

# **Pneumococcal Conjugate Vaccine: Current Supply & Demand Outlook**

**UNICEF Supply Division**

**Update: October 2013**

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## Pneumococcal Conjugate Vaccine (PCV) Supply & Demand Outlook October 2013 – Update

**Key updates on PCV: New information on countries and their scheduled PCV introductions; new awards for contracted supply of vaccine following the conclusion of the 2012 tender; new information on country demand forecasts.**

**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. Key Highlights and Update Summary

- During 2013 year-to-date, eight countries have introduced PCV into their national immunization programmes with the support of the GAVI Alliance, bringing the total to 32.
- However, the continued high demand for PCV from countries eligible to access prices and quantities under the Advance Market Commitment (AMC) has exceeded available supply. Two countries postponed introduction from 2013 to 2014 due to supply availability and two additional countries chose to delay their 2013 introductions to 2014 to allow sufficient time for introduction preparations following the mid 2013 confirmation of available PCV supply.
- The 2012 tender concluded in July 2013 with an increased award of 3 million doses in 2013, 19 million doses in 2014, and 44 million doses in 2015. An additional 50 million doses will be supplied annually from 2016.
- A reduced AMC tail price of \$3.40 for PCV10 was agreed to apply from 2014 onwards for doses under the new agreement and a price of \$3.50 applying to all previously agreed volumes. For PCV13, the price decreased from \$3.50 applicable during the first half of 2013 to \$3.40 during the second half of 2013 and a reduced tail price of \$3.30 from 2014 for all doses under agreement.
- Anticipated vaccine deliveries for 2013 have decreased from 77 million doses to 74 million, as a result of technical difficulties in scaling up the manufacturing of PCV10.

