

Pneumococcal Conjugate Vaccine: Supply & Demand Update

UNICEF Supply Division

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Pneumococcal Conjugate Vaccine (PCV): Supply & Demand Update July 2014

This update provides new information on countries and scheduled PCV introductions; supply constraints; and the need for more accurate demand forecasting.

1. Summary

- During 2013, 14 GAVI-supported countries introduced PCV into their national immunization programmes with a combined surviving infant population of ~7.8 million children. During 2014 year-to-date (June), 2 additional countries have introduced PCV, bringing the total to 40 country introductions since 2010.
- 17 other countries have been approved for GAVI support and plan PCV introduction during 2014-16, and one country is recommended for approval, pending clarifications. 15 countries remain eligible to apply to GAVI for PCV introduction. 6 of them are graduating or have graduated from GAVI support, but under Advance Market Commitment (AMC), can access AMC prices but must self-fund their vaccine purchases.
- PCV demand from countries eligible to access prices and quantities under the AMC continues to increase. In 2013, UNICEF procured a total of 59 million doses, in addition to a carry-over of 19 million doses from 2012. Of this, 68.7 million doses were supplied to countries in 2013 and 10 million doses were delivered in 1Q 2014.
- Whereas PCV13 supply availability can meet its respective country requirements, PCV10 supply availability continues to be constrained in 2014 due to delayed scale-up of production capacity. This resulted in moderate reduction in doses available in 2014, which were reduced across selected countries while avoiding disruption to existing programmes. This moderate reduction of demand was noted in the previous October update.
- Some countries have also rescheduled PCV introduction from 4Q 2013, 1Q and 2Q 2014 to 2Q and 3Q 2014 as a result of delays in programmatic readiness and in-country vaccine licensing.
- A review of the strategic demand forecast (SDF) historic results identified a tendency for the methodology used to underestimate country demand compared to quantities shipped. Some methodological changes have been implemented in SDF v9.0 and an in-depth review of vaccine requirements for 2015 and beyond is scheduled for 2H 2014 against 2014 country applications for new vaccine support and SDF v9.0 projections.
- UNICEF and GAVI have agreed not to issue a new tender during 1H 2014 based on SDF v8.0 projected demand. The need for a new tender will be re-assessed upon conclusion of the SDF v10.0 projections for 2015 and beyond.

2. General Brief and Background

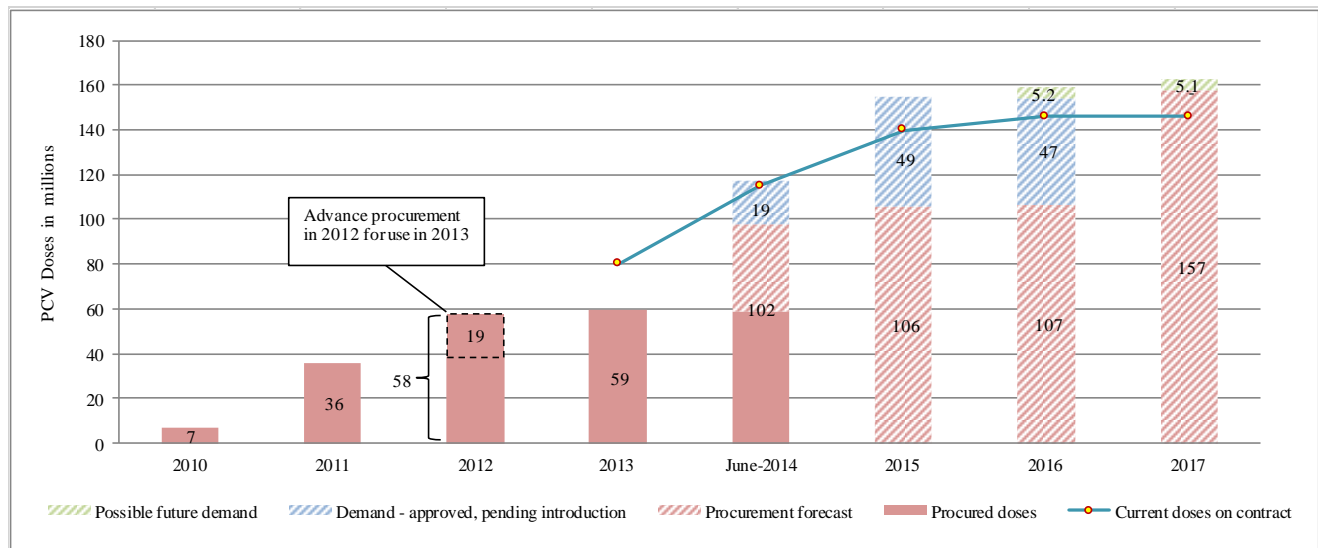
UNICEF's previous PCV Supply and Demand Updates ([October 2013](#) and [February 2013](#)) provide general market background and describe actions taken by UNICEF and partners to mitigate supply constraints. UNICEF procured 59.3 million doses in 2013 in addition to 19.4 million doses of PCV (11.4 million doses PCV10 and 8 million PCV13) carried over from end-2012 for use in 2013, ensuring maximised utilisation of available manufacturer capacity. While supply availability has suppressed some demand, country introduction postponements have also been caused by delays in cold chain

