

# ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

**Annual Report**

**1 April 2012 – 31 March 2013**

*Prepared by the GAVI Alliance Secretariat*

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## Abbreviations

AMC	Advance Market Commitment
FOC	Firm Order Commitment
GAVI	GAVI Alliance
GAVI Secretariat	GAVI Alliance Secretariat
IAC	Independent Assessment Committee
IRC	Independent Review Committee
M&E	Monitoring and Evaluation
PATH	Program for Appropriate Technologies for Health
PCV	Pneumococcal Conjugate Vaccine
PSA	Provisional Supply Agreement
PSF	Product Summary File
QSS	WHO Quality, Safety and Standards
SDF	Strategic Demand Forecast
TPP	Target Product Profile
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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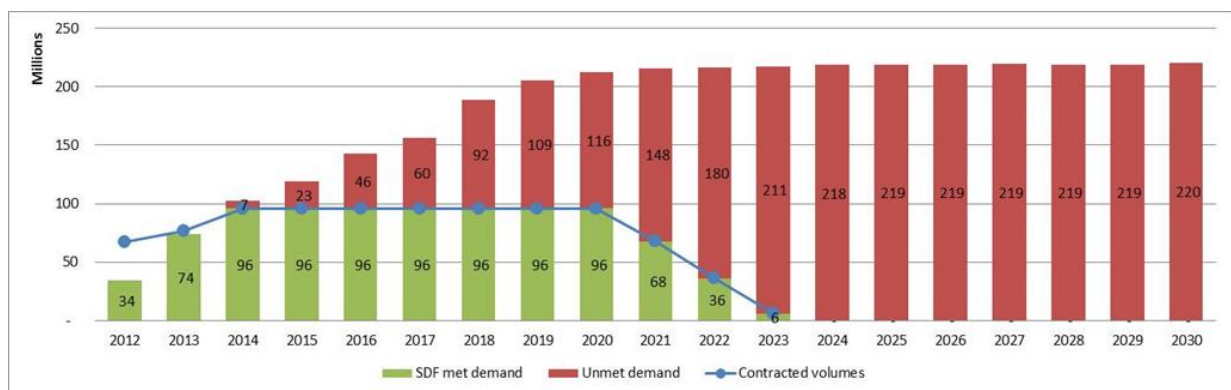
## Executive Summary

### Demand for pneumococcal vaccines procured through the AMC

The pilot Advance Market Commitment (AMC) for pneumococcal vaccines is now in its third year of implementation and significant progress has been made. In terms of country demand, 70% of eligible countries (51 out of 73) have been approved to introduce the pneumococcal vaccine. A total of 24 countries have already rolled out these lifesaving vaccines – including eight during this reporting period (1 April 2012 to 31 March 2013).

The fifth Strategic Demand Forecast was published in August 2012 and predicts that the demand for pneumococcal vaccines procured under the AMC will meet the target annual demand of 200 million doses in 2019:

Figure 1. Strategic Demand Forecast v5.0

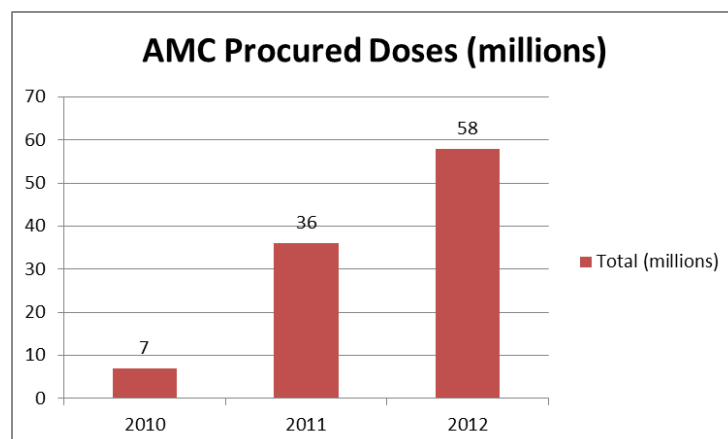


Current estimates suggest that a total of 57 countries will have introduced pneumococcal vaccines with GAVI support by 2015, compared to the GAVI target of 45 for the same period.

### Supply of pneumococcal vaccines procured through the AMC

In the reporting period, the two AMC-eligible pneumococcal vaccines remain a 10-valent produced by GlaxoSmithKline (GSK) and a 13-valent manufactured by Pfizer. In terms of supply, during the period 2010 to 2012, a total of 101 million doses have been procured and delivered under the AMC, with a significant scale up each year:

Figure 2. Pneumococcal vaccine procured volumes, in millions of doses, 2010-2012



Source: UNICEF Supply Division (Please note that the chart above indicates the number of doses placed on purchase orders during the respective years, including for delivery in a subsequent year)

There has been no change to the total number of doses contracted as reported in the previous Annual Report (960 million total doses), although additional available doses have been brought forward during the capacity development period to meet demand. In addition, some doses were pre-purchased in 2012 to cover a projected supply gap in 2013. The contracted volumes for 2013-2023 are summarised in the table below:

Table 1. Pneumococcal vaccine contracted volumes, in millions of doses, 2013-2023

Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
TOTAL	77	96	96	96	96	96	96	96	67.6	36	6

Source: UNICEF Supply Division

Due to the unprecedented demand for the vaccine, short-term supply constraints are expected in the next two years, as manufacturers continue to scale up capacity to meet the high-level of demand. The fifth Strategic Demand Forecast identified a supply gap of 60 million annual doses from 2017 onwards, which was the basis for the third Call for Supply Offers issued in August 2012 and due to conclude in the second quarter of 2013. The tender also has a focus on securing increased short term supply; therefore it is expected to ease supply constraints in 2013 and beyond. Sufficient supplies are expected to allow all of the 51 approved countries to introduce by 2015.

### **Projected impact of pneumococcal vaccines procured through the AMC**

To date (2010-2012), it is estimated that more than 10 million children have been vaccinated, with a projection of more than 75 million children vaccinated across 57 countries by 2015. The continued scale up of the vaccines expected by 2020 is forecasted to result in 1.5 million deaths averted.

### **AMC Process and Design Evaluation**

A Process and Design Evaluation of the AMC was conducted in 2012, providing insights and lessons on the AMC mechanism, by evaluating the design process, design decisions, and implementation of the AMC to date. Overall, the evaluators concluded that the AMC has demonstrated the ability of the international development community to design, establish, and administer an AMC, and provides important lessons for the development of future AMCs.

### **Media and communication activities**

The GAVI Secretariat's media and communications team aims to increase visibility of the AMC through traditional, online and social media, with activities in the reporting period focused on World Pneumonia Day and key country introductions in Ghana, Pakistan and Tanzania.

### **Financial activities**

The financial structure of the AMC remains unchanged from the prior year. From 1 April 2012 to 31 March 2013, GAVI has disbursed US \$369.2 million to UNICEF for the purchase of pneumococcal vaccines. Of this amount, US \$204.9 million was from AMC funds.

### **Conclusion**

Short term supply availability continues to be a key challenge, given the unprecedented country demand. However, even taking this challenge into account, the latest Strategic Demand Forecast estimates that a total of 57 countries will have introduced by 2015, exceeding the original target of 45.

## Background

Advance Market Commitments (AMCs) for vaccines aim to encourage the development and production of affordable vaccines tailored to the needs of developing countries. Following the announcement of the Governments of Italy, the United Kingdom, Canada, the Russian Federation, Norway and the Bill & Melinda Gates Foundation, who collectively pledged a total of US\$ 1.5 billion to fund the programme, the pneumococcal AMC pilot was designed to stimulate the late-stage development and manufacture of affordable pneumococcal vaccines for the poorest countries.

The overarching goal of the pilot AMC is to reduce morbidity and mortality from pneumococcal diseases, preventing an estimated seven million childhood deaths by 2030. The objectives of the pneumococcal AMC are:

1. **to accelerate the development of pneumococcal vaccines** that meet developing country needs (e.g. in terms of serotype composition and vaccine presentation) as specified in the Target Product Profile;
2. **to bring forward the availability of effective pneumococcal vaccines** for developing countries by guaranteeing the initial purchase price, for a limited quantity of the new vaccines, that represents value for money and incentivises manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand;
3. **to accelerate vaccine uptake** by ensuring predictable vaccine pricing for countries and manufacturers, for example through binding commitments by participating companies to supply vaccines at low, long-term and sustainable prices after the AMC finances are depleted;
4. **to test the effectiveness of the AMC mechanism** as an incentive for supplying much needed vaccines and to learn lessons for developing possible future AMCs for other vaccines.

The Pneumococcal AMC entered its implementation phase on 12 June 2009. Since then, the first vaccines became available for procurement under the AMC terms and conditions and the first roll-out occurred in Nicaragua in December 2010. To date 70% of GAVI supported countries have planned for pneumococcal vaccine introduction and submitted applications to GAVI for financial support.

On 13 June 2011, the GAVI Alliance received a strong vote of confidence from the donor community as US\$ 4.3 billion were pledged, bringing to US\$ 7.6 billion the total resources available to GAVI for the period 2011 to 2015. From a financial perspective, therefore, the GAVI Alliance is well positioned to support countries in their efforts to accelerate the roll out of existing and new vaccines, reach more children in developing countries, and prepare and expand the introduction of new vaccines.

