

# **Pneumococcal Conjugate Vaccine: Supply & Demand Update**

**UNICEF Supply Division**

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## Pneumococcal Conjugate Vaccine: Supply & Demand Update August 2016

**This update provides new information on countries, scheduled pneumococcal conjugate vaccine (PCV) introductions, and supply availability. PCV supply availability through UNICEF remained stable during 2015, and is no longer constrained on account of increased production capacity. UNICEF will continue to assess the needs for future**

**A more recent note covering PCV exists. Please visit [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html)**

### 1. Summary

- During 2014 through end-July 2016, nineteen countries, supported by Gavi, the Vaccine Alliance (Gavi) introduced PCV into their national immunization programmes. Fifty-seven countries have now introduced PCV since 2010, of which three countries have transitioned from Gavi support as of 2016, and self-finance their vaccine procurement with access to favourable pricing terms established through the Advance Market Commitment (AMC). UNICEF anticipates another one other Gavi approved country to introduce PCV during 2016-2017.
- PCV demand from countries eligible to access prices and quantities under the AMC continues to increase. In 2014 and 2015, UNICEF procured a total of 100 and 133 million doses respectively. There are fifteen remaining countries eligible to apply to Gavi for access to financing and/or AMC prices.
- The lowest AMC price per dose is currently between US\$ 3.30 to US\$ 3.50, depending on the product. The price per dose for non-Gavi middle-income countries (MICs) that procure PCV through UNICEF can range from US\$ 7.00 to US\$ 26.87 per dose. UNICEF will continue to improve the transparency of prices secured for all countries including for MICs.
- Of the two PCV vaccines currently available through UNICEF, the ten-valent vaccine (PCV10) supply availability, previously reported by UNICEF to be constrained, is now sufficient to meet demand due to increased production capacity.
- Countries access PCV in response to humanitarian emergencies through ad-hoc demand negotiated through UNICEF with suppliers.
- At the beginning of 2016, UNICEF and Gavi conducted a review of the PCV strategic demand forecasts (SDF),<sup>1</sup> as well as current levels of existing contracted supply arrangements. UNICEF and Gavi concluded that there was no imminent need to issue a Call for Supply Offers and establish new supply arrangements. UNICEF and Gavi will re-assess the needs later in 2016, based on an updated forecast and outcomes from the next round of applications from countries applying for Gavi support.
- UNICEF will continue to work with countries, partners and suppliers to improve access to affordable vaccine supply for MICs that wish to procure PCV through UNICEF and will launch a new tender for this in early 2017.

### 2. Background

UNICEF's previous PCV [Supply and Demand Updates](#) provide general market background and describe actions taken by UNICEF and partners to mitigate supply constraints. During 2014 and 2015, UNICEF procured 100 million doses and 133 million doses of PCV respectively. Constrained supply

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<sup>1</sup> SDF v11.0 and SDF v12.0.

