Pneumococcal Conjugate Vaccine: Supply and Demand Update

UNICEF Supply Division

July 2020
This update provides new information on pneumococcal conjugate vaccine demand availability and access to supply. Pneumococcal conjugate vaccine supply through UNICEF has been stable and is sufficient to meet current demand and includes an additional supplier. UNICEF encourages self-financing middle-income countries to make multi-year demand commitments to enable access to more affordable pricing through UNICEF.

1. Summary

- Since the launch of the advance market commitment (AMC) for pneumococcal conjugate vaccine (PCV) in 2009, UNICEF has procured a total of 941 million doses on behalf of 60 countries and expects to reach one billion doses by the end of December 2020. The AMC has enabled countries to access the vaccine for an estimated 300 million children. Indonesia is the latest country that will introduce PCV into their national immunization programme, scheduled during 2020.
- Since 2013, UNICEF has procured six million doses of PCV on behalf of several self-financing middle-income countries (MICs) representing only 0.7 per cent of the total PCV volume supplied through UNICEF. UNICEF expects this demand to grow over the next few years as some large countries introduce the vaccine into their routine immunization programmes. UNICEF has established multi-year contractual arrangements for PCV procurement to supply MICs at more affordable and sustainable prices.
- UNICEF’s annual procurement for PCV under the AMC has now reached an average of 160 million doses per year. UNICEF has issued its last call for supply offers under the AMC during the first quarter (Q1) of 2020 and concluded with an award to Serum Institute of India (SII). However, the demand for PCV from countries eligible to access prices and quantities under the AMC continues to increase. Eleven countries remain eligible to apply to Gavi, The Vaccine Alliance (Gavi), to access financing and/or AMC prices, of which six must fully self-finance their PCV procurement.
- UNICEF will issue the first non-AMC tender post 2020 to secure additional supply for the next five to ten years. From 2020 to 2030, more than one billion doses in new introductions and existing demand remains uncontracted, representing the needs of an estimated additional 61 million children, and supply opportunities for manufacturers through UNICEF.
- To ensure that countries have timely access to affordable PCV in humanitarian emergencies to prevent vaccine-preventable diseases in affected populations, UNICEF, Médecins Sans Frontières (MSF), Save the Children, and the World Health Organization (WHO), together with partners and industry, established the Humanitarian Mechanism in 2017.¹ Under this mechanism, UNICEF entered into supply agreements with PCV manufacturers for 990,000 doses for humanitarian emergency response activities.
- All the objectives that were set by the AMC to scale up the demand and use of PCV have been achieved, including the replication of the AMC’s model for another vaccine candidate. The COVID-19 vaccine has been selected by Gavi and partners for a second AMC through Gavi.

2. Background

Pneumococcal infections are caused by Streptococcus pneumoniae bacteria and can lead to bacteraemia, meningitis, and pneumonia, as well as other less severe conditions such as sinusitis and otitis. There are over 93 pneumococcal serotypes, of which six to eleven account for over 70 per cent of all pneumococcal disease in children. Pneumococci are typically transmitted from the nasopharynx via respiratory droplets, particularly from infants and young children.² Children with chronic medical conditions such as heart and lung disease, diabetes, or HIV infection are also especially susceptible.³ Globally, there are an estimated 14.5 million cases of serious pneumococcal disease in children under-five years of age, resulting in an

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estimated 500,000 deaths occurring mostly in low-income countries (LICs) and MICs. It is difficult to determine the proportion of meningitis and pneumonia that is caused by S. pneumoniae, but it is the most common cause of bacterial pneumonia in children, and one of the frequent causes of meningitis. WHO estimates that approximately 75% per cent of invasive pneumococcal disease (IPD) cases and 83% per cent of pneumococcal meningitis occur in children under two years of age, with a case fatality rate from IPD in children ranging up to 20 per cent for septicaemia (bacteria entering the bloodstream) and 50 per cent for meningitis in LICs and MICs.

