

Pneumococcal Conjugate Vaccine: Current Supply & Demand Outlook

UNICEF Supply Division

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Pneumococcal Conjugate Vaccine (PCV) Supply & Demand Update – February 2013

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

1. Summary

- The GAVI Alliance Partners have successfully collaborated to support the introduction of PCV into the national immunisation programmes of 24 countries.
- The substantial increase in demand for new vaccine formulations of PCV, since 2010, is currently challenging the market to supply the countries eligible to access prices and quantities under the Advance Market Commitment (AMC). Current manufacture and supply are still in the process of scaling up to meet those needs.
- In 2012, UNICEF procured a total of 58 million doses. Expected procurement in 2013 will increase to at least the 77 million doses which are currently available on contract. Procured but unutilised supplies from 2012 will supplement the 2013 procurement. Demand is projected to increase to over 100 million doses in 2013, and assumes that 27 countries will be ready to introduce PCV during 2013 (including a number of large birth cohort countries), and similarly assumes that sufficient supply will be available.
- In August 2012, UNICEF launched a new tender process to increase procurement by up to an additional 60 million annual doses by 2017. This tender includes a focus on securing increased short term supply to support additional country introductions during 2013. Awards are expected during Q1 2013.
- The present supply market for PCV is limited to both manufacturers with WHO-prequalified products that meet the criteria for funding under the AMC. No additional manufacturers are expected to have WHO-prequalified vaccines before 2016.

2. Background & Procurement History

Pneumococcal infections cause pneumonia, meningitis and febrile bacteraemia, in addition to other diseases, and lead to nearly half-a-million annual deaths in children under 5 years of age. In developing countries, the case-fatality rates for younger infants may reach up to 20% for pneumonia and 50% for meningitis. WHO recommends that PCV be included in childhood immunisation programmes worldwide, and recommends that countries with high childhood mortality (under-5 mortality of greater than 50 for every 1,000 live births) make its introduction a high priority.¹

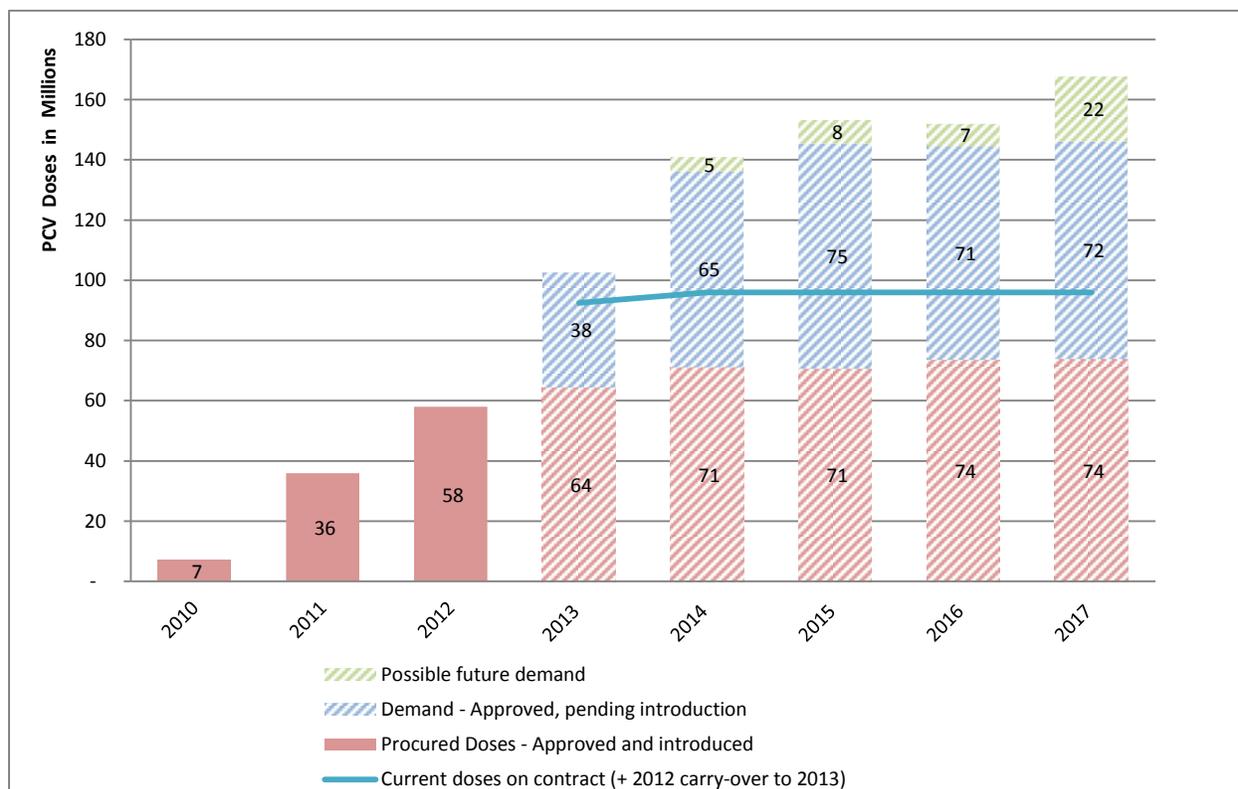
PCV is manufactured in 3 different formulations:

- PCV7: First-generation conjugate vaccine manufactured by Pfizer which offers protection against 7 pneumococcal serotypes. It was developed for Europe and the U.S. markets and is being replaced by the 10-valent and 13-valent vaccine formulations.
- PCV10: 10-valent vaccine, manufactured by GlaxoSmithKline (GSK) offering protection against 10 pneumococcal serotypes.
- PCV13: 13-valent vaccine, manufactured by Pfizer, building on their manufacture of PCV7, offering protection against 13 pneumococcal serotypes.

¹ WHO, Weekly Epidemiological Record, Pneumococcal Conjugate – WHO Position Paper, p. 130-142, April 2012 at <http://www.who.int/wer/2012/wer8714.pdf>.

73 developing countries’ access to PCV is supported by the GAVI Alliance and the [AMC funding facility](#), which “tops up” initial payments to suppliers from the Alliance and countries to a \$7.00 per dose price. Under the AMC terms, PCV for these countries is procured through UNICEF at a long-term maximum price of \$3.50 per dose. UNICEF began procurement of PCV in 2010, when PCV10 and PCV13 vaccines were first WHO prequalified and eligible for funding under the AMC. Annual procurement has since increased substantially. UNICEF expects to procure a minimum of 77 million doses which are currently on contract during 2013. In addition, approximately 15 million procured but unutilized 2012 doses have been carried over to 2013 and are included in the contracted availability for that year.

Figure 1 PCV Supply and Demand Projection²



3. Current Market Situation

3.1. Demand

The 73 countries eligible to access PCV via the AMC facility represent a total birth cohort of 75 million children. Of these, 67³ countries have access to financial support through GAVI to accelerate the uptake of PCV into their national immunisation programmes. However, 10 of these

² Source: GAVI financial projections for 2013-2017 for approved countries; for possible future demand GAVI Strategic Demand Forecast v6.0 forms the basis. The Strategic Demand Forecast v7.0 is presently forthcoming and in a subsequent note, UNICEF will update projections accordingly.

³ The 67 countries are made up of the current 57 GAVI-eligible countries in addition to the 10 GAVI-graduating countries which had previously applied and were approved, and therefore are eligible for some GAVI-financing for a finite time period.

countries are graduating from GAVI support and will therefore need to fully fund their vaccine costs over the coming years. Figure 2 presents a list of countries at different stages of introduction and approval status.

As of the beginning of February, of the 73 eligible countries, GAVI has approved 46 for introduction; four are pending approval, and one country requires further review. Of the 46 countries approved, 24 have introduced PCV into their national immunisation programmes, and 22 are approved to introduce in 2013 and beyond. An additional 12 countries are projected to introduce PCV into their national immunisation programmes at the latest by 2015, which brings the total to 58 countries, in accordance with GAVI Alliance projections. These countries represent a birth cohort of 40 million children. It should be noted that these projections do not take into consideration financial or supply constraints.

Figure 2 Country Introductions, Approvals and Future Potential Applications Status⁴

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

	Introduced
	Approved pending introduction
	Recommended for approval (not yet approved)
	Conditional approval
	Countries that have yet to apply

The current limited availability of PCV and the status of a country's readiness determine the timing of PCV introduction. 11 countries have been informed of the availability of supply for introduction in 2013. Following the conclusion of the current tender process, UNICEF will have increased visibility on additional short term supply for sustainable introductions, and additional introductions are expected in 2013.

⁴ Source: UNICEF based on GAVI's Strategic Demand Forecast v6.0. The Strategic Demand Forecast v7.0 is presently forthcoming and in a subsequent note, UNICEF will update projections accordingly.

WHO, GAVI and UNICEF jointly developed a prioritisation mechanism to allocate available supply to approved countries in situations where supply is insufficient to meet demand. The prioritisation mechanism takes into consideration factors such as disease burden and country vaccine coverage (DTP3). Figure 3 presents the country confirmed introductions based on the country prioritisations and currently available supply. The anticipated readiness of countries forms the basis of planned supply. Any delay in introduction may free up doses for other countries, and therefore this is being closely monitored.

All other countries currently approved and pending introduction are awaiting supply and have been notified that supply is limited. UNICEF will provide an update on supply availability at the conclusion of the on-going tender (end of Q1). The tender solicited incremental supply building over a 4 year period to 60 million additional annual doses by 2017. However, the actual incremental availability will be finalised at the conclusion of the tender process.