The purpose of this report is to provide an update on AMC implementation activities, including procurement activities, delivery of vaccines, monitoring and evaluation activities, media and communications work and financial reporting. This report is the fourth pneumococcal AMC Annual Report<sup>a</sup> and covers the period from 1 April 2012 to 31 March 2013. The report was developed by the AMC Secretariat at GAVI, in collaboration with the World Bank, UNICEF Supply Division (SD) and WHO, and was approved by the Independent Assessment Committee on 25 April 2013<sup>b</sup>

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<sup>a</sup> Previous AMC Annual Reports can be found on the AMC website: <http://www.gavialliance.org/library/gavi-documents/amc/>

<sup>b</sup> Note that as a public document, this report does not include any confidential information.



## 1. Procurement update

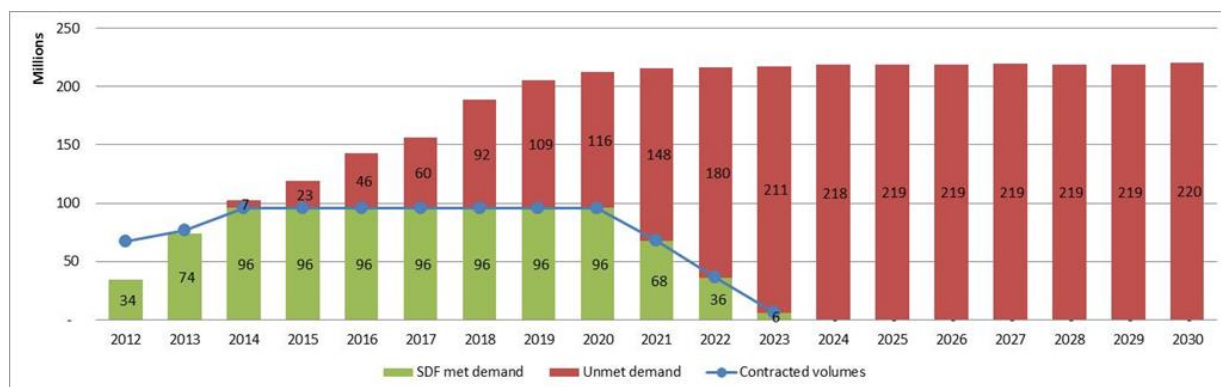
### 1.1. Strategic Demand Forecasts

According to the AMC terms and conditions,<sup>1</sup> the GAVI Alliance will publish an updated Strategic Demand Forecast (SDF) on the AMC website annually. The SDF outlines estimated demand for pneumococcal vaccines, estimated supply as contracted and the unmet demand. Based on the projected unmet demand, UNICEF may issue Calls for Supply Offers.

Previous versions of the SDF have been summarised in prior Annual Reports. SDFs published or developed in the reporting period are as follows:

- SDF v5.0 was published on the AMC website on 9 August 2012 and served as the basis for the third Call for Supply Offers issued on 27 August 2012 (see section 1.2 below).

Figure 3. Strategic Demand Forecast v5.0



- SDF v6.0 was approved in September 2012. The SDF v6.0 was not published on the AMC website as a new procurement cycle was already in process.
- SDF v7.0 was recently approved by the GAVI Secretariat and will be published in 2013 to serve as a basis for consultations between the GAVI Secretariat and UNICEF to determine if a new Call for Supply Offers should be issued. An update will be provided in the 2014 Pneumococcal AMC Annual Report.

### 1.2. Call for Supply Offers

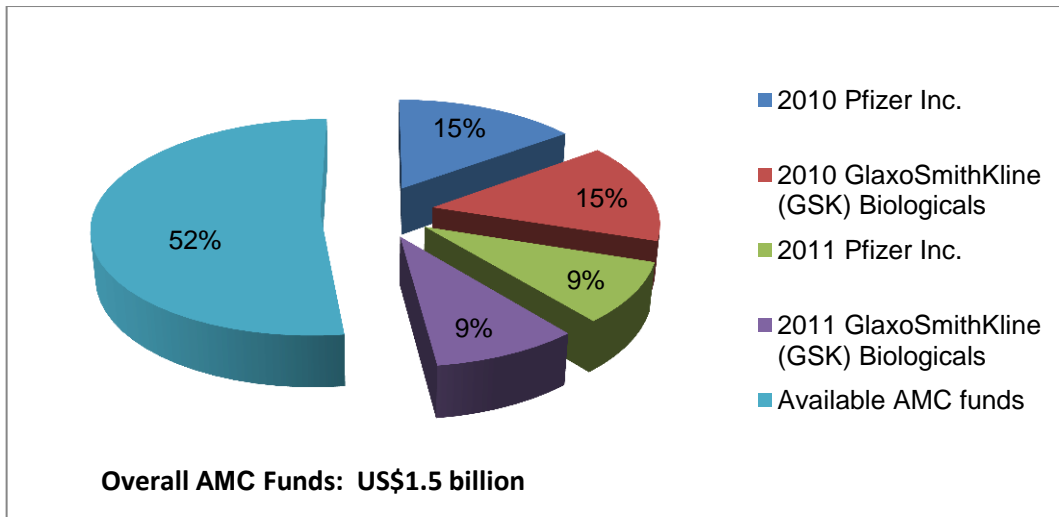
There have been three Calls for Supply Offers for pneumococcal vaccines under the AMC to date. A summary of the First and Second AMC Supply Agreements can be found in Annex 1. A summary of the current supply commitments can be found in the table below.

Table 2. Status on overall supply commitments

Manufacturer	Date of signature (week of)	Annual supply commitment (doses)	Tail price	Supply start date	AMC Funds allocated
GSK	23 March 2010	30 million	US\$ 3.50	January 2012	US\$ 225 million
Pfizer Inc.	23 March 2010	30 million	US\$ 3.50	January 2013	US\$ 225 million
GSK	12 Dec 2011	18 million	US\$ 3.50	January 2014	US\$ 135 million
Pfizer Inc.	12 Dec 2011	18 million	US\$ 3.50	January 2014	US\$ 135 million

As the current tender is still ongoing, the allocation of AMC funds remains unchanged from the previous AMC Annual Report and is summarised in Figure 4 below.

Figure 4. Allocation of AMC funds



Following the publication of SDF v5.0 in August 2012, GAVI, in consultation with UNICEF, decided to issue a third Call for Supply Offers for the procurement of pneumococcal vaccines that was published on 27 August 2012 with a maximum target of 60 million doses by 2017. The tender also includes a focus on securing increased short-term supply to support additional country introductions during 2013. UNICEF SD received five offers by 21 September 2012.

The tender is expected to conclude in the second quarter of 2013 and the results will be published on the AMC website and included in the 2014 Pneumococcal AMC Annual Report.

### 1.3. AMC registered manufacturers

Following the signature of AMC legal agreements on 12 June 2009, manufacturers can enter into an AMC Registered Manufacturers' Agreement with the GAVI Alliance and the World Bank. As part of the registration agreement, manufacturers formally agree to the AMC terms and conditions; accept to provide an annual update on expected timing for application for AMC Eligibility and for WHO prequalification; and recognise the role of the Independent Assessment Committee (IAC) in the determination of AMC eligibility. As described in the AMC Procedures Memorandum, AMC Registered Manufacturers' Registration Procedures, manufacturers interested in participating in the AMC must submit an AMC registered manufacturer application package to the AMC Secretariat. This registration does not imply any commitment from manufacturers to participate in the AMC. It is, however, a prerequisite to take part in UNICEF's calls for supply offers.

Details about the registered manufacturers are confidential unless a firm agrees to have its registration made public. There has been no change to the AMC registered manufacturers who have made their registration public. These remain as follows:

- GlaxoSmithKline (GSK) Biologicals
- Panacea Biotec Ltd.
- Pfizer Inc.
- Serum Institute of India

#### 1.4. AMC eligible pneumococcal vaccines

As of 31 March 2013, there are currently two pneumococcal conjugate vaccines (PCV) available for procurement under the AMC. No additional manufacturers are expected to have WHO-prequalified vaccines before 2016.

##### 1.4.1. *Pneumococcal conjugate vaccine, 10-valent*

GSK launched a 10-valent PCV (PCV10) in Europe in 2009. PCV10 in a 2 dose presentation obtained WHO prequalification on 12 March 2010 and was deemed AMC-eligible on 16 April 2010 by the AMC Independent Assessment Committee (IAC). PCV10 is a liquid vaccine in a novel presentation, as it is supplied in a two dose vial without preservative. Both doses are intended to be used within six hours of the vial being opened.

Due to the novelty of its presentation, the pre-qualification was first limited to Kenya until successful completion of a 12 month assessment of programmatic issues in two demographic surveillance sites, as well as the implementation of a Phase IV study to monitor adverse events following immunisation (AEFIs) associated with potential mishandling of the product. The first delivery to Kenya took place in September 2010, with the national introduction taking place in January 2011.