UNICEF and WHO seek to end preventable child deaths from pneumonia by 2025 through the Global Action Plan for Pneumonia and Diarrhoea (GAPPD). Launched in 2009, it seeks to reduce the incidence of severe pneumonia among children under-five by 75 per cent and under-five child mortality from pneumonia to fewer than three per 1000 live births. To prevent pneumococcal diseases such as bacteraemia, meningitis, and pneumonia, amongst others, WHO recommends countries include PCV in their national immunization programmes worldwide. UNICEF’s goal is to have an additional 21 countries introduce PCV into their national immunization programmes by 2021.

3. Supply

UNICEF procures PCV on behalf of countries and partners in support of routine childhood immunization programmes and campaigns in humanitarian response. In 2019, WHO prequalified an additional two PCV vaccine presentations from the Serum Institute of India (SII), which now brings the total number of WHO prequalified vaccines to seven different products from three manufacturers, including GlaxoSmithKline (GSK), and Pfizer (Table 1). Even though GSK and SII’s PCV10 contain the same number of serotypes, they differ in the replacement of one of the serotypes from three manufacturers, including GlaxoSmithKline (GSK), and Pfizer (Table 1). Even though GSK and SII’s PCV10 contain the same number of serotypes, they differ in the replacement of one of the PCV serotypes, serotype 4 in GSK’s vaccine and serotype 19A in SII’s vaccine. The 13 serotypes contained in Pfizer’s vaccine includes the serotypes from both GSK’s and SII’s PCV10 products.

Table 1 WHO Prequalified Pneumococcal Conjugate Vaccines

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Vaccine Type</th>
<th>Doses / Course</th>
<th>WHO PQ</th>
<th>Presentation</th>
<th>Form.</th>
<th>Shelf life</th>
<th>VVM</th>
<th>Cold Chain Vol / Dose</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK (Belgium)</td>
<td>PCV10</td>
<td>3</td>
<td>2009</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>48 months</td>
<td>30</td>
<td>11.50 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>2010</td>
<td>2-dose vial</td>
<td>Liquid</td>
<td>48 months</td>
<td>30</td>
<td>4.80 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>2017</td>
<td>4-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>2.40 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>Pfizer (USA)</td>
<td>PCV13</td>
<td>3</td>
<td>2010</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>12.00 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>2016</td>
<td>4-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>3.50 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>SII (India)</td>
<td>PCV10</td>
<td>3</td>
<td>2019</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>14.06 cm³</td>
<td>2-8°C</td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>2019</td>
<td>5-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>3.51 cm³</td>
<td>2-8°C</td>
</tr>
</tbody>
</table>

Source: WHO

Since 2010, GSK and Pfizer have shared the market with their respective two-and single-dose vial presentations, and subsequently with their respective four-dose vial presentations. The duopoly of the PCV market ended when SII entered the market with their PCV10 vaccines (Table 1). All the WHO prequalified vaccines from the three manufacturers come in multi-dose vial (MDV) presentations with preservatives and conform to WHO’s MDV policy. The MDV policy allows vaccines to be used for up to 28 days after opening if stored under appropriate conditions of between 2 to 8°C without contamination.

GSK phased out its PCV10 two-dose vial presentation in 2019 and it is no longer available. Both GSK and Pfizer also have PCVs in pre-filled syringes, which are not WHO prequalified, as the syringes do not come with any auto-disabling features preventing reuse. Read more on safe injection equipment (SIE) here. Walvax developed a PCV13, which was licenced in

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9 WHO. *Pneumococcal Conjugate Vaccines in Infants and Children Under 5 Years of Age*. p. 100.
12 UNICEF. *Safe Injection Equipment (SIE)*. UNICEF, Copenhagen, November 2018.
China in December 2019. They have submitted a dossier to WHO for prequalification, which UNICEF anticipates could be finalised by the end of 2021.