### 2. Current Market Situation

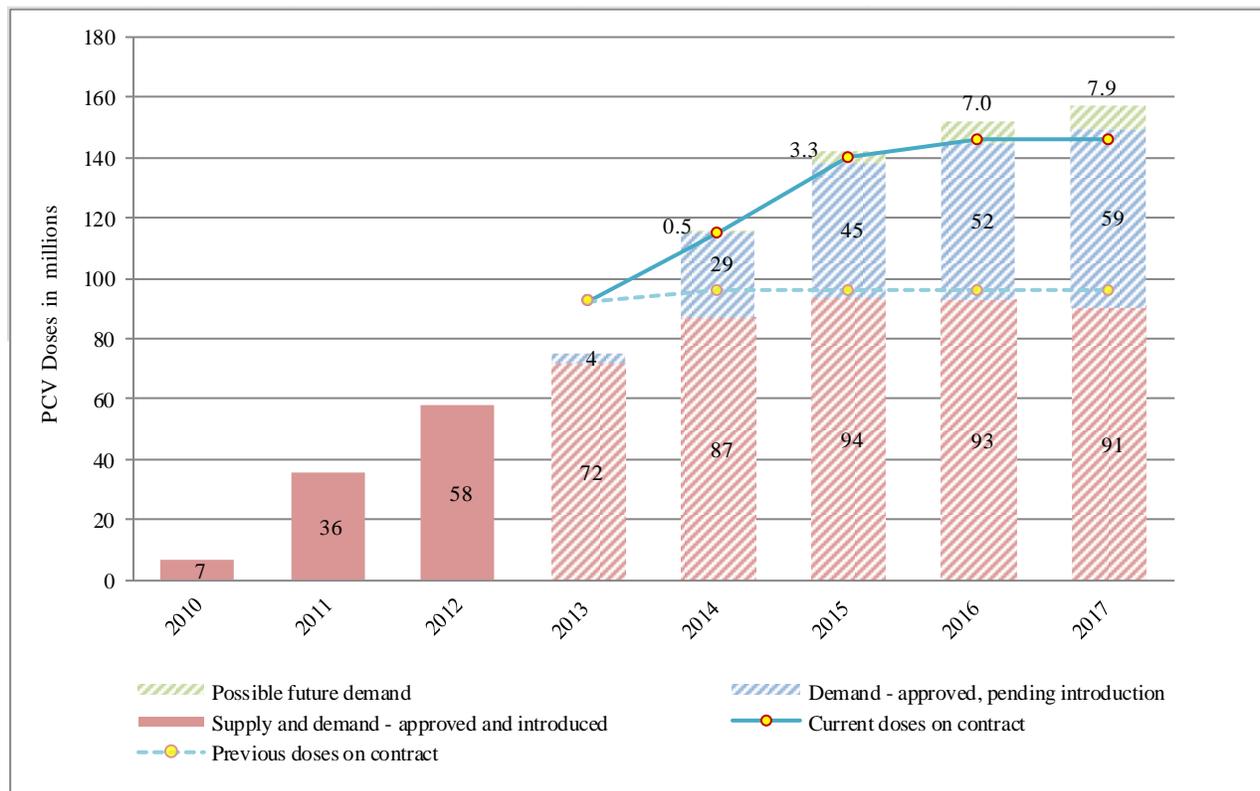
#### 2.1. Demand

73 countries, with a combined surviving infant population of 75 million children, have access to PCV supported by the GAVI Alliance and the [AMC](#). Of these, 67 countries have access to financial support through GAVI to accelerate the uptake of PCV into their national immunization programmes.<sup>1</sup> However, 10 of these countries are graduating from GAVI support and will therefore need to fully fund their vaccine costs over the coming years.

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<sup>1</sup> The 67 countries are made up of the current 57 GAVI-eligible countries in addition to 10 GAVI-graduating countries which had previously applied and were approved for support. These countries retain eligibility for some GAVI-financing subjected to a finite time period.

Figure 1 PCV Supply and Demand Projection<sup>2</sup>



Source: UNICEF Supply Division.

As of March 2013, GAVI had approved 51 countries for introduction. As of October 2013, 32 have introduced PCV into their national immunization programmes, and 19 are approved to introduce in 2013 and beyond. An additional 6 countries are projected to introduce PCV by 2015 at the latest, which would bring the total to 57 countries. These countries have a combined surviving infant population of 40 million children.<sup>3</sup> These projections do not take into consideration financial or supply constraints. In the GAVI application round that closed in September 2013, a total of 7 countries submitted applications for support for introduction of PCV, including one graduating country that applied for access to PCV under the terms and conditions of the AMC.

The allocation of limited PCV supply to introducing countries is based upon expected impact, as a function of disease burden and coverage. In addition, the status of a country's readiness continues to determine the timing of provision of supply and the introduction of PCV. At present, two of the 10 countries approved and currently planning introduction in 2014, had been previously required to postpone introduction (originally planned during 2013) due to the availability of supply.

<sup>2</sup> Source: GAVI financial projections for approved countries 2013-2017; possible future demand sourced from GAVI Strategic Demand Forecast v8.0. Data includes phased introduction in Nigeria.

<sup>3</sup> UNICEF/WHO, *Immunization Summary - 2013 edition*, UNICEF/WHO, November 2012 at <http://www.unicef.org/videoaudio/PDFs/EN-ImmSumm-2013.pdf>.

UNICEF anticipates the procurement of 74 million doses during 2013. A reduced AMC tail price of \$3.40 for PCV10 was agreed to apply from 2014 onwards for doses under the new agreement and a price of \$3.50 applying to all previously agreed volumes. For PCV13, the price decreased from \$3.50 to \$3.40 during the second half of 2013 and a reduced tail price of \$3.30 from 2014 was agreed for all doses under agreement.<sup>4</sup> Some doses on contract for 2013 will be delivered in 2014 to meet country demand and ensure sustainable introductions.