readiness, country capacity to absorb a new vaccine introduction, vaccine registration and other factors. During 2013, deliveries of 5.1 million doses for country introductions were rescheduled to 2014 and beginning 2015 on account of supply availability and 0.8 million doses were rescheduled on account of delayed vaccine licensing in selected countries where local registration is required. More details are available below.

3. Current Market Situation

3.1. Demand and Forecast

Figure 1 PCV Procurement 2010-2017



Source: UNICEF Supply Division.

As of end-June 2014, GAVI had approved 57 countries for PCV introduction (51 in 2013) with a combined surviving infant population of ~42 million children. To date, 40 countries have introduced PCV into their national immunization programmes, two of which (Bolivia and Liberia) introduced in early 2014. 17 additional countries are approved and pending introduction and one other is recommended for approval, pending some clarifications on its proposal (Table 1). UNICEF anticipates procuring 117 million doses of PCV during 2014.

15 countries remain eligible to apply for PCV under AMC terms and conditions, of which 6 countries are graduating or have graduated from GAVI support. These countries can apply to introduce PCV through the AMC provided that they procure through UNICEF and self-fund the tail price component of the price from the outset. Some countries may submit applications during the 2014 GAVI application windows which close in May and September.

Nigeria and Bangladesh introductions were postponed in 2013 due to PCV10 supply availability. Bangladesh is anticipated to receive its first deliveries during 4Q 2014, and Nigeria will receive its first vaccine shipment in September 2014 to initiate a phased introduction.

In case of limited supply availability, allocations to countries are based upon expected impact as determined by disease burden and country coverage, as well as a country's readiness to introduce. Country programmatic readiness delayed vaccine introduction to a number of countries originally planning for introduction during 1Q and 2Q 2014. Most postponed to 2Q and 3Q 2014 and one country postponed to 2015.

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

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

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

Source: UNICEF Supply Division based on GAVI's SDF v9.0.

Table 2 Approved Countries, Surviving Infants and Confirmed Introductions in 2014¹

2014							
1Q		2Q		3Q		4Q	
PCV10							
		Armenia	41,000	Georgia	58,000	Bangladesh	3,045,000
				Nepal	572,000		
Surviving infants	-	Surviving infants	41,000	Surviving infants	630,000	Surviving infants	3,045,000
PCV13							
1Q		2Q		3Q		4Q	
Bolivia	262,000	Côte d'Ivoire	675,000	Lesotho	53,000		
Liberia	141,000	Togo	229,000	Niger	812,000		
				Guinea-Bissau	57,000		
Surviving infants	403,000	Surviving infants	904,000	Surviving infants	922,000	Surviving infants	-

Source: UNICEF Supply Division based on GAVI SDF v9.0.

