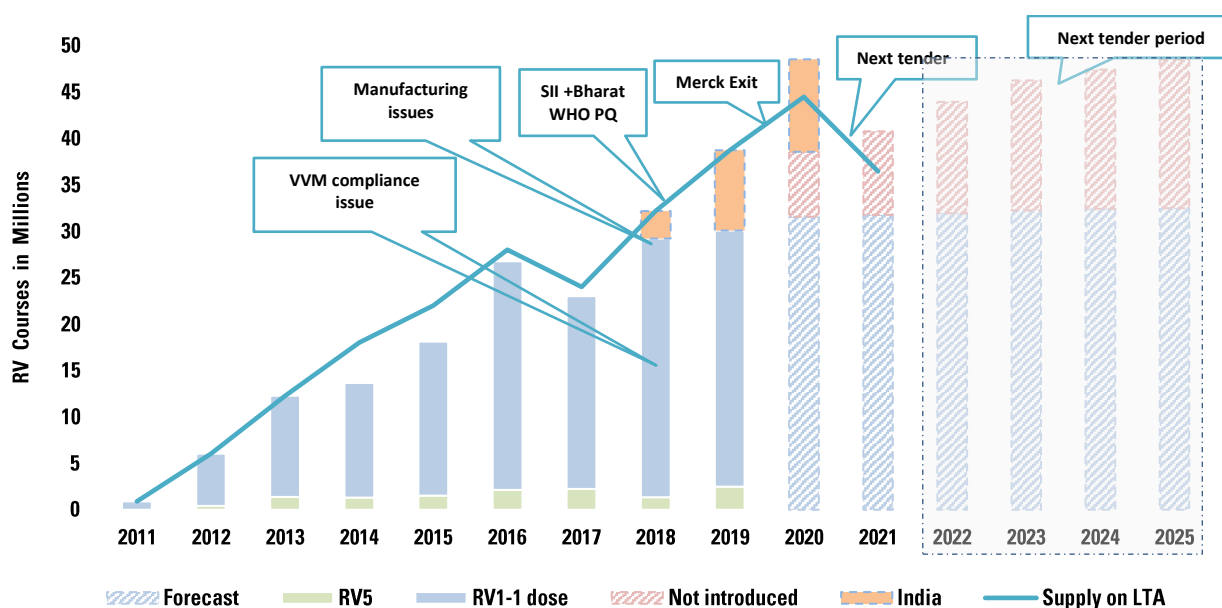
<sup>20</sup> Gavi, the Vaccine Alliance, *Supply and Procurement Roadmap: Rotavirus Vaccine*, Gavi, Geneva, 2016, p. 2.

In terms of volume, the global demand for 2020 is estimated to reach approximately 214 million doses (Figure 2) and grow at an anticipated compound aggregate growth rate (CAGR) of 4.92 per cent a year to reach 304.3 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.

To date, lower-MICs (LMICs) account for 62 per cent of the volume (132 million doses), followed by LICs with 15 per cent (32 million doses), and then upper-MICs (UMICs) and HICs with 12 per cent each, accounting for 26 and 25 million doses respectively. Current growth estimates foresee LMICs continuing to make up between 50-60 per cent of global share in doses through 2030.

Over the past nine-years (2011-2019), UNICEF has procured in aggregate a total of 172 million courses (Figure 3). In 2019 alone, UNICEF procured a total of 38.7 million RV courses, representing 79 million doses at a value of USD 134.7 million. In 2020, UNICEF anticipates procuring a total of 120 million doses for an estimated value of USD 175.1 million. This would represent approximately 56 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 2, previous page).