4. Innovation

UNICEF knows of over seventeen manufacturers that are developing new pneumococcal vaccines, including: Beijing Minhai;\(^\text{13}\) GSK;\(^\text{14}\) LG Chemicals;\(^\text{15}\) Merck;\(^\text{16}\) Panacea; Pfizer;\(^\text{17}\) PnuVax; Sanofi; Sinovac Biotech;\(^\text{18}\) and SK Bioscience (Figure 1).\(^\text{19}\)

Figure 1 A Non-Exhaustive List of Manufacturers with PCV Product Development, Type, and Pipeline Status Overview

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beijing Minhai, China, PCV13</td>
<td></td>
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<tr>
<td>GSK, UK, PCV12</td>
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<tr>
<td>LG Chemicals, South Korea, multivalent PCV</td>
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<tr>
<td>Merck, USA, PCV15</td>
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<tr>
<td>Panacea, India, PCV10</td>
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<tr>
<td>Pfizer, USA, PCV20</td>
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<tr>
<td>PnuVax, Canada, PCV13</td>
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<tr>
<td>Sinovac, China, PCV13</td>
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<td></td>
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<tr>
<td>SK Bioscience, South Korea, multivalent PCV</td>
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</table>

Source: UNICEF Supply Division

Several manufacturers are also developing vaccines for use under a controlled temperature chain (CTC). A CTC is an innovative approach that allows vaccines to be kept outside traditional cold chain requirements of 2 to 8°C, at temperatures of up to 40°C under monitored and controlled conditions for a limited period prior to use.\(^\text{20}\) Whereas Pfizer had a single dose vial (SDV) vaccine approved for use under CTC in May 2015, Pfizer withdrew it in 2016 on request by the European Medicines Agency (EMA) to ensure that both their products presentations (including MDVs) had harmonized labelling. GSK is also looking to ensure its vaccines retain stability after freezing by testing the impact of sub-zero temperatures on its PCV10.\(^\text{21}\)

Manufacturers are developing vaccines that will be programmatically suitable for low-resource settings, offering a broad range of protection against circulating pneumococcal serotypes. Protein sub-unit and whole cell vaccines have the potential to offer non-serotype specific coverage, and the development of some vaccine candidates have advanced into Phase 1 and

\(^{13}\) US National Library of Medicine, A Phase III Clinical Trial of a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants, NLM, Bethesda, October 2017.

\(^{14}\) Alderson, Mark R., Status of Research and Development of Pediatric Vaccines for Streptococcus pneumoniae, NLM, Bethesda, June 2016.

\(^{15}\) US National Library of Medicine, A Study to Evaluate the Safety and Immunogenicity of LBVE (Multivalent Pneumococcal Conjugate Vaccine) in Healthy Infants, NLM, Bethesda, October 2018.

\(^{16}\) Merck, Merck Announces First Phase Three Studies for PCV-15 (V114) Its Investigational Pneumococcal Disease Vaccine, Merck, Kenilworth, April 2018.

\(^{17}\) Pfizer, Pfizer Granted FDA Breakthrough Therapy Designation for 20-Valent Pneumococcal Conjugate Vaccine for the Prevention of Invasive Disease and Pneumonia in Adults Aged 18 Years and Older, Pfizer, New York, September 2018.


\(^{19}\) US National Library of Medicine, Immunogenicity and Safety Study of the 13-valent Pneumococcal Polysaccharide Conjugate Vaccine in 2-71 Months Old Healthy Infants and Toddlers (the Youngest Could be 6 Weeks Old), NLM, Bethesda, April 2016.


2 clinical trials, which could potentially offer a vaccine providing the most comprehensive protection against pneumococcal diseases.

5. Current Market Situation

The global PCV market revenues are estimated to be between six to seven billion USD a year (Figure 2), with anticipated growth possibly generating annual revenues up to USD 20.5 billion by 2026,\(^{22}\) representing a compound annual growth rate (CAGR) of 8.3 per cent from 2017. Key drivers of this growth include the continued market dominance of North America with the introduction of PCV in adult populations; growth in emerging markets; and efforts by various governments and private sector organizations to reduce pneumococcal disease mortality in LICs and MICs; as well as investments in research and development. The supply base for PCV is now increasing with two market entrants in 2019, SII and Walvax. Going forward new entrants are expected to increase their share of the global market.\(^{23},^{24}\)

Figure 2 PCV Market Share in USD by Supplier 2013-2019*  

Pfizer is the world’s largest producer of PCV, with a 90 per cent market share of revenue through its sale of PCV13 (Figure 2), which dominates the United States of America (US) where it is marketed at an indicative price of USD 180.00 per dose.\(^{25}\) The US market accounts for 55 per cent of global revenues reaching USD 3.645 billion, whilst GSK has a 10 per cent global market share by revenue. The overall slight decline in market revenue after the peak in 2015 reflects a declining PCV naïve population, especially in high-income countries (HICs) following widespread vaccination of elderly target cohorts.