**Figure 2 Status of Country Introductions, Approvals and Future Potential Applications**

2009	2010	2011	2012	2013 - onwards		Not approved
Gambia	Nicaragua	Benin	Congo, Rep.	Angola	Afghanistan	Bhutan
Rwanda		Burundi	Djibouti	Kiribati	Armenia	Cambodia
		Cameroon	Ghana	Lao PDR	Azerbaijan	Chad
		CAR	Madagascar	Moldova	Bangladesh	Comoros
		Congo DR	Pakistan	Mozambique	Bolivia	Cuba
		Ethiopia	Sao Tome & Principe	Sudan	Burkina Faso	Eritrea
		Guyana	Tanzania	Uganda	Cote d' Ivoire	Guinea
		Honduras	Zimbabwe	Zambia	Georgia	India
		Kenya			Guinea-Bissau	Indonesia
		Malawi			Haiti	Korea, Dem. Rep.
		Mali			Lesotho	Kyrgyzstan
		Sierra Leone			Liberia	Mongolia
		Yemen			Mauritania	Myanmar
					Nepal	Solomon Islands
				Niger	Somalia	
				Nigeria	South Sudan	
				Papua New Guinea	Sri Lanka	
				Senegal	Tajikistan	
				Togo	Timor-Leste	
					Ukraine	
					Uzbekistan	
					Vietnam	

	Approved and Introduced
	Approved pending introduction
	Countries not approved

Source: UNICEF Supply Division based on GAVI's Strategic Demand Forecast (SDF) v8.0.

All other currently approved countries are, or will be, receiving vaccine delivery in accordance with their planned introductions. The tender process, launched in August 2012, concluded in July 2013 with two new supply agreements of 24 and 26 million doses of PCV10 and PCV13, respectively, to be supplied annually. Additional short term supply was secured to meet the demand of all currently approved countries, although with some delay for two countries. Incremental supply will be built

<sup>4</sup> The price of \$3.40 is only accessible under the new contract, for which supplies start in 2014 for PCV10. For PCV13, UNICEF has paid \$3.50 up to July 2013, after which UNICEF will pay \$3.40. Only in 2014 does the price of \$3.30 become available.

over a four-year period to reach 50 million doses annually by 2016, and is incremental to the 96 million doses already on contract.

Figure 3 Approved Countries, Birth Cohort and Confirmed Introduction in Q4 2013 and Q1-Q3 2014<sup>5</sup>

2013		2014					
Q4		Q1		Q2		Q3	
<b>PCV10</b>							
Azerbaijan	177,000	Armenia	46,000				
		Georgia	49,000				
<b>Surviving infants</b>	<b>177,000</b>	<b>Surviving infants</b>	<b>95,000</b>	<b>Surviving infants</b>	<b>-</b>	<b>Surviving infants</b>	<b>-</b>
<b>PCV13</b>							
Q4		Q1		Q2		Q3	
Afghanistan	1,227,000	Cote d'Ivoire	630,000	Lesotho	56,000	Guinea Bissau	52,000
Bolivia	253,000	Haiti	250,000			Nepal	698,000
Burkina Faso	676,000	Togo	181,000				
Lao PDR	135,000						
Liberia	144,000						
Mauritania	109,000						
Moldova	43,000						
Niger	708,000						
Papua New Guinea	199,000						
Senegal	447,000						
<b>Surviving infants</b>	<b>3,941,000</b>	<b>Surviving infants</b>	<b>1,061,000</b>	<b>Surviving infants</b>	<b>56,000</b>	<b>Surviving infants</b>	<b>750,000</b>

Source: UNICEF Supply Division based on GAVI SDF v8.0

## 2.2. Supplier Base

Two manufacturers have WHO prequalified vaccines that meet the AMC's [Target Product Profile](#) (TPP). No new manufacturers are expected to receive WHO prequalification and meet AMC's TPP requirements before 2016.

- Pfizer has supplied PCV through UNICEF since 2009, initially through a donation of its 7-valent vaccine. Pfizer was contracted to supply 30 million doses of the 13-valent vaccine annually under the AMC facility in 2010 to start from 2013 to 2021. A second contract was awarded to procure 18 million doses annually from 2014, and a third recent contract was awarded for 26

<sup>5</sup> These countries' collective birth cohort of 5.9 million children requires 3 doses of PCV. The timing of country introductions can be subject to change and will be updated regularly in subsequent notes.

million doses annually from 2016. A total of 74 million annual doses will now be under contract by 2016. Pfizer supplies PCV in a 1-dose vial presentation.