Figure 3 UNICEF RV Gavi-eligible and Transitioned Supply and Projected Demand 2011-2025



Source: UNICEF Supply Division

#### 4.1 Gavi supported Country Demand and Forecast

Fifty-three countries are currently eligible for Gavi RV support through UNICEF procurement. Another fourteen countries have transitioned from Gavi support and can still access RV through UNICEF but have to fully self-finance their procurement (Table 4, 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 that are Gavi-eligible or have transitioned.<sup>21</sup>

Since 2011, Gavi has approved support for 52 countries to introduce RV with procurement through UNICEF. Nine countries are pending introduction in 2020, including Bhutan, which will self-finance its supply. Viet Nam is pending Gavi approval, leaving seven countries eligible to apply to Gavi for RV support, but which have not yet done so. A lack of programme readiness, cold chain capacity, concerns over long-term pricing, as well as an asymmetric supply and demand of country preferred product presentations account for some country hesitations and delays in introducing RV, especially in larger countries.

UNICEF anticipates unconstrained demand from Gavi-eligible and transitioned countries, excluding those in the PAHO region, to reach 48.5 million courses in 2020 (Figure 3).<sup>22</sup> UNICEF expects Indonesia and Viet Nam to self-procure domestically produced RV. Despite the number of successful RV introductions to date, UNICEF still considers overall

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

<sup>22</sup> Afghanistan, Bangladesh, the Democratic Republic of Congo, India, and Nigeria.

demand to have been less than initially anticipated due to the introduction deferrals by some large countries, and the ongoing asymmetric supply and demand of country preferred product presentations. The current high reliance on a single product and manufacturer presents a high supply security risk that also affects country demand.

**Table 4 RV Gavi Country Introductions Status (excluding PAHO) 2020**

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	Bangladesh	Bhutan*
	Malawi	Ethiopia	Congo*	Mozambique		Lesotho			CAR	Cambodia
	Moldova*	Gambia	Djibouti	Tajikistan		Pakistan			Kyrgyzstan	Chad
	Rwanda	Georgia*	Eritrea						Lao PDR	Comoros
	Tanzania	Zambia	Kenya						Nepal	Guinea
	Yemen		Madagascar						Nigeria	Indonesia*
			Mali						Solomon Island	Korea, DPR
			Mauritania						Timor-Leste*	Mongolia*
			Niger						Viet Nam	Papua New G*
			Senegal							Somalia
			Sierra Leone							Sri Lanka*
			Togo							Sudan, The
			Uzbekistan							Ukraine*
			Zimbabwe							

- Introduced
- Approved pending introduction
- Pending Gavi approval
- Countries not yet applied
- Countries not introducing
- Transitioned country - cannot apply

**Note\*:** Transitioned countries must fully self-finance RV procurement.  
Source: UNICEF Supply Division

Whereas overall supply projections based on production capacity are adequate to meet total projected requirements reaching an estimated 41 million courses by 2021 (Figure 3, previous page), actual supply availability through UNICEF on LTA is currently lower. Countries should confirm their supply requirements and ensure respective programmatic arrangements for manufacturers with newly WHO prequalified vaccines to scale up their production and ensure sufficient supply availability.

## 4.2 Gavi supported Country Supply

UNICEF seeks to secure 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).

A current imbalance remains in the RV market as 88 per cent of the demand through UNICEF has been for GSK's RV1. It presents UNICEF and countries with a high-risk level of supply security and fragility, particularly in an environment characterised by increasing demand. In 2017, RV supply availability from GSK through UNICEF declined by 3.7 million RV1 courses on account of a VVM compliance and manufacturing issue it faced when producing the vaccine (see Figure 3, previous page).<sup>23</sup> As a result, seven countries had to postpone their planned RV introductions in 2018 and 2019. 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>24, 25</sup>

Overall RV supply availability through UNICEF increased during 2019 as a result of WHO prequalifying new RV products and GSK resolving its technical manufacturing issues during the same year. To secure additional sustainable supply for large country introductions, UNICEF awarded manufacturers in 2019 an additional 23.7 million courses through 2021. UNICEF increased its awarded supply to Bharat by an additional 14.5 million courses and supply awards to SII by 9.2 million courses (Table 5, next page).

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

<sup>24</sup> Gavi, the Vaccine Alliance, [The Development of Live, Attenuated, Rotavirus Vaccines: A Manufacturer's Resource Guide](#), Gavi, Geneva, 2006, p. 5.