5.1 Impact of COVID-19

Following the outbreak of COVID-19 and the collapse in the airline industry, vaccine shipments and other critical deliveries have been heavily impacted due to the dramatic decline in available flights. The situation was further compounded by the lockdowns of receiving countries where airports were closed, which impeded UNICEF’s ability to ship vaccines as per country and supplier shipment plans. Currently, the availability of commercial flights has been improving, although some destinations still remain difficult to access with limited flight and charter options available, in addition to country lockdown and airport

\(^{25}\) Centers for Disease Control and Prevention, Vaccines for Children Program (VFC): CDC Vaccine Price List, CDC, Atlanta, September 2018.
closures. UNICEF is monitoring the situation daily. UNICEF considers land-transit options to ensure vaccines are delivered to countries, in addition to coordination with other aid agencies to consolidate shipments plans where feasible. Even though some costs have increased significantly, costs are starting to be more predictable. As flight options are increasing, UNICEF arranges special charters where vaccine shipments are being consolidated for multiple country delivery. Follow @UNICEF for updated tweets on deliveries.

5.2 The Advance Market Commitment

The AMC is an innovative financing mechanism launched in 2009, supported by six core donors, the Bill and Melinda Gates Foundation (BMGF), Canada, Italy, Norway, Russia, and the United Kingdom. It is to encourage manufacturers to accelerate vaccine development and make sufficient PCV supply available to countries eligible for Gavi support at affordable prices.26

The strategic prioritization and investments for accelerated development and introduction of pneumococcal vaccines was initiated in 2003 by Gavi, before the entry of PCV13 and PCV10 onto the market.27 The market responded to the AMC’s objectives by developing MDV presentations that specifically met the needs of the receiving countries. There are now several candidate pneumococcal vaccines under development (see 4 Innovation Figure 1, page 3.), which is an indication of how the AMC’s incentives have motivated industry to engage in the market.

The AMC helped facilitate one of the shortest ever periods of time taken from a new vaccine launched in HICs to be introduced into LICs (Table 2 and Figure 3, next page). From 2010 to 2016, manufacturers accelerated increases in production capacity to meet the corresponding demand from accelerated LIC and MIC introductions. There have also been several price reductions in the tail price (the price paid by countries and Gavi to manufacturers for PCV) reaching a record low of USD 2.00 per dose. This price is equal to a 43 per cent reduction in the tail price cap of USD 3.50 per dose. UNICEF issued its last call for supply offers under the AMC in Q1 2020. However, UNICEF’s existing supply agreements through the AMC will continue to run under the AMC’s terms and conditions until their expiry in 2030.

PCV was used as a pilot product for the AMC, with one of the objectives being to apply the lessons learnt from the AMC’s success to a new vaccine candidate. During Q2 2020, a second AMC was announced for COVID-19 vaccines, to accelerate their development and rapid production as well as to enable equitable access to LICs and MICs.28