- GSK has also been supplying PCV under the AMC facility since 2010 and was contracted to supply 30 million doses a year from 2012. A second contract was awarded for 18 million doses from 2014 and in a third recent contract, GSK was contracted to supply an additional 24 million doses a year to reach a total of 72 million annual doses by 2015. GSK supplies PCV without preservative in a 2-dose vial.

Since the launch of the AMC in 2009, UNICEF has contracted manufacturers to supply up to 1.460 billion doses of PCV by 2024. UNICEF's most recent tender concluded with an award of 50 million additional annual doses of PCV to increase annual supply to a maximum of 146 million doses by 2016. The recent awards account for 73% of the annual 200 million dose supply target for the AMC.

The GAVI Strategic Demand Forecast v.5 for 2017 projected a maximum quantity to be awarded of 156 million doses. However, UNICEF only awarded the maximum quantities required to meet current approved demand. 10 million doses of projected demand were retained in order to maintain incentives for new manufacturers to accelerate the development of PCV vaccines to ensure a healthy market with multiple suppliers with access to lower prices through future offers.

### **3. Issues / Challenges**

- Two countries are required to postpone their introduction from 2013 to 2014, and two additional countries chose to delay their 2013 introductions to 2014 to allow sufficient time for introduction preparations following the mid-2013 confirmation of available PCV supply. The anticipated delivery of PCV during 2013 has been reduced from 77 million to 74 million doses as a result of country introduction timing and some technical difficulties experienced in scaling-up PCV10 production.
- As of Q4 2014, supply will be available for all currently approved countries. From 2014 onwards, the scale-up and level of supply will be sufficient to fully meet the product-specific requirements of all countries approved for PCV. Demand is reviewed on an annual basis and additional supply is available for new awards as required from 2015/2016.
- Some countries that introduce PCV have undertaken catch-up activities by providing PCV to all children under one year of age, even though the quantities approved and supplied are based on annual surviving infant data. The implementation of catch-up activities may result in the exhaustion of country stocks. So far, UNICEF has assisted countries to meet demand by combining and bringing forward deliveries to countries introducing PCV, thereby preventing potential stock-outs at the national level.

### **4. Steps Forward**

- The outcome of the 2012 tender was concluded with the award of 50 million additional annual doses by 2016, securing 42 million additional doses from 2013-2015, as well as reduced pricing.
- The deadline to submit applications to GAVI for support for new vaccines closed on the 15 September 2013 with 7 countries submitting applications for PCV.
- UNICEF and GAVI will consult and decide if a new tender should be issued based on the applications received, as well as GAVI's Strategic Demand Forecast version 8, which projects an annual requirement by 2018 of 154 million doses.

- The GAVI Alliance continues to closely monitor the development of demand, as well as a country's readiness to introduce, introduction progress and the on-going expansion efforts in large countries. UNICEF and GAVI will continue their close collaboration with current suppliers in order to optimise the balance of supply and demand.
- UNICEF will continue to monitor the development of new products and to track the future availability of alternative products and manufacturers in support of creating a healthy market for PCV.
- UNICEF intends to regularly update the information presented in this note.

For further questions or additional information, please contact:

Meredith Shirey  
Chief, Vaccine Centre  
UNICEF Supply Division  
+45 3527 3033  
[mshirey@unicef.org](mailto:mshirey@unicef.org)

Ann Ottosen  
Contracts Manager  
UNICEF Supply Division  
+45 3527 3124  
[aottosen@unicef.org](mailto:aottosen@unicef.org)

Aadrian Sullivan  
Information Management  
UNICEF Supply Division  
+45 3527 3048  
[asullivan@unicef.org](mailto:asullivan@unicef.org)

Information notes can be found: [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html).