In 2011, the WHO Quality, Safety and Standards (QSS) team – responsible for the prequalification process – set up a committee to assess the possibility to extend PCV10 use to countries other than Kenya. The Committee approved the use of PCV10 in one further country – Ethiopia – under the same stringent conditions as in Kenya (programmatic monitoring and phase IV study). Subsequently, Ethiopia complied with these conditions and introduced PCV10 in October 2011.

In May 2012, the WHO QSS issued an update on PCV10 following the receipt and review of additional data from Kenya and Ethiopia.<sup>c</sup> In summary, after review of the evidence obtained, and taking into account risk-benefit estimates of using this presentation in high disease burden countries, which show that the benefits outweigh the potential risks, PCV10 remains prequalified and the presentation is considered suitable for supply through the UN to further countries. WHO recommends that countries ensure programmatic readiness to introduce PCV10, with a pre-condition of special training requirements (i.e. specific training on the use of this presentation must have taken place at all levels before shipment and distribution of the vaccine), and the placement of stickers that state '*do not return an opened vial of PCV10 to the fridge*' on refrigerators at all levels. WHO is responsible for assessing that these conditions are met prior to the shipment of the vaccine and will assist the countries in performing post introduction evaluations six months after the introduction, with a specific focus on assessing health care worker knowledge and behaviour related to the safe use and handling of this vaccine presentation.

##### 1.4.2. *Pneumococcal conjugate vaccine, 13-valent*

PCV13 is a liquid vaccine in a one dose vial, produced by Pfizer Inc. It obtained WHO prequalification on 22 August 2010 and was deemed AMC eligible by the AMC IAC on 23 August 2010. UNICEF Supply Division started the procurement of PCV13 to GAVI-supported countries in September 2010 upon IAC approval of the vaccine, with first delivery taking place in October 2010.

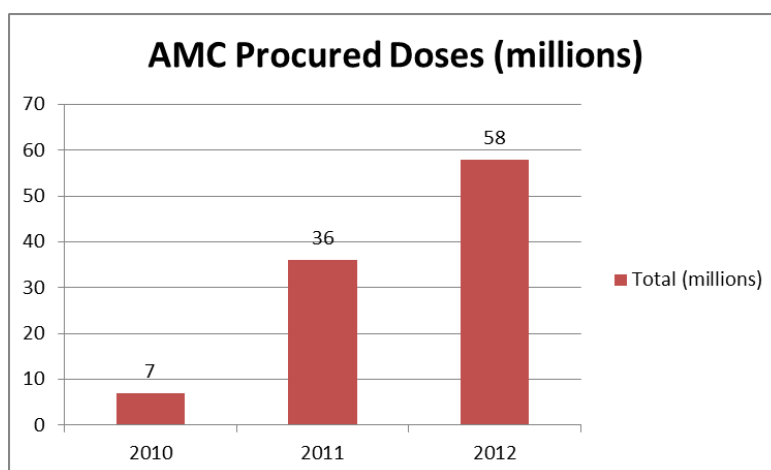
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<sup>c</sup> Available at [http://www.who.int/immunization\\_standards/vaccine\\_quality/synflorix\\_pgnote\\_2dose\\_2012/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/synflorix_pgnote_2dose_2012/en/index.html)

### 1.5. Doses procured between 2010 and 2012

The total number of doses procured and delivered to date is summarised in figure 5 below:

Figure 5. Pneumococcal vaccine procured volumes, in millions of doses, 2010-2012



Source: UNICEF Supply Division (Please note that the figure above indicates the number of doses placed on purchase orders during the respective years, including for delivery in a subsequent year).

### 1.6. Doses contracted between 2013 and 2023

With regards to contracted volumes, there has been no change to the number of doses contracted since the previous Annual Report (960 million total doses), although additional available doses have been brought forward during the capacity development period to meet demand. As of 31 March 2013, the contracted supply for 2013-2023 is as follows:

Table 3. Pneumococcal vaccine contracted volumes, in millions of doses, 2013-2023

Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total PCV10	39	48	48	48	48	48	48	48	35.4	18	0
Total PCV13	38	48	48	48	48	48	48	48	32.2	18	6
TOTAL	77	96	96	96	96	96	96	96	67.6	36	6

Source: UNICEF Supply Division

A new application round will be opened in September 2013 and countries wishing to apply for support for pneumococcal vaccines will be informed that supply may be constrained in the application guidelines. This will depend upon the results of the third tender that is currently underway and expected to conclude in the second quarter of 2013.

### 1.7. Availability of pneumococcal vaccines

The current scope and pace of pneumococcal vaccine rollouts are unprecedented in GAVI's history. Given the scale up of demand, short-term supply for these vaccines will not be able to meet all requirements, and as a result, some of the countries approved for introduction of pneumococcal vaccines in 2012 needed to postpone introduction to 2013, due to lack of availability of the preferred product presentation. This will likely also be the case in 2013, as some countries will need to postpone their introductions. From a supply allocation perspective, the first priority remains the sustainability of

programmes in countries that have already introduced - further introductions will depend on the amount of additional supply that can be made available, as well as any reduced vaccine requirements in the countries for which supply has already been allocated, as delays in countries meeting their proposed introduction schedules have occurred in the past. When there is insufficient additional supply for all approved countries to introduce, an allocation procedure is used to determine the sequence in which countries will receive vaccines. The sequencing of countries within the allocation procedure is primarily based on countries' disease burden estimates and vaccine coverage rates. The allocation procedure includes a qualitative assessment of countries' readiness to introduce new vaccines and the final outcome is reviewed by a working group that includes representatives from the GAVI Secretariat, WHO and UNICEF.

In 2012, the total supply of both pneumococcal vaccines exceeded the total country demand by more than 10 million doses following delays in country introductions. However, there was an imbalance between product availability and country preferences and as a result, two countries chose to postpone their introductions due to the unavailability of their preferred product (PCV13). A number of countries were offered the possibility of product switches for faster introduction, although only two countries to date have taken up this offer, while the rest have opted to wait for the availability of their preferred product presentation. In order to mitigate a projected supply gap for 2013, extraordinary measures were taken in partnership with the AMC-eligible manufacturers to ensure the utilisation of the maximum supply capacity in 2012. This included the pre-purchase of 11 million doses in 2012 to cover a projected supply gap in 2013.

In 2013, at the aggregate level, there is currently insufficient supply to support the introduction of the significant number of countries which have been approved to introduce in 2013 (24 countries). Supply is currently available for 11 of these countries and it is expected that the current tender will secure additional supplies to support the sustainable introduction of further countries in 2013.

It is a challenge to balance supply and demand in the early stages of a new vaccine programme. For example, in the initial years of the introduction of pentavalent vaccine, supported by GAVI, manufacturers required seven years to increase capacity to produce 40 million doses. Thanks to the AMC, the early availability of considerable quantities of pneumococcal vaccines is an improvement: 67 million doses on contract in 2012 and 77 million doses on contract in 2013. GAVI continues to encourage current manufacturers to accelerate capacity expansions even further to meet demand in developing countries and to reduce delays in introductions and thereby contribute to improving health. GAVI is also actively monitoring the pipeline development from potential future manufacturers.

Based on the current supply available, the 27 countries that have been approved for the pneumococcal vaccine, but have not yet introduced, will be able to introduce by 2015 at the latest.

## 2. Country demand and introductions overview

### 2.1. GAVI-supported countries approved for the introduction of PCV

GAVI opened a New Vaccine Support application round in 2012, with a deadline for countries to submit applications by 31 August 2012. Three countries applied for GAVI support to introduce pneumococcal vaccines in this round. An additional three countries had previously applied for GAVI support and been recommended for conditional approval (including Nigeria for Phases II and III only – Phase I was already approved).

The six countries were reviewed by the Independent Review Committee (IRC) in October 2012. Following this review, five countries were recommended for approval (including Nigeria for Phases II and III) and one country was recommended for conditional approval. This latter country was recommended for approval in the March 2013 IRC review. Therefore, 51 of GAVI's 73 countries (70%) have applied and been approved for support for pneumococcal vaccines.

Additional applications are expected in the upcoming New Vaccine Support round that is due to open in June 2013, with a deadline of 15 September 2013. The Strategic Demand Forecast v7.0 estimates that a total of 57 countries will have introduced pneumococcal vaccines by 2015, compared to the GAVI Alliance target of 45 for the same period. This projection takes known supply constraints into consideration, but excludes any potential funding constraints.

### 2.2. Graduating and graduated countries introduction of PCV

In June 2010, the GAVI Board approved that all GAVI-eligible countries as per the 2003 definition continue to have access to pneumococcal vaccines (PCV) through GAVI under the terms and conditions of the AMC. As a result of this Board decision, countries graduating and graduated from GAVI support that have not yet been approved for pneumococcal vaccine are able to apply to introduce this vaccine under the terms and conditions of the AMC. The current price (the "Tail price") to countries is US\$ 3.50. However, these countries will need to self-finance the vaccine at the tail price from the outset. Also, all countries must have achieved DTP3 coverage at or above 70% according to WHO/UNICEF estimates. As of 2013, the graduating and graduated countries that are eligible to apply are as follows:

- Bhutan
- Cuba
- Indonesia
- Mongolia
- Sri Lanka
- Ukraine
- Timor Leste

To date, no graduating or graduated countries have applied for pneumococcal vaccine through the AMC.