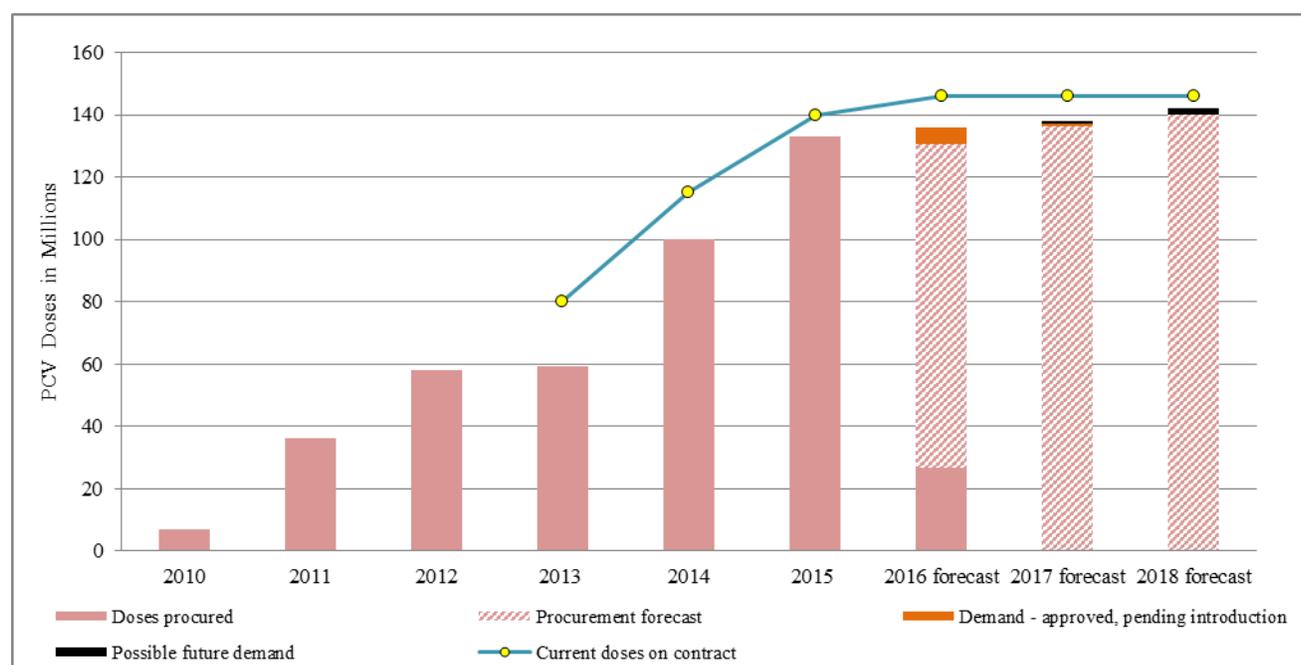
availability of one product, PCV10, suppressed some demand in 2014 and 2015. In addition, delays in cold chain readiness, country capacity to absorb new vaccine introductions, vaccine registration requirements, competing priorities between new vaccines, programmatic readiness and other factors, contributed to some country introduction postponements for both PCV products.

### 3. Current Market Situation

#### 3.1. Gavi Demand and Forecast

UNICEF anticipates PCV country demand during 2016 to reach 136 million doses (Figure 1). However, additional demand from India may increase total forecasted demand, subject to the outcome of discussions between Gavi and the Government of India (GOI), as well as discussions within the GOI to determine the phasing of introduction and product selection.

Figure 1 PCV Demand and Forecasted Procurement, 2010-2018



Source: UNICEF Supply Division.

As of end-April 2016, Gavi has approved support for PCV introduction and rollout for 58 countries with a combined surviving infant population of approximately 43 million children. To date, 57 countries have introduced PCV into their national immunization programmes, of which three (the Congo, Honduras and Mongolia) have transitioned or are transitioning from Gavi support, and will self-fund their vaccine procurement. Eight countries (Bangladesh, Cambodia, Eritrea, Guinea-Bissau, Lesotho, Nepal, Solomon Islands and Uzbekistan) introduced PCV in 2015 and three countries (Kyrgyzstan, Mongolia and Myanmar) introduced in 1Q and 2Q 2016 (Table 1). One additional country is approved for Gavi support and pending PCV introduction during 2016-2017 (Haiti).

Fifteen further countries remain eligible to apply for PCV under AMC terms and conditions. Seven of these countries are no longer eligible to receive Gavi support. These seven countries can apply to Gavi to introduce PCV through the AMC, provided they procure through UNICEF and self-finance the

vaccine purchases at a price that is equivalent to the ‘tail price’ under the AMC.<sup>2</sup> Countries may submit applications for PCV during Gavi’s 2016 application windows. The next window closes in September.