5.3 The Advance Market Commitment Demand

Table 2 PCV Country Introduction Status Procuring through UNICEF 2009-2020

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</tr>
</thead>
<tbody>
<tr>
<td>Gambia</td>
<td>Nicaragua</td>
<td>Benin</td>
<td>Congo*</td>
<td>Afghanistan</td>
<td>Armenia*</td>
<td>Bangladesh</td>
<td>Kyrgyzstan</td>
<td>India</td>
<td>Haiti</td>
<td>Bhutan*</td>
<td>Indonesia*</td>
<td>Chad</td>
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<td>Rwanda</td>
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<td>Djibouti</td>
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<td>Eritrea</td>
<td>Lithuania</td>
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<td>Cameroon</td>
<td>Ghana</td>
<td>Azerbaijan*</td>
<td>Comoros</td>
<td>Costa Rica</td>
<td>Croatia</td>
<td>Democratic Republic of the Congo</td>
<td>Dominican Republic</td>
<td>Ecuador</td>
<td>El Salvador</td>
<td>Estonia</td>
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<tr>
<td>CAR</td>
<td>Madagascar</td>
<td>Burkina Faso</td>
<td>Georgia*</td>
<td>Guinea-Bissau</td>
<td>Guinea</td>
<td>Georgia</td>
<td>Hungary</td>
<td>Iceland</td>
<td>India</td>
<td>Indonesia*</td>
<td>Iran</td>
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<tr>
<td>Congo, DR</td>
<td>Pakistan</td>
<td>Kiribati*</td>
<td>Lao PDR</td>
<td>Nepal</td>
<td>Nigeria</td>
<td>Norway</td>
<td>Pakistan</td>
<td>Paraguay</td>
<td>Peru</td>
<td>Philippines</td>
<td>Portugal</td>
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<tr>
<td>Ethiopia</td>
<td>Sao Tome &amp; Principe</td>
<td>Sao Tome and Principe</td>
<td>Serbia</td>
<td>Sri Lanka*</td>
<td>South Africa</td>
<td>St. Vincent &amp; the Grenadines</td>
<td>Swaziland</td>
<td>Tajikistan</td>
<td>Thailand</td>
<td>Trinidad &amp; Tobago</td>
<td>Turkey</td>
<td></td>
</tr>
<tr>
<td>Guyana</td>
<td>Zimbabwe</td>
<td>Mozambique</td>
<td>Tunisia</td>
<td>Turkmenistan</td>
<td>Ukraine*</td>
<td>Uzbekistan</td>
<td>Vietnam</td>
<td>Yemen</td>
<td>Zambia</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

From 2010 to 2019, UNICEF procured 941 million doses of PCV, representing the needs of 300 million children on behalf of 60 LICs and MICs, which access PCV via the AMC, for a value of USD 3.5 billion. In 2019, UNICEF procured 161 million doses for a value of USD 564 million, representing eight per cent of global market share. Whereas UNICEF represents 40 per cent of Pfizer’s PCV production volume and five per cent of their PCV revenue, UNICEF represents 70 per cent of GSK’s PCV production volume and 51 per cent of their PCV revenue.

As of July 2020, over 80 per cent of the countries eligible to access PCV using the AMC have introduced the vaccine into their national immunization programmes. By comparison, MICs not eligible to access the AMC for PCV have not broadly benefited from access to affordable prices, and only 30 per cent of self-financing MICs have introduced PCV into their national immunization programmes.

Sixty of the 73 AMC eligible countries have already introduced PCV, while Indonesia and Timor-Leste are expected to introduce in 2020 and 2021 (Table 2, previous page). Currently, there are still eleven countries that remain eligible to access PCV under the AMC’s terms and conditions. Whereas four of these have transitioned from Gavi support and must fully self-finance their vaccine purchases at a price equivalent to the ‘tail price’ under the AMC, seven others are still eligible to receive Gavi support.

From 2010 through 2020, vaccine demand per year grew to reach 164 million doses (Figure 3). Due to country stock reviews and allocation adjustments for Gavi supported vaccines, UNICEF reduced the projected demand for PCV for 2020. Taking into consideration Indonesia’s anticipated introduction in 2020 and India scaling-up their vaccine introduction into additional states, UNICEF estimates that PCV’s annual demand could possibly reach up to 258 million doses by 2030. New vaccine demand from impending country introductions as well as existing uncontracted demand from 2021 to 2030 totals over one billion doses, estimated to cover the needs of an additional 61 million children, to reach a total of approximately 361 million children (Figure 3).