### 2.3. Pneumococcal vaccine introductions to date

In the period, 1 April 2012 to 31 March 2013, eight countries introduced pneumococcal vaccines procured through the AMC. To date, there have been 24 pneumococcal vaccine introductions and these are outlined in the table below:

Table 4. Pneumococcal vaccine introductions to date

Year	Country	Product	Status	Cumulative No.	
2009	Gambia	PCV7 (donation)	Switched to PCV13 in 2011	1	
	Rwanda	PCV7 (donation)	Switched to PCV13 in 2011	2	
2010	Nicaragua	PCV13	Introduced in December	3	
2011	Guyana	PCV13	Introduced in January	4	
	Yemen	PCV13	Introduced in January	5	
	Kenya	PCV10	Introduced in January	6	
	Sierra Leone	PCV13	Introduced in January	7	
	Mali	PCV13	Introduced in March	8	
	Congo, DR	PCV13	Introduced in April	9	
	Honduras	PCV13	Introduced in April	10	
	Central African Republic	PCV13	Introduced in July	11	
	Benin	PCV13	Introduced in July	12	
	Cameroon	PCV13	Introduced in July	13	
	Burundi	PCV13	Introduced in September	14	
	Ethiopia	PCV10	Introduced in October	15	
	Malawi	PCV13	Introduced in November	16	
	2012	Ghana	PCV13	Introduced in April*	17
		Zimbabwe	PCV13	Introduced in June*	18
Pakistan		PCV10	Introduced in October	19	
Congo Rep		PCV13	Introduced in October	20	
Madagascar		PCV10	Introduced in November	21	
Sao Tome & Principe		PCV13	Introduced in November	22	
Djibouti		PCV13	Introduced in December	23	
Tanzania		PCV13	Introduced in December*	24	

\* Ceremonial launch; National introduction in the month following

Following the successful introductions of PCV10 in Kenya and Ethiopia, PCV10 was also introduced in Pakistan and Madagascar in 2012. Therefore, of the 24 pneumococcal vaccine introductions that have taken place to date, four countries are using PCV10, whereas the remaining 20 countries are using PCV13.

Ghana was the first country to simultaneously introduce the pneumococcal and rotavirus vaccines in April 2012. WHO and PATH are undertaking a series of assessments of the experiences of Ghana in planning and executing the simultaneous launch of the two products to identify any potential synergies or additional burden placed upon the routine immunisation system, as well as documenting lessons learned. In December 2012, Tanzania became the second country to simultaneously introduce the pneumococcal and rotavirus vaccine during the GAVI Alliance's Partners' Forum in Dar es Salaam.

## 2.4. Future pneumococcal vaccine introductions

In addition to providing sustainable supplies for the 24 countries that have already introduced pneumococcal vaccines, there is currently sufficient supply for an additional 11 countries to introduce the pneumococcal vaccines in 2013. Two countries have chosen to postpone their introductions to 2014. The supply for a further 14 countries is dependent upon the third Call for Offers which is currently underway. These countries have received communication to inform them of the current situation. Once the tender is concluded, GAVI will communicate with the countries the earliest available date of vaccine availability and the countries will decide upon their preferred introduction date.

The countries approved for pneumococcal vaccine introductions are outlined in the table below:

Table 5. Future pneumococcal vaccine introductions

Year	Country	Product	Status	Cumulative No.
2013	Mozambique	PCV10	Planned for April	25
	Angola	PCV13	Planned for April	26
	Azerbaijan	PCV10	Planned for April	27
	Uganda	PCV10	Planned for April	28
	Zambia	PCV10	Planned for April	29
	Kiribati	PCV13	Planned for May	30
	Sudan North	PCV13	Planned for July	31
	Niger	PCV13	Planned for July	32
	Senegal	PCV13	Planned for October	33
	Bolivia	PCV13	Planned for October	34
	Armenia	PCV10	Planned for October	35
2014	Georgia	PCV10	Planned for 2014	36
	Guinea Bissau	PCV13	Planned for 2014	37
TBC	Afghanistan	PCV13	Introduction dependent on current tender	38
	Bangladesh	PCV10	Introduction dependent on current tender	39
	Burkina Faso	PCV13	Introduction dependent on current tender	40
	Cote d'Ivoire	PCV13	Introduction dependent on current tender	41
	Haiti	PCV13	Introduction dependent on current tender	42
	Lao	PCV13	Introduction dependent on current tender	43
	Lesotho	PCV13	Introduction dependent on current tender	44
	Liberia	PCV13	Introduction dependent on current tender	45
	Mauritania	PCV13	Introduction dependent on current tender	46
	Moldova	PCV13	Introduction dependent on current tender	47
	Nepal	PCV13	Introduction dependent on current tender**	48
	Nigeria*	PCV10	Introduction dependent on current tender	49
	Papua New Guinea	PCV13	Introduction dependent on current tender	50
	Togo	PCV13	Introduction dependent on current tender	51

\* Phased introduction planned, \*\* 2014 introduction requested

## 2.5. Coordination of pneumococcal vaccine introductions

Given the increased number of introducing countries and the links between pneumococcal and rotavirus introductions, the Pneumo/Rota Operational Working Group (PROWG) was created to ensure close coordination and improved information flow around pre-launch activities, day-to-day operational issues and actions for both pneumococcal and rotavirus vaccines.



The Pneumo/Rota Operational Working Group (PROWG) members represent WHO, UNICEF SD, UNICEF Programme Division, PATH and the GAVI Secretariat. The working group meets weekly by teleconference and the focus of the calls is on the following areas:

- Monitoring of country readiness to introduce, including expected introduction date, cold chain capacity, and training;
- Monitoring the progress of implementation, such as reports of faster (or slower) uptake of the vaccine post launch;
- Country ranking and allocation of limited available supply, where appropriate;
- Supporting communication on supply availability and supply options to countries.

A list of current PROWG members is provided in Annex 2.

## **2.6. WHO Position Paper on Pneumococcal Vaccines, published April 2012**

In April 2012, WHO published a position paper on pneumococcal vaccines,<sup>2</sup> replacing the 2007 position paper on 7-valent pneumococcal conjugate vaccine. In the new paper, focusing on the currently available 10-valent and 13-valent vaccines, WHO recommends that inclusion of pneumococcal vaccines be given priority in childhood immunisation programmes world-wide, especially in countries with under-five mortality of greater than 50 per 1000 live births.

WHO further states that the use of the pneumococcal vaccine should be seen as complementary to the use of other pneumonia control measures, such as appropriate case management, promotion of exclusive breastfeeding, and the reduction of known risk factors, such as indoor air pollutants and tobacco smoke.

For administration to infants, three primary doses (3p+0 schedule) or, as an alternative, two primary doses plus a booster (2p+1 schedule) are recommended. Primary vaccination can be initiated as early as at 6 weeks of age. In choosing between the two recommended schedules, countries should take into consideration local disease epidemiology, particularly the peak age of disease and programmatic considerations that will assure the timely administration of three doses. WHO states that catch-up vaccination as part of introduction will accelerate herd protection and therefore the PCV impact on disease and carriage. This can be achieved by providing two catch-up doses at an interval of at least two months to unvaccinated children aged 12-24 months and to children aged 2-5 years who are at high risk of pneumococcal infection.<sup>d</sup>

WHO further recommends that the epidemiological impact of PCV be carefully monitored as part of routine sentinel surveillance which should be conducted in selected countries and defined populations that represent different epidemiological profiles worldwide. WHO states that serotype replacement should not be an impediment to PCV introductions; the observed increases in non-vaccine serotype invasive pneumococcal disease with the use of PCV7 are likely to be further mitigated by the use of PCVs with broader serotype coverage.

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<sup>d</sup> Please note that catch up campaigns are not supported by GAVI.

### **3. AMC Independent Assessment Committee**

The IAC serves a number of key functions. Most importantly, it has the mandate to review and approve the Target Product Profile (TPP) and thereby the minimum technical requirements that candidate products must meet to be eligible for AMC funding<sup>e</sup>. In addition, the IAC establishes when and if an adjustment of the pre-set long-term price of vaccines is necessary. During the reporting period, the IAC has only been called upon to approve the AMC Annual Report.

The IAC membership comprises ten members representing expertise in: public health, health economics, vaccine business development, vaccine industry economics, contract law, public-private finance and clinical performance and delivery systems. A list of IAC members can be found in Annex 3.

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<sup>e</sup>Also see section 3.2 of the 2010 AMC Annual Report, <http://www.gavialliance.org/funding/pneumococcal-amc/>

## 4. Monitoring and Evaluation Processes

In 2007 the United Kingdom's Department for International Development in conjunction with the Canadian International Development Agency commissioned a monitoring and evaluability assessment study on behalf of the AMC for Pneumococcal Vaccines Donor Committee. The study proposed a monitoring and evaluation framework including four key components:

- Annual monitoring to be implemented by the GAVI Secretariat;
- A Baseline Study to establish the context (industry and country situation) at the beginning of the intervention and to develop proposed counterfactuals;
- An independent Process and Design Evaluation to assess the AMC implementation process and the efficiency and effectiveness of the AMC design;
- Impact Evaluations every four years from the entry into the first AMC supply agreement to assess the achievements of the AMC and causality between the AMC intervention and observed outcomes.