**Table 1 Status of Country Introductions, Approvals and Future Potential Applications**

2009	2010	2011	2012	2013	2014	2015	2016	2017	Others
Gambia	Nicaragua	Benin	Congo*	Afghanistan	Armenia	Bangladesh	Kyrgyzstan	Haiti	Bhutan*
Rwanda		Burundi	Djibouti	Angola	Bolivia	Cambodia	Mongolia*		Chad
		Cameroon	Ghana	Azerbaijan	Cote d'Ivoire	Eritrea	Myanmar		Comoros
		CAR	Madagascar	Burkina Faso	Georgia	Guinea-Bissau			Cuba*
		Congo, DR	Pakistan	Kiribati	Liberia	Lesotho			Guinea
		Ethiopia	Sao Tome & Principe	Lao PDR	Niger	Nepal			India
		Guyana	Zimbabwe	Mauritania	Nigeria	Solomon Islands			Indonesia*
		Honduras*		Moldova	Togo	Uzbekistan			Korea, DPR
		Kenya		Mozambique					Somalia
		Malawi		Papua New Guinea					South Sudan
		Mali		Senegal					Sri Lanka*
		Sierra Leone		Sudan					Tajikistan
		Yemen		Tanzania					Timor-Leste*
				Uganda					Ukraine*
				Zambia					Viet Nam*

	Approved and Introduced
	Approved pending introduction
	Recommended for approval
	Countries not applied

Source: UNICEF Supply Division based on Gavi’s SDF v12.0.

Source: UNICEF Supply Division (based on Gavi’s SDF v12.0).

**Note\*:** Countries no longer eligible to receive Gavi support for PCV. Eligible for AMC prices only.

UNICEF issued the last Call for Supply Offers in August 2012, which concluded with the issuance of supply agreements in July 2013. Having assessed in 2015 expected levels demand, supply and utilization of existing supply contracts, UNICEF and Gavi agreed not to issue a Call for Supply Offers at this time, as current contracted quantities are sufficient to meet anticipated demand. UNICEF and Gavi agreed to re-assess the situation later in 2016, based on information from the next SDF, as well as the outcomes of the next round of applications for Gavi’s New Vaccines Support for PCV.

### 3.2. Gavi Supply

UNICEF has six long-term supply arrangements with two manufacturers that enable the procurement and supply of 1.46 billion doses of PCV under the AMC over a period from 2010 through 2023/2024 (Table 2, Figure 2).

**Table 2 UNICEF PCV Quantities Awarded to date, for period 2010-2024**

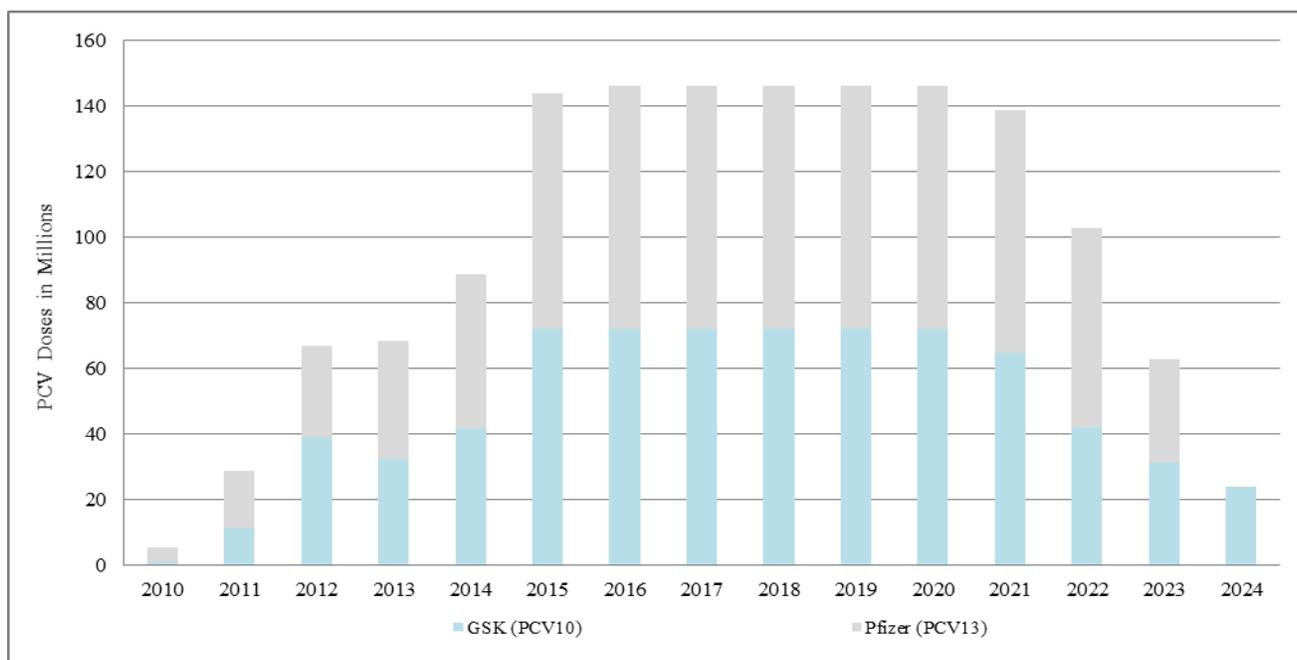
Company	Vaccine	Duration	Start	End	Present.	Doses	Courses
GlaxoSmithKline (Belgium)	PCV10	3 agreements covering 15 years	2010	2024	2 ds	720,000,000	240,000,000
Pfizer (United States of America)	PCV13	3 agreements covering 14 years	2010	2023	1 ds	740,000,000	246,000,000
<b>Total</b>						<b>1,460,000,000</b>	