Figure 3 Pneumococcal Vaccine AMC Supply and Projected Demand 2000-2030

Source: UNICEF Supply Division

5.4 The Advance Market Commitment Supply

UNICEF has eight supply agreements with three manufacturers to supply 1.75 billion doses of PCV under the AMC’s terms and conditions over a twenty-year period, from 2010 through 2030 (Table 3 / Figure 3).

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30 The ‘tail price’ is a long term, low price, agreed within AMC supply contracts. For further details on the tail price definition and relationship to the AMC, please refer to the AMC terms and conditions that can be found here.
In February 2020, UNICEF issued its fifth call for supply offers for 100 million doses of PCV over a ten-year period. The tender was triggered by an increase in demand, which exceeded 10 million doses over five years, following the application of Indonesia and Timor Leste.

Of the 61 countries approved by Gavi to introduce PCV, fourteen countries introduced GSK’s PCV10, of which five later switched to PCV13 (Armenia, Azerbaijan, Mozambique, Myanmar and Ethiopia). WHO encourages evidenced based switching based on epidemiological or programmatic factors determining the choice of product. If a series cannot be completed with the same type of vaccine, the available PCV product should be used. The other 46 countries introduced or are scheduled to introduce Pfizer’s PCV13. With SII’s entry into the market with a new PCV, UNICEF anticipates some countries could switch products as countries transition to be fully self-financing and more sensitive to vaccine pricing.

5.5 Funding Evolution

The source of financing to procure PCV on behalf of Gavi-eligible and transitioned countries has gradually changed over the course of the past five years (Figure 4). Country co-financing obligations increase over time in alignment with increases in their country gross national income (GNI) and Gavi policy as their proportion of financial responsibility increases. Despite occasional defaults and some delays, all countries have paid their obligations. UNICEF expects stable routine country demand to continue as some countries gradually transition out of Gavi support over the next ten years and fully self-finance their PCV procurement (Figure 4).

Table 3 UNICEF AMC Framework Contracted PCV Quantities 2010 to 2030

<table>
<thead>
<tr>
<th>Company</th>
<th>Vaccine</th>
<th>Duration</th>
<th>Start</th>
<th>End</th>
<th>Present.</th>
<th>Doses</th>
<th>Courses</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK</td>
<td>PCV-10</td>
<td>15 years</td>
<td>2010</td>
<td>2024</td>
<td>2 &amp; 4 dose</td>
<td>720,000,000</td>
<td>240,000,000</td>
</tr>
<tr>
<td>Pfizer</td>
<td>PCV-13</td>
<td>18 years</td>
<td>2010</td>
<td>2027</td>
<td>1 &amp; 4 dose</td>
<td>930,000,000</td>
<td>310,000,000</td>
</tr>
<tr>
<td>SII</td>
<td>PCV-10</td>
<td>10 Years</td>
<td>2020</td>
<td>2029</td>
<td>1 &amp; 5 dose</td>
<td>100,000,000</td>
<td>30,000,000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,750,000,000</td>
<td>580,000,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

Note: Data in figure 4 is based on UNICEF purchase order (PO) issuances, and not deliveries. UNICEF normally issues POs for Q1 delivery in Q4 the previous year. However, in 2017 UNICEF did not issue POs in Q4 for 2018 as its tender had not been concluded. UNICEF issued Q1 POs in Q1 2018, and hence one notes a perceived reduction in 2017 compared to volumes issued in 2016. Due to stock adjustment in some countries, there was a reduction in throughput for 2018 and a rebound in 2019. This trend is expected to recur in 2020 for another set of countries.

5.6 Middle-Income Countries (Countries not supported by Gavi) Demand and Supply

Looking beyond the Gavi-supported market segment, the demand for PCV through UNICEF from MICs not eligible to access the AMC, and that have to fully self-finance their procurement, reached cumulatively eight million doses as of the end of 2019 (Figure 5). In 2012, UNICEF issued a MIC tender consolidating its call to supply PCV, human papillomavirus (HPV) vaccines and rotavirus vaccines (RV) based on the theoretical demand of countries not eligible for Gavi funding support. Manufacturers were unresponsive, largely due to concerns over the lack of visibility of long-term demand. The heterogeneous nature of MICs also posed manufacturers a challenge in terms of being able to offer a single pricing structure. Consequently, UNICEF issued ad hoc tenders to fulfill country specific requests for PCV supply. In 2017, the vaccine industry and UNICEF acknowledged the need for a consolidated approach to supply the MIC market with longer-term arrangements to provide longer-term visibility and to achieve more affordable pricing. UNICEF undertook exploratory approaches to develop contractual frameworks tailored to the needs of MICs.