Annual monitoring is carried out by the AMC Secretariat and an Annual Report has been published on the AMC website each year from 2010.<sup>f</sup> The Baseline Study was completed in 2010 and is available on the AMC website.<sup>g</sup> The AMC Process and Design Evaluation was carried out in 2012 (see section 4.1 below). The first Impact Evaluation of the AMC will be commissioned in 2014.

### 4.1. AMC Process and Design Evaluation

The AMC Process and Design Evaluation was conducted in 2012 by Dalberg Global Development Advisors and is available on the AMC website, along with the GAVI Secretariat Management Response.<sup>h</sup>

The evaluation offers insights and lessons on the pilot AMC mechanism, by evaluating the design process, design decisions and implementation of the pilot AMC to date. Overall, the evaluators conclude that the pilot AMC has been implemented as designed and has demonstrated the ability of the international development community to design, establish and administer an AMC. The report recommends strengthening performance measurements and ensuring that the 2014 impact evaluation is well designed, as well as further work to explore potential for reductions in the tail price. In addition, the evaluation provides lessons for future AMCs or market shaping initiatives.

As recommended in the evaluation, the AMC Secretariat will review the indicators used to track progress in the AMC to identify opportunities for further increasing their relevance, timeliness and usefulness. Furthermore, as part of its preparatory work for the 2014 AMC Impact Evaluation, the AMC Secretariat will assess various evaluation design options to enhance the ability of the evaluation to generate learning about the current and future impact of the AMC. The AMC Secretariat will consult with partners on these design options and other methodological issues.

The AMC Secretariat is committed to continuing to share the results of the pilot AMC evaluations so that the potential designers of future AMCs will have access to the full range of lessons learned from the experiences of the design, implementation and evaluation of this innovative financing and procurement mechanism.

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<sup>f</sup> Available at <http://www.gavialliance.org/funding/pneumococcal-amc/>

<sup>g</sup> <http://www.gavialliance.org/results/evaluations/baseline-study-for-amc/>

<sup>h</sup> <http://www.gavialliance.org/results/evaluations/pneumococcal-amc-process---design-evaluation/>

## **4.2. Estimates of the impact of pneumococcal vaccination**

In 2011, a multidisciplinary group with expertise in mathematical modeling was convened by the GAVI Alliance and the Bill & Melinda Gates Foundation to estimate the impact of vaccination in 73 countries supported by the GAVI Alliance. As part of this review, the projected number of future deaths averted in persons vaccinated during 2011-2020 was estimated for conjugate *Streptococcus pneumoniae*. The group estimated that 4.3 deaths are averted for every 1,000 children vaccinated with PCV in GAVI-supported countries and that 1.5 million future deaths will be averted by 2020. The results of this work are expected to be published in April 2013.<sup>3</sup>

## **4.3. Special studies on pneumococcal vaccines**

GAVI is currently funding a number of special studies to help facilitate evidence-based decision making in support of the introduction and implementation of pneumococcal vaccines in developing countries. The studies include pneumococcal vaccine effectiveness studies in The Gambia, Kenya and South Africa; economic impact evaluations of pneumococcal vaccines in Ghana and The Gambia; and an evaluation of different dosing schedules for pneumococcal vaccines. In the future, additional well designed assessments of pneumococcal vaccines in selected epidemiologic settings will help to further assess the impact of vaccination on the burden of disease and serotype epidemiology. The findings of these studies will be key inputs to the planned AMC Impact Evaluations.

## 5. Media and Communications

The GAVI Secretariat's media and communications team aims to increase visibility of the AMC through traditional, online and social media. With the continued pneumococcal vaccine launches, GAVI is able to demonstrate the success of the AMC mechanism with multi-platform coverage. The media and communications activities regarding the AMC focused on three key launches in 2012, as well as World Pneumonia Day and the publication of the AMC Process and Design Evaluation report.

### 5.1. Key Events

#### 5.1.1. Vaccine Launches

The media and communications activities regarding the AMC focused on three key launches in 2012.

Ghana (April 2012): GAVI CEO Dr Seth Berkley was joined by eight journalists for the historic joint launch of pneumococcal and rotavirus vaccines in Ghana. Media reported on a field trip and were filming as the First Lady of Ghana, H.E. Dr Ernestina Naadu Mills, injected the first Ghanaian child with the AMC-funded vaccine in Accra. Alongside a full set of press releases, web stories and blogs, GAVI produced a short film commemorating the launch including interviews with parents who had brought their children to be vaccinated. The launch was the centre-piece of GAVI's work on World Immunisation Week 2012 and was complemented through social media by GAVI, the Bill & Melinda Gates Foundation, UNICEF, WHO and others.

Pakistan (October 2012): GAVI deputy CEO Helen Evans attended the launch of pneumococcal vaccine in Islamabad where she was interviewed by local and international media. A GAVI Secretariat staff member on the ground drafted blogs to highlight the detailed preparations for the pneumococcal vaccine introduction and a large social media operation helped promote the story through Twitter and Facebook.

Tanzania (December 2012): Tanzania followed Ghana's lead by introducing pneumococcal and rotavirus vaccines simultaneously during the GAVI Partners' Forum. Journalists participating in the Forum took part in field trips to communities who will benefit from vaccines supplied by GAVI and they were in attendance when the First Lady of Tanzania, Salma Kikwete, spoke of the nation's delight at the introduction of AMC-funded pneumococcal vaccine. As part of the communications strategy for this launch and for the Partners' Forum, the GAVI Secretariat refreshed the AMC and the pneumococcal disease factsheets.

### **Pneumococcal vaccine launch in Tanzania, December 2012**

Tanzania became only the second GAVI-eligible country to jointly introduce pneumococcal and rotavirus vaccines. A Tanzanian health worker is pictured below with a vaccine carrier, which keeps vaccines cold in order to maintain safety and effectiveness.



#### *5.1.2. World Pneumonia Day 2012*

GAVI published a press release highlighting the number of children that have received pneumococcal vaccine as a result of AMC funding. A briefing was also held for journalists at the Palais des Nations in Geneva.

The World Pneumonia Day partners used social media as an effective tool for sharing positive messages about tackling pneumonia with a broad audience. GAVI used Twitter and Facebook to circulate messages about the pace of pneumococcal vaccine introductions as a result of the AMC.

#### *5.1.3. Publication of AMC Process and Design Evaluation*

A comprehensive media and communications plan was devised and executed for the publication of the AMC Process and Design Evaluation report. The GAVI Secretariat's media and communications team briefed key journalists with highlights from the report and published a press release to accompany the report. Materials were supplied to AMC stakeholders to enable them to assist media with any enquiries.

## **5.2. Media and communications plan for 2013-2014**

The GAVI Secretariat's media and communications team will continue to work on securing media for high profile pneumococcal vaccine launches, using this as a platform to demonstrate the success of the AMC. The team will also seek proactive opportunities to brief journalists about the mechanism, as well as helping them to ensure that their coverage of the AMC is fair and accurate.

### **5.3. Donor & stakeholder communication**

In 2012, additional efforts were made to provide updates to AMC stakeholders, with a view to providing further opportunities to exchange information and input on key issues, such as the AMC Process and Design Evaluation, progress on implementation, and the supply and procurement of vaccines. With regards, to vaccine introductions, the AMC donors were kept informed of progress and invited to participate in the vaccine launch events.

## 6. Financial Activities

The financial structure of the AMC remains unchanged from the previous year. It is composed of the six AMC donors, the World Bank, GAVI, UNICEF, GAVI-supported countries and eligible vaccine manufacturers.<sup>i</sup>

In summary the process works as follows: the AMC donors, who have entered into grant agreements totalling US\$ 1.5 billion with the World Bank, make annual payments to the World Bank. In turn, the World Bank holds the money in trust for GAVI on behalf of the donors and confirms to GAVI the amounts being held at the World Bank for and on behalf of the AMC Initiative on a quarterly basis. To access these donor funds, GAVI submits a Quarterly Funding Request to the World Bank for the anticipated AMC donor funds required for vaccine purchase payments in the upcoming calendar quarter. The funding request is based on the most recent demand forecast, as well as on the quarterly Cash Management Plan submitted by UNICEF to GAVI.

Prior to procuring vaccines from AMC eligible vaccine manufacturers, UNICEF sends a cash disbursement request for the necessary AMC and GAVI funds, upon receipt of which GAVI transfers the requested funds into a GAVI-held and designated procurement bank account. These funds once transferred can only be withdrawn by UNICEF. GAVI-supported countries are obliged to co-finance the pneumococcal vaccine, in accordance with GAVI's standard co-financing policy. Countries make their co-financed payments directly to UNICEF.