Source: UNICEF Supply Division.

<sup>2</sup> 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](#).

Throughout 2014 and 2015, manufacturers signalled increasing availability of PCV supply to meet most existing and new country demand. During 2014 and 2015, UNICEF procured 100 million and 133 million doses respectively under the AMC for Gavi supported countries (Figure 1). Nigeria is the only country currently introducing PCV through a phased approach. Nigeria completed phase one and two in 2014 and 2015 respectively. In 2015, PCV production capacity and supply availability was confirmed sufficient to meet the demand for the national roll-out in Nigeria during 2016, one year ahead of schedule. Additional doses became available due to the introduction delays in some other large countries (i.e. Bangladesh), as well as stock adjustments. However, the additional demand from India, subject to the outcome of discussions between Gavi and the GOI, will require incremental supply above that currently awarded per year.

**Figure 2 UNICEF PCV Awards to date for period 2010-2024**



Source: UNICEF Supply Division.

Of the 58 countries approved to introduce PCV, thirteen countries introduced PCV10, and one anticipates introduction of this vaccine in 2016. Forty-two countries introduced the 13-valent vaccine (PCV13), and two countries anticipate introduction in 2016-17. In 2015, two countries requested to switch from PCV10 to PCV13 (Armenia and Azerbaijan). Gavi reviewed and approved the requests and both countries will switch PCV product during 2016.

Although UNICEF supplies PCV10 to fewer countries than PCV13, the two products account for an approximately equal share of 2014 and 2015 supply, as measured in doses. From 2016, estimated supply of PCV10 and PCV13 account for approximately 72 million and 74 million doses respectively.

UNICEF and partners do not anticipate any new manufacturers to enter the market with WHO prequalified PCV prior to 2018. However, the two incumbent manufacturers, GlaxoSmithKline (GSK) and Pfizer, are currently developing four-dose vial presentations of PCV10 and PCV13 respectively. The European Medicines Agency (EMA) recently approved Pfizer’s four-dose vial in April 2016.<sup>3</sup>

<sup>3</sup> Curry, David, [Pfizer Receives European Approval for New Multi-Dose Vial Presentation of Prevenar 13](#), The Center for Vaccine Ethics and Policy, 10 April 2016.

