Rotavirus Vaccine: Supply and Demand Update

UNICEF Supply Division

November 2018
Rotavirus Vaccine
Supply & Demand Update – November 2018

This update provides new information on rotavirus vaccine demand, supply, and country introduction, as well as on new products prequalified by WHO. Overall rotavirus vaccine supply through UNICEF is still not sufficient to meet all confirmed country demand, and two major suppliers recently announced reduced supply availability, affecting existing country programmes and pending new country introductions.

A more recent note covering rotavirus vaccines exists. Please visit http://www.unicef.org/supply/index_54214.html

1. Summary

- UNICEF procured 100.7 million rotavirus vaccine (RV) courses over 2011-2017.¹ 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 six years from 900,000 courses in 2011, to reach 23 million courses in 2017 on behalf of 41 countries. UNICEF anticipates annual aggregate demand channelled through UNICEF to reach 36.2 million courses in 2018, and to possibly increase to 61.4 million in 2019 on account of some large country introductions.

- However, product availability through UNICEF for 2018 will only reach 33.8 million courses, which is not sufficient to meet all confirmed country demand and is short by an estimated 2.4 million courses. UNICEF currently has three long-term arrangements (LTAs) to supply RV. The last supply award made in 2018 was for an additional 59.6 million courses to supply country introductions through 2021,² taking the total cumulative volume of RV contracted through UNICEF to 196.6 million courses since 2011.

- Excluding the demand from the Government of India, 91 per cent of RV demand through UNICEF to date has historically been for one vaccine product presentation currently available from one supplier. In 2018, the World Health Organization (WHO) prequalified four new RV presentations extending additional supply options for countries. However, two of UNICEF’s major suppliers (GlaxoSmithKline (GSK), and Merck) subsequently also announced substantial reductions in supply availability for 2018 and 2019. RV production remains vulnerable to complex technical manufacturing issues that affected both suppliers. GSK announced that it can no longer supply doses to support new programme introductions in 2018 and 2019 and will only confirm ongoing support to existing programmes. Merck signalled that they would no longer meet the needs of countries accessing their product through UNICEF in 2019. UNICEF is currently working with countries to mitigate the resulting effects.

- RV demand from MICs and access to affordable prices through UNICEF remains uncertain. RV pricing still remains comparatively high for self-financing MICs and prices offered by suppliers can vary significantly between countries with different income classifications.

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 the age of five years annually.³ 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,⁴ which infect nearly every child at least once before the age of five, with children aged six months to two years most vulnerable to infection.⁵

Since 2007, WHO recommends countries to include RV into national childhood immunization programmes as part of a comprehensive diarrhoeal disease control strategy, complementing improved water, sanitation, hygiene, and treatment,

¹As 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.
²Afghanistan, Bangladesh, the Democratic Republic of Congo, India, Nigeria, and Pakistan.
including the use of low-osmolality oral rehydration salts (ORS), and zinc supplementation, particularly in countries with high rotavirus gastroenteritis associated fatality rates. Yet, as of 2017, the global immunization coverage for RV was still only 28 per cent (Figure 1) against a national WHO vaccination target coverage rate of 90 per cent and 80 per cent in every district, or national equivalent administrative unit.

Figure 1 RV Immunization Coverage Rates per Income Group for One-year Olds 2006-2017

WHO has prequalified seven RV presentations from four manufacturers, all of which are administered orally (Table 1). Four were only recently prequalified in 2018. In January 2018, WHO prequalified new, live, attenuated monovalent RV (RV1) products in a five-dose and ten-dose presentation from Bharat Biotech requiring a three-dose schedule. The new prequalified vaccines have a five-year shelf life when stored at -20°C at central medical stores. The products come with a vaccine vial monitor (VVM) 2 and must be stored at 2-8°C at the point of administration until use, or until the VVM reaches its end-point, similar to bivalent oral polio vaccines (bOPV). In September 2018, WHO also prequalified two new lyophilised pentavalent RV (RV5) vaccines in a single- and two-dose presentation from Serum Institute of India (SII). These also require a three-dose schedule, as well as reconstitution at point of administration and 2-8°C storage requirements. In all, these new products extend additional WHO prequalified vaccine supply options to countries from three to seven quality assured RV products; moving the market from two to four manufacturers.