Figure 5 UNICEF PCV MICs (non-AMC) Procurement, Projected Demand, and Weighted Average Price 2013-2019

In 2019 and 2020, UNICEF successfully established long-term arrangements (LTAs) to supply MICs with PCV after an extensive pre-tender engagement with manufacturers in 2018. The LTAs cover the demand of several MICs, including those with ongoing programmes (Albania, Eswatini, Lebanon, Seychelles, the State of Palestine, and Turkmenistan) as well as countries that are planning to introduce PCV. UNICEF has set up contractual frameworks that will provide MICs long term visibility on prices, and improvements in pricing from what they have been offered or have secured through their own bilateral arrangements.

UNICEF expects aggregate long-term (non-AMC) demand for PCV from MICs through UNICEF to grow and reach up to five million doses in 2020, and possibly up to 35 million doses by 2022. However, this would be contingent on PCV introduction in some large countries supported through UNICEF. UNICEF procurement can play an important enabling role for MICs seeking to introduce PCV and other new vaccines. However, even though UNICEF anticipates continued growth in MICs using PCV vaccines, the procurement to meet the needs of MICs may not necessarily come through UNICEF in the long term as countries strengthen their procurement capacity with the support of UNICEF to secure their own LTAs with suppliers at sustainable and affordable prices.

6. Pricing

PCV prices for MICs can be five to ten times higher compared with the AMC’s tail price through UNICEF. The weighted average price (WAP) for MICs procuring through UNICEF (outside of AMC terms and conditions) has been stable from 2013-2019 at approximately USD 14.00 per dose, although pricing per MIC can now vary significantly and range from USD 2.90.
to USD 25.00 per dose depending on a manufacturer's pricing policy. UNICEF continues to work with countries, partners, and suppliers.

UNICEF is working to increase the transparency of prices secured for MICs to help countries make better-informed procurement and programmatic decisions. UNICEF publishes pricing as part of its Influencing Markets strategy and includes prices for PCV. It is part of its 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. See here: Pricing Data

Figure 6 PCV Price Trend per AMC Tenders

Source: UNICEF Supply Division

In December 2016, GSK and Pfizer announced PCV price reductions for Gavi AMC countries. Pfizer’s offered its new PCV13 four-dose vial presentation at USD 3.05 and reduced it at the beginning of 2018 to USD 2.95 per dose, and again to USD 2.90 per dose in 2019. GSK dropped the tail price of their two-dose vials to USD 3.05 per dose in 2016 and offered their new PCV 10 four-dose presentation at the same price in 2018. The 2017-2019 price reductions equated to savings of approximately USD 83 million over the remaining years of their supply agreements with UNICEF. In 2020, the last AMC tender resulted its lowest tail price offered to date, of USD 2.00 per dose from SII, which translates into a 30 per cent reduction in the current WAP for PCV, giving countries the opportunity to save up to 30 per cent of their budget on the procurement of PCV through this offer (Figure 6).

Affordability, especially of newer vaccines, remains an issue for many LICs and MICs. From 2001 to 2014, WHO added six new vaccines to their original Expanded Programme on Immunization (EPI), increasing it from six to twelve. The list of vaccines will vary from one country to another depending on their national immunization programme, which can include 12 other additional vaccines depending on the region. It significantly increased the cost to fully immunize a child from what was less than USD 1.00 in 2001 to reach approximately USD 32.00 or USD 45.60 in 2017, depending on whether HPV vaccine is included. The Access to Medicine Foundation analysed these costs, assessing price evolution, aspects of national immunization programme costs, and the extent of vaccine adoption by LICs and MICs. It found that vaccines against rotavirus and pneumococcal disease made up three quarters of the total cost of vaccinating a child. Some MICs feel that