* Note: = Graduating country.

¹ These countries' collective surviving infant population of 5.9 million children requires 3 doses of PCV per child. The timing of country introductions can be subject to change and will be updated regularly in subsequent notes.

One country postponed introduction from 4Q 2013 to 3Q 2014 on account of in-country vaccine licensing and financial delays. All countries approved for 2014 introduction will receive vaccine delivery in support of their planned projections as per above (Table 2).

A recent review of the SDF identified a tendency for the methodology to underestimate country demand compared to quantities shipped. An in-depth review of supply and demand for 2015 and beyond will be made during 2H 2014 following the GAVI May and September application rounds and the SDF v10.0 projections. Based on the strategic demand forecast (SDF v8.0) and already *contracted* quantities, a new Call for Offers for PCV will not be issued during 1H 2014. The need for the next Call for Offers will be re-assessed upon conclusion of the SDF v10.0 projections for 2015 and beyond.

3.2. Supply

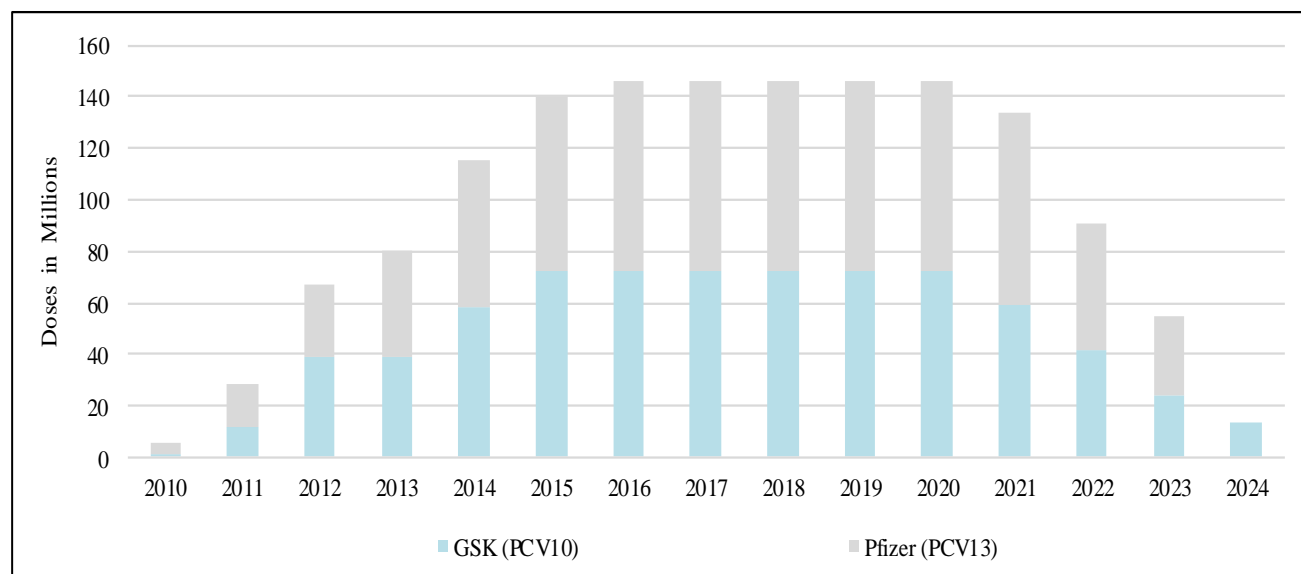
UNICEF has multiple long-term PCV Supply Agreements with two manufacturers for 1.46 billion doses (Table 3) through 2024 (Figure 2), covering a total duration from 2010 through 2023 / 2024. No new manufacturers are anticipated to enter the market with WHO prequalified PCV prior to 2018.