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. Detailed information on each manufacturers WHO prequalified rotavirus vaccines is accessible here. Even though WHO prequalified RV products can differ from each other in formulation, presentation, and/or dose schedule, WHO is yet to provide normative guidance on product interchangeability, which would support countries to easily switch between products from different manufacturers after vaccine introduction into their national immunization programmes (e.g. whether based on availability, or price), or to introduce more than one product concurrently. UNICEF and partners are working with WHO to review and provide

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6 UNICEF, Oral Rehydration Salts (ORS) and Zinc, UNICEF, Copenhagen, February 2016.
7 WHO, Rotavirus Vaccines WHO Position Paper, p. 49.
10 WHO initially prequalified GSK’s single-dose tube presentation with a VVM 14 and a 36 months’ shelf life. A VVM is a small label made of heat-sensitive material located on a vaccine’s vial. 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.
normative guidance on product interchangeability. UNICEF has procured five of these presentations (all but SII’s) on behalf of countries and donors in support of routine childhood immunization programmes.

Table 1 WHO Prequalified Rotavirus Vaccines

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Vaccine Type</th>
<th>Dose/ Course</th>
<th>WHO PO</th>
<th>Presentation</th>
<th>FormuL</th>
<th>Shelf life</th>
<th>VVM</th>
<th>Cold Chain Vol / Course</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bharat Biotech</td>
<td>RV1</td>
<td>3</td>
<td>2018</td>
<td>5 dose vial</td>
<td>Liquid</td>
<td>60 months</td>
<td>2</td>
<td>12.6 cm³</td>
<td>-20°C</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>RV1</td>
<td>3</td>
<td>2018</td>
<td>10 dose vial</td>
<td>Liquid</td>
<td>60 months</td>
<td>2</td>
<td>9.6 cm³</td>
<td>-20°C</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>RV1</td>
<td>2</td>
<td>2009</td>
<td>1 dose tube</td>
<td>Liquid</td>
<td>24 months</td>
<td>7</td>
<td>34.2 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>Merck (USA)</td>
<td>RV5</td>
<td>3</td>
<td>2008</td>
<td>1 dose tube</td>
<td>Liquid</td>
<td>24 months</td>
<td>n/a</td>
<td>120.6 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>Serum Institute of</td>
<td>RV5</td>
<td>3</td>
<td>2018</td>
<td>1-dose vial</td>
<td>Lyophilised</td>
<td>30 months</td>
<td>30</td>
<td>52.7 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>India</td>
<td>RV5</td>
<td>3</td>
<td>2018</td>
<td>2-dose vial</td>
<td>Lyophilised</td>
<td>30 months</td>
<td>30</td>
<td>31.6 cm³</td>
<td>2-8°C</td>
</tr>
</tbody>
</table>

Note: *WHO recently amended GSK’s vaccine prequalification reducing the shelf life to 24 months, and the VVM category to 7 (see footnote). Source: World Health Organization

To date (October 2018), 91 per cent of RV demand through UNICEF has been for GSK’s RV1 single-dose tube presentation. This can largely be explained by the fact that it is administered in a two-dose schedule, compared to other available products all requiring a third dose, with the programmatic implications that entails, as well as it also having significantly smaller cold chain requirements. These product characteristics have been advantageous for immunization programmes in terms of vaccine administration and costs, compared to Merck’s alternative 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.

Polyvac has an RV product marketed in Viet Nam, but has not sought WHO prequalification, and several other manufacturers have RV products in development that may improve global RV supply options in the near future, including live oral rotavirus candidates and non-replicating vaccine technologies. Bio Farma (Indonesia), the Institute Butantan (Brazil), and Lanzhou Institute of Biological Products (China), have products under clinical development, of which some are in advanced clinical trials. RV development efforts across the vaccine industry have also experienced setbacks. In 2017, Sanofi’s Indian subsidiary, Shantha Biotechs, discontinued RV development projects, and Hillelman Laboratories discontinued their RV product development in 2018. More information on RV vaccines in different stages of development can be accessed here:


3. Current Market Situation

The global market for RV grew from 12 million courses in 2010, to reach 36 million courses in 2015, largely based on country introductions supported by Gavi. Global revenues over this period increased from USD 900 million to reach total revenue estimates of USD 1.3 billion, of which over USD 1 billion were generated in HICs, and only seven per cent was generated in Gavi-supported countries. Gavi expects the global RV market to increase by 46 per cent in value by 2025, and generate an estimated USD 1.9 billion in revenues, largely driven by the demand from Gavi-eligible countries and India, which could collectively represent 60 per cent of the total projected global demand.

3.1 Gavi 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 (yellow colouring, Table 2). These numbers do not include the six Gavi-eligible/transitioned countries from Latin America and the Caribbean that access RV through the Pan American Health Organization’s (PAHO) revolving fund.