32 UNICEF, Pricing Data.
34 Ibid.
36 Cost estimates exclude transportation, shipping, handling, cold chain maintenance, training, and administration services, amongst others...
37 AMF, Vaccines Index 2017: How Vaccine Companies are Responding to Calls for Greater Immunisation Coverage, p. 51.
the cost of some vaccines, including PCV, are too high for them to consider to be sufficiently cost-effective to introduce into their country’s national immunization programme schedule.}\(^38\)

### 7. PCV for Humanitarian Emergency Response

Access to PCV for use in humanitarian emergency situations or epidemic outbreaks has also been a challenge for aid agencies trying to prevent increases in vaccine-preventable disease (VPD) morbidity and mortality in affected populations. Humanitarian emergency situations, particularly in LICs and MICs, increase the risk and severity of pneumococcal disease. Previously, demand emerged through ad hoc requests through multiple channels, which increased the risk of duplication by different partners.

UNICEF, MSF, Save the Children, WHO, and partners, established a framework called the Humanitarian Mechanism with vaccine manufacturers to improve access to PCV in emergencies.\(^39\) Manufacturers agreed to provide PCV at their lowest price for use by any country under well-defined circumstances through this mechanism. The vaccine is available to any country regardless of income level or Gavi-eligibility. As part of the mechanism, UNICEF issued a tender in 2016 to establish LTAs specifically to secure PCV supply for international aid agencies and implementing partners as part of a humanitarian response. WHO confirms any request in consultation with MSF, UNICEF, and other recognised partners to ensure that there is no duplication within 24 hours. Successful use of the mechanism in several crises has encouraged UNICEF, WHO, and partners to explore setting up similar mechanisms for additional vaccines for other diseases. Through this mechanism, 380,000 doses of PCV have been delivered to humanitarian populations to date, sufficient to immunize over 100,000 children. The recent WHO prequalification of a new PCV vaccine from SII presents an opportunity to expand the supplier base for humanitarian response.

### 8. Issues and Challenges

- Countries, whether receiving support through Gavi or self-financing, continue to face challenges in securing financing/funding to support their immunization programmes. The affordability of vaccines continues to be a priority for programme sustainability.
- PCV prices for non-AMC eligible MICs are relatively high and can be over five times the tail prices for AMC eligible countries. Affordable pricing is required for countries to introduce PCV into their routine immunization programmes and ensure that they can sustain self-financed PCV procurement.
- The buffer capacity in the market is limited, and it cannot meet any short or medium-term demand surging over 20 per cent, which can potentially arise from new country introductions or scale up in any new states/countries (i.e. China and India).
- Some Gavi-eligible countries experience delays in introducing PCV due to competing priorities between new vaccines, weak health systems, and delays in programmatic readiness.

### 9. Steps Forward

UNICEF will prioritise the following actions to achieve a healthy and sustainable market for all countries:

- UNICEF will continue to monitor demand and supply availability as well as to ensure that all country programmatic and regulatory requirements are met prior to vaccine supply through UNICEF for country introduction or possibly switching vaccine presentations during 2020-2021.
- Together with Gavi, UNICEF will continue to work closely to secure additional doses on contract to bridge uncontracted supply for the years spanning 2024 to 2030.
- UNICEF will collaborate with countries, partners, and suppliers to improve access to affordable PCV supply for MICs, and to increase the price transparency of doses secured for MICs. To this end, UNICEF will seek greater clarity on MICs requirements to provide industry with better visibility and predictability of any changes and trends in demand.
- Where there is a desire to channel demand through UNICEF, UNICEF will seek to quantify MIC demand and address associated deficiencies by engaging with self-financing MICs to consolidate credible multi-year PCV demand and encourage countries to submit multi-year commitments through UNICEF.

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UNICEF will continue to monitor new product developments and track the future availability of additional products and manufacturers in support of expanding and diversifying PCV’s supply base.

In 2021, UNICEF will issue its first non-AMC tender to secure supply for additional demand and the uncontracted doses from 2024 onwards.

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