### 6.1. Donor Funds – inflow to the World Bank

The fixed-payment donors have together pledged a total of US\$765 million to the pneumococcal AMC. The on-demand donors have pledged US\$ 735 million (see Table 6). The six donors combined bring the total available AMC funds to US\$ 1,500 million, funds that are dedicated solely to the procurement of the pneumococcal vaccine.

#### 6.1.1. Donor contribution receipts

As of 31 March 2013, the World Bank has received a total of US\$ 652 million from AMC donors (see Table 6 below).

Table 6. Contribution receipts from AMC donors, as of 31 March 2013 (in US\$)

	<u>Contribution Amount</u>	<u>Paid-in Amount</u>	<u>Remaining Balance</u>
<b>Fixed Schedule Donors</b>			
Italy	635,000,000	263,334,056	371,665,944
Russia	80,000,000	32,000,000	48,000,000
Gates Foundation (BMGF)	50,000,000	40,000,000	10,000,000
<b>On Demand Donors</b>			
UK	485,000,000	93,333,874	391,666,126
Canada	200,000,000	173,297,577	26,702,423
Norway	50,000,000	50,000,000	-
<b>Total</b>	<b>1,500,000,000</b>	<b>651,965,507</b>	<b>848,034,493</b>

Source: The World Bank

<sup>i</sup> Refer to AMC Annual Report 12 June 2009-31 March 2010 page 28-29 for the detailed description of the financial structure.

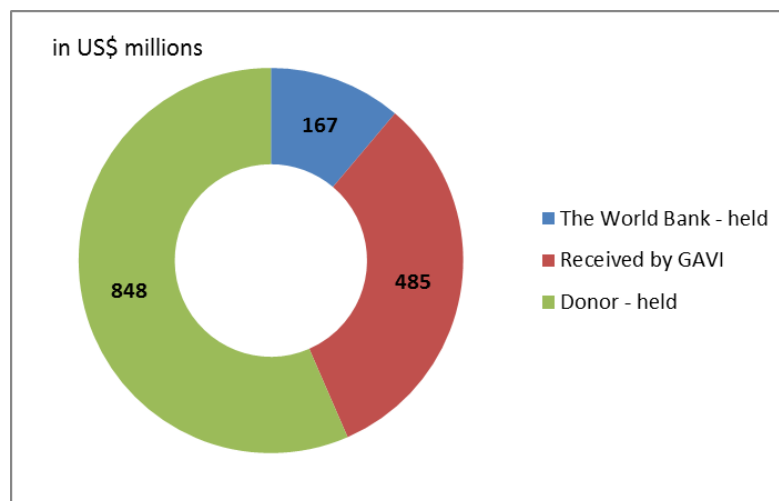


The World Bank has recorded the AMC donor funds on its financial statements as designated assets, with a corresponding liability to pass through the payments to GAVI for the purchase of pneumococcal vaccines subject to the terms and conditions of the AMC. To enhance the predictability of AMC funding, the World Bank committed to transfer funds to meet the AMC-funded portion of the vaccine price, upon request from GAVI in accordance with the AMC terms and conditions and with the schedule of donor payments, whether or not donors actually pay on schedule or default. The World Bank also provides financial management and administrative services with respect to donor contributions and AMC disbursements.

## 6.2. AMC donor funds: inflow to GAVI

As of 31 March 2013, the World Bank has disbursed US\$ 485 million to GAVI of which US\$ 227.5 million was received from 1 April 2012 – 31 March 2013. This leaves a balance of US\$ 167 million held by the World Bank, of which US\$ 85 million is available for immediate disbursement to GAVI (see figure 6).

Figure 6. Status of AMC donor funds, as of 31 March 2013 (in US\$ millions)

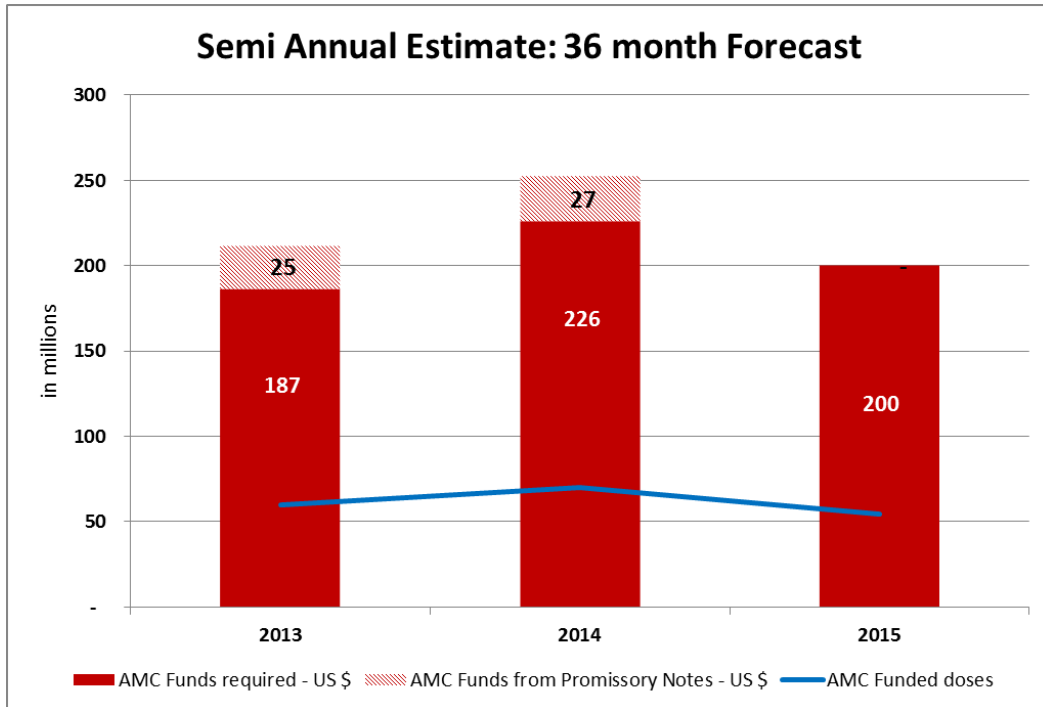


Source: GAVI Alliance Secretariat

As part of the reporting process, GAVI has submitted to the World Bank three Semi-Annual Estimates during the reporting period, the first in April 2012, the second in November 2012 and the third in March 2013. Based on the most recent Semi-Annual Estimate, submitted in March 2013, it is anticipated that US\$ 665 million of AMC funds, of which US\$ 51.9 million will be from the Promissory Notes, are needed to procure 184 million doses of the pneumococcal vaccine from 1 January 2013 – 31 December 2015. Fulfilment costs are estimated at US\$ 0.19 per dose.<sup>i</sup> Furthermore, if demand materialises as forecasted, it is anticipated that the two supply agreements signed in 2010 will have received all of their AMC top-up funds by the end of 2013 and the remaining doses relating to those agreements will be procured at the tail price (see Figure 7).

<sup>i</sup> Fulfilment costs are the extra costs incurred in supplying vaccines, in addition to the cost of the vaccine itself. These costs typically include the cost of syringes, safety boxes and freight

Figure 7. Latest Financial Forecast of AMC Funds, as of 31 March 2013



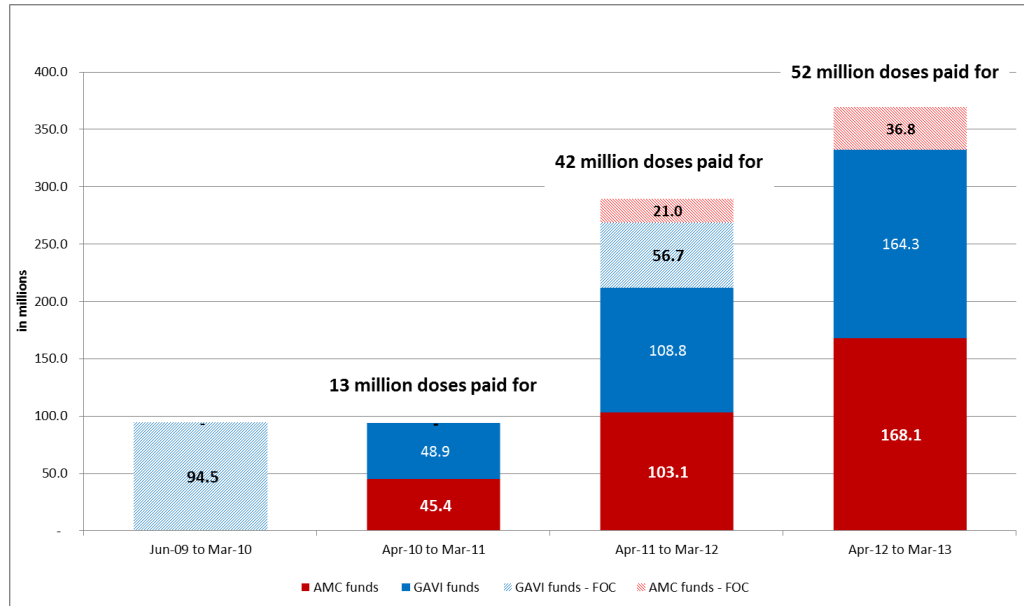
Source: GAVI Alliance Secretariat

### 6.3. UNICEF procurement: outflow of AMC donor fund

From 1 April 2012 to 31 March 2013, GAVI has disbursed US \$369.2 million to UNICEF for the purchase of pneumococcal vaccines. Of this amount, US \$204.9 million was from AMC funds. Total funds include the transfers relating to the AMC-funded portion of the minimum purchase obligation, also known as the Firm Order Commitment (FOC), on the GSK & Pfizer supply agreements signed in 2010 amounting to US \$36.8 million (see Figure 8).