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13 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, G3P[11] and G1P[8], respectively.
17 The six PAHO countries are Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua.
Gavi has approved support for 49 countries to introduce RV with procurement through UNICEF. Ten countries are pending introduction in 2018, 2019, and 2020, including Bhutan, which will self-finance its supply. Nigeria is pending Gavi approval, leaving eight countries eligible to apply to Gavi for RV support, but which have not yet done so. A lack of programme readiness, cold chain capacity, as well as concerns over long-term pricing, and supply sustainability, account for some country hesitations and delays in introducing RV, especially in larger countries.

**Table 2 RV Gavi Country Introductions: Status (excluding PAHO) 2018**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudan</td>
<td>Armenia*</td>
<td>Burkina Faso</td>
<td>Angola*</td>
<td>Guinea-Bissau</td>
<td>Liberia</td>
<td>Cote d’Ivoire</td>
<td>Afghanistan</td>
<td>Myanmar</td>
<td>Palau, Nauru, C*</td>
</tr>
<tr>
<td>Ghana</td>
<td>Burundi</td>
<td>Cameroon</td>
<td>Kiribati*</td>
<td>Sao Tome &amp; Pr.</td>
<td>India</td>
<td>Uganda</td>
<td>CAR</td>
<td>Somalia</td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td>Eritrea</td>
<td>Congo*</td>
<td>Mozambique</td>
<td>Lesotho</td>
<td>Benin</td>
<td>Kyrgyzstan</td>
<td>Pakistan</td>
<td>Vanuatu</td>
<td>Timor Leste*</td>
</tr>
<tr>
<td>Malawi*</td>
<td>Cambodia</td>
<td>Djibouti</td>
<td>Tajikistan</td>
<td>Parkistan</td>
<td>BDT, China</td>
<td>Sri Lanka*</td>
<td>Ukraine*</td>
<td>Viet Nam</td>
<td></td>
</tr>
<tr>
<td>Rwanda</td>
<td>Georgia*</td>
<td>Eritrea</td>
<td>Tanzania</td>
<td>Zambia</td>
<td>Kenya</td>
<td>Madagascar</td>
<td>Mali</td>
<td>Mauritania</td>
<td>Niger</td>
</tr>
<tr>
<td>Yemen</td>
<td>Madagascar</td>
<td>Mali</td>
<td>Mali</td>
<td>Mauritania</td>
<td>Niger</td>
<td>Senegal</td>
<td>Sierra Leone</td>
<td>Togo</td>
<td>Zimbabwe</td>
</tr>
</tbody>
</table>

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

Over the past seven-years (2011-2017), UNICEF procured in aggregate 100.7 million courses (Figure 2). In 2017, UNICEF procured 23 million RV courses, representing a global market volume share of 44 per cent (in number of courses), and 7.3 per cent of global revenues (in USD).13

**Figure 2 UNICEF RV Gavi-eligible and Transitioned Supply and Projected Demand 2011-2018**

- Initial demand forecasts that failed to materialise on account of a mix of deferred country introductions and supply availability
- VVM compliance issues reducing available supply
- 2.4 million course shortfall from recent supplier announcements, requiring alternative suppliers

Source: UNICEF Supply Division

UNICEF anticipates unconstrained demand from Gavi-eligible and transitioned countries, excluding those in the PAHO region and Viet Nam, to reach 36.2 million courses in 2018 (Figure 2), and which could reach 61.4 million courses in 2019

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(Figure 3) due to large-country introductions supported by Gavi. Over the next seven-years (2019-2025) UNICEF projects total demand from these countries could reach in aggregate up to 511.4 million courses (Figure 3), mostly on account of Gavi-support. UNICEF expects Viet Nam to self-procure domestically produced RV. Despite the number of successful RV introductions to date, UNICEF still considers overall demand to have been less than initially expected, due to introduction deferrals by some large countries, some of which expressed concerns regarding the sustainability and predictability of supply. The current high reliance on a single product and manufacturer presents a high and fragile supply security risk that also affects country demand.

Whereas overall supply projections based on production capacity appear adequate to meet a total projected demand reaching up to 80 million courses by 2024 (Figure 3), actual supply availability through UNICEF on LTA is currently far 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.

Figure 3 UNICEF RV Projected Demand and Supply 2019-2025 for Gavi-eligible Countries

Source: UNICEF Supply Division.

3.2 Gavi Country Supply

UNICEF seeks to secure sufficient and sustainable supplies 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 (typically longer than four years), phased additional supply awards, volume commitments, and contracting in different currencies (US dollars and Euros).