Table 3 UNICEF PCV Quantities Awarded for 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
Total						1,460,000,000	

Source: UNICEF Supply Division.

Figure 2 UNICEF PCV Awards for 2010-2024



Source: UNICEF Supply Division.

Incremental supply will be built over a four-year period to reach 146 million doses a year by 2016. An AMC tail price of \$3.50 applies to PCV10 reached under agreements prior to 2013. A tail price of \$3.40 will apply to doses contracted in 2013 for 2014 supply onwards. For PCV13, a reduced AMC tail price

of \$3.40 applied from mid-2013 has decreased further to \$3.30 from 2014 for all doses under agreement. 73% of the \$1.5 billion AMC funds have been committed under the six agreements reached with the two manufacturers covering the period 2010-2024.

During 2013, UNICEF procured 59.3 million doses in addition to the procurement of 19.4 million doses at the end of 2012 for use during 2013, totalling 78.7 million doses (Figure 1). 68.7 million doses were delivered and 10 million doses were also procured for delivery during 1Q 2014.

Despite sufficient quantities having been awarded, one manufacturer was not able to meet contracted quantities in 2013 and 2014. At present, PCV10 supply should meet *revised* 2014 country requirements of 55.6 million doses. Of the 57 countries approved to introduce PCV, 13 countries are introducing with PCV10, of which 5 will introduce PCV10 during 2014-15. 44 countries have chosen PCV13, of which 11 countries will introduce the vaccine during 2014-15. One country has switched from PCV13 to PCV10 prior to introduction and anticipates receiving its first shipment in 3Q 2014.

Although PCV10 is supplied to fewer countries than PCV13, the two products account for about an equal share of 2013 supply (as measured by doses). 2014 PCV10 supply is estimated to be 56 million doses and is expected to increase to 72 million doses by 2015. PCV13 supply availability is expected to reach 68 million doses during 2015 and increase to 74 million doses by 2016. As the coming years will require a significant increase in production capacity in order to meet contracted quantities, continued monitoring and risk management are required to ensure that the intended large increase in availability is indeed achieved.

4. Issues and Challenges

- Constrained PCV10 availability continues to limit the supply for some country demand; however, this is being managed closely so that continuing programmes are able to sustain vaccine use and country introductions are not further delayed. Introduction postponements also have resulted from cold chain readiness delays, vaccine licensing issues, funding availability at different national levels and other factors.
- PCV10 supply availability has been relatively fragile. Supply availability, accuracy and timing need to improve in order to ensure precise country introduction forecasting, planning and scheduling. PCV10 supply availability needs to increase by a substantial 30% by 2015 to meet country requirements.
- A review and analysis of SDF forecasts identified a tendency to underestimate the number of doses shipped. Increased accuracy in demand forecasts are required to ensure operational and planning accuracy with countries and manufacturers.

5. Steps Forward

- Upon the completion of country applications to GAVI in 2014 for country PCV introduction support and SDF v10.0, country demand projections for 2015 and beyond will be re-assessed.
- UNICEF and GAVI have agreed not to issue a new tender during 1H 2014 based on SDF v8.0 country demand requirements and current manufacturer contracted supply quantities.
- UNICEF will work with manufacturers and countries to track demand and supply availability as well as to ensure that programmatic and regulatory requirements are met prior to introduction.

- The GAVI Alliance continues to closely monitor the development of demand, as well as countries' readiness to introduce and implementation progress, focusing especially on supporting the large countries that will introduce in the near-term. UNICEF and GAVI will continue their close collaboration with current manufacturers in order to optimise the balance of supply and demand and are working with manufacturers and countries on projections for 2014-15.
- UNICEF will continue to monitor the development of new products and to track the future availability of additional products and manufacturers in support of creating a healthy market for PCV.
- UNICEF will meet with manufacturers during June 2014 to discuss 2015 supply capacity scale-up and monitor the step changes required to meet anticipated quantities, bulk availability and monthly production.

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