In total, as at 31 March 2013 US \$209 million has been transferred in relation to the FOCs on the four existing signed supply agreements and related Promissory Notes. Of this amount, US \$151.2 million represents the GAVI-funded portion of the FOCs and US \$57.8 million represents the AMC-funded portion of the FOCs. Drawdown on the transferred FOC funds for the supply agreement signed with GSK in 2010 has occurred in Q4-2011 and Q4-2012, and will continue in Q4 2013. Drawdown on the FOC funds for the supply agreement signed with Pfizer in 2010 began in Q4-2012 and will continue in Q4 of 2013 and 2014.

Figure 8. Total cash disbursements to UNICEF's procurement account, (inception to 31 March 2013)



Source: GAVI Alliance Secretariat

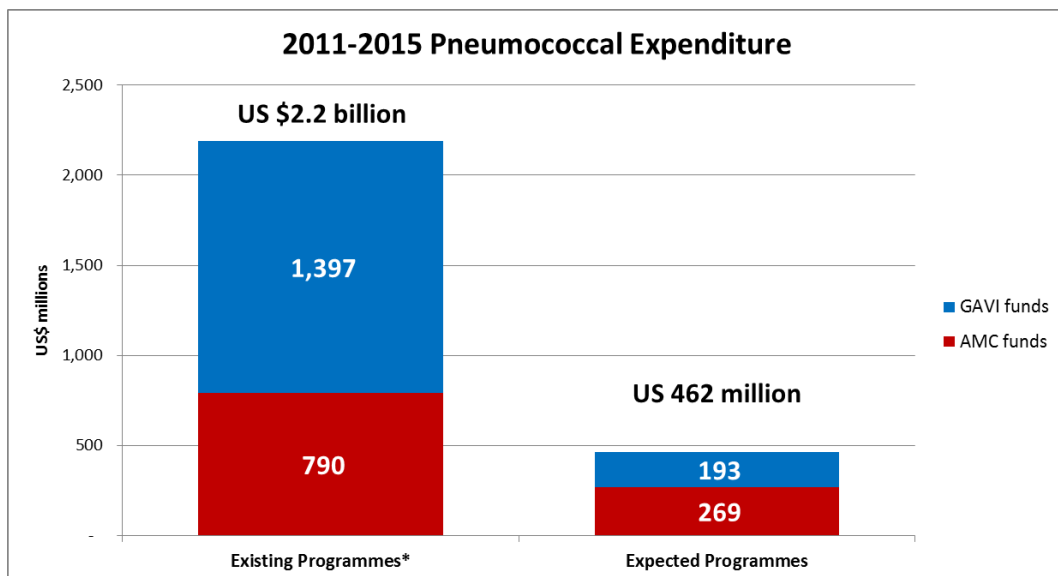
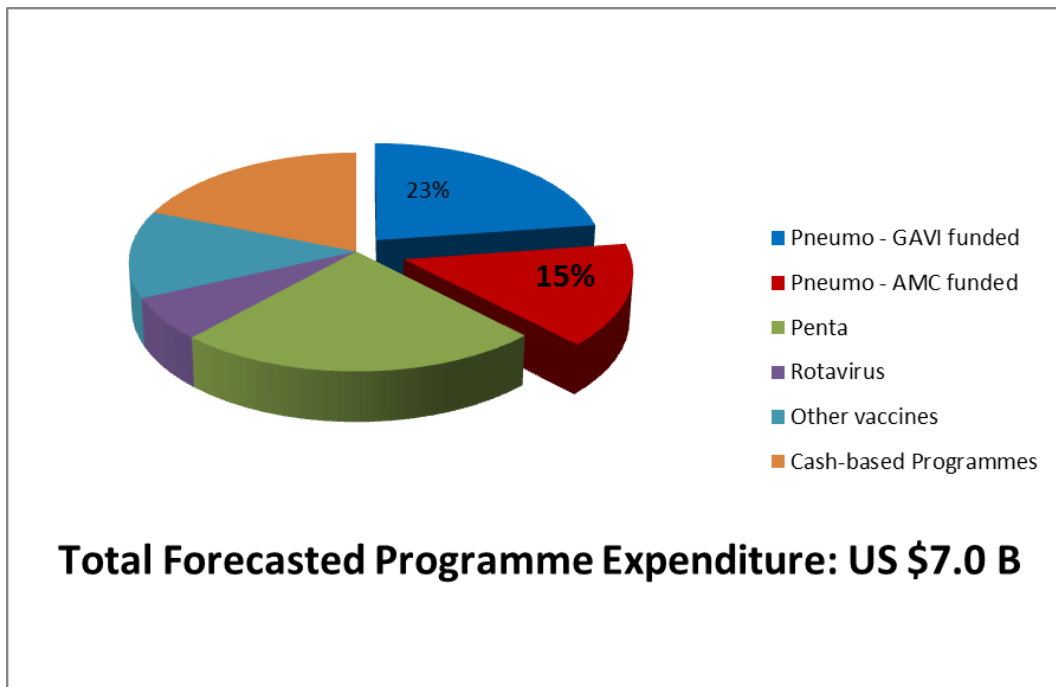
As of 31 March 2013, 51 countries had been approved by the GAVI Board to receive financial support for the procurement of pneumococcal vaccine for the 2013 and 2014 programmatic year. The 2013 approved financial support amounts to US \$551.8 million and translates into the procurement of approximately 92.2 million doses of the pneumococcal vaccine.

#### 6.4. The AMC and GAVI's Long Term Financial Forecast

At the December 2012 Board meeting, an update was presented of GAVI's Long Term Financial Forecast.<sup>k</sup> For the period of 2011-2015, total programme expenditures are projected to be US \$7.0 billion. Of this US \$7.0 billion, pneumococcal vaccine expenditures are anticipated to amount to US \$2.7 billion, representing 37.8% of total programmatic expenditures (see Figure 9).

<sup>k</sup> December 2012 Board Paper entitled "Board-2012-Mtg-Doc 05: Financial Forecast and Programme Funding Envelope approval"

Figure 9. Summary of Total Forecasted Expenditure 2011-2015



\* Existing Programmes are defined as all GAVI Board approved, endorsed and extension programmes. Expected Programmes are defined as those which have received Conditional IRC approval or are forecasted projections based on Adjusted Demand Forecast v6.0 and the latest supplier assumptions

Source: GAVI Alliance Secretariat

## 7. Challenges and Future Priorities

Country demand for the pneumococcal vaccines remains high, with 70% of GAVI-supported countries already approved for introduction. The main challenges are also the future priorities, namely the availability of the vaccines to meet this unprecedented demand, particularly in the short term, and ensuring that countries are ready to introduce the available vaccines without delays.

### 7.1. Meeting country demand

Thanks to the AMC, supply increased from zero to over 40 million doses within less than a year, and manufacturers have entered into 10-year supply agreements, contracting 63 million doses in 2012, 77 million in 2013 and 96 million in 2014 and beyond. This is unique for a GAVI-supported vaccine. However, it has been recognised that the high levels of demand for pneumococcal vaccines cannot be fully met with short term supply availability; therefore a third Call for Offers was issued in August 2012 and is due to complete in the second quarter of 2013.

Discussions and close coordination with manufacturers are ongoing to understand key milestones and timelines for additional supply availability. Given the unprecedented country demand and the time manufacturers need to scale up production, it is still expected that a number of countries will need to postpone introductions from 2013 to 2014 and beyond. At present, it is expected that all countries approved as of 31 March 2013 will be able to introduce in 2015 at the latest. The Alliance partners are focusing on completing the tender as quickly as possible, as well as planning for clear and rapid communication to countries on supply availability following the completion of the tender to ensure the maximum use of available doses.

### 7.2. Maximising the use of available supplies

While manufacturers continue to increase their production capacity in line with country demand, GAVI and partners will work closely with countries to confirm their introduction timing and to align readiness for introduction with available supply. However, country preparedness to introduce pneumococcal vaccines has resulted in a number of delays in the reporting period. For example, two countries that received supply of the pneumococcal vaccine in 2012 decided to postpone their introductions to 2013 to complete their preparations. As the pneumococcal vaccines had already been shipped at the time of postponement, the vaccine is being stored by the countries in anticipation of their introductions in early 2013.

To support the vaccination of the largest possible number of children with the available supply, it is important to ensure that countries are ready to introduce and that countries complete any phased introductions on schedule. Alliance partners are reviewing country readiness<sup>1</sup> and coordinating technical assistance activities through weekly teleconferences, with the aim of identifying and resolving issues with the support of the partners working at the country level.