A current RV market imbalance remains as 91 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 insecurity 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 issue it faced when producing the vaccine (Figure 2), and as a result, two countries had to postpone their planned RV introductions. Such complications serve as a reminder that the chemical and biological processes required to manufacture live virus vaccines, such as rotavirus vaccines, are complex, and face challenges that are not always predictable.22

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20 Afghanistan, Bangladesh, the Democratic Republic of Congo, India, and Nigeria.
Overall RV supply availability through UNICEF increased during 2018, based on GSK increasing its production capacity, and WHO prequalifying new RV products. To secure additional sustainable supply for large country introductions, UNICEF awarded manufacturers in 2018 an additional 59.6 million courses through 2021. UNICEF awarded Bharat Biotech 21.6 million courses, and increased GSK’s awarded supply by an additional 38 million courses (Table 3). However, UNICEF still only secured a total of 33.8 million RV courses for 2018, which is 2.4 million courses less than the quantities it requires to reach 36.2 million in demand for the year (Figure 2).

Table 3 UNICEF Long-term Arrangement Awards for 2017-2021

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Vaccine</th>
<th>Price per Dose</th>
<th>Duration</th>
<th>Schedule</th>
<th>New Courses Awarded in 2018</th>
<th>Total Courses Awarded in 2017-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bharat Biotech (India)</td>
<td>RV1</td>
<td>USD 0.95</td>
<td>3 years</td>
<td>3 doses</td>
<td>21,600,000</td>
<td>21,600,000</td>
</tr>
<tr>
<td>GlaxoSmithKline (Belgium)</td>
<td>RV1</td>
<td>EUR 1.88</td>
<td>5 years</td>
<td>2 doses</td>
<td>38,000,000</td>
<td>163,000,000</td>
</tr>
<tr>
<td>Merck (USA)</td>
<td>RV5</td>
<td>USD 3.20</td>
<td>5 years</td>
<td>3 doses</td>
<td>-</td>
<td>12,000,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>59,600,000</td>
<td>196,600,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

GSK subsequently announced that due to technical manufacturing issues affecting production, it could no longer supply its recently awarded additional doses to support new country introductions in 2018 and 2019, which will prevent additional large countries from introducing the vaccine. UNICEF is now seeking to award additional doses to alternative manufacturers.

Routine demand for Merck’s RV5 from Gavi-supported countries has historically been limited to only six countries, of which two countries recently switched to GSK’s RV1 in 2017. No new additional demand for Merck’s RV5 through UNICEF has materialised. 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 through UNICEF the four countries using their vaccine (Burkina Faso, Mali, Côte d’Ivoire, and Sao Tome et Principe) as of mid-2019. UNICEF and partners are maintaining close communication with suppliers and these countries to reduce the risks to programme interruptions.

Due to the supply shortages from these two manufacturers, UNICEF is supporting countries to diversify supply options and choose alternative WHO prequalified products from the two new suppliers. UNICEF awarded Bharat an LTA to secure RV supply specifically for the Government of India (GoI). Gavi is providing the GoI with catalytic funding over the next 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. Beyond this awarded supply to Bharat for India, both Bharat and SII retain supply availability should other countries choose to adopt these vaccines, although these two manufacturers will take time to scale up actual supply.

3.3 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. Only three MICs procured their RV requirements through UNICEF since 2014: Kiribati, the Philippines, and the State of Palestine, representing in aggregate 900,000 courses, of which UNICEF procured 64 per cent on behalf of the Philippines in 2014 (Figure 4). UNICEF secured all MIC quantities through ad-hoc tenders separate from those for Gavi-supported countries.

In some MICs, where diarrhoea-associated deaths are relatively infrequent, health authorities do not prioritize the need to immunize children against rotavirus despite significant rotavirus-associated outpatient consultations, hospitalizations, as well as medical and emergency room visits.24 UNICEF procurement can play an important enabling role for MICs introducing new vaccines. 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 any solid demand from MICs, together with the high price tiers of some manufacturers, make 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 procurement may not always channel their needs through UNICEF.

UNICEF will continue to engage partners to analyse the cost-effectiveness of rotavirus vaccination for MICs. 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.

### 3.4 Pricing

![Figure 5 Gavi RV5 USD WAP Price per Course through UNICEF 2011-2017](image1)

![Figure 6 Gavi RV1 EUR WAP Price per Course through UNICEF 2011-2017](image2)

The weighted average price (WAP) per dose through UNICEF for Gavi-supported countries for 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 2017 (Figure 5). The WAP for RV1 through UNICEF for Gavi-supported countries initially declined sharply (67 per cent) in 2012 from EUR 11.25 per course to EUR 3.76 per course, in large part as a result of using longer-term 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. However, prices offered by manufacturers to MICs that self-finance their RV vaccine purchases through UNICEF have been significantly higher, and can range up to USD 15.00 per course, which is a multiple of the costs of Gavi-supported procurement through UNICEF (Figure 7).