Figure 3 Approved Countries, Birth Cohort and Confirmed Introduction in 2013⁵

2013							
Jan-Mar		Apr-Jun		Jul-Sep		Oct-Dec	
PCV10							
Zambia	547,000	Uganda	1,400,000			Armenia	46,000
		Azerbaijan	175,000				
		Mozambique	810,000				
Total birth cohort (surviving)	547,000	Total birth cohort (surviving)	2,385,000	Total birth cohort (surviving)	-	Total birth cohort (surviving)	46,000
PCV13							
		Kiribati	-	Niger	687,000	Bolivia	252,000
		Angola	715,000	Sudan	1,342,000	Senegal	441,000
Total birth cohort (surviving)	-	Total birth cohort (surviving)	715,000	Total birth cohort (surviving)	2,029,000	Total birth cohort (surviving)	693,000

3.2. Supplier Base

Two manufacturers have WHO-prequalified vaccines that meet the AMC's [Target Product Profile](#) (TPP), and are therefore eligible for AMC funding. 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 the 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. They were subsequently awarded an additional contract of 18 million doses to reach a total of 48 million doses a year by 2014 (and continuing through 2021). Pfizer supplies PCV in a 1-dose vial presentation.
- GSK has also been supplying PCV through UNICEF since 2010 and was contracted to supply 30 million doses a year from 2012. They were also subsequently contracted to supply an additional

⁵ These countries' collective birth cohort of 6.4 million children requires 3 doses of PCV. Note: Country introduction timing can be fluid and will be updated accordingly in subsequent notes.

18 million doses a year to reach 48 million doses by 2013. 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 96 million doses of PCV a year by 2014. UNICEF's most recently launched tender seeks up to 60 million additional doses of PCV, to increase annual supply to a maximum of 156 million doses by 2017. Should the maximum quantity be awarded, 78% of the annual 200 million dose target will be reached by 2017.

3.3. Issues / Challenges

- The GAVI Alliance approved the first applications for introduction of PCV in 2007; however, vaccines first became prequalified and eligible for supply under the AMC from mid-2010. Initially, therefore, country introductions were considerably delayed.
- From 2010 to 2012, the overall supply of PCV has generally been sufficient, although there have been some minor delays in a few country introductions due to timing of supply availability. In 2012, at the aggregate level, PCV supply exceeded country demand by more than 10 million doses, due to delay in introductions. Two countries also chose to postpone introduction from 2012 to 2013 because the available product presentation was not the preferred one; two countries, which were allocated and received supplies, postponed introductions due to lack of readiness.
- From 2013 onwards, the current level of supply and scale-up is not sufficient to fully meet the product-specific requirements of all the countries approved for PCV. The maximum demand is currently projected to be over 100 million doses. Anticipated procurement of PCV during 2013 is anticipated to be at least 77 million doses. However, total supply availability in 2013 will depend on the outcome of the current tender.
- Considering the projected 2013 supply deficit, UNICEF secured the maximum utilisation of the supply through the early issuance of purchase orders and prepayment. One manufacturer agreed to secure the surplus stock of more than 10 million doses (mentioned above) at no extra cost to the GAVI Alliance, with planned schedule of delivery during Q1 2013.
- There are a number of large countries with a total projected requirement in 2013 of 40 million doses which are either about to introduce or are undertaking phased introduction of PCV. Any postponement or delay in such introductions will have a considerable impact on the supply and demand balance for 2013.
- Some countries that introduce PCV have undertaken catch-up campaigns targeting all children under-1 year of age. Quantities approved and supplied are based on annual surviving infant statistics, which are less than the total requirements. The implementation of catch-up campaigns may result in the exhaustion of country stocks. So far, UNICEF has assisted countries to meet demand by combining and bringing forward delivery schedules to countries introducing PCV, thereby avoiding any stock-outs at the national level. However, as the current supply capacity is limited, countries are advised by their respective National Immunisation Technical Advisory Group (NITAG) not to implement catch-up campaigns.⁶

⁶ GAVI, Pneumococcal AMC Annual Report: 1 April 2011 to 31 March 2012, p. 13 at <http://www.gavialliance.org/funding/pneumococcal-amc/>.

4. Steps Forward

- Proposals for the most recently issued tender have been received and are currently under review in consultation with a Procurement Reference Group (PRG). These discussions are still on-going and will likely be concluded by the end of the Q1 2013.
- The GAVI Alliance will continue to closely monitor the development of demand, country readiness to introduce, country introduction progress and on-going expansions in large countries.
- UNICEF and GAVI will continue their close collaboration with current suppliers to improve the balance in supply and demand. The process will include oversight of annual projections and increased flexibility due to uncertainties in the early stages of introduction, combined with multiple introductions.
- UNICEF will continue to monitor the development of new products in the pipeline to track the future availability of alternative products.
- UNICEF intends to update the information presented in this note over the next few months to incorporate the next GAVI Strategic Demand Forecast (v7.0), conclusion of the ongoing tender activities and additional introduction and planning details.

For further questions or additional information, please contact:

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Information notes can be found: http://www.unicef.org/supply/index_54214.html