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<sup>1</sup> Country readiness refers to the broad range of activities required at the country level to prepare the country for introduction, including cold chain expansion and/or rehabilitation, logistics, social mobilisation, training, funding etc.

## 8. Conclusion

With the early availability of pneumococcal vaccines, a total of 24 countries have already rolled out these lifesaving vaccines – including eight during this reporting period. At least 11 countries are expected to introduce in 2013; with additional country introductions possible depending on the outcome of the ongoing tender.

The pneumococcal vaccines procured through the AMC are expected to have a significant reach and impact. It is estimated that more than 10 million children have been vaccinated in the period 2010-2012,<sup>4</sup> with a projection of more than 75 million children vaccinated by 2015.<sup>m</sup> Furthermore, the pneumococcal vaccines procured through the AMC are expected to save up to 1.5 million lives by 2020.<sup>3</sup>

The short term supply availability will continue to be a challenge in 2013 and 2014, given the unprecedented country demand. However, even with this challenge, the latest Strategic Demand Forecast<sup>n</sup> estimates that a total of 57 countries will have introduced by 2015, exceeding the original target of 45.

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<sup>m</sup> SDF v7.0 (supply-constrained scenario)

<sup>n</sup> SDF v7.0 (supply-constrained scenario)

## **Annex 1 – Summary of Previous Call for Offers**

### **First AMC Supply Agreements**

The first procurement cycle for the supply of pneumococcal vaccines under the AMC was initiated with the issuance of a Call for Supply Offers on 4 September 2009. UNICEF SD received four offers in response to this first call. In March 2010, UNICEF SD entered into Provisional Supply Agreements (PSA) with two manufacturers – GlaxoSmithKline Biologicals (GSK) and Pfizer Inc. – the only companies whose Product Summary File (PSF) had been accepted by WHO for prequalification review. Each manufacturer committed to supply 30 million doses annually, with GSK starting in January 2012 and Pfizer Inc. in January 2013, and continuing for 10 years. Consequently, 15% of AMC funds were allocated to each manufacturer under this procurement round.

In addition to the above-mentioned PSAs, GSK and Pfizer agreed to provide in total 7.2 million, 24.2 million and 20 million doses in 2010, 2011 and 2012, as part of the AMC Capacity Development Period.<sup>o</sup> Both suppliers have subsequently communicated the ability to increase such early supplies, should there be demand and based on demand, quantities on contracts have been increased by 7.8 million doses in 2011 and 4 million doses in 2012. The total quantities on these contracts with each supplier remain 300 million doses each, only the distribution over the years has changed.

Both GSK and Pfizer's products received WHO prequalification in 2010 and were deemed AMC Eligible by the AMC Independent Assessment Committee (IAC) respectively on 16 April 2010 and 23 August 2010. This was communicated to suppliers with a copy to UNICEF on 6 May 2010 and on 23 August 2010. As a result the PSAs automatically turned into effective Supply Agreements, allowing the procurement of those two vaccines.

### **Second AMC Supply Agreements**

Following the publication of SDF v3.0 in March 2011, GAVI, in consultation with UNICEF, decided to issue a new Call for Supply Offers for the procurement of pneumococcal vaccines that was published on 8 April 2011 with a maximum target of 74 million doses by 2016. UNICEF SD received four offers by 6 May 2011.

In the week starting 12 December 2011, UNICEF as procurement agency on behalf of GAVI confirmed the entry into new supply agreements with GSK and Pfizer Inc. Per the timeline set out in the AMC legal agreements, the supply agreements should have been finalized by 9 September 2011. However, UNICEF SD and GAVI agreed to delay the procurement timeline in order to be able to take into account any new demand recommended for approval by the IRC following the May 2011 round in the award recommendations.

Both GSK and Pfizer Inc. will start supplying 18M doses annually (Annual Supply Commitment) from 2014 for a period of 10 years, up to a maximum of 180M doses. The tail price for this agreement is US\$3.50. Consequently 9% of the AMC funds are allocated to each of the two manufacturers under this agreement according to the AMC terms and conditions. The total doses awarded to GSK and Pfizer Inc. under both supply agreements amounts to 48M annually.

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<sup>o</sup>The capacity development period is defined as the period during which suppliers develop dedicated manufacturing capacity to serve GAVI-eligible countries under their respective Supply Agreements.



As part of the supply agreements, manufacturers have agreed to provide in total 30 million doses in 2012 and 2013 as part of the AMC Capacity Development Period.

UNICEF opted not to award the full quantities of the GAVI Strategic Demand Forecast for 2016 in response to this second tender. In order to incentivize manufacturers to accelerate the development of new vaccines, to contribute to the creation of a healthy market with multiple suppliers, and to enhance the possibility to access lower tail prices through future offers, quantities have been reserved for award at a later point in time. It should be noted, however, that 100% of the quantities offered for supply in 2012-2013 in response to tenders have been contracted. Furthermore, UNICEF considered that the unexpected ramp up of demand led to a faster than expected commitment of the AMC funding and that it would be prudent to pause to allow for a discussion with AMC stakeholders before proceeding to commit more than 50% of AMC funding at this early stage.

Fifty-two percent of the AMC funds corresponding to US\$780 million remain unallocated following the completion of the second Call for Offers and will be available for successive rounds of calls for offers.



## Annex 2 - Membership of the PROWG

The Pneumo Rota Operational Working Group (PROWG) is a sub-team of the Vaccine Implementation Management Team. Members are as follows:

Organisation	Members
<b>GAVI Secretariat</b>	<p><b>Carol Szeto</b> Senior Programme Manager, Vaccine Implementation, Country Programmes</p> <p><b>Emily Wootton</b> Programme Manager, Vaccine Implementation, Country Programmes</p>
<b>PATH</b>	<p><b>Lisa Menning</b> Country Communication Officer</p> <p><b>Candace Rosen</b> Senior Policy and Advocacy Officer (representing VI TAC)<sup>p</sup></p>
<b>UNICEF PD</b>	<p><b>Osman Mansoor</b> Senior Health Advisor (New Vaccines)</p>
<b>UNICEF SD</b>	<p><b>Yalda Momeni</b> Contracts Specialist (alternate member)</p> <p><b>Ann Ottosen</b> Contracts Manager</p>
<b>WHO</b>	<p><b>Hemanthi Dassanayake-Nicolas</b> Technical Officer – Strategic Information Group EPI</p> <p><b>Carsten Mantel</b> Leader – Priority Area New Vaccines and Innovation</p>

Source: GAVI Secretariat, as of 31 March 2013

<sup>p</sup> A technical assistance consortium of PATH, Johns Hopkins University (JHU), US Centers for Disease Control and Prevention (CDC) and others. - See more at: <http://www.gavialliance.org/about/gavis-business-model/avi/#sthash.jUgDPQpx.dpuf>

## **Annex 3 – Membership of the Independent Assessment Committee**

### **Claire Broome (Chairperson)**

Adjunct Professor Division of Global Health Rollins, School of Public Health Emory University Atlanta, Georgia, USA

### **Ingrid Callies**

Adviser to the Vice-President for Medical Affairs, Institut Pasteur, France

### **Arthur Elliott**

Senior Program Manager, Vaccines and Anti Viral Agents, US Department of Health and Human Services, USA

### **Bernard Fanget**

CEO, Bernard Fanget Consulting; and VP R&D and Pharmaceutical Development, Neovacs, France

### **Shahnaaz Kassam Sharif**

Chief Medical Specialist, Senior Deputy Director Medical Services, Head of Preventive and Promotive Health Services, Ministry of Health, Kenya

### **Mary Kitambi**

Public Health Specialist, Ministry of Health and Social Welfare Tanzania

### **Soonman Kwon (Vice Chairperson)**

Director, Brain Korea Centre for Aging and Health Policy, South Korea

### **Tracy Lieu**

Director, Division of Research, Kaiser Permanente Northern California

### **Halvor Sommerfelt**

Professor of Epidemiology, Center for International Health, University of Bergen, and Senior Consultant, Norwegian Institute of Public Health, Norway

### **Vitaly Zverev**

Director, I.I. Mechnikov Institute of Vaccine Sera under the RAMS, Russia

*Source: GAVI Secretariat, as of 31 March 2013*

## Sources

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<sup>1</sup> Revised AMC Offer Agreement. Geneva, GAVI Alliance, 2011 (<http://www.gavialliance.org/funding/pneumocccal-amc/amc-legal-agreements/>, accessed 21 March 2013).

<sup>2</sup> WHO. *Pneumococcal vaccines WHO position paper – 2012*. Weekly epidemiological record. No. 14, 2012, 87, 129-144. <http://www.who.int/immunization/documents/positionpapers/en/index.html>, accessed 26 March 2013.

<sup>3</sup> Lee et al. *The estimated mortality impact of vaccinations forecast to be administered during 2011-2020 in 73 countries supported by the GAVI Alliance*. Vaccine, Volume 31, Supplement 2, Pages B61-B72, 18 April 2013. <http://dx.doi.org/10.1016/j.vaccine.2012.11.035>

<sup>4</sup> WHO. *WHO Report on GAVI Progress 2000-2011 & Projected Achievements 2012*. Department of Immunization, Vaccines, and Biologicals, October 2012.