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Whereas SII’s indicative price per course for Gavi-eligible countries is USD 3.60 for a single dose vial, Bharat’s new WHO prequalified RV1 five-dose vaccine to supply the GoI costs USD 2.85 per course, which is a lower cost per course than alternative manufacturers by at least 36 to 70 per cent. With new additional product availability on the market, there is an opportunity for competition and some price improvements. However, it is difficult to predict as there remains a very high reliance in the Gavi segment on a single product and manufacturer.

*Figure 7 MIC RV1 USD WAP Price per Course through UNICEF 2014-2018*

The State of Palestine received donor support to introduce RV1 with vaccines procured through UNICEF. It will soon self-finance its RV procurement once donor support has ended beginning in 2019. To sustain its RV immunization programme, the State of Palestine recently switched to Bharat RV1 as it is a more affordable option. Generally, RV MIC vaccine prices are still high compared with Gavi-supported countries, and can vary significantly between countries depending on the manufacturers’ pricing policies.

Source: UNICEF Supply Division

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). As noted earlier, demand from MICs through UNICEF is low and variable. With more certainty in demand from MICs, and longer-term forecasting, pricing to support MIC access could improve.

*Figure 8 RV Price per Dose Ranges per Income Group 2013-2017*

Source: World Health Organization, Vaccine Product, Price and Procurement (V3P) database UNICEF Supply Division

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27 *Figure 8* UNICEF uses a “box and whisker” chart to show data distributed per quartile. It highlights price data and ranges in sections each containing 25 per cent. The “box” spans the interquartile range showing 50 per cent of the price data, with the median price 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.
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 low-income countries (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. 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.

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.

4. Healthy Market Framework

Figure 9 Healthy Markets Framework for RV 2017

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 HMF evaluation for RV (Figure 9) demonstrates that the RV market is in an unsatisfactory low-state of health, with supply largely dependent on one supplier that did not have sufficient production capacity to meet country product preferences.

The RV market does not meet three of the eight healthy market attributes, which are: supply meets demand, country preferences, and buffer capacity. It partially meets three of the healthy market attributes: total system effectiveness, long-term competition, and individual supplier risk, and only meets two of the eight attributes: national regulatory authority risk and product innovation.

Ninety per cent of the RV demand through UNICEF has to date been for GSK’s RV1 product. Even though WHO recently prequalified four RV presentations from two other manufacturers, the product preference imbalance remains. New market entrants providing products with programmatic advantages and lower cold chain volume requirements can improve long-term competition and diversify supply.

5. Issues and Challenges

- The recent disruptions to supply in 2017 and 2018 characterise the RV market’s imbalance, high-risk level of supply insecurity and fragility, low-state of health, and identifies the need for additional interchangeable supply and supplier diversity.
- The recent announcements from GSK and Merck of supply interruptions affecting some existing programmes and planned country introductions will require some countries to adopt alternative sources of supply. Projected supply availability from manufacturers with new WHO prequalified products will take time to materialise, as countries need to confirm their demand before manufacturers can scale up production.

• Insufficient in-country readiness in some countries has delayed the introduction of RV resulting in low programmatic uptake, which has in turn undermined the forecast accuracy, and created uncertainty of demand. Support for country preparations and planning for realistic introduction timelines are required to optimize supply.

• Market imbalance for one manufacturer’s product has created supply constraints for this product leading to delays in RV introductions in several large countries. It also presents a high and fragile supply security risk, particularly in an environment characterised by increasing demand and a lack of confirmed supply availability.

• Country demand from MICs is currently uncertain and makes it a challenge to establish LTAs to secure access to affordable prices. In MICs where diarrhoea-associated deaths are relatively infrequent, health authorities often fail to recognize the need for rotavirus vaccines.

6. Steps Forward

• UNICEF, Gavi, and partners, will continue to monitor closely the supply capacity and requirements through 2021 and beyond. They will re-assess the demand upon the successful RV introduction in large countries during 2018 and 2019, and against Gavi’s strategic demand forecast projections, and will work with countries to diversify supply.

• UNICEF, Gavi, and other partners, will continue to support country implementation and work with governments to address system readiness to introduce new vaccines.

• 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 ensure additional availability to secure increased supply to meet the anticipated demand from large countries. UNICEF will continue to seek a diverse manufacturer base.

• UNICEF is working with manufacturers and countries to increase the price transparency for doses secured on behalf of self-funding MICs. UNICEF has since 2011 published its 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.  

For further questions or additional information, please contact:

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Other UNICEF information notes are found at http://www.unicef.org/supply/index_54214.html