<sup>25</sup> World Health Organization, [Statement on Rotarix® and Vaccine Vial Monitor \(VVM\) Compliance](#), WHO, Geneva, February 2017.

Table 5 UNICEF Long-term Arrangement Awards for 2017-2021

Manufacturer	Vaccine	Price per Dose	Duration	Schedule	New Courses Awarded 2019-2021	Total Courses Awarded 2017-2021
Bharat Biotech (India)	RV1	USD 0.85	3 years	3-doses	14,500,000	36,166,667
SII (India)	RV5	USD 0.95	3 years	3-doses	9,200,000	9,200,000
GlaxoSmithKline (Belgium)	RV1	EUR 1.88	5 years	2-doses		163,000,000
Merck (USA)	RV5	USD 3.20	5 years	3-doses		12,000,000
<b>Total</b>					<b>23,700,000</b>	<b>220,366,667</b>

Source: UNICEF Supply Division

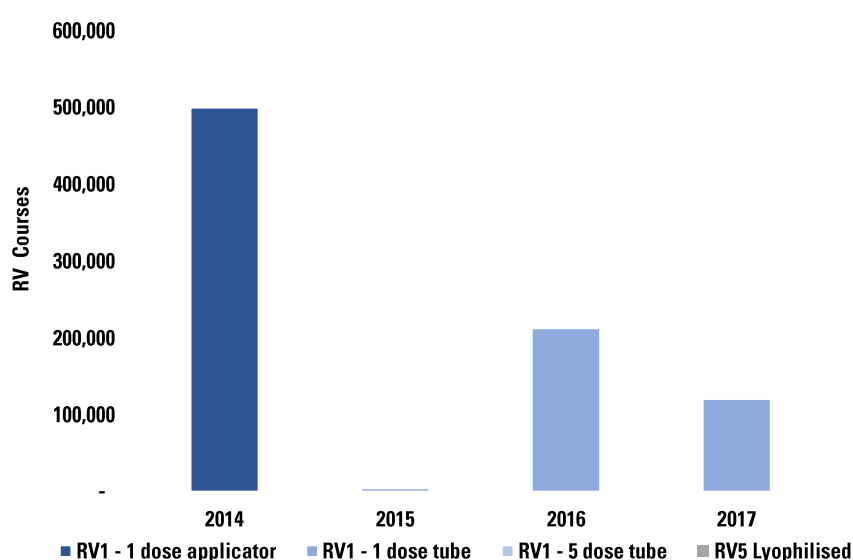
Routine demand for Merck’s RV5 from Gavi-supported countries has historically been limited to only six countries, of which three countries recently switched to GSK’s RV1. No new additional demand for Merck’s RV5 through UNICEF has materialized. Concurrently, higher than expected HIC global demand for Merck’s vaccine, combined with supply reductions due to unanticipated manufacturing issues, has strained their manufacturing capacity. As such, Merck recently announced that it would no longer supply the four countries procuring their vaccine through UNICEF as of the first quarter in 2020 (Burkina Faso, Côte d’Ivoire, Mali, and Sao Tome et Principe). As a result of the supply stoppage, UNICEF is supporting countries to diversify supply options and choose alternative WHO prequalified products. In 2019, Côte d’Ivoire switched to GSK’s product. In 2020, Burkina Faso and Mali will switch to SII’s product while Sao Tome will switch to BBIL’s product.

UNICEF awarded an LTA to Bharat to secure RV supply specifically for the Government of India (GoI). Gavi is providing the GoI with catalytic funding over three-years to accelerate and scale up vaccine introduction in the state of Uttar Pradesh with vaccines procured through UNICEF. The GoI will assume and self-finance their RV procurement once Gavi support has ended in 2020. Beyond this awarded supply to Bharat for India, both Bharat and SII retain supply availability should other countries choose to adopt these vaccines.