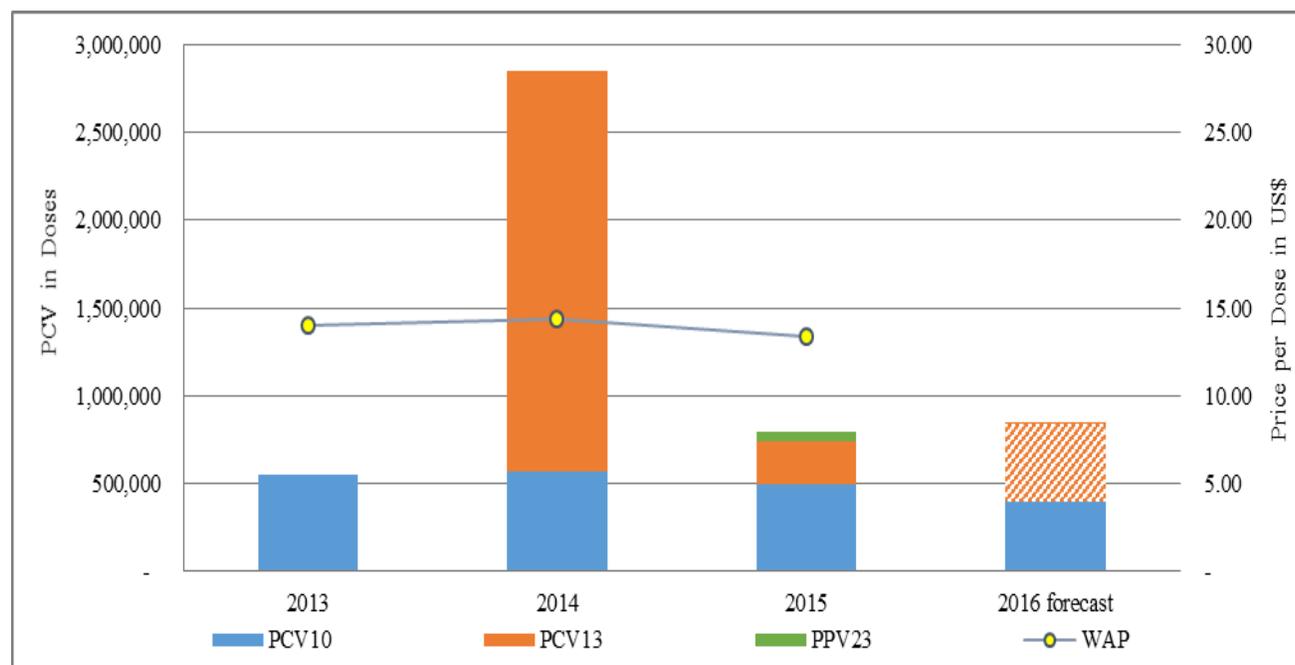
UNICEF anticipates the availability of the new PCV10 and PCV13 presentations during 2017 and 2018 respectively. Country product preference, particularly for new presentations, remains uncertain and could have an impact on demand forecasts. Any new introductions will require early planning, assessment of country interest, and a decision by Gavi to include new presentations in their product menu.

### 3.3. Middle-Income Countries (Non-Gavi Countries) PCV Vaccine Demand

Looking beyond the Gavi-supported market segment, PCV demand through UNICEF from non-Gavi self-financing MICs increased from approximately 550,000 doses in 2013 and could reach approximately 840,000 doses in 2016. Whereas non-Gavi MIC demand for PCV10 through UNICEF has been relatively stable and averaged approximately 500,000 doses a year, demand for PCV13 has been subject to more ad hoc requests or exceptional procurement on behalf of MICs: e.g. in 2014, UNICEF procured 2.3 million doses on behalf of the Philippines, of which some supply was delivered during 2015 (Figure 3). Some non-Gavi MICs have indicated an interest in, and have procured, polysaccharide vaccines for their routine immunization programs.<sup>4</sup>

Since 2013, UNICEF has procured PCV on behalf of six MICs (Albania, Armenia, Lebanon, Mauritius, the Philippines and State of Palestine), of which two countries (the Philippines and State of Palestine) account for 82% of all procurement volume, with Albania, the Philippines, and State of Palestine regularly procuring PCV through UNICEF.

Figure 3 UNICEF PCV Procurement Volumes and WAPs for Non-Gavi MICs 2013-2016



Source: UNICEF Supply Division.