### 4.3 Middle-income Country Demand and Supply

Looking beyond UNICEF’s procurement for the Gavi-supported countries, RV demand through UNICEF from MICs has been modest. Six MICs procured their RV requirements through UNICEF since 2014: Albania, the Kingdom of Eswatini, Kiribati, the Philippines, the State of Palestine, and Turkmenistan, representing in aggregate one million courses, of which UNICEF procured 50 per cent on behalf of the Philippines in 2014 (Figure 4). UNICEF secured all supply quantities for MICs through ad-hoc tenders as demand materialized from countries.

Figure 4 UNICEF RV Procurement for Middle-income Countries 2014-2019 (as of end-August)



Source: UNICEF Supply Division

In some MICs, where diarrhoea-associated deaths are relatively infrequent, health authorities have not prioritized the need to immunize children against rotaviruses despite significant rotavirus-associated outpatient consultations,



hospitalizations, as well as medical and emergency room visits.<sup>26</sup> UNICEF procurement can play an important enabling role for MICs seeking to introduce new vaccines and maintains ongoing discussions with countries to secure multi-year commitments to allow UNICEF to establish LTAs 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 of 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, MIC 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 develop a RV MIC procurement strategy based on supporting supply to MICs by consolidating credible RV demand, where there is interest to channel such demand through UNICEF.

#### 4.4 Pricing

Figure 5 Gavi RV5 USD WAP Price per Course through UNICEF 2011-2019

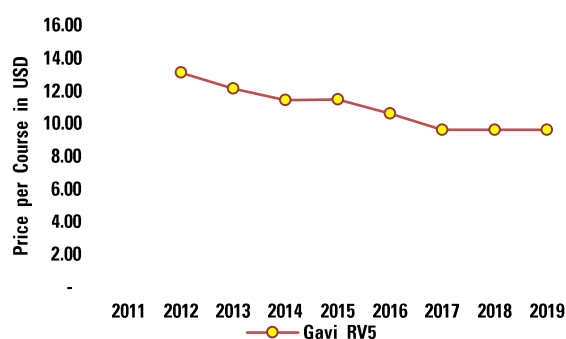
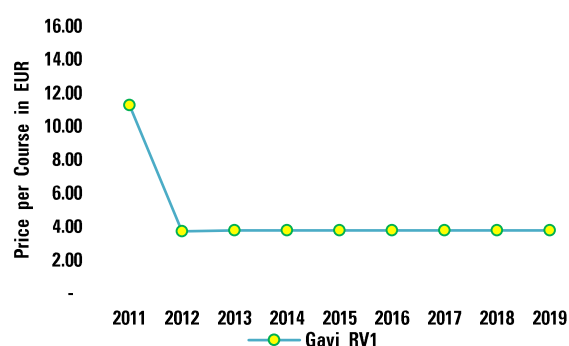


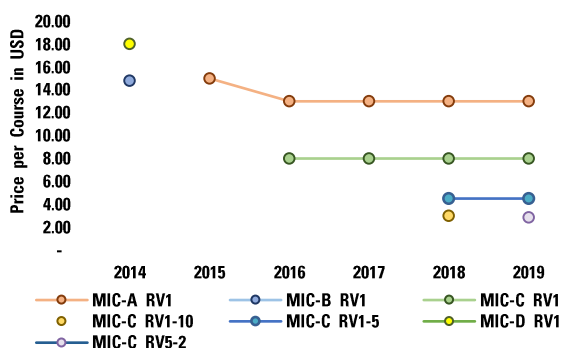
Figure 6 Gavi RV1 EUR WAP Price per Course through UNICEF 2011-2019



Source: UNICEF Supply Division

The weighted average price (WAP) per dose through UNICEF for Gavi-supported countries for Merck's RV5 declined by 26 per cent over the past six years from USD 13.09 per course in 2012, to reach USD 9.60 per course in 2019 (Figure 5). The WAP for GSK's RV1 through UNICEF for Gavi-supported countries initially declined sharply in 2012 from EUR 11.25 per course to EUR 3.76 per course (67 per cent), in large part as a result of using longer-term special contracting arrangements and has since remained stable (Figure 6). Both GSK and Merck have committed to continue to provide countries that have transitioned from Gavi support with vaccines at prices similar to those paid when they were Gavi-eligible, albeit under specific conditions and for a limited period of time.<sup>27</sup>

Figure 7 MIC RV USD WAP Price per Course through UNICEF 2014-2019



Source: UNICEF Supply Division

Generally, RV prices for MICs are still high compared with Gavi-supported countries and can vary significantly between countries depending on the manufacturers' pricing policies. Prices offered by manufacturers to MICs that self-finance their RV vaccine purchases through UNICEF have reached up to USD 18.00 per course, which is a multiple of the costs of Gavi-supported procurement through UNICEF (Figure 7).

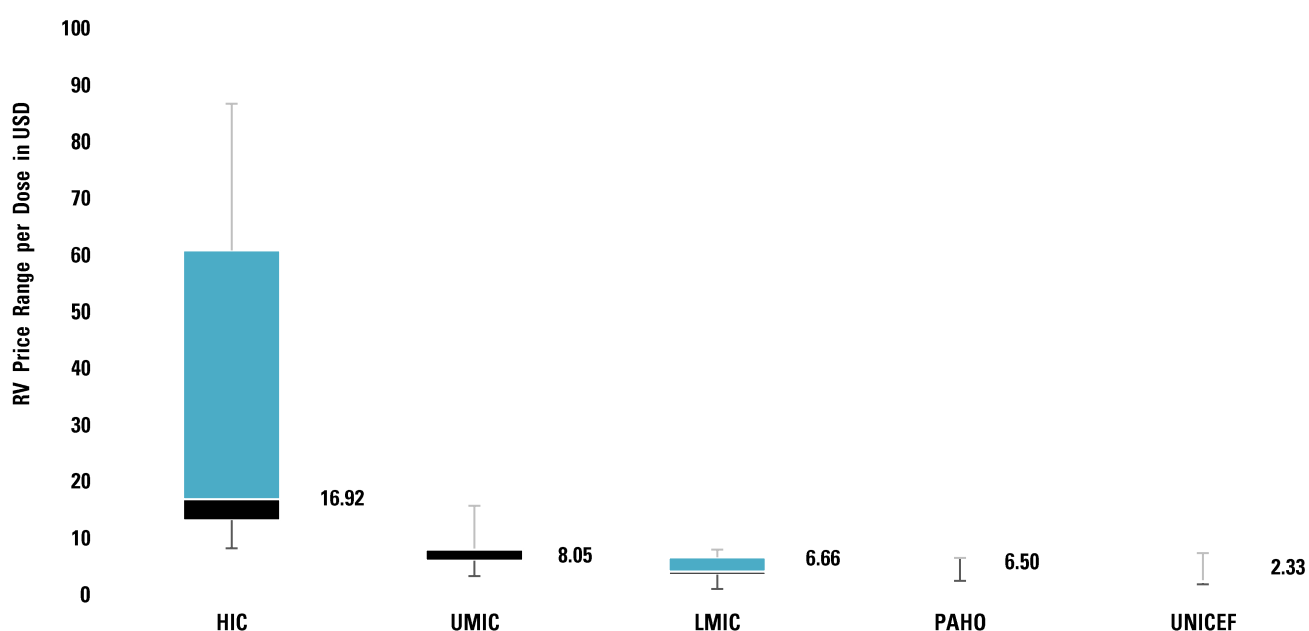
<sup>26</sup> O'Ryan, Miguel, *Rotavirus Vaccines: A Story of Success with Challenges Ahead*, PubMed Central, US National Institutes of Health, Bethesda, August 2017.

<sup>27</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 8).<sup>28</sup> The Access to Medicine Foundation analysed the cost to fully immunize 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>29</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>30</sup>

Figure 8 RV Price per Dose Ranges per Income Group 2013-2019 <sup>31</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 could improve.