<sup>4</sup> Pneumococcal polysaccharide vaccine (PPV23) is a pneumococcal vaccine that protects against 23 types of pneumococcal bacteria. It is included to show completeness of data on pneumococcal vaccine procurement, which is primarily for conjugate vaccines. WHO recommends high- and middle-income countries choosing PPV23 to target populations demonstrated to be at increased risk of morbidity and mortality from pneumococcal infection, including adults aged >65 years.

The aggregate longer-term demand for PCV through UNICEF from the non-Gavi MIC segment remains uncertain. Most non-Gavi MICs tend to confirm their demand through UNICEF annually, rather than making multi-year commitments.

UNICEF procurement can play an important enabling role for MICs seeking to introduce new vaccines such as PCV, even if these countries decide to self-procure their quantities in subsequent years after successful introduction. Thus, even though UNICEF anticipates the use of PCV vaccines by MICs to continue and increase, procurement to meet these countries' growing needs may not come through UNICEF in the longer-term. However, during 2016, UNICEF will:

- Make challenges transparent:
  - Publish previous PCV prices secured for MICs by UNICEF during 2016.
- Quantify demand and address associated deficiencies:
  - In collaboration with partners, and particularly through the WHO-led MICs Taskforce, identify issues and bottlenecks that limit self-financing MICs new vaccine procurement (through UNICEF or otherwise) and explore the avenues to resolve them.
  - Engage with self-financing MICs during remainder of 2016 to consolidate credible demand for PCV where there is a desire to channel such demand through UNICEF.
  - Generate a new PCV demand forecast for MICs based on above.
- Secure tangible commitment from countries:
  - Identify MIC participation in UNICEF PCV procurement activities.
  - Secure firm country buy-in for a concerted procurement efforts to improve access to and affordability of PCV for self-financing MICs.
- MIC PCV procurement strategy developed:
  - Seek input from MICs on the PCV procurement strategy design and finalize this by end-2016.
- Implement a MICs PCV procurement tender during early 2017.

#### **4. Pricing**

An AMC tail price of US\$ 3.50 applies to PCV10, reached under agreements prior to 2013. A tail price of US\$ 3.40 applied to doses contracted in 2013 for 2014 supply onwards. In March 2016, GSK announced a further reduction in PCV10's price per dose to US\$ 3.05, from 2017. It represents a 10 percent price reduction and equates to a saving of approximately US\$ 1.00 per child for a full vaccination course. For PCV13, a reduced AMC tail price of US\$ 3.40 applied from mid-2013 and decreased to US\$ 3.30 from 2014 for all doses under agreement. Pfizer further committed to a price of US\$ 3.10 per dose for their four-dose vial when available.

PCV prices for non-AMC eligible MICs are high, compared with AMC tail prices. The WAP for non-AMC eligible MICs procuring through UNICEF from 2013-2015 has been stable at approximately US\$ 14.00, although pricing for individual MICs procuring PCV through UNICEF varies significantly (ranging from US\$ 7.00 to US\$ 26.87 per dose) depending on manufacturers' differential pricing policies. UNICEF continues to work with countries, partners and suppliers in order to explore ways to improve access to affordable and timely supply of PCV for MICs that self-finance their purchases. In addition, UNICEF is working to increase the transparency of prices secured for MICs in order to help countries make better-informed procurement, and programmatic decisions.

#### **5. Access to PCV through UNICEF for Humanitarian Emergency Response**

Outside of routine immunization programmes, in humanitarian emergencies and particularly those affecting low and middle-income countries, many factors exacerbate the risk and severity of

pneumococcal disease. Indeed, WHO assigns a high relevance to the majority of risk factors usually present in most humanitarian emergencies in relation to pneumococcal disease (Table 3). UNICEF and partners are therefore working to access PCV to help prevent pneumococcal disease in populations affected by humanitarian emergencies.