## 5. Healthy Market Framework

The Bill and Melinda Gates Foundation (BMGF), Gavi, and UNICEF, developed the Healthy Markets Framework (HMF). HMF is a tool to support market shaping and 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 9) demonstrates that the RV market is now in a low to moderate state of health, with supply largely dependent on one supplier that faced manufacturing issues and lack buffer capacity.<sup>32</sup>

<sup>28</sup> World Health Organization, [MI4A: Market Information for Access to Vaccines](#), WHO, Geneva, March 2018.

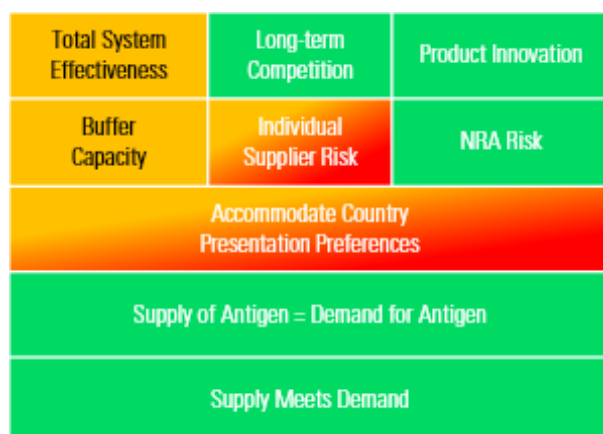
<sup>29</sup> AMF, [Vaccines Index 2017: How Vaccine Companies are Responding to Calls for Greater Immunisation Coverage](#), p. 51.

<sup>30</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>31</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>32</sup> Gavi, the Vaccine Alliance, [Rotavirus Vaccine Roadmap: Public Summary](#), Gavi, Geneva, 2016.

Figure 9 Healthy Markets Framework for RV 2019



Even though WHO recently prequalified four RV presentations from two other manufacturers, eighty-eight per cent of the RV demand through UNICEF has to date been for GSK's RV1 product. The RV market does not meet two of the eight healthy market attributes, which are: individual supplier risk and country preference, and only partially meets the market attributes of buffer capacity and total system effectiveness. It does however now meet four of the eight attributes, up from only two previously, of supply meets demand, NRA risk, product innovation, and long-term competition. New products with programmatic advantages and lower cold chain volume requirements can improve long-term competition and diversify supply.

Source: UNICEF

## 6. Issues and Challenges

- The RV market is in a low to moderate state of health characterized by a supply-demand imbalance, high-risk level of supply insecurity and fragility as portrayed by the recent disruptions to supply in 2017-2019, identifying the need for additional interchangeable supply and supplier diversity.
- Country preparations and planning with realistic introduction timelines are required to optimize supply. This is undermined by forecast inaccuracy and 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.
- Delays in RV introductions in several large countries are as a result of asymmetric supply and demand of country preferred product presentations that has created supply constraints for one product. Even though projected supply availability in 2020 and beyond in general has improved and will enable and facilitate countries to introduce the vaccine, asymmetric supply contributes to a higher and fragile supply security risk, particularly in a market constituting increased demand and a lack of confirmed supply availability.
- The health authorities in some MICs where diarrhoea-associated deaths are relatively infrequent often fail to recognize the need for rotavirus vaccines. 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 2021 and beyond. Demand will be reassessed upon the successful RV introduction in large countries during 2020, and against Gavi's strategic demand forecast projections.
- UNICEF will work with countries to benefit from the increasingly diverse supply base.
- UNICEF anticipates issuing a new tender in 2020 to secure supply from 2022 onwards. UNICEF, Gavi, and partners, will continue to support country implementation and work with governments to address system readiness to introduce new vaccines.
- 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 that are 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.
- 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, recognizing that the free flow of information and correcting information asymmetry is critical to underpin an efficient market, and which is accessible [here](#).<sup>33</sup>

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Other UNICEF information notes are found at [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html)

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<sup>33</sup> UNICEF, [UNICEF Pricing Data](#), UNICEF Copenhagen, July 2018.