Currently, access to PCV through UNICEF to respond to humanitarian emergencies is secured on an ad-hoc basis involving discussions with country governments affected by the emergencies, and negotiations between UNICEF and suppliers. In view of the often-pressing needs facing children in these settings, UNICEF and other partners have accepted shorter-term solutions (e.g. vaccine donations) to access vaccine supply on a case-by-case basis. It is recognized that these are not sustainable solutions for future emergency response efforts, nor do they provide long-term certainty (e.g. to address the needs of populations affected by protracted crises). Therefore, UNICEF continues to work with suppliers and partners to find more sustainable arrangements to access supply of PCV at affordable prices for all countries, and all situations including humanitarian emergencies.

**Table 3 Pneumococcal Disease Risk Factor Levels Present in Humanitarian Emergencies**

	<b>High prevalence of malnutrition</b>	<b>Young population and/or high birth rate</b>	<b>High HIV/AIDS burden</b>	<b>Low access to curative health services</b>	<b>High prevalence of chronic diseases</b>	<b>Over-crowding</b>	<b>Insufficient water, sanitation and hygiene</b>
Pneumococcal disease	High	High	High	High	High	High	Low

Source: WHO.

## **6. Issues and Challenges**

- PCV introductions in some countries were delayed on account of challenges related to cold chain capacity, vaccine licensing requirements, funding availability at different national levels, competing priorities in new vaccine introduction, programmatic readiness, as well as other factors.
- Some Gavi countries have faced challenges in paying their co-financing obligations, notably those countries that are transitioning or have recently transitioned from Gavi support.
- PCV prices for non-AMC eligible MICs are relatively high depending on the country, product, and manufacturers’ pricing policies, compared with the AMC tail prices offered to AMC eligible countries. Affordable pricing is required for countries to introduce PCV into their routine immunization programs to ensure they sustain self-financed PCV procurement.
- PCV forecast demand for MICs has been uncertain, particularly for PCV13. In absence of a clear demand forecast, and procurement based on ad hoc requests, UNICEF is limited in communicating a more secure demand outlook to manufacturers, or negotiating lower prices for MICs. A more accurate MIC country demand forecast would facilitate supply availability and could influence improved pricing.
- Country product preference and demand for the four-dose presentations anticipated to be available during the course of 2017-2018 is uncertain and could have an impact on demand forecasts.
- Increased demand from new introductions, including India, against current awards per year, could risk the balance between supply and demand.
- Access to PCV at discount prices remains a challenge for non-AMC countries and NGOs in response to humanitarian emergencies.

## 7. Steps Forward

- UNICEF and Gavi agreed at this stage not to issue a Call for Supply Offers based on the 2015 SDFs and the applicable regulations of the AMC. A re-assessment of the situation, with information from the next SDF and outcomes of the next rounds of applications for New Vaccines Support for PCV to Gavi, will take place again later in 2016.
- UNICEF will work with countries and manufacturers to monitor demand and supply availability, as well as to ensure that all country programmatic and regulatory requirements are met prior to vaccine introduction and product switches, during 2016-2017.
- UNICEF and Gavi will assess country product preferences and the interest for new four-dose vial presentations. They will work closely to manage demand forecast and any product share preferences that could lead to supply constraints.
- UNICEF and Gavi will continue to work closely to monitor and manage the balance between PCV supply and demand, as demand increases from new applications, including India, could lead to supply constraints, subject to choice of product preference and product presentation.
- UNICEF will continue to work with countries, partners and suppliers to improve access to affordable vaccine supply for MICs that self-finance PCV purchases, and to increase the transparency of prices secured for MICs. To this end, UNICEF will seek greater clarity on MIC requirements to provide industry with better visibility and predictability of the evolution of demand, as well as securing MICs participation in a PCV tender for MICs, with the intention of implementing the new approach in early 2017.
- UNICEF will continue to seek sustainable commercial arrangements with manufacturers to access PCV supply at affordable prices in response to humanitarian emergencies.
- UNICEF will continue to monitor the development of new products and track the future availability of additional products and manufacturers in support of creating a more robust supply base for PCV.
- UNICEF will meet with manufacturers during its annual Vaccine Industry Consultation in 2016 and discuss forecasted demand for 2017 as well as any changes required to meet anticipated product preferences, demand quantities, bulk availability, and monthly production capacity.

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